

The Regulation of New Technologies in Professional Service Sectors in the United Kingdom: Key Issues and Comparative Lessons

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Executive Summary

New technologies, such as artificial intelligence, machine learning, and blockchain, coupled with rapid and ongoing developments in both information and biotechnologies, promise to transform the provision of professional services—transforming who provides such services, to whom they are provided, which services are provided, and how they are provided.

Against this background, the scope of this discussion paper is limited to the regulation of the adoption of new technologies by professional service providers for (outward) consumer-facing purposes; and the focus is on what regulators of legal services might learn from the experience of other regulators of professional services (particularly in the health and financial service sectors) in engaging with new technologies.

Although the regulatory challenge in each professional service sector is to some extent context-specific, and although different technologies provoke different concerns, it is suggested (in Part 2 of the paper) that there are a number of generic regulatory challenges: namely, the challenges of connection and sustainability, effectiveness/compliance, and acceptability. Where new technologies are the subject-matter of the regulation, these challenges are especially demanding. For example, one notorious difficulty is putting in place legislative frameworks (such as the legal framework for the collection and processing of personal data) that stay connected to rapid technological developments and the purposes for which technology is employed. While sectoral regulators might not have responsibility for such legislative frameworks, their own regulatory success is likely to be conditioned on the performance of upstream legislatures and regulators.

Drawing on the generic regulatory challenges, it is suggested that sectoral regulators, including regulators in the legal services sector, should be guided by a three-pronged general principle. This is the principle that regulators should ensure that practice and provision in their sector is lawful, socially acceptable, and geared for compliance and sustainability. The application of this principle to various consumer-facing uses of new technologies, mainly in the health and financial service sectors, is elaborated in Parts 3 and 4 of the paper.

At the core of the general principle is the demand for social acceptability. What this means is that the regulation of new technologies should be broadly acceptable to the most proximate stakeholders in the service (the service providers and consumers) as well as being compatible with general societal interests. Stated shortly, regulation will not be acceptable if a technology is permitted to cross any ‘red lines’ (or touches any ‘third rails’) for the community (in health, for example, new technologies have been something of a lightning rod for concerns about both human dignity and privacy). Nor will regulation be acceptable if it is seen as over-regulating (neglecting the social interest in innovation) or under-regulating (neglecting the interests of consumers and exposing them to unacceptable risks). Moreover, even if regulation seems to pass muster at its inception, it will sooner or later be regarded as socially unacceptable if it has unanticipated negative consequences (witness the current anxious re-assessment of the responsibilities of online intermediaries).

In Part 5 of the paper, discussion turns to the way in which new technologies can disrupt the market for professional services, opening up the possibility that new and alternative providers might offer their services to consumers and presenting both providers and consumers with new service options (including direct-to-consumer online provision). For regulators, such as those

in the legal services sector, who wish to encourage new providers and new provision that promises to be beneficial to consumers, the basic challenge is again neither to over-regulate (impeding innovation) nor to under-regulate (exposing consumers to unacceptable risks).

The lessons for the regulators of legal services are gathered up in Part 6. Learning from the mistakes of the past—such as those associated with the unsatisfactory consultation on GM crops, and the lack of consultation and communication (coupled with an under-estimation of public resistance to the commercialisation of NHS patient records) that derailed the care.data initiative—one of the key lessons is to recognise the importance of consultation. To introduce a new technology without consultation, without preparation of the regulatory space, and without an appreciation of likely resistance is a recipe for problems. Particularly with regard to AI and taking humans out of the loop, we just do not know how consumers of legal services will react.

Another important lesson is that some precaution is in order. While some of the technologies that immediately evoke concerns about catastrophic risks—for example, nuclear technology, synthetic biology, nanotechnologies, and the like—are probably not going to be relevant to the provision of legal services, we know that the technologies upon which legal service providers will rely are far from risk-free. For example, the famous denial-of-service attack on the Estonian critical cyber infrastructure and the many recent hacks, viruses and security breaches serve as a reminder that reliance on information technologies creates risks for individuals as well as sector and society-wide vulnerabilities; and, although we do not yet know just how risky AI might be, it is suggested that we should certainly proceed with care. Furthermore, the common insistence on AI being developed and applied in ways that respect humanity or that are human-centric should be read broadly as going beyond avoiding direct and obvious physical harm to humans to include a sensitivity to the full range of human interests. New technologies (such as surveillance and identification technologies) can change the context in which humans operate, impacting on autonomy and self-development as well as the opportunity for moral development and the building of relationships based on trust and personal responsibility. Moreover, some of the most insidious impacts might arise from technologies (such as AI-enabled digital devices) that are designed to assist humans but which, in human hands, lead to an over-reliance that is corrosive of human responsibility and that expose humans to new vulnerabilities.

Finally, insofar as it is possible to do so, regulators of legal services would also do well to learn from the successes of both the past and the present—such as the flexible soft law approach to genetics and insurance and the innovative idea (originating in the financial services sector) of a regulatory sandbox. While regulators who work with the grain of their regulatees' interests will expect this to improve compliance, in the legal services sector, regulators have a responsibility to protect the interests of consumers and, distinctively, great importance is attached to the independence of the regulatory bodies (and to the separation of professional representative and regulatory functions). In other words, the regulatory environment for legal services must command the confidence of consumers and this necessarily shapes regulatory thinking about how to relate to established service providers, to new service technologies, and to prospective new providers.

1. Introduction

In the United Kingdom, there are a number of professional service sectors—for example, health, finance, education, and law—within each of which there has been some regulatory engagement with emerging technologies. Drawing on this prior regulatory experience, primarily experience in the health and financial sectors, the purpose of this discussion paper is to assist the Legal Services Board by clarifying the kind of guidance that it might usefully offer to the ten ‘approved regulators’ and regulatory bodies that are subject to its oversight.¹

Already, in the health sector, there is considerable experience in regulating modern biotechnologies and, in both health and finance, regulators have engaged with the information and communication technologies that support online service provision. Technological innovation, however, does not stand still. Recent technological developments—particularly blockchain (distributed ledger technologies) and artificial intelligence (AI) coupled with machine learning—present service providers and consumers with new options and they present regulators with fresh challenges.

Given this experience, what do we know about the *key issues* to be addressed by regulators and what, if any, *major lessons* are to be taken and shared? Is it the case, for example, that there are some *generic* principles of good regulatory practice in relation to new technologies? If so, what are they? To what extent might regulators need to act in a *sector-specific* way—in particular, how relevant is experience in the health and financial service sectors to legal services? Moreover, to what extent is regulatory experience *technology-specific*? For example, is regulatory experience in relation to modern biotechnologies, which have been something of a lightning rod for ethical concerns that centre on the importance of human dignity² as well as for concerns about environmental integrity, safe foods, and the like, relevant to the regulation of, say, online banking, let alone to the development of sound regulatory practice in relation to blockchain and cryptocurrencies or AI?

In these introductory remarks, the following three matters are briefly addressed: (i) (in 1.1) the nature of the regulatory space (the regulation of professional service provision) with which we are dealing; (ii) (in 1.2) a proposed three-pronged general guiding principle for regulators of professional services (namely, that practice and provision in their sector, including the use of technology, should be lawful, socially acceptable, and geared for compliance and sustainability); and (iii) (in 1.3) the scope and structure of the paper.

1.1 The regulatory space

This paper is concerned with the regulation of technologies that are applied in the professional service sectors. While each sector—that is, each regulatory space—has its own particular

¹ <https://www.legalservicesboard.org.uk/> (last accessed March 10, 2019). In this sector, the ‘approved regulators’ (such as the Law Society and the Bar Council) are required to separate out their representative functions from their regulatory functions. Accordingly, the regulation of professional conduct and complaints is undertaken by independent regulatory bodies (such as the Solicitors Regulation Authority and the Bar Standards Board).

² Famously, Francis Fukuyama took the view that, while the development of the Internet raised some concerns about privacy and a possible ‘digital divide’, it was developments in human genetics that should most concern us (because of their implications for human dignity): see Francis Fukuyama, *Our Posthuman Future* (London: Profile Books, 2002).

characteristics,³ the general pattern is that there will be three principal parties: the *regulators* (or the regulatory body or agency), the *providers* of professional services (whether in the public or the private sector), and the *consumers* of the services so provided. In addition to the interests of these parties, we should also take into account the interests of other parties—for example, the interests of innovators, technology suppliers, and the families of those who are consumers—as well as the larger societal and public interest.

The sectoral regulatory bodies—such as the Prudential Regulatory Authority and the Financial Conduct Authority, the Institute of Chartered Accountants in England and Wales, the Human Fertilisation and Embryology Authority, the Human Tissue Authority, the Medicines and Healthcare products Regulatory Agency, the Legal Services Board itself and the Solicitors Regulation Authority, and so on—perform a number of functions which include setting standards, licensing, monitoring compliance, and dealing with professional conduct, discipline, and consumer complaints. In so doing, they operate against a backcloth of national legal institutions and laws as well as the supervision of cross-sectoral agencies such as the Information Commissioner’s Office, the Equality and Human Rights Commission, and the (independent and self-regulatory) Advertising Standards Authority. In the health and financial service sectors, there is an extensive legislative backcloth, much of which derives from EU law; and, in all sectors, the general principles of the common law—especially the principles that apply to questions of liability for professional negligence—are potentially relevant where new technologies are (or are not) used (for example, the use, or non-use, of robots in surgery, or the use of AI tools for diagnostic or advisory purposes).

Accordingly, in the regulatory space which is our focus, although the principal parties are the sectoral regulators, the providers and the consumers of the services in question, this has to be set in context of the larger legal and regulatory landscape as well as the broad sweep of interests.

1.2 A three-pronged general guiding principle for sectoral regulators

Whatever the purposes for which service providers adopt new technologies—whether for their own *inward-facing* business or professional use (such that consumers do not interact or transact with the technologies) or for *outward-facing* use in their communications and dealings with consumers—it is suggested that regulators should be guided by a three-pronged general principle. This general guiding principle demands that practice and provision in the sector should be lawful, socially acceptable, and geared for compliance and sustainability.

First, the practice and provision of both sectoral regulators and service providers should be lawful. Of course, consumers, too, should act in ways that are lawful; but sectoral regulators might not have any specific authority or jurisdiction in relation to acts by consumers. By ‘lawful’ we mean, in the first instance, that the acts of the sectoral regulators and their regulatees, the service providers, should be in line with whatever legislative provisions or general principles of law apply. To be sure, some legislative provisions might be vague and unclear (for example, the notion of ‘personal data’ which anchors data protection law is far from clear); and the same might be true of general principles of law (for example, the idea of a ‘reasonable expectation’ on which privacy law is founded is unclear). Nevertheless, as a matter

³ For the particular regulatory characteristics of the legal services sector, see n 1.

of general principle, it is to be expected that technologies will be applied to professional service provision only in ways that are compliant with background law.

Secondly, regulators should strive to put in place a regulatory scheme that is socially acceptable. In other words, regulation should be broadly acceptable to the most proximate stakeholders in the service (the service providers and consumers) as well as being compatible with general societal interests. Where the use of a new technology is proposed, the social acceptability of the technology, its use, and the covering regulatory scheme, will depend on several considerations. One very important consideration is whether the technology (or its particular application) crosses any ‘red lines’ (or touches any ‘third rails’) for the community. For example, a community might have fundamental objections to the use of robots in the provision of some services; or to blood transfusions or to organ transplantations, even though these are life-saving; or, to the use of IVF (in vitro fertilisation) except with the parties’ own sperm and eggs, or to surrogacy, even though this would be life-giving. Provided that no such red lines are crossed, the question of social acceptability will hinge typically on achieving a balance of benefits and risks, as well as a distribution of benefits and risks, that is judged to be reasonable or ‘acceptable’. In this respect, one of the key roles for regulators is to ‘de-risk’ new technologies so that both providers and consumers are willing to adopt them. Later in the paper, we will discuss the development of ‘regulatory sandboxes’ for testing novel financial products and services, this being an interesting recent example of regulators acting with de-risking intent. If a technology is found in its operation to have unintended (negative) effects, then this will militate against its acceptability and the initial balance of interests will need to be re-assessed. Indeed, just such a re-assessment is underway today in relation to the responsibilities of Internet intermediaries, the argument being that they should be required to be far more active in monitoring the content they carry, failing which they should be held accountable for the negative consequences that ensue, where these consequences range from teenagers self-harming and committing suicide, to parents declining vaccines for their children, and to acts of terrorism.⁴

Thirdly the general principle enjoins regulators to act in ways that are geared for both compliance (i.e., practice by regulatees that is compliant relative to regulatory provision and policy) and sustainability (i.e., regulatory provisions that remain fit for purpose for a reasonable time, new technologies and new uses of technology notwithstanding). To facilitate compliance within their sector, regulators might find that, rather than imposing ‘command and control’ measures on their regulatees, the better strategy is to encourage self-regulation by professional providers or to co-regulate with providers; and, to facilitate sustainability, regulators might find that, instead of ‘hard’ and inflexible regulatory provisions, the ‘softer’ provisions of codes of practice, guidance and governance instruments might prove to be more fit for purpose. In both respects, regulators might learn from the governance of genetic tests and information in the context of insurance. Here, practice is regulated by the joint ABI and Government *Code on Genetic Testing and Insurance*.⁵ Now in its sixth iteration, the two guiding principles of the

⁴ See, HM Government, *Online Harms White Paper* (CP 57, April 2019); and, for discussion of the issues, see Lilian Edwards, “‘With Great Power Comes Great Responsibility?’: The Rise of Platform Liability” in Lilian Edwards (ed), *Law, Policy and the Internet* (Oxford: Hart, 2019) 253, esp 285-289.

⁵ Available at <https://www.abi.org.uk/globalassets/files/publications/public/genetics/code-on-genetic-testing-and-insurance-final.pdf> (last accessed June 21, 2019).

Code are (i) that an insurer will not require or pressure an applicant to undertake a predictive or diagnostic test in order to obtain insurance, and (ii) that the results of genetic tests may only be considered in an application for the very largest relevant insurance policies and only for conditions which have been shown to be highly predictive of a relevant risk. For individuals who require life insurance, critical illness insurance, or income protection insurance, the Code offers assurance that they will not be unfairly excluded on genetic grounds. Moreover, facilitating sustainability, the Code is of a flexible nature such that insurers are assured that they can make minor adjustments if they are required.

1.3 The scope and structure of the paper

The principal focus of this paper is on the adoption of technologies by providers of professional services for *outward-facing* purposes in their dealings with consumers. This means that the scope of the paper is limited in two important respects.

The first limitation is that there will be no discussion of the use of new technologies by *regulators* in connection with the performance of their regulatory functions—for example, to monitor compliance by their regulatees and to identify non-compliant regulatees.⁶ Nevertheless, it should be noted that regulators are increasingly responsive to the thought that new technologies, while they might be part of the problem, might also be part of the solution. For example, recalling the problems created by unauthorised drones at Gatwick airport in December 2018, regulators might think not only about rendering the rules (relating to exclusion zones around airports) more fit for purpose but also about employing technological measures that are designed to exclude and disable drones.

The second limitation is that there will be no discussion of the use of new technologies by professional service providers for their own *purely inward-facing* purposes, especially for monitoring their own employees. However, where providers seek to improve their own organisational efficiency—for example, in the case of legal services, by taking up new technologies that enable much routine documentary checking to be automated⁷—we can treat this as falling within the scope of our discussion. To be sure, the immediate impact of automation is likely to be on the workforce, both unskilled workers and, it seems, skilled professionals;⁸ and, it hardly needs to be said that such disruptive effects (both economically and socially) give rise to society-wide questions that are a matter of intense public debate.⁹ For

⁶ See, e.g., the Financial Conduct Authority’s work on RegTech, <https://www.fca.org.uk/firms/regtech>, and <https://www.cnbc.com/2017/07/13/uk-regulator-looking-to-use-a-i-machine-learning-to-enforce-financial-compliance.html> (both last accessed June 21, 2019).

⁷ See, e.g., *The Future of Legal Services* (London: the Law Society, 2016) 38, where technology is said to be impacting on legal services in the following ways: enabling suppliers to become more efficient at procedural and commodity work; reducing costs by replacing salaried humans with machine-read or AI systems; creating ideas for new models of firm and process innovation; generating work around cybersecurity, data protection and new technology laws; and, supporting changes to consumer decision-making and purchasing behaviours..

⁸ Richard Susskind and Daniel Susskind, *The Future of the Professions* (Oxford: Oxford University Press, 2015).

⁹ See, e.g., Martin Ford, *The Rise of the Robots* (London: Oneworld, 2015). Geoff Colvin, *Humans are Underrated* (London: Nicholas Brealey Publishing, 2015); Andrew Keen, *The Internet is Not the Answer*

our purposes, however, the point is that new technologies, adopted for reasons of efficiency, can lead to service provision that is beneficial to consumers, being more accessible, cheaper, and possibly delivered more promptly.¹⁰

Given these two limitations, and with a focus on *outward-facing* uses of new technologies by professional service providers, this paper proceeds in the following six main stages.

First, the bigger picture of the regulatory challenges presented by new technologies is sketched. Here, the generic challenges relating to regulatory connection, regulatory effectiveness (compliance) and the acceptability of regulation are outlined. Insofar as there are general principles of good regulatory practice, they are reflected in regulatory engagement with these challenges and how we think regulators should go about responding to them.

Secondly, we look at some of the key regulatory issues that are relevant to the adoption of technologies—particularly the adoption of AI—by service providers for the purpose of risk-assessing prospective recipients of the service (making access decisions about who is and who is not to be provided with the service) and determining which service options to take. From this, we draw a number of lessons, some relating to legality, some to social acceptability, and others to compliance and sustainability.

Thirdly, we discuss some of the key regulatory issues that are relevant to the adoption of technologies by service providers where this bears on the nature of the service delivery to consumers and/or presents new options for consumers. From this, we draw some further lessons, some relating to legality, many to social acceptability, and others to compliance and sustainability.

Fourthly, we focus on the regulation of new and alternative providers (as opposed to traditional and established providers in the sector) who exploit new technologies to offer new service options to consumers. While regulators might welcome the positive disruptive impact of such providers, they need to engage with any potential negative impacts such as risks to the interests of consumers as well as any systemic risks. Moreover, with so many services being made available by direct-to-consumer online providers, a key challenge is to try to ensure that adequate protection is in place for consumers who deal with such providers.

