

Chapter 1: Introduction

‘The life of the law has not been logic: it has been experience. The felt necessities of the time, the prevalent moral and political theories, intuitions of public policy, avowed or unconscious, even the prejudices which judges share with their fellow-men, have had a good deal more to do than the syllogism in determining the rules by which men should be governed. The law embodies the story of a nation's development through many centuries, and it cannot be dealt with as if it contained only the axioms and corollaries of a book of mathematics. In order to know what it is, we must know what it has been, and what it tends to become. We must alternately consult history and existing theories of legislation. But the most difficult labor will be to understand the combination of the two into new products at every stage.’ - Oliver Wendell Holmes Jr.¹

I. Problem statement

The law must adapt, and more accurately must be adapted by actors and institutions, to address the evolving needs of society. As the introductory quote eloquently states, this is no easy feat. At the heart of this work lies one specific problem of adaptation that many societies are only just beginning to confront: the medical uses of artificial intelligence (AI).

A preliminary definition of AI can be given as a technology that is capable of performing the kinds of tasks that humans solve by drawing on their intuition, knowledge and skill.² It is a technology that is rapidly gaining acceptance in the clinical sphere. Devices incorporating machine learning (ML), the currently dominant form of AI, are being developed, rigorously examined and approved for these purposes.³

1 Holmes Jr. *The Common Law* (1881) 1-2.

2 The justification for this definition will be provided in Chapter 1.

3 This will be explored in Chapter 2, but one can already note that in October 2022 the U.S. Food and Drug Administration added 178 entries to their list of AI/ML enabled medical devices: U.S. Food & Drug Administration, ‘Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices’ (5.10.2022) <<https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-le>

The novelty distinguishing this technology relates to its capabilities. It does not only provide information to which medical professionals can apply their own expertise, their medical judgment. It provides such expertise and judgment itself. Indeed, in some circumstances it has demonstrated the ability to displace human specialists in the performance of demanding cognitive tasks and even to determine aspects of clinical decision making.

The societal challenges that this generates are related to the assumption that all such decision making has a normative component and that this type of choice is properly the prerogative of the patient.⁴ Such a prerogative is both well-established and relatively new. It is well-established because the right of persons to take medical decisions has been widely recognised in many societies for some time – at least in so far as they have a right to reject interferences from other actors, including clinical professionals.

It is relatively new because this negative and defensive framing did not actually suffice to place the patient in a position where they could determine the course of their care. To make a meaningful decision the patient needed the information that the professional, usually the physician, possessed. Without it the control in the clinical encounter continued to rest with the professional and the patient's ability to choose remained subject to their discretionary judgment. It was within the physician's power to decide whether to share their expertise regarding a recommendation and, if so, how far.⁵ In short, there was a real danger that the patient would have normative positions thrust upon them under the guise of clinical expertise.⁶

The primary legal instrument that emerged to rebalance the professional-patient relationship is the doctrine of 'informed consent'.⁷ Hereunder the medical profession is obligated to disclose and discuss certain classes of information with the patient, to facilitate their decision making. This

arning-aiml-enabled-medical-devices> accessed 19.3.2023. For an analysis of these figures over time see: Selanikio, 'A Closer Look at FDA's AI Medical Device Approvals' (12.10.2022) <<https://www.futurehealth.live/blog/2022/10/10/closer-look-at-fda-ai-approvals>> accessed 19.3.2023.

4 Kennedy in Byrne, *Rights and Wrongs in Medicine* (1986) 8.

5 *ibid* 13-15.

6 Veatch, 'Doctor Does Not Know Best: Why in the New Century Physicians Must Stop Trying to Benefit Patients' (2000) 25(6) *The Journal of Medicine and Philosophy* p. 701.

7 The term itself was coined in the Californian case of *Salgo v. Leland Stanford Jr. University Bd. of Trustees* (1957) 154 Cal.App.2d 560, 578. In its specification this mechanism can itself embody the described tension and development: Jackson in McLean, *First Do No Harm* (2016) 279.

doctrine has been widely recognised today,⁸ and it is said to have led to widespread rejection of paternalistic practices in medicine.⁹

In spite of these achievements, informed consent remains a highly dynamic and open-textured doctrine, subject to contestation and evolution. Partly this must be related to the fact that, although it has been realised through legal norms, the doctrine has developed – and remains closely associated with – the bioethical discourse on patient autonomy.¹⁰ It is this value that has generally been stated to provide the primary justification for the creation and operation of the relevant norms.¹¹

Returning to the law's ability to adapt to shifts in circumstances, expert decision making by an AI/ML device poses the danger of reinvigorating the mismatch between expert knowledge and individual choice. It could overturn the ethical and legal position that has come out in favour of protecting the patient's access to the information. With this background in mind one can now formulate the challenges that emerge from clinical AI use more precisely. Given that AI is providing the expertise that was previously the preserve of human professionals, what specific information must be granted to a patient regarding AI/ML to maintain an acceptable balance between specialist skill and their personal decision-making? How must AI expertise be framed and conveyed to them? Does the technology fit within established paradigms? Could it necessitate the creation of novel ones?

To answer these questions our analysis must also engage with a much more fundamental question that goes towards the relationship between law and innovation. One must consider, particularly, the method that should be deployed in this type of analysis. It is asked: how is the law's interaction with technological change to be assessed?

One influential view of the relationship between law and innovation envisages a 'legal lag' between developments within (one aspect) of society

8 Vansweevelt and Glover-Thomas, *Informed Consent and Health: A Global Analysis* (2020).

9 Montgomery, 'Law and the Demoralisation of Medicine' (2006) 26(2) *Legal Studies* p. 185, 187; Sharpe and Faden, *Medical Harm: Historical, Conceptual, and Ethical Dimensions of Iatrogenic Illness* (2001) 67.

10 Brazier and Cave, *Medicine, Patients and the Law* (Sixth Edition 2016) 67.

11 Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (2009) 149-150.

and the adaptation of legal norms.¹² Specifically in the case of novel technologies, the paradigmatic position leads one to believe that an innovation emerges, causes frictions and reveals flaws in rules that were previously rigidly established.¹³ According to these external demands, the rules are then ideally adapted to fit the new state of affairs.¹⁴ As further developments emerge and the law is forced to respond, this cycle repeats.

Hallmarks of this view are the belief that the adaptation to technology is an external response to the limitations of legal rules and that this should be guided by rationales that stand behind or beyond the law, i.e. are extra-legal themselves.¹⁵ For some contexts it has even be argued that the nature of regulation must itself become technological rather than legal, to maintain an effective oversight over innovations.¹⁶

One can already begin to see that the above framing of medical AI's challenges does not fall neatly into this paradigm. It does not purport to react to a development that has already taken place, but to anticipate, to guide, the response to a process that is only just beginning to take hold. In addition, the demands of the informed consent doctrine are themselves relatively novel, in a state of development and they are closely connected to a more abstract norm of patient autonomy that, alongside its legal manifestation, has fundamental ethical significance. This combines a factual dynamism with a normative dynamism that is intertwined with the law's operation. The paradigmatic view does not engage with this perspective, but the present work must account for it.

In consequence, the stated research problem calls for a legal methodology that is forward-looking and takes seriously the distinct contribution of

12 Dror, 'Law and Social Change 1958-1959' (1959) 33(4) *Tulane Law Review* p. 787; Rustad and Koenig, 'Cybertorts and Legal Lag: An Empirical Analysis' (2003) 13(1) *Southern California Interdisciplinary Law Journal* p. 77, 77-80.

13 Mandel in Brownsword, Scotford and Yeung, *The Oxford Handbook of Law, Regulation and Technology* (2016) 228.

14 Rustad and Koenig, 'Cybertorts and Legal Lag' (2003) 13(1) *Southern California Interdisciplinary Law Journal* p. 77, 77-80, 118-122; Brownsword and Somsen, 'Law, Innovation and Technology: Fast Forward to 2021' (2021) 13(1) *Law, Innovation and Technology* p. 1, 4-6. See also the concrete illustrations provided by: Kirby in Brownsword and Yeung, *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (2008) 368-373.

15 Mandel in Brownsword, Scotford and Yeung, *The Oxford Handbook of Law, Regulation and Technology* (2016) 230-231.

16 Lessig, 'The Constitution of Code: Limitations on Choice-Based Critiques of Cyberspace Regulation' (1997) 5(2) *CommLaw Conspectus: Journal of Communications Law and Policy* p. 181.

the legal process to the resolution of non-legal, specifically technological, problems. The development of such an approach is itself no easy feat and will be considered in the next section.

II. Methodology and research question

To offer a response to the unique challenges associated with medical AI and patient autonomy, as well as the more general questions hanging over them, a number of analytical steps ought to be further elaborated.