Fifthly, having compared the experience in a range of sectors, we identify what are likely to be the key regulatory issues and the major regulatory lessons for the Legal Services Board to flag up in its guidance to the regulatory bodies over which it has oversight. These lessons again relate to lawfulness, social acceptability, and compliance and sustainability; and, in relation to social acceptability, the lessons can be divided into those that are imperative/mandatory, those that are in the nature of cautions and alerts, and those that are advisory. (An indicative check list for regulators in the legal services sector is presented in Appendix A).

(London: Atlantic Books, 2015); Jaron Lanier, *Who Owns the Future?* (London: Allen Lane, 2013); and Kenneth Dau-Schmidt, 'Trade, Commerce, and Employment: the Evolution of the Form and Regulation of the Employment Relationship in Response to the New Information Technology' in Roger Brownsword, Eloise Scotford, and Karen Yeung (eds), *The Oxford Handbook of Law, Regulation, and Technology* (Oxford: Oxford University Press, 2017) 1052.

¹⁰ See, the Law Society (n 7).

Finally, in the sixth part, some short concluding remarks are presented, in which the general questions with which we opened these introductory remarks—questions about the possibility of drawing generic regulatory lessons, about the comparability of service sectors, and about the specific characteristics of different technologies—are addressed.

2. The generic regulatory challenges

In the context of rapid technological development, with one technological ‘revolution’ after another, regulators are presented with a range of challenges.¹¹ Here, we can speak briefly to the three principal generic challenges. These relate to ‘regulatory connection’ (which includes the ideal of sustainability) (in 2.1), ‘regulatory effectiveness (or compliance)’ (in 2.2), and ‘regulatory acceptability’ (in 2.3). Given that regional and national lawmakers will often set out the legislative framework for the adoption and use of new technologies, it is a matter of some importance to sectoral regulators (who operate in the shadow of the background law) that the generic challenges have been successfully handled by these lawmaking bodies.

While these challenges are generic in the sense that they are presented by all emerging technologies and in all sectors (including all service sectors), at least some of these challenges are likely to be eased as we move away from regional or national lawmakers operating in a top-down regulatory fashion. For example, where a profession self-regulates, and where the ‘law’ is of a softer variety (such as codes and guidelines), this might improve the chances of both compliance by regulatees and the ability of regulators to make rapid adjustments to the regulatory provision. On the other hand, if self-regulation unduly favours professional interest over the public interest, there are likely to be problems with the social acceptability of the regulatory arrangements; and, this might invite a co-regulatory approach.

In this regard, it should be noted that, in relation to the legal services sector, both the Legal Services Board and the Competition and Markets Authority are strongly in favour of independent regulation of the profession (as opposed to professional self-regulation) in order to ensure accountability in general and, specifically in the case of technology, to prevent regulation being used in a protectionist manner to slow or block innovations which would benefit consumers.¹²

Accordingly, while regulators might achieve more satisfactory compliance and more agility by moving away from a top-down hierarchical and hard-wired approach towards a closer collaborative relationship with their regulatees, there might be sectoral features that militate against this.

¹¹ See Roger Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford: OUP, 2008); Roger Brownsword and Karen Yeung (eds), *Regulating Technologies* (Oxford: Hart, 2008); and Roger Brownsword and Morag Goodwin, *Law and the Technologies of the Twenty-First Century* (Cambridge: CUP, 2012).

¹² Currently, the Legal Services Board is undertaking a review of the Internal Governance Rules which ensure that the regulatory bodies (the Solicitors Regulation Authority, and so on) operate as independently as possible from the approved regulators (see, n 1): for the consultation, see https://www.legalservicesboard.org.uk/what_we_do/consultations/open/index.htm (last accessed June 16, 2019).

2.1 Regulatory connection

The first challenge is that of regulatory connection. This challenge refers to the problem of knowing when and how to engage with emerging technologies (the risk profile of which might be unknown), and then how to keep the law sustainably connected to both the development of the technology and the purposes to which it is applied.

In this regard, one dilemma facing regulators, ‘Collingridge’s dilemma’¹³ as it is known, is that an early regulatory intervention might be inappropriate and counter-productive but that a later (more appropriate intervention) might encounter major resistance because the technology is now relied on and valued. The Internet is one such example of this dilemma. For some time, the nature and scale of the risks presented by the Internet were not clearly appreciated; but, now that the risks are better understood, reliance on the Internet is so embedded that it is hard to see how effective regulatory interventions can be made. Similarly, while we might think that regulators in those countries, including the UK, who are resisting a rapid response to concerns about new financial technologies, such as blockchain and virtual currencies, are to be congratulated for their measured approach, they might find that procrastination has a price. Hence, this is the question: How are regulators to strike the right balance between making a properly informed intervention and making an intervention that actually has some practical influence and effect?

A related dilemma is knowing when and how to make use of hard law. The problem is that hard law, particularly if there are penalties for non-compliance, is expected (not unreasonably) to be clear and precise. Accordingly, legislators strive to describe technologies in terms that accurately capture their current state. However, the better they manage to achieve this, the quicker the terms of the law are likely to lose touch with the state of the technological art. The alternatives—such as drafting the law in vaguer terms (relying on standards rather than rules), or delegating updating power and responsibility to a Minister or to a regulatory agency, or leaving it to industry to self-regulate through flexible voluntary codes, or the like—are not always attractive or acceptable; but, where these alternatives are acceptable and can be used, the particular challenge of sustainable connection is likely to be eased.

Given this challenge, we might expect communities to have a developed strategy—so to speak, a standard operating procedure—for horizon scanning and making an initial engagement with new technologies. However, in the UK, there is no such strategy determining the who, when, and how of such engagement.¹⁴ Often, the policy teams in the Royal Society or the Academies have made the first move in scoping the law, ethics and governance of new technologies; sometimes it has been the Nuffield Council on Bioethics (particularly in relation to new biotechnologies) or NESTA (the Innovation Foundation)¹⁵; sometimes it has been parliamentary committees, and so on. When human genetics entered the modern phase of its development, the government set up the Human Genetics Commission (which has since been

¹³ After David Collingridge, *The Social Control of Technology* (Palgrave Macmillan, 1981).

¹⁴ See Roger Brownsword, ‘Law, Regulation, and Technology: Supporting Innovation, Managing Risk and Respecting Values’ in Todd Pittinsky (ed), *Handbook of Science, Technology and Society* (Cambridge: Cambridge University Press, 2019) 109.

¹⁵ <https://www.nesta.org.uk/>.

wound up) but it did not set up an equivalent Commission for the Internet. Responding to both concerns and opportunities associated with big data and AI, the government has established a Centre for Data Ethics and Innovation. The wide-ranging terms of reference for the Centre require it to analyse and anticipate risks and opportunities, to agree and articulate best practice, and to advise on the need for action, under the last of which there is a responsibility to identify ‘steps to ensure that the law, regulation and guidance keep pace with developments in data-driven and AI-based technologies.’¹⁶ At the same time, though, and perfectly legitimately, the Law Society (acting in its representative capacity) has been one of the first-movers in this field, publishing a horizon scanning report on AI and the legal profession (in 2018),¹⁷ and very recently a major report by the Law Society Commission on the Use of Algorithms in the Justice System.¹⁸

While there might be some advantages in having a variety of eyes looking at the regulation of new technologies, there is a risk that this is inefficient and wasteful of accumulated experience. For sectoral regulators, it is important that channels of regular communication with one another are maintained so that relevant experience can be shared.

2.2 Regulatory effectiveness

A second challenge is that of effectiveness (or regulatory compliance). Where there is a close or collaborative relationship between regulators and their regulatees, there is joint ownership of agreed regulatory codes and a reasonable prospect of compliance. However, for many top-down regulators, paradigmatically lawmakers who enact road traffic laws, the record of compliance (with speed limits, with the prohibition on the use of phones while driving, and so on) leaves something to be desired. No doubt, it is unrealistic (and possibly undesirable) to expect perfect compliance with top-down regulatory requirements. Nevertheless, where (as with some road traffic laws, or with recreational drug use) there is widespread non-compliance, then this indicates that there are serious problems for both the regulators and their regulatory interventions.

In what we might regard as normal conditions, there are likely to be several limits on the effectiveness of a regulatory intervention. These limits, although varied in their nature, largely fall within one of three clusters, these clusters being regulator-related, regulatee-related and external.

The first cluster of limits is regulator-related. The limits might reside in the regulators’ own lack of capability or lack of ‘know how’¹⁹—particularly, where the subject-matter of the

¹⁶ Department for Digital, Culture, Media and Sport, *Centre for Data Ethics and Innovation: Government Response to Consultation* (November 2018) p 17.

¹⁷ See, <https://www.lawsociety.org.uk/support-services/research-trends/horizon-scanning/artificial-intelligence/> (last accessed March 26, 2019).

¹⁸ See, the Law Society, *Algorithms in the Criminal Justice System* (London, June 2019).

¹⁹ On which, there is a huge literature, particularly about acting in ‘smart’ and ‘responsive’ ways: see, e.g., Neil Gunningham and Peter Grabosky, *Smart Regulation* (Oxford: Oxford University Press, 1998); Ian Ayres and John Braithwaite, *Responsive Regulation* (Oxford: Oxford University Press, 1992); and Bronwen Morgan and Karen Yeung, *An Introduction to Law and Regulation* (Cambridge: Cambridge University Press, 2003). While the Legal Services Board is itself committed to acting in accordance with the so-called ‘Better Regulation’ principles (namely, that regulatory activities should be transparent,

regulation is specialised and technologically sophisticated; or, it might be that, while regulators have sufficient resources to consult and to promulgate rules and standards, their resources are not sufficient for monitoring regulatee compliance or for dealing with individual complaints. No doubt, many factors accounted for regulatory failure in the years leading to the global financial crisis but the complex and opaque nature of the financial instruments being deployed was probably some part of the explanation. In this same cluster, the susceptibility of regulators to capture (by regulatees) or corruption is potentially a crucial limit. Moreover, it is a limit that can bear on the effectiveness of all phases of the regulatory enterprise—on the rules or standards that are set, on monitoring, detection, and correction.

The second cluster of limits is regulatee-related. Wherever regulation cuts across the grain of regulatees' interests (whether the regulatees in question are professional criminals or simply professionals, or whether they are otherwise law-abiding motorists or persistently offending petty criminals, and so on) there is likely to be resistance. Moreover, in some sectors, there might be a culture of non-compliance, resistance, and avoidance amongst regulatees—particularly where there is a strong provider-push coupled with a strong consumer-pull (as in the textbook example of the supply and use of recreational drugs).

The third cluster of limits is represented by various kinds of external competition or interference (such as the availability of tax havens and, more generally, the practice of regulatory arbitrage). New technologies change the dynamics between regulators and regulatees in all sorts of ways but, without doubt, the development of the Internet has exposed national regulatory environments to unprecedented external interference.

To the extent that regulators are in control of their regulatory capability, the challenge is to optimise their regulatory interventions. At this point, we can turn to the matter of the social acceptability of regulatory interventions because there is no shortage of evidence that regulatees are more likely to comply where they believe that regulators are acting in a fair and reasonable way.²⁰

2.3 Regulatory acceptability

A third, and critical, challenge for regulators is to proceed in ways that are socially acceptable and to take up positions that are socially acceptable.

One important dimension of acceptability is how regulators operate, in particular which regulatory tools they use. With regulators increasingly considering technological measures or technical solutions rather than rules or standards, this is likely to become a major issue for

accountable, proportionate, consistent, and targeted only at cases in which action is needed), the Financial Conduct Authority is committed to considering the principles of what it calls 'good regulation' (namely, efficiency and economy, proportionality, sustainable growth, consumer responsibility, senior management responsibility, recognising the differences in the businesses carried on by different regulated persons, openness and disclosure, and transparency) see, <https://www.fca.org.uk/about/principles-good-regulation> (last accessed June 19, 2019).

²⁰ See, e.g., Tom R. Tyler, *Why People Obey the Law* (Princeton: Princeton University Press, 2006).

debate.²¹ However, given the limits of the present discussion (which is not looking at the use of technologies to improve regulatory performance), this is not something that we will consider.

Rather, with our focus on the content of regulation—in particular, with regard to outward-facing uses of technology by professional service providers—this is where questions of social acceptability are engaged. Recalling our introductory remarks, a regulatory position will not be acceptable if it crosses any red lines; and, nor will it be acceptable if the balance of interests is not judged to be reasonable. In many communities there will be some plurality and some tension as between competing or conflicting interests. However, some technologies have exacerbated these differences. For example, while, for some people, genetic engineering is a red line, for others, it is the key to feeding the world and tackling human disease.²² Similarly, even if red lines are not involved, there are very different preferences and positions in relation to taking a precautionary or a pro-active approach to new technologies. Essentially, the challenge to regulators is to find a sweet-spot, neither over-regulating the development and use of a potentially beneficial technology nor under-regulating it and thereby exposing the community and its members to unacceptable risks.

Finally, it bears repetition that these three challenges are characteristic of the difficulties that all regulators (especially top-down regulators), in all sectors, face in putting in place an adequate regulatory environment for the development and application of new technologies. Accordingly, while we will turn now to some specific sectors of service provision, where we will focus on some foreground issues, two points should be borne in mind. One point is that there is a bigger picture of legislative and regulatory activity in the background; and the other point is that the prospects of downstream sector regulators will be impacted (positively or negatively) by the extent to which the upstream regulatory challenges have been met.

3. Technologies employed for outward-facing purposes I: risk-assessment and access decisions

Where professional service providers employ new technologies to mediate their provision to consumers, one of their purposes might be to make decisions about access to a particular service, about who is and who is not to be provided with that service—for example, legal service providers might rely on new technologies to select clients and cases; and, at a later stage, they might be guided by new tools to decide which cases to settle, which cases to litigate, which cases to appeal, and so on. Given the current suite of technologies that can be employed to risk-assess and triage prospective consumers of a professional service, it is AI that stands out as being a tool of emerging importance.

In line with the general guiding principle, regulators need to be sure that such use is compatible with whatever legal requirements apply in their sector (for example, with the law relating to equal treatment and non-discrimination) as well as being socially acceptable; and they need to

²¹ For discussion, see Roger Brownsword, *Law, Technology and Society—Re-imagining the Regulatory Environment* (Abingdon: Routledge, 2019).

²² Compare Roger Brownsword, ‘Cloning, Zoning, and the Harm Principle’ in Sheila McLean (ed), *First, Do No Harm* (Festschrift for Ken Mason) (Aldershot, Ashgate, 2006) 527.

take steps to ensure that regulatory provision and practice is geared for compliance and sustainability.

3.1 Key issues

In order to draw out some of the key issues, we will start (in 3.1.1) with a troubling case involving the use of an AI tool to measure the performance of school teachers. Although this is an inward-facing use by a professional service provider, centring on the employer/employee relationship, it highlights a number of issues that are equally relevant to the use of such a tool for outward-facing risk-assessment and access decisions.

Having narrated the particular troubling story, we can explore five key issues to which it gives rise, namely: (i) (in 3.1.2) the legality of the use of AI tools for automated decision-making, (ii) (in 3.1.3) the need for transparency (openness, explainability, and justification) when such tools are used, (iii) (in 3.1.4) the use of such tools to make decisions that result in denial of access to services or that are employed to determine how best to take a case forward; (iv) (in 3.1.5) the risk of ‘false positives’, and (v) (in 3.1.6) the risk of unintended consequences.

3.1.1 A troubling case

In the Introduction to her book, *Weapons of Math Destruction*,²³ Cathy O’Neil recounts the troubling story of Sarah Wysocki, a fifth-grade school teacher in Washington DC. Washington evaluated the performance of its school teachers by using a tool called IMPACT. The tool was designed to measure the added value given by a teacher year-on-year, with some complex algorithms attempting to make allowances for a range of variables that were independent of the teacher’s input. At the end of the academic year 2010-11, Wysocki’s IMPACT score was below the required threshold and she was duly dismissed.

Although Wysocki’s dismissal was in line with Washington’s policy, although it was indicated by the IMPACT score, and although there was no suggestion that there had been a technical malfunction, the case cried out for an explanation because the IMPACT score simply did not align with the high regard in which Wysocki was otherwise held as a teacher.

O’Neil suggests that the most likely explanation was that fourth-grade teachers had inflated their students’ exam grades so that, when IMPACT was used to evaluate Wysocki’s performance in relation to those (now fifth-grade) students, the baseline data on which the algorithms operated was inaccurate. However, where there is confidence (and, in some cases, over-confidence) in the technology, it is for those who contest the scores to come up with compelling counter-evidence and, in this particular instance, this was something that Wysocki could not do.

The story, although troubling, does not end altogether badly. Having been dismissed, Wysocki almost immediately was hired by a school in an affluent part of northern Virginia. The upshot of this, as O’Neil wryly puts it, was that ‘thanks to a highly questionable model [i.e. the IMPACT tool], a poor school lost a good teacher, and a rich school, which didn’t fire people on the basis of their students’ scores, gained one.’²⁴

²³ Penguin Random House 2017.

²⁴ At 11.

3.1.2 Legality

If a case such as that of Sarah Wysocki were to occur in Europe, an obvious question would be whether reliance on a tool such as IMPACT would be lawful. According to Article 22(1) of the General Data Protection Regulation (GDPR)²⁵, supplemented in the UK by the Data Protection Act 2018, ‘The data subject shall have the right not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her.’ This provision only offers any protection where the decision at issue was based ‘solely’ on automated processing, and where the outcome produced either legal effects in relation to the data subject or affected him or her in a similarly ‘significant’ way.

Whether or not a decision is based on ‘solely’ automated processing and whether or not the effect of such a decision is ‘significant’ might prove to be tricky legal questions.²⁶ To focus only on the former, having a token human somewhere in the loop seems to be too easy a way of preventing the right arising in the first place. However, if a decision can still be ‘solely’ automated, some degree of human involvement notwithstanding, it remains to be seen just how material the human involvement must be. In the Wysocki case, a human was brought into the loop but it seems that the decision made by IMPACT was all but determinative.

Suppose, then, that Sarah Wysocki now wished to sue her previous employers for wrongful dismissal. If law firms, guided by their own AI tools, declined to take on the case, or perhaps advised against litigation, Wysocki would surely be entitled to an explanation and, arguably, she should be entitled to appeal to a human arbitrator. However, if there is to be an adequate explanation, if there is to be meaningful human review, or if there is to be an opportunity for a meaningful appeal, there has to be transparency that goes beyond simply reporting that the tool has given a certain score (or classified a person in a particular way). That said, while there is a consensus that transparency matters, what exactly is required in the way of ‘transparency’ or ‘explanation’ is still subject to intense debate.

3.1.3 Transparency: openness, explainability, and justification

It is something of a mantra that assessment tools such as IMPACT should be ‘transparent’ and that the operation of such tools should be ‘explainable’. However, it is not always clear what such demands amount to and nor is it clear that, whatever ‘transparency’ and ‘explainability’ might mean, they are necessarily a good thing.

In a recent Recommendation adopted by the OECD’s Council on Artificial Intelligence,²⁷ Article 1.3, headed ‘transparency and explainability’, states that ‘AI Actors should commit to

²⁵ Regulation (EU) 2016/679.

²⁶ According to the ICO guidance on this point, ‘A legal effect is something that adversely affects someone’s legal rights. Similarly, significant effects are more difficult to define but would include, for example, automatic refusal of an online credit application, and e-recruiting practices without human intervention.’ Available at <https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/rights-related-to-automated-decision-making-including-profiling/> (last accessed, October 29, 2018).

²⁷ OECD/LEGAL/0449, adopted on 22/5/2019. Available at <https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449> (last accessed June 21, 2019).

transparency and responsible disclosure regarding AI systems.²⁸ It continues that such actors ‘should provide meaningful information, appropriate to the context, and consistent with the state of the art:

- i. to foster a general understanding of AI systems,
- ii. to make stakeholders aware of their interactions with AI systems, including in the workplace,
- iii. to enable those affected by an AI system to understand the outcome, and
- iv. to enable those adversely affected by an AI system to challenge its outcome based on plain and easy-to-understand information on the factors, and the logic that served as the basis for the prediction, recommendation or decision.’²⁹

This articulation of transparency and explainability puts a considerable emphasis on those who rely on AI to contribute to the awareness and understanding of those who interact with or who are affected by the use of AI. However, there is quite a distance between fostering a general understanding of AI (which is in the nature of public education) and enabling an individual who is adversely affected by the use of AI (such as Sarah Wysocki) to challenge a decision.

Given such a sweep of requirements, it is well to be clear about the demands being advanced in the name of transparency. This is not to say that the demands are inappropriate. To some extent, as the OECD explicitly recognises, this is context-dependent. However, before we can assess the social acceptability of the use of AI tools, we need to be clear about what it is exactly that is being demanded in the name of transparency.

Here, we can outline three interpretations of the demand for transparency: transparency as openness (in 3.1.3.1); transparency as explainability (in 3.1.3.2); and transparency as justification (in 3.1.3.3).

3.1.3.1 Transparency as openness

We might interpret the call for ‘transparency’ as a demand for openness. But, openness about what precisely, and why? Minimally, the demand might be that service providers should be open about their use of certain sorts of tools (such as AI tools). In other words, not only should the use of such tools not be a secret but service providers should give consumers a fair warning or reasonable notice that such tools are being employed. Moreover, transparency in this sense would imply that the particular purposes for which such tools are to be used is openly declared. However, the demand might not end here. Some might argue that there needs to be transparency in relation to the nature and mechanics of the tool being employed.

To take another example, in the government’s *Code of conduct for data-driven health and care*,³⁰ we read that there is a general responsibility to use the latest technological tools ‘in a safe, ethical, evidenced and transparent way.’ More specifically, no fewer than four of the ten

²⁸ According to the Recommendation, ‘AI actors are those who play an active role in the AI system lifecycle, including organisations and individuals that deploy or operate AI.’

²⁹ OECD (n 27).

³⁰ Department of Health and Social Care, updated February 19, 2019. Available at: <https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology>

principles in the code of conduct are (explicitly or implicitly) about transparency. Principle 4 enjoins being ‘fair, transparent and accountable about what data is being used’; Principle 5 (which is about interoperability) prescribes the use of open standards; Principle 6 enjoins being ‘transparent about the limitations of the data used’; and Principle 7 prescribes that we should ‘show what type of algorithm is being developed or deployed, the ethical examination of how the data is used, how its performance will be validated and how it will be integrated into health and care provision.’

Clearly, there is quite a difference between these various articulations of transparency—which, to repeat, is not to suggest that what is prescribed is not appropriate. The initial point is simply that, where transparency is prescribed or demanded, it is as well to ask a little more about what kind of transparency is contemplated: and, if transparency is equated with openness, then we should ask openness of what, openness to or for whom, and openness for what purposes?³¹

3.1.3.2 Transparency as explainability

In a similar way, there is a tendency to treat ‘explainability’ as a good thing. This is apparent in both the OECD Recommendation³² and in the final report by the EC High-Level Expert Group on Artificial Intelligence.³³ Moreover, it is commonly assumed that a ‘right to an explanation’ is provided for by the GDPR. This, however, is a moot point. On its face, the GDPR does not explicitly give such a right; and, even if we believe that such a right should be included within the GDPR, to hold that it is included by implication is not without its difficulties.³⁴ Even if we concede that the law gives data subjects a right to an explanation for decisions of the kind made using the IMPACT tool, it is unclear what kind of explanation it is and how far the interest in transparency reaches.

To the extent that the explanation to which any such claimed right applies is basically an account of how the tool works, and to the extent that our ability to explain our own actions sets the benchmark for an acceptable explanation, then some might think that the bar is pretty low. How often can we give an adequate explanation for our own actions? However, if the right to an explanation is at all demanding, then there are several reasons for pushing back against it. For example, it would not be socially acceptable if disclosure of the working of the tool meant that some people (such as the teachers in the Wysocki story; or, to take the stock example, well-advised taxpayers) were able to game the system. This is not what we want from transparency. Nor might it be socially acceptable if the difficulty of explaining how the tool works (because,

³¹ See, e.g., Tal Zarsky, ‘Transparent Predictions’ (2013) *University of Illinois Law Review* 1503.

³² (n 27).

³³ See, the EC High-Level Expert Group on Artificial Intelligence, *Ethics Guidelines for Trustworthy AI* (European Commission, Brussels, April 8, 2019) at 28-29, where ‘transparency’ is presented as comprising elements of ‘traceability’, ‘explainability’, and ‘communication’. Under ‘explainability’, one of the questions for AI developers is: ‘Did you ensure an explanation as to why the system took a certain choice resulting in a certain outcome that all users can understand?’ Both the OECD Recommendation and the EC guidelines highlight the idea of ‘trustworthy’ AI and see transparency and explainability as critical to the trustworthiness of such tools.

³⁴ See, Sandra Wachter, Brent Mittelstadt, and Luciano Floridi, ‘Why a Right to Explanation of Automated Decision-Making Does Not Exist in the General Data Protection Regulation’ (2017) 7 *International Data Privacy Law* 76.

as in some AI, the operation of the algorithms really is a ‘black box’) means that potentially beneficial innovation is stifled. Accordingly, not everyone might agree with the House of Lords Select Committee on Artificial Intelligence when it recommended that where, as with deep neural networks, ‘it is not yet possible to generate thorough explanations for the decisions that are made, this may mean delaying their deployment for particular uses until alternative solutions are found.’³⁵ On the other hand, of course, a community might treat ‘black box’ technologies as unacceptable and endorse the view taken by the Select Committee.

3.1.3.3 Transparency as justification

A different take on transparency and the claimed right to an explanation is that what we actually want is to be given justifying reasons for the decision. What we want to know is not so much ‘how’ but ‘why’ the decision was made. In particular, the idea is that, for a decision to be socially acceptable, the variables that are taken into account and the weight given to particular variables must be judged to be appropriate. As the OECD Recommendation puts it, an individual who is adversely affected by an AI decision, should be able ‘to challenge its outcome based on plain and easy-to-understand information on the factors, and the logic that served as the basis for the...decision.’³⁶

Suppose, for example, that John Doe applies for a credit facility but that he is turned down by a smart machine that classifies him as a bad risk. When John Doe challenges the decision, he learns that one of the previous occupiers of his house, one Richard Roe, had a record of non-payment of loans. But, why, Doe asks, should the credit record of an unrelated third-party, Roe, count against my application? Is that not unfair and irrational? Is this not a postcode lottery? To which the response is that the machine makes more accurate decisions when it uses third-party data in this way; and that, if such data were to be excluded from the calculation, the cost of credit would increase.

On facts of this kind, in the case of *CCN Systems Ltd v Data Protection Registrar*,³⁷ the tribunal held that, while it accepted that such third-party information might have general predictive value and utility, its use was unfair to the individual and should not be permitted. Similarly, Doe might argue that he has been treated unfairly if his application for credit is successful but the terms and conditions of the facility reflect the fact that (because of unrelated third-party data) he is classified as a higher-than-average risk; and, once again, the response to the objection will be that the costs of credit will be increased if such data is excluded. While many will agree with the tribunal’s protection of the individual’s interest in access to credit, the decision highlights that there is a difficult choice to be made between the general utility of the credit algorithms and the unfairness of their application to particular individual cases.

If we have concerns about the use of AI to decide whether or not to advance credit to an applicant, these concerns are likely to be amplified if risk assessment tools are used by legal

³⁵ Report on *AI in the UK; ready, willing and able?* (Report of Session 2017-19, published 16 April 2017, HL Paper 100) at para 105: available at https://publications.parliament.uk/pa/ld201719/ldselect/ldai/100/10007.htm#_idTextAnchor025 (last accessed August 11, 2018).

³⁶ (n 27).

³⁷ Case DA/90 25/4/9, judgment delivered 25 February 1991.

service providers to select their clients and cases. After all, if a prospective client seeks legal advice and assistance in connection with a perceived injustice, their sense of injustice will be compounded if they are denied access to the service by a technology that either operates in ways that cannot be explained or that acts on reasons that seem to put the interests of the provider or the collective good above individual justice.

In sum, a professional service provider's use of a technology to make decisions about who is, and who is not, to receive the service will be acceptable only if it meets relevant standards of transparency and explainability; and it must be operated and applied in ways that are at the very least not obviously unfair—this latter condition often presenting societies with hard choices to be made between general utility and fair treatment of individuals.

3.1.4 Decisions about whom to provide and with which services

Some new technologies, AI being the obvious example, might assist service providers to decide which services should be provided and to whom they should be provided. For example, in health, new technologies might be relied on to indicate which treatments are likely to succeed for particular patients and which are less effective or even futile; and, in legal services, the technologies might be used to decide which cases are taken on and how they are then taken forward.

While there are likely to be rules that limit some of the choices that service providers might otherwise make, there are two matters that merit some remarks in this context. First, in 3.1.4.1, we discuss the importance of inclusion and the potential seriousness of being denied professional services; and, then, in 3.1.4.2, we draw attention to the way in which the general principles of medical law now require service-providing doctors to ensure that their patients (consumers) are made aware of the treatment options available to them so that they can make an informed choice about how to proceed.

3.1.4.1 The importance of inclusion and the seriousness of denial of service

In 2017, the House of Lords Select Committee on Financial Exclusion³⁸ highlighted the importance of financial inclusion in the following terms:

For most people, access to financial services is an important part of everyday life. At the most basic level, a bank account is used for paying bills and receiving income; access to a bank account is also usually a pre-requisite for gaining employment and receiving social security benefits. Access to savings and affordable credit is an important factor in allowing people to meet unexpected expenses, while conscientious provision for retirement relies upon pension products. These services are a recognised feature of day-to-day life for most people.

A sizeable minority, however, lack access to these products. This presents a significant barrier to engagement in modern society, and can also lead to individuals incurring significant additional costs due to reliance on suboptimal forms of financial access. Those who are financially excluded in this way typically experience other forms of social exclusion, or have other vulnerabilities related to old age, disability, deprivation

³⁸ House of Lords Select Committee on Financial Exclusion, *Tackling financial exclusion: A country that works for everyone?* (Report of Session 2016–17, HL Paper 132).

or a lack of digital skills, meaning that the effects of financial exclusion are compounded or reinforced. Free markets do not always serve the financial needs of these customers effectively.

Expressing concerns about, *inter alia*, the closure of bank branches, these sentiments were echoed recently by the House of Commons Treasury Committee.³⁹ According to the Committee,

Access to financial services and financial inclusion are issues of fundamental importance to the Treasury Committee, UK consumers, but also the functioning of the economy. Financial inclusion matters to everybody, not just the disadvantaged or vulnerable.⁴⁰

Indeed, as at least one witness put it to the Committee, financial services are ‘an essential... a utility...’⁴¹; and, as the Committee itself recognised, being in control of one’s finances ‘is all the more important in a society where the pace of change is increasing all the time as new technology emerges.’⁴²

If we set legal services (and the needs that are serviced) alongside health and financial services, where would they stand? If new technologies brought with them new efficiencies but also meant that bricks and mortar solicitors’ offices were being closed rather than bank branches or doctors’ surgeries or local hospital A & E departments, how serious would this be – or, at any rate, how serious would this be where face-to-face provision was necessary? Given that, within each sector, there is a broad spectrum of services (in health, for example, from dealing with life-threatening conditions to treating the common cold), some of which look more important than others, this is not a straightforward question. In each sector, at the top end of the range of services, a lack of access to the required services could have very serious consequences (concerning one’s health and well-being); at the bottom end, however, a lack of access might be no more than inconvenient. Nevertheless, in general terms, a denial of access to legal services should be taken extremely seriously.

Whatever our view about the importance of legal services, we can surely agree that denial of access to an important service is particularly troubling if the reasons for such denial are flawed. It is one thing being denied access to a flight, or to credit facilities, or to legal advice and assistance, for legitimate reasons; but it is quite a different matter if the risk-assessment undertaken by the technology is in error. This leads to the important issue of the risk of false positives, a matter that we will take up in 3.1.5.

3.1.4.2 Consumers and informed choices

³⁹ House of Commons Treasury Committee report on consumers’ access to financial services, Twenty-ninth report of session 2017-2019, May 13, 2019 (HC 1642). Available at <https://publications.parliament.uk/pa/cm201719/cmselect/cmtreasy/1642/1642.pdf> (last accessed May 19, 2019).

⁴⁰ *Ibid.*, para 17.

⁴¹ *Ibid.*, para 7.

⁴² *Ibid.*, para 18.

Where professional services are being provided to consumers, there will sometimes be more than one way of proceeding. In some cultures, it might be acceptable to leave it to the professionals to exercise their judgment as to the best way to proceed; and, professionals might, in future, exercise their judgment with the aid of tools that indicate the best way forward. However, following the landmark decision of the UK Supreme Court in *Montgomery v Lanarkshire Health Board*,⁴³ it is clear that, at any rate in relation to health services, this is not the culture that is supported by the modern law.

The principal question in *Montgomery* was whether a pregnant woman who was a diabetic, and whose pregnancy was regarded as high-risk requiring intensive monitoring, should have been informed that there was a risk of shoulder dystocia and given the option of delivery by Caesarean Section. Instead, she was not made aware of this particular risk; the risk eventuated during an attempted vaginal delivery; and, as a result, the baby was born with severe disabilities. The lower courts, following the *Bolam* principle,⁴⁴ held that the acts of the consultant obstetrician and gynaecologist who did not disclose the risk, and who was by her own admission reluctant to steer women towards a Caesarean Section, was sufficiently supported by medical practice. However, the UK Supreme Court, resoundingly rejecting the applicability of the *Bolam* test to such matters of patient information and physician disclosure, held that the relationship between clinicians and patients must be rights-respecting rather than paternalistic and that patients have a right to be informed about their options (together with their relative benefits and risks).

In a few paragraphs, the Supreme Court rewrote the legal framework governing the relationship between physicians and patients. First, the Court recognised that ‘patients are now widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession’.⁴⁵ Secondly, the Court noted that patients, while not medical experts, are not wholly uninformed. Accordingly, it would be ‘a mistake to view patients as uninformed, incapable of understanding medical matters, or wholly dependent upon a flow of information from doctors’, from which it followed that it would now be ‘manifestly untenable’ to make this ‘the default assumption on which the law is to be based’.⁴⁶ Thirdly, professional guidance to doctors already reflects these changes by encouraging ‘an approach based upon the informed involvement of patients in their treatment’.⁴⁷ Signalling a distinct movement away from medical paternalism and patient-dependence, the new approach is built on mutual rights and responsibilities, treating patients ‘so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices’.⁴⁸ That said, *Montgomery* recognises that, in exceptional circumstances, doctors may

⁴³ [2015] UKSC 11.

⁴⁴ *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118.

⁴⁵ [2015] UKSC 11, para 75.

⁴⁶ [2015] UKSC 11, para 76.

⁴⁷ [2015] UKSC 11, para 78.

⁴⁸ [2015] UKSC 11, para 81.

legitimately withhold information under cover of the so-called ‘therapeutic privilege’. However, the Court emphasises that this exception ‘is not intended to subvert [the general principle] by enabling the doctor to prevent the patient from making an informed choice where she is liable to make a choice which the doctor considers to be contrary to her best interests’.⁴⁹ In short, patients have a right to make their own judgments, prudential and moral, of what is in their best interests;⁵⁰ and it is the responsibility of doctors not to override these judgments but to assist patients by ensuring that their choices are suitably informed.

How far the thinking in *Montgomery* can be translated across to other service sectors such as legal services is, of course, moot. However, to the extent that the principle in *Montgomery* is applicable, it implies that where a tool is used to identify and risk-assess the options available to a consumer, the professional service provider should make the consumer aware of the resulting information; and, it might also imply that where there is an option of using such a tool in the first place, this is something about which the professional should also inform the consumer.

3.1.5 The possibility of an individual being a false positive

Picking up the discussion from 3.1.4.1, what makes Sarah Wysocki’s case particularly troubling is the assumption that she was actually a ‘false positive’. The technology incorrectly classified her as a poor teacher. What, then if technologies routinely generate false positive decisions? How many false positives will a community tolerate? Where large numbers are involved, even a tiny percentage of false positives will affect a significant number of persons.

Moreover, attitudes towards the acceptability of false positives might vary from one context to another. In the criminal justice system, for example, while advocates of human rights and liberal values will be greatly concerned about false positives (the innocent who are convicted and punished), populist political views might be far more concerned about false negatives (the guilty who escape conviction and punishment). As Andrea Roth points out:

[A]lthough the motivation of law enforcement, lawmakers, and interest groups who promote ‘truth machines,’ mechanical proxies, and mechanical sentencing regimes, is often a desire for objectivity and accuracy, it is typically a desire for a particular type of accuracy: the reduction of false negatives.⁵¹

Hence, whether or not a community would regard the use of a technology as acceptable when a certain number of false positives are known to be implicated in its outcomes would be a matter for general debate and discussion.