A. Comparative method

A first significant choice is made to evaluate the developing problem through a legal comparison and, in particular, through the use of the functional method. As the problem-statement implies, the object of the present investigation is a real-life situation – AI/ML's impact on patient decision making – with which legal systems are anticipated to interact. The envisaged application of legal doctrine to this situation, conceptualising the law as thereby fulfilling a role within society, sits comfortably within the functionalist tradition.¹⁷

Admittedly, the consideration of some pervasive informed consent doctrines may seem anomalous within this framework, since they possess an undeniable legal dimension. However, this is justified both by the need to account for the existing clinical reality, which is partially shaped by the law, and by the already mentioned, intertwined nature of legal and wider bioethical analyses. Positing that it is normatively significant to obtain a patient's informed consent, and why this is so, is central to understanding the common problem with which legal systems are faced.¹⁸

Understood in these terms, the benefits to be gained from a legal comparison recommend themselves. Assessing the responses to a novel problem can improve the understanding of this phenomenon and its relation to the law, potentially providing insights into different approaches and how these can inform one another. Relatedly, it can indicate what the appropri-

17 Michaels in Reimann and Zimmermann, *The Oxford Handbook of Comparative Law* (Second Edition 2019) 347-348.

18 *ibid* 374.

ate societal response to the problem could be.¹⁹ All in all the comparison envisaged here has both descriptive and evaluative components, asking: how will the existing legal structures be applied to AI/ML in medicine? What does this tell one about the law's interaction with a novel technological phenomenon? Does it point the way towards an appropriate response, given the deeper normative significance of the problem?

To employ the comparative method, it is of course necessary to make a selection of countries to compare. Three factors are considered determinative in this respect. A first limitation flows from the necessity for potential comparators to experience a sufficiently widespread adoption of AI/ML in their healthcare systems. This renders the factual problem applicable and relevant – something worthy of a legal response. Such adoption takes not only a certain societal prosperity as a prerequisite, but also a preparedness to embrace technological change at scale, specifically in the healthcare sector.

Second, the outlined problem has the aforementioned ethical, normative dimension. To enable the identification of a common problem under this head one should select legal systems that are hypothesised to have sufficiently similar conceptions of patient autonomy. This is what will render the conceptualisation of AI's challenges to patient decision making comparable.

Third, the question hanging over the law's creative, pro-active (rather than reactive) role in adapting to technological change suggests the fruitfulness of examining legal systems that employ methods of legal reasoning that themselves seek to achieve a certain dynamism, capable of being directly responsive to wider societal values and shifts. This arguably points towards the examination of a common law system. As Green and Sales have pointed out 'the common law (and particularly the law of obligations under the common law) is an entity that has been defined by its capacity for evolution, incremental development and flexibility'.²⁰

Not only does this family of legal systems attribute a generative role to the judge, but they demarcate methods of legal reasoning that are designed to guide:

19 Zweigert and Kötz, *Einführung in die Rechtsvergleichung: Auf dem Gebiete des Privatrechts* (Third Edition 1996) 14.

20 Green and Sales, 'Law, Technology and the Common Law Method in the United Kingdom' [2023](5) *Europäische Zeitschrift für Wirtschaftsrecht* p. 205, 205.

complex judgments at every step—from the identification and interpretation of foundational principles, over the determination and weighing of applicable social propositions, to the assessment of the social congruence and systemic consistency of doctrinal propositions, and the adjustment between these requirements as well as the demands of doctrinal stability, which is effected through the choice between different modes of legal reasoning and overturning²¹

Of course one should not overstate the differences between common law and civil law systems.²² However, the creative role envisaged for the judge and the development of methodologies for requisite forms of responsive legal reasoning are arguably two aspects in which significant differences persist.²³ In so far as one wishes to assess how the open-textured doctrine of informed consent, shaped as it is by a wider societal shift, can interact with the deployment of medical AI, it is hypothesized that such a system offers the most intriguing case studies.

It is on these bases that this thesis examines the United Kingdom (UK) and the United States (U.S.). Regarding the first element, these are states that are leading seats of AI innovation,²⁴ and they undoubtedly possess the resources for implementing AI within their healthcare systems.²⁵ This is already evidenced by the fact that there are hundreds of medical devices

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- 21 Hohmann, 'The Nature of the Common Law and the Comparative Study of Legal Reasoning' (1990) 38(1) *The American Journal of Comparative Law* p. 143, 158; See similarly: Green and Sales, 'Law, Technology and the Common Law Method in the United Kingdom' [2023](5) *Europäische Zeitschrift für Wirtschaftsrecht* p. 205, 211-212.
 - 22 See: Lawson, 'The Family Affinities of Common-Law and Civil-Law Legal Systems' (1982) 6(1) *Hastings International and Comparative Law Review* p. 85. Further one should be mindful of the differences in the possibilities for adaptation within distinct types of civil law systems: Beck, Demirgüç-Kunt and Levine, 'Law and Finance: Why Does Legal Origin Matter?' (2003) 31(4) *Journal of Comparative Economics* p. 653.
 - 23 See also Calabresi's seminal analysis, relating the traditional common law reasoning of the courts to the task of balancing adaptation and 'the burden of inertia': Calabresi, *A Common Law for the Age of Statutes* (1985) 117-119.
 - 24 Comparing these jurisdictions to other European nations, see: Franke, 'Artificial Intelligence Diplomacy: Artificial Intelligence Governance as a New European Union External Policy Tool' (2021) <[https://www.europarl.europa.eu/thinktank/en/document/IPOL_STU\(2021\)662926](https://www.europarl.europa.eu/thinktank/en/document/IPOL_STU(2021)662926)> accessed 26.3.2023 10-11.
 - 25 Note in this respect also the relevance of the digital divide between developed and developing nations noted in: World Economic Forum, 'The 'AI divide' between the Global North and Global South' (16.1.2023) <<https://www.weforum.org/agenda/2023/01/davos23-ai-divide-global-north-global-south/>> accessed 26.3.2023.

employing AI that have applied for and have been granted market access in these jurisdictions.²⁶

Things are admittedly more complex when one strives to account for the reimbursement of the clinical uses of the technology and the commissioning of it by providers.²⁷ As is to be expected from our preliminary analysis of the technology, integration of AI/ML into existing systems is still an emerging phenomenon in these respects.²⁸ Nevertheless, the two countries do boast significant strategic frameworks for the purposes of promoting all dimensions of AI adoption as the technology's development proceeds.²⁹ In sum therefore, there are good reasons for supposing that AI is beginning to assume a role in clinical decision making in these states.

A further reason for selecting these jurisdictions is the relation between their understanding of patient autonomy that will inform the identification of relevant AI/ML challenges. Without reaching a definitive conclusion,

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- 26 This will be explored in detail in Chapter 2. See also the guidance issued on how such technologies fit within existing regulatory frameworks: U.S. Food & Drug Administration, 'Artificial Intelligence and Machine Learning in Software as a Medical Device' (2021) <<https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device>> accessed 6.3.2022.
- 27 Davenport and Glaser, 'Factors Governing the Adoption of Artificial Intelligence in Healthcare Providers' (2022) 1(1) Discover Health Systems; Parikh and Helmchen, 'Paying For Artificial Intelligence in Medicine' [2022](5) NPJ Digital Medicine.
- 28 Few devices are being reimbursed in the U.S. and UK healthcare systems: Parikh and Helmchen, 'Paying For Artificial Intelligence in Medicine' [2022](5) NPJ Digital Medicine; Davenport and Glaser, 'Factors Governing the Adoption of Artificial Intelligence in Healthcare Providers' (2022) 1(1) Discover Health Systems; Chaudhury, 'AI in Health in the United Kingdom: An Overview for SME's and Research Institutes on the Trends, Challenges and Opportunities for AI Applications in the British Healthcare Sector' (2021) <https://www.rvo.nl/sites/default/files/2021/06/AI-in-Health-UK-market-report_0.pdf> accessed 26.3.2023.
- 29 In the U.S. there is a flurry of such strategies – covering also the healthcare sphere – by federal and state policymakers, non-profit organisations and private companies: Zhang and others, 'Artificial Intelligence Index Report 2022' (2022) <<https://aiindex.stanford.edu/report/>> accessed 26.3.2023. Specifically regarding reimbursement and adoption one can point to the Centers for Medicare and Medicaid Services' adoption of concrete measures, including reimbursement pathways, for AI: AI Healthcare Coalition, 'AI Healthcare Coalition Appreciates CMS' Efforts to Support Access to Innovative AI Services' (2021) <<https://ai-coalition.org/news/ai-healthcare-coalition-appreciates-cms-efforts-to-support-access-to-innovative-ai-services>> accessed 26.3.2023. In the United Kingdom the central role for AI strategies in healthcare has been granted to the NHS AI lab, which is responsible for accelerating the adoption of AI in healthcare by providing initiatives and guidance. See NHS Transformation Directorate, 'The NHS AI Lab' <<https://transform.england.nhs.uk/ai-lab/>> accessed 26.3.2023.

which must necessarily await the comprehensive examination in Part II., one can hypothesise on this connection.

For these purposes it is notable that the bioethical, and related legal, literature has been at pains to delineate an Anglo-American approach to autonomy. Often this is deployed to distinguish other, especially continental European, systems that place more emphasis on other values, such as solidarity, which shape their understanding of the concept.³⁰ It is also manifested in the pronouncements of American judges and law academics who draw on the close cultural and legal affinities with the UK to emphasise the historical continuity of their adopted concept.³¹ In turn British judges have borrowed from their transatlantic counterparts in shaping relevant legal standards in light of changing perceptions of society and individual interests.³² These interests and shifts were implicitly deemed sufficiently similar to warrant such inferences.

With this one can transition to the common law nature of the selected legal systems. Building on the historical heritage already referred to, both the UK and U.S. engage norms that often evolved from the same legal sources and which remain interconnected by similar modes of legal reasoning.³³ It has been argued that these norms are particularly well-suited to

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- 30 Gaille and Horn, 'Solidarity and Autonomy: Two Conflicting Values in English and French Health Care and Bioethics Debates?' (2016) 37(6) Theoretical Medicine and Bioethics p. 441; Prainsack and Buyx, 'Thinking Ethical and Regulatory Frameworks in Medicine From the Perspective of Solidarity on Both Sides of the Atlantic' (2016) 37(6) Theoretical Medicine and Bioethics p. 489. One must consider the burgeoning, differentiated analyses from other regions too: Orfali, 'A Journey Through Global Bioethics' (2019) 16(3) Journal of Bioethical Inquiry p. 305.
 - 31 *Natanson v. Kline* (1960) 186 Kan. 393, 406-407; Schultz, 'From Informed Consent to Patient Choice: A New Protected Interest' (1985) 95(2) The Yale Law Journal p. 219, 220. See also *In re Gardner* where the court cited John Stuart Mill in their identification of this common concept: *In re Gardner* (Me. 1987) 534 A.2d 947, 950.
 - 32 *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, 886, 899; *Chester v Afshar* [2004] UKHL 41, [2005] 1 AC 134 [53]. See also: Maclean, 'The Doctrine of Informed Consent: Does It Exist and Has It Crossed the Atlantic?' (2004) 24(3) Legal Studies p. 386.
 - 33 For one attempt to ascertain more nuanced differences between American and English legal cultures and reasoning, even concerning analytically identical formulations, see Posner, *Law and Legal Theory in England and America* (2003) 39-45. See also Duxbury who highlights the interconnectedness of such reasoning: 'If a national court has to (...) apply a contentious common law principle, and it is brought to the court's attention that the court (...) of another common law jurisdiction, has already considered at length and in the same language how that (...) principle might best be understood, it would be somewhat odd (though not improper) if that national court

accommodating legal rules to the demands of technological change.³⁴ The judge has the ability to 'extend a rule to a new set of facts provided the differences are irrelevant in light of the principles underlying the rule'.³⁵

For the present context it is concretely envisioned that the judge-led adaptation of common law can serve to accommodate the shifts in social value caused by technological innovation.³⁶ This has led some commentators to state a preference for the common law over legislative solutions within a common law system: 'Often it is better to wait and allow the common law to develop its response before rushing in with new statutes. Because common law rules are inherently more flexible, statutory law reform risks reducing the law's ability to respond to future change'.³⁷

Although not framed comparatively, these insights reinforce the above findings concerning the nature of these systems' legal reasoning. The common law judge ideally keeps abreast of societal developments and is prepared to shape and apply norms to functionally similar scenarios (i.e. scenarios posing sufficiently similar normative problems) even where the precise factual matrix has been drastically altered by novel innovations.³⁸

were to refuse so much as to take a glance at the foreign court's ruling': Duxbury, 'The Law of the Land' (2015) 78(1) *The Modern Law Review* p. 26, 30-31.

34 See Moses, 'The Legal Landscape Following Technological Change: Paths to Adaptation' (2007) 27(5) *Bulletin of Science, Technology & Society* p. 408; Moses, 'Adapting the Law to Technological Change: A Comparison of Common Law and Legislation Courts and Parliament' (2003) 26(2) *UNSW Law Journal* p. 394; Sales and Green critique the generalised nature of this argument: Green and Sales, 'Law, Technology and the Common Law Method in the United Kingdom' [2023](5) *Europäische Zeitschrift für Wirtschaftsrecht* p. 205. The advantages in adaptation to social change, including technological progress, also informed Calabresi's analysis of the common law's role in an age of statutes: Calabresi, *A Common Law for the Age of Statutes* (1985) 69-80.

35 Moses, 'The Legal Landscape Following Technological Change' (2007) 27(5) *Bulletin of Science, Technology & Society* p. 408, 411.

36 'Technological developments in society may also be a relevant type of social value, adding momentum to the need for changes in the law, until the tipping point of incremental adjustment in the existing law is met': Green and Sales, 'Law, Technology and the Common Law Method in the United Kingdom' [2023](5) *Europäische Zeitschrift für Wirtschaftsrecht* p. 205, 210. The reference to the tipping point is representative of these authors' sound argument that the common law possesses only a limited flexibility and can only adjust after a sufficient amount of pressure has built up. Nevertheless, the fundamental point regarding flexibility and adaptability stands.

37 Moses, 'The Legal Landscape Following Technological Change' (2007) 27(5) *Bulletin of Science, Technology & Society* p. 408, 416.

38 The statement of Lord Nicholls of Birkenhead in *Re Spectrum Plus Ltd* is instructive: 'judges themselves have a legitimate law-making function. It is a function they have long exercised. In common law countries much of the basic law is still the common

Selecting the UK and U.S. allows one to examine how well-suited two common law jurisdictions are to adapt to AI innovation in the informed consent context. Crucially also, it allows one to understand and contrast how such adaptation proceeds under a specified legal doctrine.

B. Scope of inquiry

With the legal comparison to be undertaken established, it is now necessary to restrict its object. One limitation emerges from the outlined nature of the comparison. If one aim is to gauge a legally dynamic adaptation to an emerging technological problem, and this directs us towards the examination of common law legal systems, then it stands to reason that the legal mechanisms to be examined should not primarily be statutory in nature. Principally we are directed towards judge-made law.

This excludes certain regimes generally relevant to patient consent in the clinical environment. For example, both jurisdictions have certain statutory regimes for the disclosure of information on the basis of strict product liability and on the basis of data protection considerations. Neither of these will be examined in any depth in this work, since they lack the breadth and flexibility to adapt to the fundamental normative challenges associated with novel impairments of meaningful patient decision making. They are not amenable to the kinds of generative development associated with the common law. Furthermore, although both England and the U.S. possess statutory regimes relevant to the consent of research subjects, these will not be considered. Indeed, here one can adduce the additional rationale that this work's principal concern is the therapeutic deployment of AI.

Given this exclusion, the focus of this work will be made up of the consent obligations that have been developed under the established common law mechanisms of negligence and battery. In both jurisdictions these are the primary instruments determining what information a patient must be provided with under therapeutic circumstances. Battery requires that an individual's person not be interfered with unless there is a relevant legal

law. The common law is judge-made law. For centuries judges have been charged with the responsibility of keeping this law abreast of current social conditions and expectations. That is still the position. Continuing but limited development of the common law in this fashion is an integral part of the constitutional function of the judiciary': *Re Spectrum Plus Ltd* [2005] UKHL 41, [2005] 2 AC 680 [32].

justification, including an individual's valid consent. By comparison negligence requires that healthcare professionals exhibit due skill and care in the performance of their tasks, including in the disclosure of information to the patient. The term 'informed consent' may be applied to refer to the cumulative demands that the courts have imposed on healthcare professionals under the head of these requirements.³⁹

This terminology closely reflects the connection between the developed legal doctrine and the underlying bioethical discourse surrounding patient autonomy. This value arguably provides the principle underlying the common law's fashioning and refashioning of battery's and negligence's more specific rules in light of patient consent.

Lastly for this section, it must be noted that the focus on common law mechanisms must be accompanied by a restriction of jurisdictional scope. In the UK the implications of this delimitation are less severe given that the highest court, the UK Supreme Court, often judges on common law principles, including issues of tort law and informed consent.⁴⁰ Although its decisions are then strictly binding only in the relevant jurisdiction in which the case arose – Scotland, Northern Ireland, or England and Wales – they command considerable respect and persuasive authority in all constituent nations and have generally been followed across the UK.⁴¹ For ease of exposition the author sometimes refers to the law of a specific nation (especially England where a majority of cases arise), but this should not be taken to represent a hard and fast limitation on the scope of the research.

Things are very different in the United States. The federal nature of the system precludes the U.S. Supreme Court from judging on most matters of common law, which fall in the preserve of the individual states. Commenting on one leading exposition of tort law in the U.S. Gardner has critically remarked 'They give the impression that they are writing about the tort law of the United States of America. But it is doubtful whether there is such a thing. There are at least 51 legal systems in the United States with tort

39 Maclean, 'The Doctrine of Informed Consent' (2004) 24(3) Legal Studies p. 386, 392-393. Although the author notes a distinction that can be drawn between 'real consent' required for battery and the 'informed consent' under negligence.

40 The leading informed consent decision of *Montgomery v Lanarkshire Health Board* is itself a Scottish case, but it has shaped the common law across the UK: *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [2015] AC 1430.

41 Bankowski, MacCormick and Marshall in MacCormick and Summers, *Interpreting Precedents: A Comparative Study* (2016) 315.

jurisdictions'.⁴² There is no doubt some uniformity of principle amongst these jurisdictions, but there are also important differences. Any detailed examination of what specific mechanisms require, and how legal reasoning engages with these requirements, must therefore be conducted at the level of the individual system, the individual state. Although cases from other states may serve as persuasive authority for the determination of specific questions, as in the common law more widely, these are not automatically or routinely followed.