Where the tolerance of false positives and false negatives is debated by the community in the spirit of trying to do the right thing, we are likely to find that we are back to the ethical issues raised by the case of John Doe (in 3.1.3.3) and, with that, to the choice between general utility and individual fairness. Whereas a utilitarian will set the disutility of false positives against the overall utility of the technology (arriving at an all, utilitarian, things considered view) an

⁴⁹ [2015] UKSC 11, para 91.

⁵⁰ Nb Lady Hale in *Montgomery* at para 115.

⁵¹ Andrea Roth, ‘Trial by Machine’ (2016) 104 *Georgetown Law Journal* 1245, at 1252.

advocate of human rights and individual fairness will focus on the injustice of falsely treating a human as a positive (potential wrongdoer).

3.1.6 Unintended consequences

In a helpful analysis of the challenges presented with regard to the regulation of cyberspace, Stuart Biegel sets out twenty guidelines for regulators.⁵² These guidelines largely reduce to matters of regulatory acceptability and effectiveness—essentially, regulators need to be smart in their choice of regulatory instruments, knowing when and how to intervene, and they need to be sensitive to the views and values of their regulatees (and, concomitantly, the likely reactions of regulatees). Biegel’s final guideline, however, is more in the way of a reminder, namely that

Perhaps the most important of all the inherent limits of our legal system is the rule of unintended consequences. Especially in the light of the fact that cyberspace technology will inevitably continue to change, it is essential that we seek to avoid modifications that may have unanticipated effects.⁵³

No doubt, there will always be consequences that could not have been anticipated—as the Wysocki case itself vividly illustrates. However, Biegel’s point is that the more carefully that regulators inform themselves, the better the chance that their interventions will have the effects that they intend.

One thing that regulators should certainly anticipate is that commercial enterprises will react to regulatory interventions that increase the burdens on business by exploring lawful options to reduce those burdens. So, for example, if regulators take steps to improve the quality of rented accommodation by placing additional requirements on landlords, the upshot might be that some landlords decide to sell their properties leading to an unintended shortage in the rental housing market. In communities, such as the United Kingdom, where government policy is to encourage science, technology and innovation, it is important that regulators send the right signals: if regulatory acts or omissions result in tech businesses relocating away from the UK, or not locating here in the first place, these are effects that are both unintended and undesired.

Another point for regulators to bear in mind is that, if they nurture new technologies, and if (as is characteristically the case) those technologies have disruptive effects, then some of those effects are likely to be negative. For example, when it became clear that e-commerce was an opportunity not only to expand the marketplace for small businesses but also to give consumers more choice, regulators who cleared the way for the development of online marketplaces must have expected this to have some impact on traditional offline consumer marketplaces. However, they probably did not anticipate, or intend, that the growth of the online marketplace would have such a dramatic negative impact on retailers, both small and large, trading in traditional high streets and, concomitantly, such a deleterious effect on town centres.

3.2 Lessons

⁵² Stuart Biegel, *Beyond Our Control?* (Cambridge Mass.: MIT Press, 2003) 359-364.

⁵³ At 364.

Building on and elaborating the issues discussed in 3.1, we can begin to identify some of the lessons to be drawn. In particular, what we are looking for are key lessons relating to the three prongs of our general principle: (in 3.2.1) lawfulness, (in 3.2.2) social acceptability, and (in 3.2.3) compliance and sustainability.

3.2.1 Lawfulness

The conventional jurisprudential wisdom is that uncertainty as to the legal (and regulatory) position can arise from two sources, namely: (i) (in 3.2.1.1) the ‘open texture’ of language, often reflected in the vagueness (and, sometimes, ambiguity) found in legislative provisions; and (ii) (in 3.2.1.2) a failure by lawmakers to anticipate changes in the context in which the law is to be applied. Data protection law, to which we have briefly referred in relation to the solely automated processing of decisions is a prime example of a body of law that is problematic in both respects and which, as a result, can give rise to major issues concerning compliance.

3.2.1.1 Open texture and vagueness

It is axiomatic that law should be clear, non-contradictory, relatively constant, and so on.⁵⁴ Sadly, although the general principles of data protection law are clear, the founding concepts (particularly the concept of ‘personal data’ itself) and the detailed provisions are notoriously unclear. Applying these standards to the regulation of cyberspace, Chris Reed identifies many shortcomings.⁵⁵ As he summarises it, ‘Complexity makes laws hard to understand, contradictory rules make compliance impossible and frequent change compounds these difficulties.’⁵⁶

Although a degree of vagueness might help parties to sign off on contested legal rules, it militates against confident compliance. Faced with vague rules, regulatees will simply not know where they stand; even if they wish to comply with the regulatory standard, they will not know what it requires or prohibits.

So should regulators try to avoid vagueness and aim to be clear, precise and specific in their provision? While this might be appropriate in many contexts, in the setting of rapidly developing technologies, it is likely to solve one problem only to exacerbate another—namely, the uncertainty that arises from the rapid development of technologies (that are the subject of the law) and the consequent (unanticipated) changes in the context for the application of the law.

3.2.1.2 Unanticipated changes in context

In a well-known critique of the 1995 Data Protection Directive⁵⁷, Peter Swire and Robert Litan argued that the Directive was flawed at its inception because it was predicated on a world of

⁵⁴ Lon L. Fuller, *The Morality of Law* (New Haven: Yale University Press, 1969).

⁵⁵ Chris Reed, ‘How to Make Bad Law: Lessons from Cyberspace’ (2010) 73 *Modern Law Review* 903, esp at 914-916.

⁵⁶ *Ibid.*, at 927.

⁵⁷ Directive 95/46/EC.

main frame computers and highly visible ‘data controllers’ who could be held responsible for compliance with the data protection principles.⁵⁸ Quite correctly, Swire and Litan foresaw that this world was rapidly being overtaken by highly distributed micro computing in which data controllers and data processors were less like the ‘elephants’ presupposed by the law and more like ‘mice’. With the enactment of the GDPR, history might be about to repeat itself. In the near future, the pervasive connectedness of devices (representing the Internet of Things and drawing on cloud storage, data analysis, and so on) might make it very difficult to isolate particular automated ‘decisions’ from the background networks and noise. In smart cities, as currently envisaged, a sophisticated technological infrastructure will be processing countless data points to control human interactions. Quite where we find the relevant solely automated ‘decisions’ in such a processing context is unclear.

In part 4.1.2.1, we will return to this theme, highlighting the general problem of keeping the law connected to fast-moving technological development, and focusing in that part of our discussion on the particular case of reproductive technologies.

3.2.2 Social acceptability

The lessons to be drawn in relation to the social acceptability of newly adopted technologies are varied. While some lessons caution regulators against thinking that the road ahead is clear and unproblematic (for example, advising regulators to think hard about what they understand by ‘transparency’, or to anticipate a tension between considerations of general utility and individual fairness, or to be alert to unintended consequences, and so on), others are more prescriptive (for example, to invest in prior consultation with regulatees).

In what follows, we will highlight: (i) (in 3.2.2.1) the importance of prior consultation and consent; (ii) (in 3.2.2.2) two recurrent tensions; (iii) (in 3.2.2.3) the potential importance of keeping humans in the loop; (iv) (in 3.2.2.4) the importance of transparency where smart machines make decisions that have significant impacts; and (v) (in 3.2.2.5) the need to guard against the ‘technology effect’ (that is, having too much confidence in a technology).

3.2.2.1 The importance of consultation and consent

Before regulators permit service providers to introduce a new technology, they should undertake their own consultation. To license the use of a new technology without any kind of consultation is a recipe not only for resistance and rejection but also for failing to appreciate what negative impacts there might be and for which parties.

Even where consultation is undertaken, it needs to be right if it is to result in general agreement as to the social acceptability of the technology. In the United Kingdom, the public consultation on GM crops and on the ill-fated care.data scheme are stock examples of how a consultation should not be run.⁵⁹ While, there is no simple formula for getting a consultation right, it is important that those who are consulted are treated with respect, that the consultation is inclusive

⁵⁸ Peter Swire and Robert E. Litan, *None of Your Business* (Washington: Brookings Institution Press, 1998).

⁵⁹ For a critical assessment of the former, see Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton: Princeton University Press, 2005); and, for care.data, see Nick Triggle, ‘Care.data: How did it go so wrong?’ BBC News, 19 February, 2014, available at <https://www.bbc.co.uk/news/health-26259101> (last accessed June 18, 2019).

(both in its agenda and in who is to be consulted), and that it is held in good faith. Crucially, it is imperative that the process not only is run but is seen to be run, not with a view to ‘legitimizing’ a position that has already been taken, but with a view to taking a position that can be plausibly presented as a rational and reasonable accommodation of many different viewpoints.

In line with these remarks, the Royal Society and Royal Academy of Engineering, jointly reporting on the governance of nanotechnologies, advised that effective consultation hinges on a number of factors: in particular, early engagement and dialogue—well before critical decisions about the technology have become irreversible or ‘locked in’; dialogue being designed around clear and specific objectives; those who consult publicly committing to take account of the views of consultees; consultation being properly integrated with other related processes of technology assessment; and sufficient resourcing being available for the exercise.⁶⁰ Even with attention to these matters, however, there are likely to be difficult questions about precisely how the dialogue and consultation is to be integrated with other processes of technology assessment, especially how to treat lay views on matters (of health and safety, environmental integrity, the application of legal and ethical principles, and so on) that are being concurrently assessed by expert bodies. In a context where there is a lack of trust in both ‘consultations’ and ‘experts’, getting a consultation right is a considerable challenge.

3.2.2.2 Two recurrent tensions

In the course of their consultations, regulators are likely to find that their consultees have competing and conflicting interests. Indeed, they are likely to find two recurrent tensions.

The first of these tensions is between the view that regulatory regimes should be geared for the general utility (for the collective good) and the view that such regimes should be responsive to individual fairness (and the interests of particular individuals). This tension is not peculiar to the introduction or application of new technologies. Even without technology on the radar, the design of the criminal justice system, of the civil justice system, and of the administrative justice system will involve some tension and trade-off between utility and individual fairness.⁶¹ Once new technologies are introduced, this tension manifests itself in many ways, particularly (as we have seen) in relation to the acceptability of a certain number of false positives and of reliance on unrelated third-party data (irrelevant considerations).

The second of these tensions is between the view that regulatory regimes should be geared for innovation and the view that they should be designed to prevent unacceptable risks to persons, to property, to privacy, to the environment, and so on. While the former view is concerned that regulation should not stifle innovation, the latter is concerned that regulators should manage the known harmful effects of particular technologies and handle the uncertain effects of new technologies with caution (see, further, 4.1.1.1 and 4.1.2.2).

⁶⁰ Royal Society and the Royal Academy of Engineering, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* (RS Policy document 19/04) (London, 2004) para 38. See, too, the excellent report by the Nuffield Council on Bioethics, *Emerging Biotechnologies: Technology, Choice and the Public Good* (London, 2012).

⁶¹ John N Adams and Roger Brownsword, *Understanding Law* (London: Thomson, 2006).

In some communities, there might be a clear cultural steer for regulators. However, where regulators face strong lobbies on both sides of these tensions, they need to take their position provisionally, keep it under review, and be ready to make adjustments.

3.2.2.3 Keeping humans in the loop

Where service providers automate their processes, taking humans out of the loop, this might be of little concern to consumers. On the other hand, it might be a matter of considerable concern: consumers might be reluctant or unwilling to lose the human touch.

Earlier this year, for example, it was reported that Ernest Quintana’s family were shocked when they saw that a ‘robot’ displaying a doctor on a screen was used to tell Ernest that doctors could do no more for him and that he would die soon.⁶² It was explained that, at the Californian hospital in question, ‘the evening video tele-visit was a follow-up to earlier physician visits.’ In other words, humans were not wholly out of the loop. Nevertheless, as one commentator put it, this incident highlighted the fear that ‘human-to-human relationships are going to be replaced with sanitized, mechanized, factory-medicine—where information is delivered without compassion, where people are left to their own devices to deal with the human element of birth, death, sickness [and] disease.’⁶³

The lesson for regulators is that they should not assume that consumers will accept that the loss of human interaction is a reasonable price for greater ‘efficiency’. In the Quintana case, the family did not like the idea that bad news was being transmitted by a machine; and, it is perfectly possible that some consumers who are steered away from, or denied access to, a particular service option on an automated basis will also find this unacceptable.

3.2.2.4 Transparency

In the context of data processing and AI, we have seen that ‘transparency’ has become something of a ‘buzz’ word. Thus, if regulators aspire to achieve more rather than less transparency, they are doing the right thing. However, we have also seen that regulators need to think quite carefully about their understanding of ‘transparency’ (whether it is about openness, or explainability, or the justification of a decision); they need to think about what precisely is to be made transparent and about any unintended negative effects that might flow from openness. For regulators, the lesson probably is that transparency flags up an important question to be asked in their engagement with regulatees rather than indicates the action to be taken.

3.2.2.5 Avoiding the ‘technology effect’

During the test stage of new technologies—for example, during the trials of autonomous vehicles—regulators might require a human operator not only to be present but also to be able to take control. However, there comes a point when the technology completes its trials and it is judged to be safe and reliable. At this point, there is a risk that we are over-optimistic about

⁶² See, Michael Cook, ‘Bedside manner 101: How to deliver very bad news’ Bioedge (March 18, 2019). Available at <https://www.bioedge.org/bioethics/bedside-manner-101-how-to-deliver-very-bad-news/12998>.

⁶³ Ibid.

what technologies can achieve and over-confident about their reliability and accuracy.⁶⁴ This so-called ‘technology effect’ can be highly prejudicial.

In the particular case of AI, one of the many helpful questions in the EC High-Level Expert Group’s assessment list for trustworthy AI is: ‘Did you take safeguards to prevent overconfidence in or overreliance on the AI system for work processes?’⁶⁵ This is an important reminder. Nevertheless, if we come to have more confidence in the technology than in our own skills and judgment, then this raises huge questions about the significance of bringing humans back into the loop. If AI and automated decisions are perceived to outperform humans, how realistic, reasonable or rational is it for humans, having reconsidered the matter, to override the automated decision? As Hin-Yan Liu⁶⁶ has argued in an insightful commentary, humans become vulnerable because of their now perceived inferiority to smart machines. Thus:

A general vulnerability that erodes our means of resisting AI power involves a narrative about perceived or actual human inferiority. This has the effect of eroding human confidence and ability in challenging and countering AI, stoking the automation bias whereby proximate human beings acquiesce to AI ‘recommendations’, and effectively relegate human overseers to mere button-pushers. As this is a form of categorical superiority, because AI can be pitted against the human being, that has not emerged before it threatens to blindside us entirely. As well as being unprecedented and therefore difficult to identify, however, it will be hard to recognise this form of erosion in available responses because it is nebulous by affecting the very orientation of human beings in relation to AI. As such, the subtle yet pervasive narrative of human inferiority suggests a great weakness in our collective ability to respond to and regulate AI.⁶⁷

In such circumstances, the possibility of bringing humans back into the loop might be little more than an empty gesture. On the one hand, as with many ostensibly remedial pathways, the gradient might be simply too steep; even for those prospective complainants who know about the availability of a remedy, the cost and complexity of pursuing a complaint is just too great. On the other hand, the humans who are brought back into the loop might be reluctant to gainsay the automated decision—in which case, this will further disincentivise individual complainants. Not only do we know that ‘repeat players’ tend to do better in disputes than ‘one-shot’ players,⁶⁸ we can anticipate that automated decision-makers will prove to be repeat players par excellence. If humans are to be brought back into the loop, and if smart machines are to be effectively monitored, it is probably not at the behest of individual complainants.

⁶⁴ See, e.g., <https://www.techtimes.com/articles/45232/20150410/study-shows-that-were-too-confident-about-technology.htm> (last accessed June 21, 2019).

⁶⁵ See (n 33).

⁶⁶ Hin-Yan Liu, ‘The Power Structure of Artificial Intelligence’ (2018) 10 *Law, Innovation and Technology* 197.

⁶⁷ At 222.

⁶⁸ Seminally, see Marc Galanter, ‘Why the “Haves” Come Out Ahead: Speculation on the Limits of Legal Change’ (1974) 9 *Law and Society Review* 95.

Rather, it will be left to regulatory bodies to undertake ex ante licensing of AI and ex post audit of its performance.

3.2.3 Compliance and sustainability

The problems that we identified in 3.2.1 are rooted in the rule-making or standard-setting capability of lawmakers and regulators. However, as we have said, the generic challenge of regulatory effectiveness is one that also engages the interests and reactions of regulatees as well as possible intervention or interference by third parties. Clearly, while regulators will have to grapple with various kinds of drafting difficulty, their chances of achieving compliance will depend to a considerable extent on other factors, including the compliance culture amongst regulatees and the social acceptability of the regulation.

Perhaps the most important lesson for regulators is that it is not sufficient to draft clear rules and to anticipate how technologies might be developed and applied. If there is to be compliance by regulatees, and particularly where those regulatees are professional service providers, it makes sense—*provided that other things are equal*—to secure their cooperation, ensuring that they are properly invested in and have a degree of ownership of the regulatory scheme. To the extent that the regulatory scheme is articulated in a flexible instrument, this will also assist with sustainability.

The proviso in the previous paragraph should be accentuated (and, particularly so in the legal services sector, where great importance is attached to regulatory bodies being independent). The nature of the proviso here is that regulators must not allow cooperation to compromise their responsibility for ensuring that the regulatory arrangements are broadly socially acceptable. The regulatory regime definitely will not be socially acceptable if it exposes consumers to serious risks or crosses red lines for the community as a whole. It follows that regulators' cooperation with regulatees cannot be simply a matter of regulating in a way that suits the professional service providers. Cooperation with regulatees must not turn into regulatory capture. The aspiration for compliance and sustainability has to be read in the context of the responsibility for socially acceptable regulation.

4. Technologies employed for outward-facing purposes II: new forms of service delivery and new options for consumers

Professional providers might employ all manner of technologies in the delivery of their service—for example, we have seen this with the introduction of automated teller machines, online banking and mobile payment facilities, in vitro fertilisation (IVF), genetic tests, imaging equipment (such as MRIs), and online distance learning courses, and so on; and, there are now debates about how additive manufacturing tools, telematics (in insurance), cloud computing, AI, blockchain and distributed ledgers, and augmented reality technologies might enable the delivery of services. Where technologies of this kind are employed to deliver the service to consumers, then consumers' experience of that service (whether a financial, reproductive, health, or educational service) is technologically mediated and, of course, the interests of consumers are directly impacted (for better or worse) by such mediation.

For regulators who oversee the adoption of such service delivery technologies, the critical questions (given the general guiding principle) are whether practice and provision in the sector

passes muster as lawful and socially acceptable; and whether practice and provision is geared for compliance and sustainability.