In consequence, the present analysis will not examine the approach of all U.S. jurisdictions. Rather, California is selected as a targeted case studied, enabling a nuanced evaluation of this system's requirements. One reason for selecting this state is the finding that its Supreme Court is consistently one of the most cited courts in the country.⁴³ This suggests that it is a state whose pronouncements of the law are more influential and can be expected to provide a better approximation to the state of affairs across the U.S. Nevertheless, it is by no means representative and significant divergent approaches will be touched upon where relevant in the course of the analysis.

A second reason is the particular role that California has played in the development of the informed consent doctrine. By operating in a manner responsive to wider socio-cultural changes, it has reinterpreted and reshaped the common law. Not only is it a decision of this jurisdiction – *Salgo v. Leland* – that provided the terminology of 'informed consent', but the seminal Californian Supreme Court case *Cobbs v. Grant* outlined applicable principles that have been widely cited and applied in California's sister jurisdictions.⁴⁴ Many more examples of such influential generative activity will be provided in Chapter 7.⁴⁵ Suffice it to say here that it is a

42 Gardner, *Torts and Other Wrongs* (2019) 1-2, referring primarily to Goldberg and Zipursky, 'Torts as Wrongs' (2010) 88(5) *Texas Law Review* p. 917.

43 Hinkle and Nelson, 'The Transmission of Legal Precedent among State Supreme Courts in the Twenty-First Century' (2016) 16(4) *State Politics & Policy Quarterly* p. 391, 399.

44 *Salgo v. Leland Stanford Jr. University Bd. of Trustees* (1957) 154 Cal.App.2d 560; *Cobbs v. Grant* (1972) 8 Cal.3d 229. For a high profile case outside of California citing these principles see, for example: *Mink v. University of Chicago* (N.D.Ill. 1978) 460 F.Supp. 713, 716-718.

45 Touching on cases like: *Truman v. Thomas* (1980) 27 Cal.3d 285 (imposing informed consent requires where there was a refusal of treatment) and *Moore v. Regents of University of California* (1990) 51 Cal.3d 120 (extending informed consent requirements beyond the realm of treatment risks and alternatives to include professional conflicts of interest).

state that is hypothesised to be particularly well suited to the adaptation of informed consent requirements to the dynamic challenges posed by medical AI.

C. Legal reasoning and technological innovation

Within this scope it is a fundamental aim of this work to further an understanding of the law's dynamic and variable interaction with the phenomenon of social change and specifically technological innovation.⁴⁶ The method developed here seeks to anticipate the possibilities for applying and adapting common law mechanisms to meet the challenges posed to patient autonomy by one such innovation: medical AI/ML.

As the quote at the beginning of this chapter illustrates, the law's ability to adapt to changing social, extra-legal circumstances has been a topic of long-standing interest. It has informed foundational schools of thought such as legal realism⁴⁷ and the economic analysis of the law.⁴⁸ In the selection of our comparator countries it has also been discussed that the adaptability of the law has informed examinations of different legal families (common law vs. civil law systems) and of different sources of law (common law vs. legislation).

Further, it is important to note that the responsiveness to external factors cannot be regarded as uniform across different legal subject areas. While the focus of this work, private law, has traditionally been regarded as less responsive to social and political influences,⁴⁹ this is not at all true for other

46 That AI is one instantiation of such technological innovation is the key point for our purposes: Liu and others, 'Artificial Intelligence and Legal Disruption: A New Model for Analysis' (2020) 12(2) *Law, Innovation and Technology* p. 205. For a more general definition of technology see: Crootoof and Ard, 'Structuring Techlaw' (2021) 34(2) *Harvard Journal of Law & Technology* p. 347, 348-349.

47 Cohen, 'Transcendental Nonsense and the Functional Approach' (1935) 35(6) *Columbia Law Review* p. 809; Gilmore, 'Legal Realism: Its Cause and Cure' (1961) 70(7) *The Yale Law Journal* p. 1037.

48 Landes and Posner, *The Economic Structure of Tort Law* (1987). On the knock-on impact of this school of thought on Lessig's prominent theory of the regulation of technology (specifically cyberspace) see: Mayer-Schonberger, 'Demystifying Lessig' [2008](4) *Wisconsin Law Review* p. 713, 723-724.

49 Robertson in Robertson and Tang, *The Goals of Private Law* (2009) 269-279. This characterisation holds at least in the sense of the formally recognised influences on legal actors and commentators in this area: Landes and Posner, *The Economic Structure of Tort Law* (1987) 5-6.

fields, such as social law⁵⁰ and constitutional law.⁵¹ Even generalisations within a given field must be questioned and this is one aspect that our methodology will uncover and emphasise. Structured adaptation under conditions of uncertainty and flux is a ubiquitous aspect of legal orders and many normative analyses thereof, but it is recognised to be highly variable. It exists in a state of tension between the law's stabilising function and its need to provide guidance that is appropriate to the subjects' circumstances.⁵²

For technological innovation there has been a recurring problematization of this tension and its implications for the capacity of law to regulate the underlying phenomenon.⁵³ Although the literature on this subject remains highly fragmented and multi-faceted,⁵⁴ associated challenges are

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- 50 'Sozialrecht zeichnet sich aber durch seine besondere Funktionalität aus. Es beruht nur in wenigen Grundzügen auf normativen Vorgaben, seine Existenz wie seine Ausgestaltung sind stärker von sozialpolitischen als von verfassungsrechtlichen Erwägungen geprägt. Und selbst diese Erwägungen sind oft hinter den einmal geschaffenen und dann ein eigenes Beharrungsvermögen entwickelnden Einrichtungen kaum mehr erkennbar': Becker, 'Sozialrecht und Sozialrechtswissenschaft' (2010) 65(4) *Zeitschrift für öffentliches Recht* p. 607, 619; Zacher in Zacher, Maydell and Eichenhofer, *Abhandlungen zum Sozialrecht* (1993) 17. The need for a legal framework responsive to social policy, so as to accommodate specifically the demands of the welfare state, has also been highlighted in common law systems: Harris in Harris, *Social Security Law* (2000) 3-5; Calabresi, *A Common Law for the Age of Statutes* (1985) 74.
- 51 It is impossible to provide a comprehensive listing of the literature that engages with the potential for the adaptation of constitutions in accordance with extra-legal pressures. Examples include: Johnson and Yi Zhu, *Sceptical Perspectives on the Changing Constitution of the United Kingdom* (2023); Harrison and Boyd, *The Changing Constitution* (2006); Ackerman, 'The Storrs Lectures: Discovering the Constitution' (1984) 93(6) *The Yale Law Journal* p. 1013. Interesting approaches falling under this rubric can, naturally, also be found in different legal families: Hornung, *Grundrechtsinnovationen* (2015).
- 52 Becker, 'Sozialrecht und Sozialrechtswissenschaft' (2010) 65(4) *Zeitschrift für öffentliches Recht* p. 607, 618.
- 53 The distinctness of the technological nature of change from other processes of social change and the particular legal problems posed by this are highlighted in: Moses, 'Why Have a Theory of Law and Technological Change?' (2007) 8(2) *Minnesota Journal of Law, Science & Technology* p. 589. See also: Crotoft and Ard, 'Structuring Techlaw' (2021) 34(2) *Harvard Journal of Law & Technology* p. 347, 349-350; Price, 'The Newness of New Technology' (2001) 22(5-6) *Cardozo Law Review* p. 1885, 1888; Calabresi, *A Common Law for the Age of Statutes* (1985) 74-77.
- 54 Guihot, 'Coherence in Technology Law' (2019) 11(2) *Law, Innovation and Technology* p. 311; Brownsword, Scotford and Yeung, *The Oxford Handbook of Law, Regulation and Technology* (2016) 7-8: 'Any attempt to identify an overarching purpose or com-

widely and consistently discussed. Above all these discussions tend to exhibit three prevalent assumptions that frame the law as a problematic regulator of innovation: (1) the pre-eminence of an instrumentalist perspective that judges ‘good outcomes’, attained through the law or otherwise, primarily according to policy-orientated yardsticks (2) the identification of a substantial, unavoidable difference in the speed of adaptation or change between technology and the law (3) a preference for non-legal regulatory modalities that are said to be better placed to realise policy-objectives in relation to technological innovation.

In the remainder of this section the nature of these assumptions and the support they enjoy in the literature is outlined. Simultaneously, by indicating the manner in which the present methodology challenges, and to some extent departs from, them it is anticipated how the ensuing analysis of AI/ML devices and informed consent will contribute to the fundamental conversation concerning the law’s relationship to innovation.

1. Instrumentality of law

The first theme to be found in the literature relates to the focus on policy-orientated reasoning and the assumption that legal modes of regulating technology are and ought to be directed by these ends.⁵⁵ Given the open-ended nature of policy-orientated reasoning, it is difficult to pin down one definitive account in this respect; the relevant ends are highly, potentially infinitely, variable. However, it is clear that prominent examples include the need: to support and promote innovation, to minimise harm and/or to suitably allocate economic resources and incentives.⁵⁶ These objectives are taken to be the *raison d’être* for legal and extra-legal technology regulation. To the extent that the legal system falls short in accomplishing the tasks set

mon identity in the multiple lines of inquiry in this field may well fail to recognize the richness and variety of the individual contributions and the depth of their insights’.

55 Brownsword, ‘Law Disrupted, Law Re-Imagined, Law Re-Invented’ (2019) 1 Technology and Regulation p. 10 24-27. This is also evident in Guihot’s exposition of technology law: Guihot, ‘Coherence in Technology Law’ (2019) 11(2) Law, Innovation and Technology p. 311, 322-325.