4.1 Key issues

To identify some of the key issues arising from this kind of use, we focus on four types of risks that regulators might need to manage, namely: risks to the interests of consumers, risks to societal interests, risks to the interests of third-parties, and the risk of unintended consequences. By highlighting these risks, we see the main dimensions of social acceptability and the tensions therein.

Starting with the risk to consumer interests (in 4.1.1), we draw on two illustrative cases: one case, generated by the development of blockchain and cryptocurrencies, concerns the infamous hack of Mt. Gox in 2014, the first major hack of a cryptocurrency exchange; and the other case concerns the pressure to introduce so-called ‘right to try’ laws. In the former case, it is the financial interests of consumers that are at risk, and in the latter it is their life, their health, and their well-being that is at risk.

We turn then (in 4.1.2) to societal interests. Here, we start with another illustrative case, this one—generated by the revolution in reproductive technologies—concerning so-called ‘saviour siblings’; and then we review the important interest in innovation.

Beyond these cases of risks to consumers and to society, we then consider possible risks to third-parties (in 4.1.3) and the risk of unintended consequences (in 4.1.4).

4.1.1 Risks to the interests of consumers

Consumers have a broad range of interests. They have interests in both their freedom (including their practical options, their privacy, and their autonomy) and their well-being (including their physical and psychological well-being, their financial interests and their reputational interests). However, consumers do not all necessarily value these interests in quite the same way. For some consumers, the role of regulators is to help them to make informed choices; but, for others, it is protection against harm and promotion of one’s welfare that is the priority. Accordingly, regulators need to be clear about which interests—the interest in autonomy and informed choice or the interest in welfare—they are prioritising in their consumer protection regimes and whether this is the right approach.⁶⁹

In this part of our discussion, we will juxtapose one case (in 4.1.1) in which the financial interests of consumers are arguably under-protected with another (in 4.1.2) in which the health interests of consumers as a class are arguably over-protected relative to the interests of individual consumers of health care services.

4.1.1.1 Blockchain, Bitcoin and the hack at Mt. Gox

In the early days of Bitcoin, Mt. Gox was the leading cryptocurrency exchange in the world. However, in February 2014, there was a hack that resulted in the loss of some 750,000 Bitcoins. Mt. Gox, which was based in Japan, was unable to continue trading and filed for bankruptcy. This was not the first such hack and nor was it the last. According to the FCA, in the first half of 2018, some \$731 million worth of cryptoassets were stolen, including two hacks amounting

⁶⁹ For critical reflections on EU consumer protection policy, see Geraint Howells, Christian Twigg-Flesner, and Thomas Wilhelmsson, *Rethinking EU Consumer Law* (Abingdon: Routledge, 2019).

to \$540 million on the Coincheck and Coinrail exchanges.⁷⁰ The hack at Mt Gox and subsequent hacks raise questions about the vulnerability of individual customers who use these exchanges, about the losses incurred by customers, about the security of the exchanges and about the adequacy of the regulatory environment.

From a consumer protection perspective, the regulatory environment in which Mt. Gox was operating seems to be deficient. Admittedly, there have been some criminal proceedings arising from the hack but, for the customers at Mt. Gox, the theft of their Bitcoins and the bankruptcy of the exchange seem to be entirely at their own risk—there is no regulatory cushion to soften the impact of the ensuing financial loss. On the other hand, it might be argued that customers at Mt. Gox had no reasonable expectation that regulators would shield them against these kinds of risk or cushion them in the event of loss. At that time, Bitcoin and blockchain were bywords for shady criminal activity and, in some places, they might well have been viewed as a challenge to fiat currencies as well as the recovery of the global financial system. In the circumstances, it might be argued, no one could reasonably expect regulators to ‘de-risk’ and regularise cryptocurrencies and exchanges by putting in place the kind of safeguards for consumers that are standard in the financial services sector.

However, that was then. Five years on from Mt. Gox, the world has changed, cryptoassets have proliferated, all this leaving regulators to figure out how best to engage with cryptocurrencies—for example, whether to prohibit Bitcoin, whether to treat cryptocurrencies as a form of ‘money’, whether to treat initial coin offerings as falling under national securities and investment law, how to tax cryptocurrency transactions, and whether to regularise consumer participation in these currency markets and associated crowd-funding ventures. Different positions are being taken in different national legal systems; and, while some national governments have moved very quickly to stake out their position on the leading regulatory issues, others are taking their time to articulate their position.⁷¹

The UK government is one of those governments that is taking its time. Quite apart from working out how the existing regulation of banks and financial services maps onto cryptocurrencies—in other words, which crypto-activities are regulated financial service activities and which are not under the Financial Services and Markets Act 2000 and its regulatory scheme⁷²—a key question is the perennial one of finding the right balance between capturing the benefits of the new technologies and managing whatever risks are presented. As Martin Wheatley has put it, the regulatory challenge is to achieve a level of oversight that reduces the risk of financial services becoming ‘a kind of tech-led Wild West’ without damaging the ‘new wave of possibility’ presented by global technology and innovation. Accordingly, the overarching regulatory responsibility is to ‘confront the challenges, to take

⁷⁰ Financial Conduct Authority, *Guidance on Cryptoassets* (Consultation Paper CP 19/3, January 2019) para 2.28.

⁷¹ For a general overview, see Primavera De Filippi and Aaron Wright, *Blockchain and the Law* (Cambridge: Harvard University Press, 2018) Chs 3 and 5.

⁷² See FCA, *Guidance on Cryptoassets* (n 70) Ch. 3.

hold of the advantages, and ultimately, to create a better future for our financial services and their customers.⁷³

In line with this thinking, the Cryptoassets Taskforce (comprising the FCA, HM Treasury, and the Bank of England) has framed the challenge in terms of addressing the risks (to consumers, to market integrity, and of enabling financial crime) while encouraging future beneficial innovation (for example, innovation that reduces transaction costs and expands opportunities for investment).⁷⁴ Thus, in the Foreword to the Taskforce's report, we read:

The Taskforce has concluded that while DLT is at an early stage of development, it has the potential to deliver significant benefits in financial services and other sectors in the future, and all three authorities will continue to support its development

There is limited evidence of the current generation of cryptoassets delivering benefits, but this is a rapidly developing market and benefits may arise in the future. There are substantial potential risks associated with cryptoassets, and the most immediate priorities for the authorities are to mitigate the risks to consumers and market integrity, and prevent the use of cryptoassets for illicit activity. The authorities will also guard against threats to financial stability that could emerge in the future, and encourage responsible development of legitimate DLT and cryptoasset-related activity in the UK.⁷⁵

Speaking at an event on the regulation of cybercurrencies in London last November, Christopher Woodward (from the FCA) elaborated on the perceived risks in the following terms:

The first harm is to consumers, who may buy unsuitable products, face large losses, be exposed to fraudulent activity, struggle to access market services, or be exposed to the failings of service providers, such as exchanges.

Then there's potential harm to market integrity. Opaque practices and misconduct could damage confidence in wider market functioning.

And of course, we cannot overlook the risk of financial crime, where cryptoassets have been used as part of illicit activity such as money laundering and fraud.

⁷³ Financial Conduct Authority reporting a speech by Martin Wheatley on 'The technology challenge' (10.06.2014). Available at <https://www.fca.org.uk/news/speeches/technology-challenge> (last accessed May 5, 2019).

⁷⁴ See HM Treasury, the Financial Conduct Authority, and the Bank of England, *Cryptoassets Taskforce: final report* (October 2018): available at <https://www.gov.uk/government/publications/cryptoassets-taskforce> (last accessed May 5, 2019).

⁷⁵ *Ibid*, at pp 2-3.

Finally, while we, like the Financial Stability Board, don't believe that cryptoassets pose a current financial stability risk, it's crucial we remain vigilant...should the market grow or cryptoassets become more widely adopted.⁷⁶

Given these risks, the strategy is, first, to establish which cryptoassets fall within the FCA's regulatory regime and which do not; and then to consult on whether the boundaries of the regime need to be extended.⁷⁷ Secondly, because of a concern that 'retail consumers are being sold complex, volatile and often leveraged derivatives products based on exchange tokens with underlying market integrity issues' there will also be a consultation on a possible 'prohibition of the sale to retail consumers of derivatives referencing certain types of cryptoassets (for example, exchange tokens), including contracts-for-difference, options, futures and transferable securities.'⁷⁸ Thirdly, in order to 'combat financial crime risks, the Treasury will undertake one of the most comprehensive responses globally to the use of cryptoassets for illicit activities by applying and going further than the existing directive, the fifth EU Anti-Money Laundering Directive (5AMLD). On this, HMT will first consult and then legislate on how to transpose 5AMLD and broaden the scope of anti-money laundering and counter-terrorism financing regulation further.'⁷⁹ Finally, 'the Taskforce has also concluded that exchange tokens present new challenges to traditional forms of financial regulation. The Treasury, therefore, plan to complete further analysis on whether regulation could meaningfully and effectively address the risks posed by exchange tokens and what, if any, regulatory tools would be most appropriate. HMT will consult in early 2019 on whether and how exchange tokens, as well as related actors such as exchanges and wallet providers, could be regulated effectively.'⁸⁰

4.1.1.2 Consumer interests and 'right to try' laws

When we focus on social acceptability relative to the perceived benefits and risks presented to consumers by new technologies, we are allowing for a range of possible impacts (positive and negative). As individuals, we will be differently disposed to the interests so impacted, to their weight and importance, to our willingness to make trade-offs between them, and to whether we prioritise the short-term or the longer-term. It is simply not possible for regulators to respond to the plurality of interests in a way that means that everyone gets exactly what they want; there has to be an accommodation; and to be socially acceptable, that accommodation of interests has to be reasonable. Whether or not any accommodation is perceived to be reasonable depends not only on whether it is reasonable but also whether regulatees themselves are reasonable people.

⁷⁶ Available at <https://www.fca.org.uk/news/speeches/conclusions-cryptoassets-taskforce> (last accessed May 2, 2019).

⁷⁷ This is the principal purpose of FCA Consultation Paper 19/3 (n 70).

⁷⁸ See, <https://www.fca.org.uk/news/speeches/conclusions-cryptoassets-taskforce> (last accessed May 2, 2019).

⁷⁹ Ibid.

⁸⁰ Ibid.

In both the United Kingdom and the United States, the plurality of competing interests forms the backcloth to highly contentious ‘right to try’ laws, seeking to allow patients who have exhausted all other options to access experimental or off-label medicines. In the United Kingdom, the proponents of what was to become the Access to Medical Treatments (Innovation) Act 2016, were anxious to ensure that the liability rules did not inhibit innovative, potentially life-saving, medical treatment. According to some critics of the draft law, such anxiety was unnecessary because the common law already immunised doctors against claims for negligence where they departed from accepted medical standards in a ‘responsible’ manner.⁸¹ In the event, the legislation, as enacted, does not even purport to achieve that particular objective. Rather, section 1 of the Act declares that the purpose of the legislation is:

to promote access to innovative medical treatments (including treatments consisting in the off-label use of medicines or the use of unlicensed medicines) by providing for—

- (a) the establishment of a database of innovative medical treatments, and
- (b) access to information contained in the database.

While this might be of some assistance in helping to inform both patients and physicians about the latest innovative developments, it does not explicitly address the balance of interests. On the other hand, it does not expose patients to some of the risks that critics of the Bill feared might be licensed by (even) ‘responsible’ departures.

By contrast, in the United States, many States have enacted ‘right to try’ laws which, broadly speaking, are designed to give terminally ill patients access to investigational drugs (or, at any rate, drugs that have completed Phase I testing on humans) without the authorisation of the regulatory agency (the FDA).⁸² According to these laws, manufacturers are permitted to supply such drugs to patients where various conditions relating to the recommendations of the consulting physician and informed consent are satisfied; and there are various immunities (for physicians) against disciplinary action and (for physicians and manufacturers) against civil liability. While access advocates can point to some compelling individual cases there are also some cautionary individual tales. However, even if an individual were sufficiently informed to make a sound assessment of the potential risks and benefits of resorting to a drug that has not gone through standard clinical trials, there is still the question of whether individual access of this kind would undermine collective efforts to establish the safety and effectiveness of drugs. As Rebecca Dresser observes:

The right-to-try campaign may be a small policy development, but it raises fundamental questions about our nation’s attitudes toward death and dying. Right-to-try laws portray unproven interventions as desirable, even praiseworthy, responses to life-threatening illness. A more informed debate could reveal the human costs of this approach, drawing

⁸¹ See Margaret Brazier and Emma Cave, *Medicine, Patients and the Law* (6th ed) (Manchester: Manchester University Press, 2016) at 205.

⁸² See Rebecca Dresser, ‘The “Right to Try” Investigational Drugs: Science and the Stories in the Access Debates’ (2015) 93 *Texas Law Review* 1630; and Jose Miola, ‘Postscript to the Medical Innovation Bill: Clearing Up Loose Ends’ (2019) 11 *Law, Innovation and Technology* 17.

attention to alternative policies offering more meaningful help to people near the end of their lives.⁸³

Unless a State takes a decisive step towards a libertarian culture or, in the other direction, to a culture of solidarity, announcing to the world that this is the particular kind of community that it wants to be, the ‘right to try’ will not be either constitutionally privileged or prohibited. Instead, it will be one element in an ongoing negotiation of the various interests pressed by stakeholders in health care and research, with the balance of interests and acceptability of risk being subject to routine assessment and adjustment.

4.1.2 Societal interests

Like consumer interests, societal interests are broad-ranging and they vary from one society to another. In this part of our discussion, we juxtapose one case (in 4.1.2.1) in which there is a push-back from conservative societal interests against new technologies and the expansion of consumer options with another case (in 4.1.2.2) in which the emphasis is on the progressive societal interest in innovation and what this means if the regulatory environment is to be designed in a way that is technology-friendly.

4.1.2.1 The revolution in reproductive technologies and saviour siblings

In the 1970s, Patrick Steptoe and Robert Edwards pioneered the development of the technique of in vitro fertilisation (IVF), famously leading to the birth of Louise Brown in 1978. Although the collaboration between Steptoe and Edwards did not involve any unlawful activity as such, the use of IVF was not explicitly legally authorised and, following the successful use of IVF, the Warnock Committee was set up to make recommendations concerning both assisted conception and the use of human embryos for research. The Committee reported in 1984 but it was not until 1990 that the legal framework, in the shape of the Human Fertilisation and Embryology Act, was put in place.

However, in the years that followed, it became apparent that the legislation (even with the assistance of several updating Codes of Practice issued by the Human Fertilisation and Embryology Authority) was becoming disconnected from the latest work in embryology. Moreover, in some cases, state-of-the-art embryology accentuated concerns about the commercialisation and the commodification of life. This particular concern that red lines were being crossed came to a head in the so-called saviour sibling cases.

In the best-known such case, the Hashmi family, desperate to find a suitable bone-marrow donor for their sick son Zain, and as a last resort, sought advice from Dr Simon Fishel, a leading figure in IVF. Fishel, who had worked with Edwards and Steptoe, told the Hashmis that it might be possible to use pre-implantation genetic diagnosis (PGD) in conjunction with the latest tissue-typing technologies in order to give birth to a child who could serve as a bone-marrow donor for Zain. However, this was at the leading edge of IVF, success was not guaranteed, and there was also a question about whether this procedure would be legally compliant.

Stated simply, the question of law was whether the legislative intent in the 1990 Act, which was to enable women, who could not otherwise have their own genetically related children, to

⁸³ Dresser (n 82) at 1657.

be assisted to have children, extended to potentially life-saving assistance for the benefit of children who were already born. A judicial review was commenced by a group who believed that it was clearly unethical (because the ‘saviour’ was being instrumentalised for the sake of the sick sibling, and because this further underlined the commodification of pregnancy), and that it must be unlawful for the HFEA to license such a procedure.⁸⁴ In a perhaps surprising reading of the somewhat opaque legislative provisions, the House of Lords held that it was *the particular reproductive purposes of the particular client woman* that should be taken as focal. As the House conceded, this reading meant that mothers could choose at will, whether for trivial or for eugenic reasons, and the only thing standing between unethical reproductive purposes and access to these technologies was the good sense of the licensing Authority. Clearly, this was not entirely satisfactory. However, given the pressure on legislative time as well as the complexity of the issues, it was not until 2008 that an acceptable regulatory re-connection was made in a new legislative framework.

What the Hashmis’ case highlights is that, where there is a strong consumer-pull, the limits of the law will be tested. If the limits are not extended as desired, then some consumers might try to find ways of working round the law (for example, by paying for the reproductive services that they require in another country); and, if the limits are stretched, then there will be a push-back from those who feel that red lines are being crossed (or, simply, that the Rule of Law is being observed in the breach).

By way of a postscript to this case, in his recent book, *Breakthrough Babies*,⁸⁵ Simon Fishel reflects on what he calls the ‘paradox of IVF’, saying:

To develop something innovative that will help people in a way that’s not been done before, we need to do new things. These new things may not work, and they might even offend people. The regulator doesn’t like that uncertainty. But how can we know if they work on humans, unless we try them on humans? You can see the catch-22 situation I’ve worked in for most of my career.

Here’s a thought: in regulated countries such as the UK, IVF couldn’t be invented today. The regulatory bodies that govern medical research would forbid it.⁸⁶

In other words, Dr Fishel judges that we have the balance wrong in health care—that is, we over-regulate for fear of causing harm to patients; and, presumably, he also thinks that we over-value the dignitarian ethical concerns that underlay the judicial review in the Hashmis’ case. This contrasts somewhat with the view of the HFEA who claim that ground-breaking

⁸⁴ *R (Quintavalle on behalf of Comment on Reproductive Ethics) v Human Fertilisation and Embryology Authority* [2002] EWHC 2785 (Admin); [2003] EWCA 667; [2005] UKHL 28. For extended discussion, see Roger Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford: Oxford University Press, 2008) Ch 6.

⁸⁵ Simon Fishel, *Breakthrough Babies* (Tadley: Practical Inspiration Publishing, 2019).

⁸⁶ Reported by Michael Cook, ‘The robot who will conceive your baby’ *Bioedge* March 17, 2019. Available at <https://www.bioedge.org/bioethics/the-robot-who-will-conceive-your-baby/13000> (last accessed May 27, 2019).

innovation in the UK (in IVF, mitochondrial replacement, and gene-editing) ‘has happened because of regulation not in spite of it.’⁸⁷

4.1.2.2 The societal interest in innovation

It is important to understand that innovation is not manna from heaven, it does not come out of nowhere. It follows that, in a community that values innovation, it is imperative that regulators attend to the risks not only to the interests of consumers and third-parties but also to prospective innovators⁸⁸—hence, the calls for ‘light-touch’, or ‘better’, or ‘proportionate’, or ‘targeted’ regulation, where the agenda is typically to create the right environment for innovation.⁸⁹

To create the right regulatory environment in a community that values innovation, care needs to be taken that research and development is not disincentivised and, indeed, that it is suitably incentivised. ‘Over-regulation’ is to be avoided: ex ante, regulators should not set an unnecessary obstacle course for researchers⁹⁰; and, ex post, liability regimes should not disincentivise researchers or divert innovators or risk prompting a move to defensive practice.⁹¹ At the same time, to incentivise innovation, there might need to be some tweaking of intellectual property law, competition law, the tax and subsidy regime; or, there might need to be some waiver or relaxation of regulatory restrictions or requirements (as we find in regulatory sandboxes: see further 4.2.2.3), and so on.

Gregory Mandel⁹² nicely captures the dilemma facing regulators:

Emerging technology governance must traverse a fine line. Insufficient protection could lead to excessive or unknown human health and environmental risks and undercut public confidence. Excessive regulation could limit the development of an extremely promising technology and foreclose potentially great social, health, environmental, and economic benefits. This combination of vast potential benefits and uncertain risks presents unique and difficult challenges. All stakeholders, however, have significant incentives to develop a protective and well-defined governance structure.⁹³

So, for example, in debates about the responsibilities of ‘share economy’ operators, such as Uber and Airbnb, to those who use their platforms, there have been different views. On the one

⁸⁷ See, HFEA, HFEA: Innovation in regulation (February 2017) p 2. Available at <https://ifqlive.blob.core.windows.net/umbraco-website/1796/innovation-and-regulation-plan-post-consultation-tagged.pdf> (last accessed May 6, 2019).

⁸⁸ For an excellent analysis, see Anna Butenko and Pierre Larouche, ‘Regulation for Innovativeness or Regulation of Innovation?’ (2015) 7 *Law, Innovation and Technology* 52.

⁸⁹ See n 19 for the Legal Services Board’s commitment to the Better Regulation principles.

⁹⁰ Compare the criticisms and recommendations (for streamlining) in the Academy of Medical Sciences, *A New Pathway for the Regulation and Governance of Medical Research* (London, January 2011).

⁹¹ See, e.g., Tzachi Keren-Paz, Tina Cockburn, and Alicia El Haj, ‘Regulating Innovative Treatments: Information, Risk Allocation and Redress’ (2019) 11 *Law, Innovation and Technology* I (introducing a special issue on the potentially inhibiting effect of tort liability).

⁹² Gregory N. Mandel, ‘Regulating Emerging Technologies’ (2009) 1 *Law, Innovation and Technology* 75.

⁹³ At 82.

hand, in its initial response, the European Commission advocated a light-touch approach;⁹⁴ but, against this, others have pressed for intervention in order to protect the health and safety of both providers and users. Indeed, in some places, local regulators (including Transport for London which, in September 2017, declined to renew Uber's licence to operate) have already taken action to restrict the activities of the platforms. Whether it is the Commission or the local regulators who have got this right is a matter for debate. As we have already said, for regulators, finding the sweet-spot between over-regulating a promising new technology and under-regulating it is a major challenge.

4.1.3 Risks to third-party interests

The development of online social networking sites facilitates the world-wide exchange of information and views. In the area of health, online sites such as patientslikeme⁹⁵, with many thousands of members, are an important resource and, on the face of it, a highly beneficial application of new technologies. However, on some of these sites, participants effectively set up their own 'research' trials, in which their own patient needs and interests (rather than the needs and interests of the professional research community) are prioritised. Sometimes, the results of the trials are duplicated in mainstream trials; but, often, the online trials will seem 'unscientific' both in their methodology and in the hypotheses that are being tested.

There are several important questions to ask about how this expression of participant-led research relates to mainstream research.⁹⁶ For example, rather like complementary medicine, does it actually compete with, and possibly undermine trust and confidence in, traditional medicine and the 'medical establishment' (compare the discussion in Part 5)? However, the point for present purposes is that the social acceptability of this use of these sites is likely to be affected by the capacity, competence and possible vulnerability of the participants. Where the participants are competent and non-vulnerable adults about whom we would raise no concerns if they were to enrol for a standard research trial, then this is relatively unproblematic. By contrast, where the participants are children who have been enrolled by their parents, this is likely to be viewed much more critically and paternalistically. Of course, recalling recent tragic cases such as that of Charlie Gard⁹⁷, the question of how regulators might then make an acceptable and effective intervention for the protection of such children is another matter altogether.

⁹⁴ European Commission: Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'Online Platforms and the Digital Single Market: Opportunities and Challenges for Europe' COM(2016) 288/2, Brussels, May 25, 2016.

⁹⁵ www.patientslikeme.com. By June 2011, patientslikeme had 100,000 members; it covered more than 1200 health conditions; and, with 4500 ALS patients, it has the largest online ALS population in the world. Other sites include curetogether (www.curetogether.com) and reg4all (www.reg4all.org) (all accessed on January 26, 2014).

⁹⁶ See Effy Vayena, Roger Brownsword, John Tasioulas and others, 'Research led by participants: a new social contract for a new kind of research' (2015) *Journal of Medical Ethics* doi: 10.1136/medethics-2015-102663.

⁹⁷ For discussion, see Jonathan Montgomery, 'The "Tragedy" of Charlie Gard: A Case Study for Regulation of Innovation?' (2019) 11 *Law, Innovation and Technology* 155.

In some health care (particularly reproductive) contexts, there might also be protective concerns about the interests of future children. As new technologies and techniques empower geneticists, there is a concern that the new born will be commodified prejudicing their right to ‘an open future’.⁹⁸ There is also a concern that where new screening tests (which we will discuss later in 5.1) provide early and accurate information to pregnant women about whether their baby has Down’s or one of the other trisomies, then this will lead to more terminations where the screen is positive. Where a termination is chosen following a positive screen, this has an impact on the terminated fetus as well as, some would argue, on those members of the community who have one of the trisomies—because the termination of a pregnancy in such circumstances sends out a negative message about how persons with disabilities are regarded.

4.1.4 The risk of unintended consequences

If they are to avoid interventions that have unintended consequences, regulators need to have 360-degree vision (aided by proper consultation), they need to have long sight rather than short sight, and above all perhaps they need to understand that regulatees are likely to respond *actively* to whatever interventions are made. Failure to do this will increase the risk that, even if the intervention succeeds in relation to its primary objectives, it might have unintended and negative secondary consequences. As the Financial Conduct Authority remarks in its recent consultation paper on cryptoassets, its aspiration is to ensure that its Guidance is ‘as clear and complete as possible so we don’t create inappropriate barriers to entry, or conflicts with our aims and objectives’⁹⁹; and, before the Guidance is finalised, as a part of its consultation process, the Authority ‘will consider feedback from stakeholders...to mitigate unintended consequences’ and ‘continue to monitor developments in the market.’¹⁰⁰

We have already highlighted the risk that providers, guided by their professional norms or by their prudential judgments of what makes business sense, might react to regulatory interventions in ways that (lawfully) defeat the regulatory objectives. However, it is not only the reactions of providers that regulators need to anticipate. For example, in her Gifford lectures, Onora O’Neill rightly observes that strategies that are intended to increase consumer trust in professionals (in scientists and medical professionals) might sometimes have the opposite effect.¹⁰¹ Thus, key performance indicators, audits, and codes can become the dominant and unhelpful reference points for professional conduct; and, while such signals of trustworthiness might assure some consumers, for others they raise questions about why they are necessary, leading to a diminution of trust. Similarly, while online reputation and rating systems might have some value in assuring consumers, they can also be ‘gamed’ and abused which then leads to a lack of system credibility.¹⁰²

⁹⁸ Seminally, see Joel Feinberg, ‘The Child’s Right to an Open Future’ in Joel Feinberg (ed), *Freedom and Fulfillment: Philosophical Essays* (Princeton: Princeton University Press, 1992).

⁹⁹ FCA, *Guidance on Cryptoassets* (n 70) para 1.16.

¹⁰⁰ *Ibid.* para 1.17.

¹⁰¹ Onora O’Neill, *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press, 2002). See, too, Mark Henaghan, *Health Professionals and Trust* (Abingdon: Routledge, 2012).

¹⁰² See, https://en.wikipedia.org/wiki/Reputation_system (last accessed June 21, 2019). For a recent example, where estate agents and banks were accused of gaming Trustpilot, the largest UK online ratings

4.2 Lessons

The lessons that can be derived from experience in regulating the adoption of technologies that present consumers with new options in relation to the provision of professional services relate to the lawfulness of the provision (in 4.2.1), to social acceptability (in 4.2.2), and to compliance and sustainability (in 4.2.3).

4.2.1 Lawfulness

One of the key lessons in this part of our discussion concerns the challenge of regulatory connection. Here, experience indicates that, in the early stages of a technology's development, the legal position might be unclear. For example, in many legal systems, it has been unclear how current legal provisions apply to cryptoassets; and, as we have noted, one of the points for action signalled by the Cryptoassets Taskforce is to establish how UK law applies here. By contrast, in the early days of IVF, it seems that Steptoe and Edwards were not violating any legislative prohibition or general principle of law; nevertheless, many in the profession disapproved of their activities. Moreover, as we have seen (in 4.1.2.1), even with the regularisation of IVF by the covering legislation, this was not the end of all uncertainty as to the legal position.

Of course, just because a technology is new, it does not follow that its application will not be caught by existing law. New technologies rarely fall into a complete regulatory void. For example, AI needs data; and, although AI might be new, data governance is not. There are laws about data collection and processing. Accordingly, when the Royal Free Hospital, pursuant to an AI-development agreement with Google DeepMind, sent patient data to the latter, this needed to be in line with the legal requirements, particularly requirements relating to the consent of the data subjects (patients). Critics challenged the legality of the data transfer; and, in due course, the Information Commissioner's Office ruled that the hospital had breached the legal requirements.¹⁰³

For sectoral regulators, the lesson here is that they can find themselves needing upstream clarification of the law. This might be because upstream lawmakers and regulators are taking their time to introduce the law (as with cryptocurrencies); or, it might be because (as with the Human Fertilisation and Embryology Act and the General Data Protection Regulation) the legislative provisions that have been introduced do not answer all questions of legality (particularly in a changing context of technological development and application).

4.2.2 Social acceptability

So far as social acceptability is concerned, the key lessons relate to: (i) (in 4.2.2.1) the importance of consulting the community and obtaining consent; (ii) (in 4.2.2.2) the need, especially where the impact of a particular technology is uncertain, for precautionary measures

website, see Tom Calver and Andrew Ellson, 'Firms pay Trustpilot to filter reviews' *The Times*, March 23, p 21.

¹⁰³ See, Julia Powles, 'Google DeepMind and healthcare in an age of algorithms' (2017) 7 *Health and Technology* 351; and, for the ICO ruling on the case, see <https://ico.org.uk/about-the-ico/news-and-events/news-and-blogs/2017/07/royal-free-google-deepmind-trial-failed-to-comply-with-data-protection-law/> (last accessed December 9, 2018).

and pilots; (iii) (in 4.2.2.3) the promising use of ‘regulatory sandboxes’ that both protect the interests of consumers and encourage and support innovation; (iv) (in 4.2.2.4) the importance of human review; (v) the importance of keeping humans in the loop (in 4.2.2.5); and (vi) (in 4.2.2.6) reversibility and ‘stop switches’. While some of these lessons are really imperatives (‘must do’) for regulators, others are more in the way of options and general awareness.

4.2.2.1 Consultation and consent

If the regulatory position (and, concomitantly, the nature and availability of the service that is provided) is to be socially acceptable, the default procedure has to be first to consult. Unless regulators can be absolutely confident that the adoption and use of a technology will be perfectly acceptable, they really need to consult. Without consultation, they cannot know whether there are red lines that the technology threatens to transgress, and they cannot know what kind of balance of interests will be the most satisfactory accommodation. Do we know, for example, whether schoolchildren will prefer to have lessons with robots or with human teachers, whether patients will accept bad news from robot doctors, whether consumers will want to know when they are dealing with a chatbot and when with a human, and whether clients and consumers will accept legal advice from robots or regard the use of blockchain with suspicion?

Apparently, in Japan, some schoolchildren do prefer classes with robots (because they are less judgmental and not impatient) to lessons with humans.¹⁰⁴ Recalling the case of Ernest Quintana, we also suspect that, in many parts of the world, patients will prefer to have bad news conveyed by humans. And, there is some evidence that British motorists are unhappy about the automated enforcement of road traffic offences.¹⁰⁵ However, we generalise these indications at our risk. Quite simply, in pluralist societies, there are going to be many different views about what is and what is not acceptable and new technologies tend to provoke new articulations of pluralist views.

This is not to say that regulators cannot anticipate some matters that are particularly sensitive in their community. For example, we know that reproductive technologies and developments in embryology are especially sensitive—particularly in relation to a distinctive dignitarian ethic. For this reason, the Human Fertilisation and Embryology Authority has regularly consulted before taking a position on sensitive issues such as social sex selection, the use of mitochondrial replacement techniques, the use of non-human egg cells by researchers working on the technique of cell nuclear replacement, and so on.¹⁰⁶ Similarly, regulators should probably assume that the use of technologies to make decisions about access to services (especially if these services are regarded as important) is going to be controversial and that, where humans are taken out of the decision-making loop, this will be even more controversial.

¹⁰⁴ Nicola Woodcock, ‘Pupils prefer lessons with robot teachers’ *The Times*, March 16, 2019, p 28.

¹⁰⁵ See H. Wells, ‘The techno-fix versus the fair cop: procedural (in)justice and automated speed limit enforcement’ (2008) 48 *British Journal of Criminology* 798.

¹⁰⁶ <https://www.hfea.gov.uk/> .

4.2.2.2 Precaution and pilots

In its early stages, a new technology might have an uncertain risk profile, being seen as anything from low risk to high risk. Moreover, while risk-assessment experts tend to accentuate the *likelihood* of a risk eventuating (so that, where there is judged to be little likelihood of the risk eventuating, the technology is characterised as ‘low risk’ or as ‘safe’), members of the public often focus more on the *gravity* of the consequences should the risk eventuate (so, that even if there is little likelihood of a catastrophe, the gravity of this means that the technology is perceived to be ‘high risk’). Where the scientific and technological community is guided by principles of ‘responsible’ research and innovation, this might allay some public concerns.¹⁰⁷ However, the public might still look to regulators to ensure that their concerns have been fully addressed.

In 1974, American molecular biologists, fearing the accidental creation of dangerous new pathogens, called for a voluntary moratorium on the rapidly developing practice of recombinant DNA. A year later, at a famous meeting at Asilomar State Beach in California, a large group of professional biologists agreed safety guidelines for their research community. By contrast, the early development of the Internet (which largely took place in California and which was not perceived to be ‘dangerous’), was guided less by precautionary thinking than by a pro-actionary approach such that any difficult bridges would be crossed as and when they were met. However, in 2017, Asilomar was once again in the news, when researchers met to develop a set of precautionary guidelines for the use of AI. Here, we read that AI has already proved beneficial and that ‘guided by the following principles, [it] will offer amazing opportunities to help and empower people in the decades and centuries ahead.’¹⁰⁸ For those who are concerned that there might not be too many decades and centuries ahead, because AI will be the death of us, Principle 11 provides that ‘AI systems should be designed and operated so as to be compatible with ideals of human dignity, rights, freedoms, and cultural diversity’; and Principle 21 states that ‘risks posed by AI systems, especially catastrophic or existential risks, must be subject to planning and mitigation efforts commensurate with their expected impact.’

On our side of the Atlantic, the regulatory culture in Europe is thought to be relatively precautionary. Reacting to scandals with drugs (famously, Thalidomide) and food (famously, beef and vCJD), Europe has invested heavily in ex ante trials and checks to ensure that products and processes do not present unacceptable risks to human health and safety or to the environment. Where products and processes, having gone through the required regulatory checks, reach the market, there is still the risk that something dangerous will have slipped through. Accordingly, the ex ante regulatory precautions are complemented by various ex post provisions for reporting adverse incidents and compensating consumers. Whether or not these arrangements strike the right balance is a constant topic for debate, because the more extensive such precautionary regulatory measures are, the more burdensome and difficult it is for innovators to get their products to market and to stay in business.

¹⁰⁷ There is a large literature on the ideal of ‘responsible’ research and innovation: see, e.g., Richard Owen, John Bessant, and Maggy Heintz (eds), *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society* (Chichester: John Wiley, 2013).

¹⁰⁸ Available at <https://futureoflife.org/ai-principles/> (last accessed March 18, 2019).

So, what is the lesson for regulators of professional services? Certainly, regulators should be alert to the possibility of existential or catastrophic risk. If there is any suggestion of this kind of risk, things should be put on hold until it has been properly investigated. Similarly, regulators should proceed very cautiously if they suspect that they might be in danger of crossing red lines (or touching third rails). This apart, there is no simple ‘this is how you should do it’ lesson. Rather, the lesson is that regulators should not focus only on the interest of consumers in their health and safety or financial security; and nor should they focus only on the interests of innovators or prospective providers (and, indirectly, the interests of consumers in having fresh options). Both sets of interests need to be taken fully into consideration, a balance needs to be struck, and that balance will probably need ongoing adjustment. In this light, the idea of ‘regulatory sandboxes’, to which we turn next, is a really promising vehicle for finding an informed and appropriate initial balance when the technology is rolled out.

4.2.2.3 Regulatory sandboxes

In 2015, the Financial Conduct Authority (FCA) introduced the idea of a ‘regulatory sandbox’, the general purpose of which is to enable providers to test innovative financial products and services in a modified regulatory environment. While the details of each particular environment are tailored to each product or service being tested, with each having its own dedicated case officer, the general intention is to better inform both regulators and innovators as to the particular risks associated with the product or service, to reduce regulatory uncertainty, and to protect the interests of consumers. Not surprisingly, at a time when FinTech is such a dynamic field of innovation¹⁰⁹, the regulatory sandbox (with its three-way responsiveness to the interests of regulators, innovators, and consumers) is an idea that has attracted interest (and that has been adopted and adapted) in many parts of the world.¹¹⁰

In our introductory remarks, we noted that regulatory sandboxes are an example of regulators initiating a de-risking strategy. It is important, however, to understand that this kind of strategy is not just for experimental or innovative products and services in the *financial* sector. The sandbox as devised by the FCA might not be right for all regulators, but the idea of a tailored environment in which new service technologies can be tested is one that all regulators of professional service provision should consider. Indeed, the Department of Health and Social Care has already indicated that it intends to support innovators by introducing ‘a healthtech regulatory sandbox...[which] will let us test, iterate and de-risk the most promising innovations – and the relevant regulation – so that when they are ready for uptake across the NHS, clinicians can use them with confidence.’¹¹¹ Given that there is already an elaborate pathway for the pre-

¹⁰⁹ See, e.g., the editorial introduction by Emiliios Avgouleas, Iris H-Y Chiu, and Pierre Schammo to (2019) 20:1 *European Business Organization Law Review* 1 (special issue on Fintech Revolution and Regulation).