56 Cockfield and Pridmore, ‘A Synthetic Theory of Law and Technology’ (2007) 8(2) Minnesota Journal of Law, Science & Technology p. 475, 503-504; Brownsword, *Law 3.0: Rules, Regulation, and Technology* (2021) 21-22; Hoffmann-Riem, *Innovation und Recht - Recht und Innovation: Recht im Ensemble seiner Kontexte* (2016) 28-35.

according to these malleable yardsticks, the law is subject to censure and ought to be reformed, supplemented or abrogated.⁵⁷

In responding to this prevalent assumption, this work builds on critical accounts that object to a conception of the law as purely an instrument for the realisation of external values.⁵⁸ Instrumentality is partly objectionable from a purely descriptive perspective because it posits an inaccurate unidirectional relationship between law, society and technology. But more than this, it is objectionable on normative grounds because it ignores the way in which values are transformed through their interaction with the legal process and it does not account for the wider relevance of the outputs of this process.⁵⁹ Assuming an instrumentalist perspective consequently closes off or distorts this contribution of the law to society's adjustments to technological change.

57 Brownsword, *Law 3.0: Rules, Regulation, and Technology* (2021) 17-20.

58 For critical overviews see: Tranter, 'The Law and Technology Enterprise: Uncovering the Template to Legal Scholarship on Technology' (2011) 3(1) *Law, Innovation and Technology* p. 31; Tribe, 'Technology Assessment and the Fourth Discontinuity: The Limits of Instrumental Rationality' (1973) 46(3) *Southern California Law Review* p. 617, 631: 'By focusing all but exclusively on how to optimize some externally defined end state, policy-analytic methods distort thought, and sometimes action, to whatever extent process makes—or ought to make—an independent difference'. For recent examples of such an approach see: Marchant in Marchant, Allenby and Herkert, *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem* (2011); Brownsword, 'Law Disrupted, Law Re-Imagined, Law Re-Invented' (2019) 1 *Technology and Regulation* p. 10, 15; Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) 241.

59 Gutwirth and others have expressed a deep-seated dissatisfaction with the state of discourse in this area with which the present author sympathises: 'what we wanted to express was a disappointment towards a position that now dominates the legal discussions around new technologies—while at the same time rendering it impossible to go further. We do not consider that regulation is a terminus. On the contrary, we rather see it as a point where to start in order to build a more interesting legal appreciation of the emergence of new technologies. At the end of the present paper, it is not a mystery that we would see this legal appreciation formulated in the terms of the legal practice itself, rather than in the terms of what, for lack of better words, we are forced to qualify as political science. We trust that to ask the lawyers themselves how they deal with new technologies would always be more interesting and more enlightening than to define some very sophisticated program, however balanced and nuanced it might be, in order to avoid their escape': Gutwirth, Hert and Sutter in Brownsword and Yeung, *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (2008) 216. See also: Hildebrandt, *Smart Technologies and the End(s) of Law: Novel Entanglements of Law and Technology* (2015) 163-165.

Beginning with the descriptive component, critical commentators have picked up on the fact that instrumental accounts tend to imply a certain relationship between technology, society and the legal system. Specifically, it is claimed that they exhibit ‘technological determinism’ – positing a relatively simple, unidirectional influence of technological progress on the law.⁶⁰ Law serves extraneous ends *because* innovation will inevitably affect its functioning, whereas accelerating and self-reinforcing technological progress could not be stopped or, at any rate, only at an unrealistic cost.⁶¹ In this manner, law and society are bound to conform to the new reality shaped by innovation and legal actors – scholars, judges, legislators – must adjust their thinking as best they can.⁶²

However, such a determinism is objectionable because it is inaccurate. This is evidenced by the fact that it is widely eschewed in other areas of social science enquiry.⁶³ To the extent that accounts in the law and technology field reproduce this narrative, they are ignoring the way in which technology is socially constructed and, partially also, constructed by the surrounding legal framework.⁶⁴

60 Jones, ‘Does Technology Drive Law? The Dilemma of Technological Exceptionalism in Cyberlaw’ [2018](2) University of Illinois Journal of Law, Technology & Policy p. 249, 253-260; Mayer-Schonberger, ‘Demystifying Lessig’ [2008](4) Wisconsin Law Review p. 713, 737-738.

61 This is all the more true as there are now synergies between fundamental fields of technological development that speed up the progress of the others, including: ‘nanotechnology, biotechnology, robotics, information and communication technology (ICT), and applied cognitive science’: Allenby in Marchant, Allenby and Herkert, *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem* (2011) 7-11.

62 Jones, ‘Does Technology Drive Law? The Dilemma of Technological Exceptionalism in Cyberlaw’ [2018](2) University of Illinois Journal of Law, Technology & Policy p. 249, 256; Tranter, ‘The Law and Technology Enterprise’ (2011) 3(1) Law, Innovation and Technology p. 31, 76: ‘The message is that it is law’s function to implement policy, not to debate the merits of policy’.

63 Jones, ‘Does Technology Drive Law? The Dilemma of Technological Exceptionalism in Cyberlaw’ [2018](2) University of Illinois Journal of Law, Technology & Policy p. 249, 253-259; Mayer-Schonberger, ‘Demystifying Lessig’ [2008](4) Wisconsin Law Review p. 713, 739-740. For a good overview of the intellectual development of the approach in the social sciences see: Winner, ‘Upon Opening the Black Box and Finding It Empty: Social Constructivism and the Philosophy of Technology’ (1993) 18(3) Science, Technology, & Human Values p. 362; Grattet, ‘Sociological Perspectives on Legal Change: The Role of the Legal Field in the Transformation of the Common Law of Industrial Accidents’ (1997) 21(3) Social Science History p. 359, 363-365.

64 ‘[T]echnologies must be understood as integrated cultural, economic, institutional, and built phenomena. To consider technology to be merely artifacts, while appropri-

The described arguments indicate that the descriptive criticism maintains some relevance. However, as many legal scholars do now address the interrelationship between law, technology and society,⁶⁵ and seemingly to a growing extent,⁶⁶ it does not constitute the focus of this analysis. In particular, critics of law as a regulatory tool submit that the legal framework plays a role in shaping technological development and society's reaction to that development.⁶⁷ This role is often encapsulated precisely in the arguments of those who fear that it threatens the instrumental goal of furthering, promoting (rather than stifling) innovation.⁶⁸

Where the existing accounts still fall short is arguably in respect of the aforementioned normative dimension. They maintain a limited outlook on the nature of legal norms and fail to account for the wider relevance of values that are constructed or transformed through the legal process. Even if the law is seen to have an influence on innovation, avoiding technological determinism, it is still framed in terms of quite limited standards.

Specifically, in so far as the primary emphasis of commentators remains (in a relatively narrow positivistic fashion)⁶⁹ on rules, this allows them to frame the legal system as a discretionary tool that can realise any ex-

ate in many cases, would lead to gross over-simplification and dysfunctional analysis and policy formulation if applied to technology systems': Allenby in Marchant, Allenby and Herkert, *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight* (2011) 7.

65 Kaminski charts how one prominent early scholar of cyberlaw addressed this dimension, but occupied a minority position: Kaminski, 'Technological "Disruption" of the Law's Imagined Scene: Some Lessons from Lex Informatica' (2021) 36(3) *Berkeley Technology Law Journal* p. 883, 888. See also: Moses, 'Why Have a Theory of Law and Technological Change?' (2007) 8(2) *Minnesota Journal of Law, Science & Technology* p. 589, 599-600.

66 For a recent nuanced engagement with this point see: Crootoof and Ard, 'Structuring Techlaw' (2021) 34(2) *Harvard Journal of Law & Technology* p. 347, 355-356.

67 Lessig, *Code: Version 2.0* (2006) 61-80; Brownsword, *Law 3.0: Rules, Regulation, and Technology* (2021) 51-53; Cockfield and Pridmore, 'A Synthetic Theory of Law and Technology' (2007) 8(2) *Minnesota Journal of Law, Science & Technology* p. 475, 497-500.

68 'In some cases, lethargic development of new legislation or adaptation of existing legislation in response to scientific discovery or development can impede research and innovation, resulting in blocking of new technology': Marchant in Marchant, Allenby and Herkert, *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight* (2011) 25.