¹¹⁰ Compare Emily Lee, ‘Financial Inclusion: A Challenge to the New Paradigm of Financial Technology, Regulatory Technology and Anti-Money Laundering Law’ [2017] *Journal of Business Law* 473, in which she remarks that ‘Since trial and error is expected and frequent in FinTech development, the regulatory sandbox is a good example of steering regulatory initiative to ensure that innovation is not stymied by current regulatory constraints.’

¹¹¹ See, the Department of Health and Social Care’s policy paper on ‘The future of healthcare: Our vision for digital, data and technology in health care’ (October 17, 2018). Available at <https://www.gov.uk/government/publications/the-future-of-healthcare-our-vision-for-digital-data-and->

market testing of medical devices and drugs (especially the latter), some thought will need to be given to which kinds of innovation are suitable for the sandbox.

Some thought should also be given to possible objections to the use of sandboxes.¹¹² For example, we might wonder whether sandboxes are consistent with a regulatory commitment (such as that in financial services) to a ‘technology neutral’ approach. In part, this commitment is simply a matter of prudent regulation, not wishing to focus regulatory permission (even less so regulatory requirement) on a particular technology (for encryption, for identification, for distributed ledgers, or whatever) and then finding that all our eggs are in the wrong technological basket. However, ‘technological neutrality’ might also be understood as involving a commitment to regulatory fairness in competitive markets. Given such a commitment and, concomitantly, given the general expectation amongst regulatees that they are operating on a level playing field, how are regulators to justify special rules for nascent technologies? To this, perhaps the best short answer is that the FCA’s regulatory sandbox is open to all providers, established as well as prospective; the rules are the same for everyone.

That said, there is no denying that regulatory sandboxes are tilted towards innovative technological applications. Moreover, where regulators support and facilitate such innovation, they must be taken to know that this might have major disruptive consequences, impacting on established providers and their service provision; and, they must appreciate that there is a tension between the interests of such providers as well as of those who rely on them for their livelihoods and the interest of consumers in enjoying new benefits in their service provision. What should we make of this?

While it is one thing for a small start-up, such as Instagram, to wipe out a major multinational corporation, such as Kodak, and the local community that relied on that corporation,¹¹³ it is perhaps something else for regulators to facilitate innovation when they know (or, at any rate, should know: compare the discussion of unintended consequences in 3.1.6) that new technologies can radically disrupt the distribution of benefits and disbenefits in society. However, the alternative—namely, to do little or nothing to open markets to new providers and new services—is no more attractive. Faced with these choices, there is no short answer. These are large policy questions for the community; and, ideally, whatever policy choices are made should then be translated into the mandates and missions for sectoral regulators.

4.2.2.4 Human review

Reporting on the lessons learned in the first year (2016-2017) of the sandbox’s operation, the FCA comments on a number of the products and services tested.¹¹⁴ Of particular interest here

[technology-in-health-and-care/the-future-of-healthcare-our-vision-for-digital-data-and-technology-in-health-and-care#cs12-main](#) (last accessed April 15, 2019).

¹¹² Compare the remarks in Dirk A. Zetsche, Ross P. Buckley, Janos N. Barberis, and Douglas W. Arner, ‘Regulating a Revolution: From Regulatory Sandboxes to Smart Regulation’ (2017) 23 *Fordham Journal of Corporate and Financial Law* 31, 80. See, too, Avgouleas, Chiu, and Schammo (n 109) at 2, reporting that ‘the FCA’s approach has not been without critics among incumbents, with some accusing it of double standards’.

¹¹³ Evidently, in its final years, Kodak closed thirteen factories and 130 photolabs, and cut 47,000 jobs. See, Andrew Keen, *The Internet is not the Answer* (London: Atlantic Books, 2015) 87-88.

¹¹⁴ Financial Conduct Authority, *Regulatory sandbox lessons learned report* (2017).

is what is said about ‘robo-advice’.¹¹⁵ The salient points are: (i) that, to mitigate the risk that robo-advisers give unsuitable advice, the typical requirement is that, before live testing, qualified financial advisers should check the automated outputs generated by the underlying algorithms; (ii) that, in one case, an experienced human adviser was present when a consumer received automated advice; and (iii) that, in another case, when consumers are given advice, they are warned that they should not act on the advice until they receive a second notification that confirms that the advice is suitable (a qualified financial adviser being involved in this process).

Clearly, when professional advice, whether financial, medical or legal, is being delivered by experimental robo-advisers (or chatbots), it is imperative that human experts are in the loop. Once robo-advisers have completed their trials and are operating outside the regulatory sandbox, the extent to which the law and the community will insist on humans continuing to be in the loop remains to be seen.

4.2.2.5 Humans in the loop

Recalling the case of Ernest Quintana, service providers should not assume that consumers will readily accept a technology where it means that humans are no longer interacting or transacting with them. Moreover, the reasons for wanting to retain the human dimension can run deep.

In her book, *Alone Together*¹¹⁶, Sherry Turkle, reports the views of one of her interviewees, ‘Richard’, who was left severely disabled by an automobile accident. Despite being badly treated by his human carers, Richard apparently prefers this to the care and attention given by robots. As Turkle reads Richard’s views,

For Richard, being with a person, even an unpleasant, sadistic person, makes him feel that he is still alive. It signifies that his way of being in the world has a certain dignity, even if his activities are radically curtailed. For him, dignity requires a feeling of authenticity, a sense of being connected to the human narrative. It helps sustain him. Although he would not want his life endangered, he prefers the sadist to the robot.¹¹⁷

This highlights the possibility not just that each individual will have their own views about when and for what purpose (such as for simple communication, to convey bad news, to review a decision, to undertake caring functions, and so on) they want the human touch, but also that such preferences can go deep to how we see ourselves as humans. Automated processes might be more efficient and smart machines might be quicker and more reliable than humans but taking humans out of the loop needs to be handled very carefully.

¹¹⁵ At paras 4.39-4.42.

¹¹⁶ Sherry Turkle, *Alone Together* (New York: Basic Books, 2011).

¹¹⁷ *Ibid.*, at 281-282.

In this context, we should also note that the emphasis on the importance of ‘human-centric’ governance and application of new technologies, especially in robotics and AI¹¹⁸, needs to be interpreted broadly. It is not enough that these technologies are designed in ways that ensure that humans cannot be physically harmed or injured—even benign (and ‘caring’) technologies can compromise our human sense of identity and agency, as well as our sense of value and usefulness.¹¹⁹

4.2.2.6 Reversibility and ‘stop’ switches’

Some technologies elicit a concern that, if things go wrong, they cannot be reversed. For example, there is a concern that once gene editing techniques are applied to the germ line, the changes could be irreversible. In the case of blockchain, the position is more complex: the irreversibility of the transfers and the immutability of the record or register is seen by its advocates as a virtue; but, where the blockchain has been compromised by a hack, there are different views about whether a fresh start (and a fork) should be created.

At all events, for regulators of professional service sectors, a question that should certainly be asked is whether, once the technology is operating, there is the possibility of reversal or (recalling various flash crashes in the financial sector¹²⁰) of pulling a stop switch. Once again, the FCA’s regulatory sandbox sets a good example by making it a requirement that all participating firms ‘develop an exit plan to ensure the test can be closed down at any point whilst minimising the potential detriment to participating consumers.’¹²¹

4.2.3 Compliance and sustainability

Where technologies develop rapidly, we have said that regulators need to be able to operate with some flexibility and agility. In the early stages of the development of a technology, hard-wired legal interventions are unlikely to be successful. However, this lesson has to be set in the bigger picture of the regulatory challenges.

We have emphasised that compliance with regulation cannot be taken for granted. Those who are regulating the provision of professional services can be smart in their use of the right kind of instruments at the right time, starting with softer law measures and then using harder law only when some stability has been reached. They can try to draft measures in terms that are technologically neutral and they can strive for clarity in their drafting. However, this will not guarantee either compliance or sustainability and this is especially so where there is a strong provider-push behind a new technology and/or a strong consumer-pull for it. As many observers have noted, there are limits to what laws or regulations can achieve—or, at any rate,

¹¹⁸ Compare the thinking of the EC High-Level Expert Group on AI (n 33) for whom it is axiomatic that trustworthy AI should be human-centric. Similarly, Article 1.2 of the OECD Recommendation (n 27) insists on respect for human-centred values and fairness.

¹¹⁹ The same applies if the fundamental principle of governance and application is expressed as being that the interests of ‘humanity’ should be treated as paramount.

¹²⁰ Such as that of May 6, 2010, on which see Frank Pasquale and Glyn Cashwell, ‘Four Futures of Legal Automation’ (2015) 63 *UCLA Review Discourse* 26, at 38-39.

¹²¹ (n 114) at para 2.17.

there are likely to be serious limits to what can be achieved unless the ground has been carefully prepared and the social acceptability of a regulatory intervention has been fully considered.¹²²

5. New technologies, new service provision, alternative service providers

Thus far, we have focused on a regulatory space constituted by the sector regulators, largely by the established regulatee service providers, and by consumers. However, with new technologies offering new service options (including direct-to-consumer online provision), there is the possibility that new and alternative providers might offer their services to consumers. Indeed, where regulators see this as an opportunity to stimulate competition in their sector as well as to expand the choices available to consumers, they are likely to want to support and encourage such providers. At the same time, though, regulators need to be mindful that the disruption caused by such providers might not be entirely for the good, possibly undermining trust and confidence in the established service providers and putting consumers at risk. Moreover, where there are rules (backed by the criminal law) limiting the provision of specified ('regulated' or 'restricted' or 'reserved') services to specified providers, there will need to be some monitoring of new and alternative providers to ensure that they are not acting unlawfully.

Regulators who seek to respond to concerns about the activities of new and alternative providers face two complicating factors: one is that such providers might operate online; and the other is that they might be based outside the jurisdiction (the UK), compounded nowadays by their online presence and provision. Where providers are in the UK, any unlawful activities should be controlled by the police or other enforcement agents; and, we should also note that the UK courts have been in the vanguard in using web-blocking orders, directed at intermediaries, where the web-sites to be blocked (such as 'pirate' sites) have been infringing copyright.¹²³ Where the activities of new and alternative providers are not unlawful, but there are other concerns—for example, about whether consumers are acting on a properly informed basis or about the financial risks that they are running—then regulators will need to take whatever steps they can to correct this; and, as ever, the challenge will be to make an adequate response to the concerns without over-regulating and losing the benefits that such providers might bring to the 'unregulated', 'unrestricted', or 'unreserved' part of the sector.

In this part of the paper, our focus is on the challenges presented to regulators by new and alternative providers who offer consumers services that exploit new technologies. First (in 5.1), what are the key issues that are raised by such service provision? Secondly (in 5.2), turning to the lessons, in practice, how are regulators to respond effectively to concerns raised by such providers particularly where they deal with consumers online and who are themselves based outside the UK?

5.1 Key issues

5.1.1 A further troubling story

¹²² For a sustained examination of this idea, see Iredell Jenkins, *Social Order and the Limits of Law* (Princeton: Princeton University Press, 1980).

¹²³ See Edwards (n 4) at 283-285.

Developments in genetics have generated a number of new health-related services for consumers, exemplified perhaps by the range of services offered by 23andMe. Our troubling story, however, concerns a blood test that is now to be offered to pregnant women.

About twenty years ago, it was discovered that placental cell free DNA can be detected in the blood of pregnant women. Following this discovery, it is now possible to use a simple blood test—so-called ‘non-invasive prenatal testing’ (NIPT)—to ascertain, at a relatively early stage of a pregnancy, genetic information about both the woman and the fetus. On the face of it, NIPT represents a significant addition to the reproductive options that are available to women (and their partners).

However, while NIPT is being carefully piloted in the NHS screening pathway for fetal anomalies (and, there, mainly for Down syndrome), the test is available (i) from private providers and (ii) for obtaining information that goes beyond the trisomies.¹²⁴ Clearly, this gives rise to concerns about the purposes for which NIPT might be used (in 5.1.1.1) as well as whether the information given to prospective consumers is accurate and adequate (in 5.1.1.2).¹²⁵ This leads (in 5.1.1.3) to questions about the possibility of making effective regulatory responses to such concerns.

5.1.1.1 The purposes for which NIPT is used

NIPT can be used to derive a broad spectrum of genetic data and these data might then be applied for a variety of purposes (including sex selection). Some of these purposes will be lawful, others unlawful; some will be publicly approved (and publicly funded), others not. The question is whether regulators can hold the line on the purposes that they regard as both lawful and acceptable.

On the face of it, regulators have better prospects for effective implementation of their policy in the public sector than in relation to private sector provision. Even then, we should not assume that there will not be resistance to limited availability and use within the NHS. Already, for example, the UK National Screening Committee (UKNSC) has experienced significant resistance to its unwillingness to introduce routine screening for group B Streptococcus in pregnancy and, concomitantly, to make more use of antibiotics.¹²⁶ If, following its piloting of NIPT, the UKNSC adopts a restrictive policy to which there is significant opposition, it might

¹²⁴ Until recently, these private providers have fallen beyond the supervisory range of the Care Quality Commission: see, <http://nuffieldbioethics.org/news/2019/care-quality-commission-regulate-private-providers-noninvasive-prenatal> (last accessed May 1, 2019).

¹²⁵ For discussion of the full range of legal and ethical questions raised by the availability of NIPT, see Roger Brownsword and Jeff Wale, ‘The Development of Non-Invasive Prenatal Testing: Some Legal and Ethical Questions’ (2016) 24 *Jahrbuch für Recht und Ethik* 31; and ‘Testing Times Ahead: Non-Invasive Prenatal Testing and the Kind of Community that We Want to Be’ (2018) 81 *Modern Law Review* 646.

¹²⁶ See, in particular, the lobbying activities of the Group B Strep Support campaign (<http://gbss.org.uk/campaigning/parliament/contact-your-mp/>) and its response to the latest consultation on the matter by the UK National Screening Committee (<http://gbss.org.uk/latest-news/say-group-b-strep-uk-national-screening-review/>) (both sites last accessed July 13, 2017).

find that its experience with the group B Strep community is repeated with a new lobbying group for NIPT.

However, with regard to the private sector provision of NIPT, there are additional factors in play. Most importantly, many private providers will have an online presence. Hence, any attempt to restrict access to NIPT for what regulators judge to be unacceptable purposes might be ineffective. It seems that, while we might endlessly debate the rights and wrongs of particular uses of NIPT, we should lower our expectations about the effective implementation of any policy that impinges on the reproductive choices that pregnant women—or, at any rate, pregnant women with sufficient resources—might want to make.

The general point here (underlining what was said in 4.2.3) is that, in any service sector, where there is both significant provider-push and consumer-pull, regulators who try to place restrictions on either the supply side or the demand side will face significant compliance challenges; and, where online provision is involved, the compliance challenges will be compounded (see further 5.1.1.3).

5.1.1.2 The quality of information about the test

How confident can we be that the online information about NIPT (given by new and alternative providers) is commensurate with what is required for the proper exercise of reproductive autonomy? On the face of it, there is some cause for concern. For instance, there is evidence that commercial test providers are pitching their online communications above the recommended reading age for public health information,¹²⁷ and that some commercial web advertising may contain inadequate or outdated information (the latter being a particular risk when technology advances so quickly). Even if we discount the possibility of deliberate mis-selling or fraud, it is no surprise that commercial test providers tend to emphasise the benefits rather than the limitations of the technology in their marketing material. Links to peer reviewed citations are not always present and this can make it difficult to evaluate the nature and currency of the claims made.¹²⁸ Further, private test providers do not always mention the specific abnormalities that can reliably be detected through conventional trimester screening,¹²⁹ or the differentials in failure rates between different testing technologies.¹³⁰

¹²⁷ MB Mercer, PK Agatisa and RM Farrell, 'What patients are reading about non-invasive prenatal testing: an evaluation of Internet content and implications for patient-centered care' (2014) 34(10) *Prenatal Diagnosis* 986; JW Aarts et al., 'Patient-focused internet interventions in reproductive medicine: a scoping review' (2012) 18(2) *Hum Reprod Update* 211, at 212; and Heather Skirton et al., 'Non-invasive prenatal testing for aneuploidy: a systematic review of Internet advertising to potential users by commercial companies and private health providers' (2015) 35(12) *Prenatal Diagnosis* 1167.

¹²⁸ The ARC website suggests that 'to be of the highest quality, test performance data should be published in a peer reviewed scientific journal and should report pregnancy outcomes from studies involving 1000s of women.' Available from: <http://www.arc-uk.org/tests-explained/non-invasive-prenatal-testing-nipt> (last accessed February 16, 2017).

¹²⁹ See Mercer et al (n 127).

¹³⁰ Yuval Yaron, 'The implications of non-invasive prenatal testing failures: a review of an under-discussed phenomenon' (2016) 36(5) *Prenatal Diagnosis* 391.

Clearly, if regulatory policy is that consumers in the sector should be properly informed, the provision of NIPT gives some cause for concern.

5.1.1.3 Compliance challenges

How effectively might regulators respond to such concerns? Although there are challenges to effective implementation, the position is not completely hopeless.¹³¹ NIPT cannot be undertaken without blood being drawn and it might be possible to exert some domestic control over professional health care workers drawing samples for this purpose. This apart, if regulators in the UK are to exert some control over online provision of NIPT by providers who are based outside the jurisdiction, they have a number of possible options.