69 Cf. Tranter, 'The Law and Technology Enterprise' (2011) 3(1) *Law, Innovation and Technology* p. 31, 69.

ternal policy objective.⁷⁰ Rules themselves could apparently be interpreted, amended, abrogated or replaced simply in accordance with the desired ends of a relevant authority.⁷¹ When examined in isolation they appear easy to refashion in a way that is directly transparent to desired values. With a background assumption that technological progress amounts to social progress, it can only be expected that the innovation context heightens the perceived malleability of the law even further.⁷²

Of course, there are also voices that recognise a broader role for the law in guiding societal adjustment to innovation. This perspective is promoted mostly by those who assert the importance of basic human rights standards.⁷³ The recognition of the relevance of these fundamental normative goalposts provides an invaluable contribution to the law and technology literature, moving away from an instrumentalist perspective and recognising the law's unique potential in this area.⁷⁴ However, it arguably does not

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- 70 It is notable how often the framing is focused on the specific, rule-based framework. See: Mandel in Brownsword, Scotford and Yeung, *The Oxford Handbook of Law, Regulation and Technology* (2016); Rustad and Koenig, 'Cybertorts and Legal Lag' (2003) 13(1) Southern California Interdisciplinary Law Journal p. 77; Kaminski, 'Technological "Disruption" of the Law's Imagined Scene' (2021) 36(3) Berkeley Technology Law Journal p. 883, 892. Epstein presents a version of this position in response to economic analyses of the law: Epstein, 'The Static Conception of the Common Law: Legal and Economic Perspectives' (1980) 9(2) The Journal of Legal Studies p. 253, 269-273.
- 71 The apparent unfettered discretion that a focus on rules granted judges was one of Dworkin's criticisms of the positivist conception of law: Dworkin, *Taking Rights Seriously* (1987) 37-39.
- 72 Jones, 'Does Technology Drive Law? The Dilemma of Technological Exceptionalism in Cyberlaw' [2018](2) University of Illinois Journal of Law, Technology & Policy p. 249, 256-257.
- 73 Brownsword, 'Law Disrupted, Law Re-Imagined, Law Re-Invented' (2019) 1 Technology and Regulation p. 10, 27; Murphy, *New Technologies and Human Rights* (2009). Cf. Askland who hints at a broader role: 'If the changes are unavoidable, but their form is unspecified, then law ought to be able to negotiate about that form. This negotiation role surely should not be limited to law, but as law reflects important ethical, social and economic values, it ought to be included among the negotiators': Askland in Marchant, Allenby and Herkert, *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem* (2011) xvii.
- 74 Sator makes an instructive statement in this regard 'Human rights are indeed important since they provide us with a framework for articulating some basic normative structures for the governance of the information society, in the awareness of the human values at stake. It is true, authoritative formulations, doctrinal developments and social understanding of human rights cannot provide us with a complete regulatory framework: economical and technological consideration must be taken into account,

go far enough in recognising the pervasive presence of relatively abstract legal norms (i.e. norms that are not fundamental rights and which do not originate in public or international law) that co-exist, conflict and possess relevance to society's co-evolution with innovation.

The method of this work will bring out this dimension by emphasising the role of principles in legal argumentation. Such principles may be motivated by external normative influences, but they have manifestly been translated into unique terms that allow them to perform a structured role in the resolution of conflicts.⁷⁵ This prevents an arbitrary repurposing of legal mechanisms and, critically, it demonstrates how the law offers instructive guidance going beyond its immediate area of application.

2. Technological dynamism and legal inertia

The second assumption that is widespread in the literature focuses on the inertia of legal regulation. It is stated that legal regulation lags, and must lag, behind technological developments.⁷⁶ Technological innovation embodies

while legal traditions and political choices play a decisive role in many regards (even with regard to the very understanding of human rights and their balance). However, the human-rights discourse still play an important role: it identifies some basic fundamental needs and entitlements, it links our understanding of such needs and entitlements to successes and failures of human history, it enables us to provide a context for our analysis of the new issues emerging in the information society, linking such analysis to a rich background including legal cases as well as social, political and legal debates': Sartor in Azevedo Cunha and others, *New Technologies and Human Rights: Challenges to Regulation* (2013) 19. Another commentator who highlights the benefits of human rights, especially their ability to be flexibly adapted to local circumstances is: Somsen in Murphy, *New Technologies and Human Rights* (2009) 115.

- 75 Compare Brownsword who has undertaken a normative analysis of 'a newly recognised interest in human dignity', selecting a contested understanding of that interest and hypothetically integrating this interest into the existing tort system, but not deeming it necessary to conceive of the value itself in a way that transforms it into a legal norm: Brownsword, 'An Interest in Human Dignity as the Basis for Genomic Torts' (2003) 42(3) *Washburn Law Journal* p. 413, 416-419. In Part II. we will see similar trends in the literature on autonomy, treating it purely as a value that is utilised in legal reasoning.
- 76 Friedman and Ladinsky, 'Social Change and the Law of Industrial Accidents' (1967) 67(1) *Columbia Law Review* p. 50, 73; Rustad and Koenig, 'Cybertorts and Legal Lag' (2003) 13(1) *Southern California Interdisciplinary Law Journal* p. 77; Marchant in

the idea of rapid, even revolutionary, change.⁷⁷ This change bypasses or disrupts existing legal paradigms.⁷⁸ These paradigms must be adjusted or abandoned, in line with the instrumentalist approach, to serve external goals. This represents an orthodox understanding of the 'legal lag',⁷⁹ or the 'pacing problem'.⁸⁰

Although connected, this narrative of the law's inflexibility in the face of change is more commonly made explicit in the literature on the interaction between law and technology than the instrumentalist thesis.⁸¹ Still, one would be remiss if one did not properly account for the spectrum of positions that have emerged from the basic assumption that the law struggles to adapt to the speed of innovative developments.

At one end of this spectrum there is a refined, but unfaltering account of the pacing problem. It is submitted that the law does possess capabilities for adaptation, but that technological change challenges these in a manner, or at a scale, that other social developments do not.⁸² In consequence, the gap in relation to the law's ever-shifting regulatory target remains a problem of considerable magnitude – at the very least given the speed of change that modern societies are experiencing.⁸³ At the other end of the spectrum, there are a miscellany of approaches that view the law as more adaptable than it

Marchant, Allenby and Herkert, *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight* (2011).

77 Price, 'The Newness of New Technology' (2001) 22(5-6) *Cardozo Law Review* p. 1885, 1886, 1912-1913.

78 Brownsword, *Law 3.0* (2021) 17-20.

79 Rustad and Koenig, 'Cybertorts and Legal Lag' (2003) 13(1) *Southern California Interdisciplinary Law Journal* p. 77, 77-78.

80 Marchant in Marchant, Allenby and Herkert, *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight* (2011) 23.

81 Friedman and Ladinsky, 'Social Change and the Law of Industrial Accidents' (1967) 67(1) *Columbia Law Review* p. 50, 73.

82 Askland in Marchant, Allenby and Herkert, *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight* (2011) xviii-xix.

83 'On the face of it, coherentism belongs to relatively static and stable communities, not to the dynamic and turbulent technological times of the Twenty-First Century not as a response to unauthorised drones at airports, or to dangerous or distressing online content, or to accidents involving robot carers (...) to assume that traditional legal frameworks enable regulators to ask the right questions and answer them in a rational way seems over-optimistic': Brownsword, 'Law Disrupted, Law Re-Imagined, Law Re-Invented' (2019) 1 *Technology and Regulation* p. 10, 17; Marchant in Marchant, Allenby and Herkert, *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight* (2011) 25-27; Post, 'Against "Against Cyberanarchy"' (2002) 17(4) *Berkeley Technology Law Journal* p. 1365, 1374-1384.

is generally given credit for and innovation is not generally understood to represent an exceptional challenge in this respect.⁸⁴ Naturally these latter approaches still submit, however, that law can only change to a limited extent. Stability remains an important reference point.⁸⁵

The interesting question that emerges from this line of thinking for the present work, is not that this spectrum exists, which has been the subject of considerable discussion,⁸⁶ but the manner in which the law's adaptability is properly conceived from a methodological standpoint. To the extent that some adaptability is associated with the law, one must ask how this is properly represented and accounted for in the doctrinal analysis of a fast-evolving, allegedly disruptive innovation, such as AI. Only once the law's potential for dynamism has been scrutinised within a given context, should one make a specific judgment on the existence of an allegedly irreducible legal inertia.⁸⁷

One starting point is certainly to attempt to anticipate the nature of an emerging innovation and its wider implications.⁸⁸ This work addresses this

84 Tranter offers an overview of early legal analyses of technology that were optimistic in this regard: Tranter, 'The Law and Technology Enterprise' (2011) 3(1) *Law, Innovation and Technology* p. 31, 38; Morgan's specific analysis of tort law goes so far as to state an 'adaptability hypothesis' according to which tort law can be developed to respond to the harms of new technologies: Morgan in Brownsword, Scotford and Yeung, *The Oxford Handbook of Law, Regulation and Technology* (2016) 524-526. In a recent contribution Ard has also considered that, at the level of doctrine, changes demanded by technological innovation are often less problematic than widely perceived: Ard, 'Making Sense of Legal Disruption' (2022) *Forward Wisconsin Law Review* p. 42, 46-48.

85 Predictability and stability are valuable contributions of the law's functioning and they usually constitute an asset rather than an insurmountable problem: Kaminski, 'Technological "Disruption" of the Law's Imagined Scene' (2021) 36(3) *Berkeley Technology Law Journal* p. 883, 888.

86 Berman, *Law and Society Approaches to Cyberspace* (2007) xiii-xiv.

87 Friedman and Ladinsky, 'Social Change and the Law of Industrial Accidents' (1967) 67(1) *Columbia Law Review* p. 50, 73-75.

88 Tranter, 'The Law and Technology Enterprise' (2011) 3(1) *Law, Innovation and Technology* p. 31, 38; Cockfield, 'Towards a Law and Technology Theory' (2003) 30(3) *Manitoba Law Journal* p. 383, 384-388; Askland in Marchant, Allenby and Herkert, *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight* (2011) xv-xvii. In contrast Moses highlights the difficulty of anticipating such developments: Moses, 'Why Have a Theory of Law and Technological Change?' (2007) 8(2) *Minnesota Journal of Law, Science & Technology* p. 589, 599-600.

aspect in Part I. But the question remains how a pre-existing legal doctrine then adjusts itself in the light of the identified shifting circumstances.⁸⁹

A common method is to situate legal responses on a continuum of more liberal approaches and more restrictive, conservative one.⁹⁰ Naturally, this represents a simplification. But more concerningly, it often does not represent a considered attempt to track legal reasoning at all. Instead, it is based on an instrumental perspective. For example, the choice of a court to assume one stance or the other is framed by reference to consequentialist concerns or by reference to the goal of making other regulatory interventions more likely.⁹¹ Given this, such approaches fail to engage with the law's internal capacity for adaptation. Again, the posited vision is that of external pressures refashioning a legal system that has already failed to 'get with the programme'.

More detailed considerations emerge in works that examine how legal adaptation proceeds according to uniquely legal demands.⁹² Here the pro-

89 'Altered flows of information, resulting from new technologies, change the balances that previously existed in a legal framework. But it is hard to know when those changes undo the preexisting formulaic approaches to a task': Price, 'The Newness of New Technology' (2001) 22(5-6) *Cardozo Law Review* p. 1885, 1913. One common pitfalls is to think too narrowly, to focus only on narrow analogical arguments in this regard. This has provided a convincing basis for critique: Post, 'Against "Against Cyberanarchy"' (2002) 17(4) *Berkeley Technology Law Journal* p. 1365, 1373-1376.

90 Cockfield, 'Towards a Law and Technology Theory' (2003) 30(3) *Manitoba Law Journal* p. 383, 407-408; Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) 167; Crootof and Ard, 'Structuring Techlaw' (2021) 34(2) *Harvard Journal of Law & Technology* p. 347, 379-386.

91 Respectively: Cockfield, 'Towards a Law and Technology Theory' (2003) 30(3) *Manitoba Law Journal* p. 383, 407-408; Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) 182-184.

92 Gutwirth and others have recognised these procedural aspects by forcefully asserting that external, technological questions must be transformed into 'legal matter' to become 'the object of the legal operation': Gutwirth, Hert and Sutter in Brownsword and Yeung, *Regulating Technologies* (2008) 204-205. In the context of tort law, Bell and Ibbetson have analysed and affirmed the distinct role that legal doctrine plays in the process of adaptation to social change. Such adaptation is not free but is directed by existing forms of thought and the need to ensure coherence within a system of norms: Bell and Ibbetson, *European Legal Development: The Case of Tort* (2012), 162-163. This is true especially within judge-made law, but legislative activity too is subject to the implicit constraints of the legal operation, interacting with established modes of thought and often proceeding incrementally: Bell and Ibbetson, *European Legal Development: The Case of Tort* (2012) 171-172. It is a separate question in how far legislative activity is bound by its own rules and in how far this is detrimental when confronted with novel or extraordinary circumstances. I have commented on

cess of legal reasoning is conceived of as providing the potential for a creative activity, allowing a dynamic and contestable crystallisation of legal commitments.⁹³ When interacting with novel social circumstances, judicial actors must be mindful of the limitations of their enterprise, they are performing legal operations, but this does not preclude creativity – there can be “obligations” of creativity’.⁹⁴

Under such an account it is evident that the law’s response to technological uncertainty inherently makes a generative contribution that is distinctly related to the legal process.⁹⁵ It is not exhausted by an analysis of limiting rules that are subject to adaptation according to vicissitudes of external necessity and external evaluations: ‘One must take into account the law’s own dynamics, the own *devenir* of the law’.⁹⁶ Overall this is hypothesised to yield a more nuanced and informative account of the law’s co-evolution with technology and with society more generally.

The present work, through its common-law lens, engages precisely with this generative dimension of the law and seeks to offer one concretisation of it. Again, by focusing its analysis on the role of principles – which impact and alter existing, potentially inapposite, norms in a structured manner – a richer account of the law’s potential for adaptation is provided. The underpinnings for this approach are developed in Part II. and its implications are seen in Part III., where it is examined how well the law is placed to adapt to the autonomy-based challenges posed by medical AI.

this elsewhere: Günther, ‘Legal vs. Extra-Legal Responses to Public Health Emergencies’ (2022) 29(1) *European Journal of Health Law* p. 131.

93 An excellent exposition of this point is provided in the German context by: Hoffmann-Riem, *Innovation und Recht - Recht und Innovation: Recht im Ensemble seiner Kontexte* (2016) 80-84. See also Kaminski, ‘Technological “Disruption” of the Law’s Imagined Scene’ (2021) 36(3) *Berkeley Technology Law Journal* p. 883, 892-895.

94 Gutwirth, Hert and Sutter in Brownsword and Yeung, *Regulating Technologies* (2008) 205-208. This general point going towards the creative potential of legal restrictions also echoes elements of Lon Fuller’s work, especially his conceptualisation of a ‘liberating limitation’: Fuller in Winston, *The Principles of Social Order: Selected Essays of Lon L. Fuller* (Revised Edition 2001) 66.

95 Gutwirth, Hert and Sutter in Brownsword and Yeung, *Regulating Technologies* (2008) 207-209, 214-215. The authors here also refer to Dworkin and MacCormick’s theories, which will be utilised in our understanding of legal reasoning. However, while identifying their relevance to the underlying issue, they mainly refer to them in order to distinguish them from Latour’s description of legal practice (the theory that they themselves rely on).

96 *ibid* 216.

3. Desirability of non-legal regulation

If one pairs the instrumental assessment of law with the view that there is a substantial lag in the legal system's adjustment to technological change, then one can already see why the legal regulation of technology can be judged ineffective. A third strand in the law and technology literature adds to these views the conviction that, not only does technology evolve quicker in terms of generating societal challenges, but that it is simultaneously better placed to offer solutions to these challenges through relevant designs and architectures.⁹⁷ To be clear, this does not mean that law cannot have a role in framing technological solutions, but only that it should be supplemented to a sufficient degree by these and that it should perform a secondary function.⁹⁸

Having outlined the nature of the first two assumptions, we can deal with this third aspect more succinctly. For, it builds upon the *relative* slowness of the law and it is based upon an instrumental mentality that prizes the *relative* effectiveness of technological solutions. Specifically, the potential benefits of technological over legal regulation relate to the direct, unmediated effect of the former and the rapidity with which any necessary adjustments can be made.⁹⁹

For example, a change in the design of cyberspace – effectively *ex ante* regulation through code – has been described as the application of a rule ‘through a kind of physics’.¹⁰⁰ It has often been repeated in the context of cyberlaw that the architecture, the design of a technical environment can leave users with no choice other than to obey. This ensures compliance

97 Famously Lessig referred to such solutions as West Coast Code, as opposed to the legal East Coast Code: Lessig, *Code* (2006) 71-74. For a recent critical examination of the relationship between code and law as regulatory modalities and the influences between the two see: Kähler in Kuhli and Rostalski, *Normentheorie im digitalen Zeitalter* (2023).

98 Reidenberg, ‘Governing Networks and Rule-Making in Cyberspace’ (1996) 45(3) Emory Law Journal p. 911, 927-930; Lessig, *Code: Version 2.0* (2006) 114-119; Brownsword, *Law 3.0: Rules, Regulation, and Technology* (2021) 28-30.

99 Reidenberg, ‘Lex Informatica: The Formulation of Information Policy Rules through Technology’ (1997) 76(3) Texas Law Review p. 553, 577-581. Here Reidenberg refers also to ‘jurisdictional advantages’, which are excluded in the following as they are less relevant to the regulation of physical technologies such as AI medical devices.

100 Lessig, *Code* (2006) 81-82.

much more effectively than the legal system's behaviour-guiding norms could ever hope to achieve.¹⁰¹

Similarly, it has been remarked that customisations in the technological sphere can be achieved with lower costs and increased flexibility (in the sense of a personal tailoring of measures) than would be possible for legal regulation.¹⁰² Such increased adaptability offers one apparent response to the pacing problem. Whereas the law is cumbersome, time-consuming and expensive to change, technology is not. This has also been used as an argument for the overhaul of legal thinking in favour of a more instrumentalist mindset: since non-technological solutions score comparatively worse under the selected parameters they are said to be fundamentally disrupted and it only makes sense to exhibit a general tendency towards technological solutions.¹⁰³

This thesis will touch upon the nature of extra-legal solutions in the clinical AI context. The Part I. analysis of ML devices seeks to anticipate whether changes to the underlying technology can immediately and effectively make contributions to the resolution of relevant normative problems. Rather than framing this as an assessment that arises from a disruption of legal thinking, however, this step is conceived of as an orthodox element in the functional, comparative evaluation of the law. The touted benefits of technological modalities will then be questioned in the final evaluation of this work, drawing lessons from the concrete example of clinical AI.

4. Summation

Throughout the following evaluation of the selected legal systems' response to the autonomy challenges posed by clinical AI, the significance of these underlying methodological commitments will emerge in manifold ways. It should not be forgotten that one aim of the specific analysis is to present a dynamic and nuanced perspective of the way in which the law adapts to emerging technologies. This provides a further thread connecting its three parts and, in the final analysis, the fundamental insights to be gleaned from this case study will be elaborated upon.

101 Berman, *Law and Society Approaches to Cyberspace* (2007) xvi-xvii; Brownsword, *Law 3.0: Rules, Regulation, and Technology* (2021) 23-25.

102 Reidenberg, 'Lex Informatica' (1997) 76(3) *Texas Law Review* p. 553, 579-581; Lessig, *Code: Version 2.0* (2006) 126-127.

103 Brownsword, *Law 3.0: Rules, Regulation, and Technology* (2021) 22-25.

D. Research question

Having established the method to be applied in this work, the research question can now be formulated. Drawing on the common law's ability to realise principles as well as laying down specific norm, it is asked:

Can the common law doctrine of informed consent ensure an adequate protection of patient autonomy as artificial intelligence is introduced into medicine?

It is with respect to this question that the state of the existing research must be ascertained and, subsequently, the requisite analytical structure must be provided.

III. State of the art

Regarding the informed consent requirements that are to be applied to AI, there is a valuable repository of academic literature dealing with the ethical dimension of this doctrine. Above all such commentators identify types of information that may be necessary to meet these challenges.¹⁰⁴ In doing so they complement the concerns raised in professional guidance and policy documents,¹⁰⁵ but they fail to construct or deploy an underlying normative ideal by reference to which legal instruments could be applied or assessed.

In comparison, some specific debates go further – seeking to understand what particular bioethical conceptions of autonomy entail for interactions with the patient and the information that must be disclosed to them to secure the protection of this conception.¹⁰⁶ While offering insightful systematisations of challenges and emphasising the connection between general

104 See for example: Gerke, Minssen and Cohen in Bohr and Memarzadeh, *Artificial Intelligence in Healthcare* (2020). Although insightful, the authors touch only relatively briefly on informed consent issues, focussing their analysis on other matters. See also: Di Nucci, Jensen and Tupasela, 'Ethics of Medical AI: The Case of Watson for Oncology' (5.12.2019) <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3432317> accessed 5.4.2020.

105 Nuffield Council on Bioethics, 'Bioethics Briefing Note: Artificial Intelligence (AI) in Healthcare and Research' (2018) <<http://nuffieldbioethics.org/wp-content/uploads/Artificial-Intelligence-AI-in-healthcare-and-research.pdf>> accessed 17.6.2022.

106 Miguel Beriain, 'Should We Have a Right to Refuse Diagnostics and Treatment Planning by Artificial Intelligence?' (2020) 23(2) *Medicine, Health Care, and Philosophy* p. 247; See also: Ploug and Holm, 'The Four Dimensions of Contestable AI Diagnostics - A Patient-Centric Approach to Explainable AI' (2020) 107 *Artificial*

standards and specific norms, these debates remain of limited relevance to the present analysis. If at all, they do not engage with the relevant legal material and reasoning in the requisite depth.

Within the legal literature it is possible to find some preliminary analyses of the issue of informed consent. Many of these are regrettably cursory in nature,¹⁰⁷ while others focus on quite specific aspects of the doctrine.¹⁰⁸ In the UK context, one of the most insightful articles attempting to seriously grapple with the informed consent obligations of AI has been framed almost exclusively by reference to risk-disclosure.¹⁰⁹ Although this author does appeal to a certain understanding of patient autonomy, he does not offer a detailed analysis of its nature.¹¹⁰ Nor is there any extensive scrutiny of relevant legal norms.¹¹¹

By comparison Glenn Cohen is one author who has engaged with the issue of informed consent to AI use much more comprehensively, and through an analysis of U.S. common law no less. However, his analysis is fundamentally different from the present. For one, he makes a blanket assessment, spanning the different common law jurisdictions of the U.S. The extent to which this yields a persuasive picture of the operation of specific legal mechanisms has been questioned above.

Intelligence in Medicine; Ploug and Holm, 'The Right to Refuse Diagnostics and Treatment Planning by Artificial Intelligence' (2020) 23(1) *Medicine, Health Care, and Philosophy* p. 107; Bjerring and Busch, 'Artificial Intelligence and Patient-Centered Decision-Making' (2021) 34(2) *Philosophy & Technology* p. 349; Rubel, Castro and Pham, *Algorithms and Autonomy* (2021); Debrabander and Mertes, 'Watson, Autonomy and Value Flexibility: Revisiting the Debate' [2021] *Journal of Medical Ethics* p. 1043.

107 Dismissing the possibility of novel informed consent obligations *tout court* see: Schönberger, 'Artificial Intelligence in Healthcare: A Critical Analysis of the Legal and Ethical Implications' (2019) 27(2) *International Journal of Law and Information Technology* p. 171, 188: 'even AI applications in riskier areas would not add anything novel. An explanation of the inner workings of the respective algorithms would not empower patients to make an informed choice about a given treatment'. For a brief, practical approach see also: Keating and Wright in Hervey and Lavy, *The Law of Artificial Intelligence* (2021).

108 Nolan, 'Artificial Intelligence in Medicine - Is Too Much Transparency a Good Thing?' [2023] *The Medico-Legal Journal Online* first.

109 Kiener, 'Artificial Intelligence in Medicine and the Disclosure of Risks' (2020) 36(3) *AI & Society* p. 705.

110 *ibid* 706.

111 Although one does find scattered references to prominent case law: *ibid* 706-708.

Cohen also focuses on drawing incremental analogies to relatively limited classes of existing case law.¹¹² He terms this a doctrinal approach and distinguishes it expressly from a normative approach that could appeal to the principle of patient autonomy.¹¹³ Although his treatment of this dimension is relatively cursory,¹¹⁴ he does not purport to offer a close analysis. Rather, he states explicitly: ‘The goal is to begin a conversation, not definitively answer it’.¹¹⁵

One manner in which to interpret the present research, is to respond to this call and to formulate one such answer. Yet it also goes further. The normative approach accounts for the outlined relationship between legal reasoning and technological innovation and anticipates the legal developments that may be generated in response. Without it one risks ignoring both the law’s generative potential and its guiding function. In short, the positive, proactive role that it plays in shaping responses to innovation.

Overall, then, there is a real gap in the existing literature regarding the implications of AI/ML technologies for the legal doctrine of informed consent. What is missing is precisely a normative analysis of the underlying legal mechanisms to anticipate the common law’s response to this novel societal challenge.

IV. Outlook and structure

To answer the research question in a manner that takes seriously the generative and dynamic nature of common law reasoning, the following analysis is split into four parts.

Part I. begins with the underlying factual phenomenon. It seeks to describe and categorises the AI currently found in the healthcare systems of the two outlined jurisdictions. Alongside this, it conveys the foundational understanding of the technology and its operation in clinical environments that is necessary for any serious legal assessment thereof. On the basis of these insights, it determines the normative challenges posed by AI/ML devices from the perspective of a procedural, rationalist account of patient autonomy.

112 Cohen, ‘Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?’ (2020) 108(6) *The Georgetown Law Journal* p. 1425, 1444-14449.

113 *ibid* 1449, 1557.

114 *ibid* 1557.

115 *ibid* 1449.

Part II. argues that this normative conception of autonomy offers one defensible interpretation of the jural concept found in the UK and U.S. jurisdictions. It further asserts that this concept is properly understood to operate as a common law principle in the domain of medical law. With this understanding one can frame a general standard, that is able to: justify existing norms, institute norm change, aid interpretation, generate new norms, create exceptions to rules and, potentially, to ground actions directly. In short, it lays the foundation for an analysis that goes beyond narrow deductive or incremental analogical reasoning. At the same time, it recognises that the doctrinal pressures exerted by the legal framework and other applicable norms cannot be ignored. Creative reasoning must be conducted within limitations.

Part III. turns to a comprehensive analysis of the specific legal mechanisms of negligence and battery in the UK and California. These offer a response to AI's autonomy challenges by requiring forms of consent and information disclosure. Where possible – i.e. where realistically permissible within the recognised constraints – argumentation is framed by reference to the autonomy principle. The varying strengths of such forms of argumentation, in light of countervailing normative considerations, is also accounted for. In the final analysis, a detailed picture emerges of the kinds of situations in which a patient may be able to assert a legal right to certain classes of information that can safeguard their autonomous decision making.

Chapter 8 represents an overall assessment of the relevant findings and demonstrates the wider significance of the pursued approach. It is analysed in how far the anticipated adaptations of the specific tort law instruments in the compared jurisdictions suffice to meet the novel autonomy challenges posed by medical AI/ML devices. It will be seen that there are several grounds for concluding that the common law's generative process provides only imperfect solutions. Nevertheless, its outputs play a guiding role. The law's operation transforms a technological problem for society and helps to discern normatively desirable resolutions. This is further demonstrated through an analysis of existing legislative schemes in England and California that supplement the common law and which are based upon a closely connected rationale. Ultimately, the three prevalent assumptions concerning the relationship between law and innovation are re-examined and critiqued. In light of the preceding arguments, it is not possible to claim that, as a matter of course, extra-legal solutions adapt more rapidly and provide effective, normatively defensible, resolutions to technological problems. Nor is it true that the law can be, or should be, straightforwardly

instrumentalised to serve innovation-related ends. Finally, the law's multifaceted potential for adaptation is differentiated and categorised. This refutes the claim that there is a problematic and inevitable disjuncture between legal thinking and fast-paced innovation.