First, if regulators have some leverage over the provider's assets or personnel or reputation within the UK, they might be able to bring regulatees into line. In this connection, we should recall how, in *LICRA v Yahoo!*,¹³² the Paris court managed to exert some influence over Yahoo! whose auction site offended the French Jewish community by offering for sale Nazi memorabilia. In an attempt to improve this kind of leverage, the UK government is consulting, inter alia, on the proposed independent regulator for online content having the option 'to require companies which are based outside the UK to appoint a UK or EEA-based nominated representative...similar to the concept of nominated representatives within the EU's GDPR.'¹³³

Secondly, regulators might be able to persuade internet service providers, or other online intermediaries, to act as 'chokepoints', restricting supply of goods, services, or information from target sites;¹³⁴ or, indeed, in relation to certain kinds of (especially IP) wrongdoing, as we have said, they might be able to obtain web-blocking injunctions that require intermediaries to act as gatekeepers.

Thirdly, in principle, a further option is to take action against consumers who have procured the service (that is, where the consumers' actions involve a breach of UK law). This has been one of the strategies for controlling IP breaches; but, where the law is itself unpopular, this is not a strategy that appeals in practice. Arguably, the better strategy is to concentrate on informing consumers about the full range of risks that they might be running by dealing with online commercial providers who are not based in the UK and who have no bricks and mortar presence in the jurisdiction.

Finally, in an ideal world, there would be a coordinated international response to problems of this kind. In the absence of such a response, there might be opportunities for various kinds of reciprocal cross-border enforcement or other forms of cooperation between national

¹³¹ Generally, see Roger Brownsword and Morag Goodwin, *Law and the Technologies of the Twenty-First Century* (Cambridge: Cambridge University Press, 2012) Ch 14; and Mark Leiser and Andrew Murray, 'The Role of Non-State Actors in the Governance of New and Emerging Digital Technologies' in Roger Brownsword, Eloise Scotford and Karen Yeung (eds) *The Oxford Handbook of Law, Regulation and Technology* (Oxford: OUP, 2017) 670.

¹³² https://en.wikipedia.org/wiki/LICRA_v._Yahoo! (last accessed February 26, 2017).

¹³³ HM Government, *Online Harms White Paper* (CP 57, April 2019) para 6.10.

¹³⁴ Natasha Tusikov, *Chokepoints: Global Private Regulation on the Internet* (Oakland: University of California Press, 2016).

regulators¹³⁵—for example, there might be opportunities to develop co-operative global state engagement by agreeing guidelines in relation to the leading issues.¹³⁶

5.2 Lessons

Relative to our three-pronged guiding principle for regulators, what lessons should we draw where new and alternative service providers are operating?

First, where providers are acting unlawfully, enforcement action needs to be taken. This is always a challenge; but, where the providers are operating online and where they are based outside the UK, the challenge is much greater. If there is little or no demand from consumers for the particular service, the problem is eased. In other cases, however, there is no easy fix or silver bullet. Sector regulators need to liaise with relevant national regulators and enforcement agents; and, if there is a prospect of international cooperation, then it should be pursued.¹³⁷

Secondly, where new and alternative providers are acting lawfully, their operations—if not always in line with the interests of the established providers—might be welcomed by sectoral regulators (as well as by consumers). On the other hand, the impact of these new providers might be to disrupt what the sectoral regulators regard as a socially acceptable regulatory environment. For example, the activities of such providers might (as sectoral regulators judge it) put consumers at unacceptable risk, and they might also diminish trust and confidence in established providers of ‘regulated’, ‘restricted’, or ‘reserved’ services (indirectly putting consumers, and quite possibly, larger society at risk).¹³⁸ Here, there are potentially tensions between what regulators judge to be a socially acceptable regulatory scheme and what some consumers now see as beneficial provision. Regulators might respond through their communications strategy, taking whatever steps they can to alert consumers to the risks of dealing with new providers. In this way, from the regulators’ perspective, they have at least discharged their responsibility to assist consumers to make informed, if not always prudent, choices. As for maintaining trust and confidence in traditional providers, this again might be tackled by regulators through their communications strategy. However, if this does not suffice, more prescriptive measures might be needed—in the way, for example, that some national regulators have prohibited Bitcoin and other cryptocurrencies in order to defend their fiat currencies and banking systems.¹³⁹

¹³⁵ See, e.g. Lawrence Lessig, *Code Version 2.0* (New York: Basic Books, 2006) Ch 15.

¹³⁶ See, for e.g., Heather Skirton et al., ‘Offering prenatal diagnostic tests: European guidelines for clinical practice guidelines’, (2014) 22(5) *Eur J Hum Genet* 580: (available at <http://www.ncbi.nlm.nih.gov/pubmed/?term=24022298>).

¹³⁷ Compare HM Government, *Online Harms White Paper* (CP 57, April 2019) para 6.9.

¹³⁸ Compare, for example, the concern that homeopathic alternatives to the measles vaccine pose a risk to public health (as expressed in *The Times* leader, ‘Dangerous Quackery’, on May 4, 2019). For a sceptical critique of alternative medicine, see Ben Goldacre, *Bad Science* (London: Fourth Estate, 2008). It should be noted, too, that the Legal Services Board has statutory power to make recommendations to the Lord Chancellor to change the list of reserved activities.

¹³⁹ See, https://en.wikipedia.org/wiki/Legality_of_bitcoin_by_country_or_territory (last accessed May 5, 2019).

Thirdly, there is the question of compliance. As the above remarks already indicate, regulators might find themselves faced by a provider-push from parties who are supplying online and who are based outside the UK coupled with a consumer-pull within the UK. It is all very well saying that regulators should be geared for compliance but, in practice, it might not be obvious how best to do this. The fact of the matter is that it might be extremely difficult to block the provision or take effective enforcement action; and it might be all too easy to alienate consumers and strengthen their resistance. The lesson is that regulators do have some options, they are not in a hopeless situation, but our expectations of what can be achieved need to be realistic.

6. Key Issues and Lessons for the Legal Services Board

Given the general guiding principle for regulators, the key issues (in 6.1) for the Legal Services Board and the regulators over whom they exercise oversight relate to questions of lawfulness (in 6.1.1), social acceptability (in 6.1.2), and compliance and sustainability (in 6.1.3); the key lessons (in 6.2) to be drawn from experience in other service sectors also relate to lawfulness (in 6.2.1), social acceptability (in 6.2.2), and compliance and sustainability (in 6.2.3); and, in the case of social acceptability, the lessons comprise a number of regulatory imperatives, alerts and advisories.

6.1 Key issues

6.1.1 Lawfulness

Broadly speaking, regulators in the legal services sector might be presented with three difficulties regarding the lawfulness of acts within their sector (including the legality of their own acts).

First, the background legal position might not be clear. In English law, the default position probably is that if an act is not explicitly prohibited, then it should be treated as permitted. However, even if there is explicit provision in relation to some act, it might still be unclear whether a particular case falls within the ambit of the legal provision. New technologies—from reproductive technologies to cryptocurrencies—exacerbate these difficulties by coming onto the regulatory radar before bespoke legal provision has been made; and, the application of general principles of tort law to new technologies (such as autonomous vehicles and robots) might be both unclear and unsatisfactory.¹⁴⁰ Furthermore, even when a covering legal framework is in place, the regulatory provisions might quickly lose connection with the way in which the technology and its application have subsequently developed.

Secondly, where background legal principles are in place (as with data protection law) and sectoral regulators wish to fine-tune those principles, they might find that there is a difficulty in aligning their wishes with the law. For example, there have been questions about the validity of the broad consents taken by big biobanks (where participants consent to a wide range of health-related research uses) and the GDPR provision for specific and explicit consent¹⁴¹; and, there is a debate about the tension between blockchain records and repositories and the

¹⁴⁰ See Roger Brownsword (n 21) Ch. 10.

¹⁴¹ See, Roger Brownsword (n 21) Ch. 12.

provisions for rectification and withdrawal of data in the GDPR.¹⁴² In such circumstances, sectoral regulators will need to work with general regulators and lawmakers to try to resolve whatever difficulties there might be.¹⁴³

Thirdly, the activities of what we have termed new and alternative service providers might present problems for sectoral regulators. The regulators' response will depend on a number of factors, including: (i) whether the activities in question are lawful—specifically in relation to legal services, this will depend on whether or not the service is a 'reserved legal activity' within the meaning of the Legal Services Act 2007; (ii) whether, relative to regulatory objectives, the activities are viewed in a positive light (for example, because they diversify provision, achieve greater equality of access to justice, serve unmet legal need, and so on) or as unduly risky (in particular, because they threaten the interests of consumers of legal services); and (iii) whether the providers are based in the UK.

Picking up the first two of these considerations, it should be noted that, in the UK legal sector, the small number of reserved activities creates the opportunity for a flourishing market in the provision of unreserved legal services, with new providers exploiting new service technologies for the benefit of consumers. While the available evidence suggests that this market is small, there is a distinct possibility that new technologies for legal service provision could lead to its expansion—and not just by improving transparency for consumers. To be sure, within the sector, views on such providers might differ; however, the starting point currently is that such providers are a legitimate part of the market, providing increased access to legal services. Indeed, in its 2016 market study the Competition and Markets Authority was keen to address barriers to sustainable entry for these providers.¹⁴⁴

Taking up the third consideration, where the service providers are based in the UK and are in breach of UK law (for example, if, in breach of s. 14 of the Legal Services Act 2007, they are

¹⁴² See, e.g., the European Union Blockchain Observatory and Forum's report, *Blockchain and the GDPR* (October 16, 2018), available at https://www.eublockchainforum.eu/sites/default/files/reports/20181016_report_gdpr.pdf (last accessed May 20, 2019); and, CMS, 'The tension between GDPR and the rise of blockchain technologies' (January, 2019), available at <file:///C:/Users/Roger/Downloads/The%20tension%20between%20GDPR%20and%20the%20rise%20of%20blockchain%20technologies.pdf> (last accessed March 29, 2019).

¹⁴³ In this context, we should note that one of the ICO's regulatory objectives (Objective 5) is stated as follows:

To work with other regulators and interested parties constructively, at home and abroad, recognising the interconnected nature of the technological landscape in which we operate and the nature of data flows in the expanding digital economy. Our aim is to establish effective networks with other regulators to cut down on regulatory burden and red tape.

See, Information Commissioner's Office, Regulatory Action Policy, p 5: available at <https://ico.org.uk/media/2258810/ico-draft-regulatory-action-policy.pdf> (last accessed May 26, 2019). And, for the relationship between the ICO and the new Centre for Data Ethics and Innovation, see <https://www.gov.uk/government/consultations/consultation-on-the-centre-for-data-ethics-and-innovation/centre-for-data-ethics-and-innovation-consultation> (last accessed May 26, 2019).

¹⁴⁴ Competition and Markets Authority, *Legal services market study: final report* (December 2016): available at <https://assets.publishing.service.gov.uk/media/5887374d40f0b6593700001a/legal-services-market-study-final-report.pdf> (last accessed May 5, 2019).

carrying on a reserved legal activity when not entitled to do so) then the problem needs to be addressed by the appropriate law enforcement agencies. However, where the service providers are in breach of UK law but are not based in the UK, then the task for the law enforcement agencies is more difficult—and, particularly so, where the service relating to a reserved activity is provided online. As we have said, there are some steps that can be taken to make it more difficult for online service providers to supply consumers, but there is no quick answer to this.

Conversely, where the service providers are in the UK but they are not in breach of UK law (or not clearly in breach of UK law), sectoral regulators might want to press for appropriate changes to the law or for legal clarification. Depending on whether regulators view the provision in a positive or negative light, they might want to support and encourage the provision or they might want to warn consumers about whatever risks they might be running. Where the service providers are not based in the UK, and where they are not in breach of UK law (but simply viewed in a negative light), then sectoral regulators should take appropriate action such as warning consumers about the risks that they might be running in dealing with such online providers, especially if they have no bricks and mortar presence in the UK.

6.1.2 Social acceptability

If legal services regulators are to operate successfully in integrating new technologies in their sector, the technologies and their uses must be socially acceptable. This means that no red lines should be crossed; and it means that the accommodation of conflicting preferences and interests must be reasonably acceptable.

In the health sector, we have seen that there are a number of red lines; some things, particularly things that touch a nerve relative to human dignity or privacy, are categorically unacceptable. Are there any such analogues in the legal services sector? Arguably, Article 6(3)(c) of the European Convention on Human Rights¹⁴⁵ might be the source of one red line (particularly bearing on access to legal services where the criminal justice system is engaged); and, society might view access to basic legal services (going beyond criminal justice) as a fundamental right from which it follows that any use of technologies that denies access to such services will be regarded as unacceptable. As for the use of technologies for the outward-facing delivery of services, the major unknown here is whether communities will treat the replacement of professional persons by smart machines as raising red line concerns.

Red lines aside, the social acceptability of the use of technologies by legal service providers will hinge on the balance of interests. Here, the general challenge will be the recurrent one of neither over-regulating (relative to the interest in beneficial innovation) nor under-regulating (relative to the risks presented to consumers, to third-parties, and to society). However, the specific characteristics of this challenge in the legal services sector are not yet known. It is clear that some providers will be very keen to make use of technologies that enable them to make economies or that open up new markets. However, we do not know which of the most recently emerging technologies—AI and blockchain in particular—will be perceived as risky and why—or, at any rate, we do not know until there has been some consultation on these issues.

¹⁴⁵ This Article provides that everyone charged with a criminal offence has the right ‘to defend himself in person or through legal assistance of his own choosing or, if he has not sufficient means to pay for legal assistance, to be given it free when the interests of justice so require’.

6.1.3 Compliance and sustainability

Regulators in the legal services sector should strive to give their regulatees clear guidance in relation to the adoption of new technologies. To the extent that regulators are neutral about whether or not the technologies in question are adopted by providers or made available to (and taken up by) consumers, compliance by regulatees is not directly related to any larger regulatory policy. However, where regulators are not neutral about such matters, where regulators are clearly signalling that certain technologies, certain uses, certain applications, should or should not be adopted, then compliance is the first step towards fulfilment of larger regulatory policy and it can (and should) be assessed.

Where regulators have clearly indicated that certain uses of technology are permitted but that there are red lines which should not be crossed, we should not assume that compliance will follow. The regulatory guidelines need to be kept under review lest they become disconnected from the technology; and, where there is a strong provider-push coupled with consumer-pull for a particular application, then there is likely to be resistance to regulatory rules that stand in the way of this use. As in other professional service sectors where commercial considerations are in play, legal service providers are likely to respond in ways that reflect these considerations, from which it follows that compliance cannot be assumed to be a given.

There is also the matter of sustainability. Regulators need to keep their interventions closely connected to the uses to which technologies are put in their sector. Notoriously, while law moves slowly, technology moves quickly. To a considerable extent, sectoral regulators might be reliant on appropriate connection being made by upstream legislators and regulators. However, insofar as they can make their own contribution to sustainability, they need to do so.

6.2 Lessons

The lessons for regulators in the legal services sector concern lawfulness, social acceptability, and compliance and sustainability.

6.2.1 Lawfulness

Although regulators of legal services have no direct control over the background law and its enforcement, they have an important role in alerting those who are responsible for the law and for its enforcement about legal lacunae and application issues.¹⁴⁶ In this spirit, the Law Society Commission on the Use of Algorithms in the Justice System has recently highlighted its concern that police use of facial recognition systems and mobile device extraction ‘lack a clear and explicit lawful basis’, and (with reference to the use of algorithms in the criminal justice system) it has recommended a number of ‘clarifications and changes to data protection legislation, procurement codes, freedom of information law, equality duties and statutory oversight and scrutiny bodies.’¹⁴⁷

¹⁴⁶ However, it should be noted that the remit of the regulatory bodies, such as the Solicitors Regulation Authority, is limited. For example, bodies like the SRA would not be responsible for taking action against unregulated providers illegally providing reserved legal activities. Equally, if someone unqualified was holding themselves out as being a solicitor, the SRA would not lead in taking action against them.

¹⁴⁷ The Law Society (n 18) at 71.

Regulators of legal services also need to liaise with other sectoral regulators and more general regulators to smooth out any difficulties¹⁴⁸—as, indeed, the Law Society (acting in its representative capacity) is already liaising with the UK Government through the LawTech Delivery Panel and the FCA is assisting as a technical advisor in relation to the consultation on cryptoassets, DLTs and smart contracts.¹⁴⁹ Furthermore, guided by their own regulatory objectives, they have a responsibility to respond appropriately to the activities of new and alternative providers. On the one hand, it might be regulatory policy to support such providers (with a view to stimulating competition and innovation in ways that benefit consumers); but, at the same time, regulators need to monitor the activities and the impact of such providers and, in appropriate cases, they might need to alert consumers to any risks that they might be running in dealing with such providers.

6.2.2 Social acceptability

Here, we can usefully divide the lessons for the regulators of legal services into imperatives concerning consultation and consent, and precaution and pilots (in 6.2.2.1), alerts (in 6.2.2.2), and advisories (in 6.2.2.3).

6.2.2.1 Imperatives

The importance of consultation and consent

We know that regulators should steer clear of red lines, and strive for an acceptable balance of interests; but, if we do not know what the red lines are and what interests are at stake, it is essential to consult. In the case of the provision of legal services, it is not clear what red lines might be implicated; it is not clear what the interests of providers are; and it is not clear what risks will concern, or will most concern, consumers. There has to be consultation before the regulatory framework for a new technology is adopted.

Precaution and pilots

While we might not think that the technologies that might be taken up by legal service providers are likely to present catastrophic threats to human health and safety, or to the biosphere, precaution is in order. The first responsibility of regulators is to ensure that no technology is licensed where it might present an existential or catastrophic threat; and we do not yet know just how dangerous AI might prove to be. Moreover, even if we do not think that legal service technologies are likely to kill us, they could present very serious (and wholly unacceptable) risks to the financial interests of consumers; they could expose consumers to new vulnerabilities (where digital replaces analogue and paper); and there are more subtle threats to ‘humanity’ where we become over-reliant on technological tools. Indeed, some of the most insidious impacts might arise from technologies (such as AI-enabled digital devices) that are designed to assist humans but which, in human hands, lead to an over-reliance that is corrosive of human autonomy and human responsibility.

¹⁴⁸ Note the ICO’s regulatory objectives (n 143) and its relationship with the Centre for Data Ethics and Innovation (n 143).

¹⁴⁹ See, UK Jurisdiction Taskforce of the LawTech Delivery Panel, public consultation paper on ‘The status of cryptoassets, distributed ledger technology and smart contracts under English private law’ (May 2019).

In this light, regulators should make sure that new technologies are piloted, that redundancy is designed into critical systems, that ‘stop’ switches are available, and that, where appropriate, reversibility is assured.

6.2.2.2 Alerts

In the course of their consultations and pilots, regulators will be able to fine-tune their appreciation of the characteristics of a technology and how it maps onto the interests of providers and the interests of consumers, third-parties, and the general public. Here, they might not find the red lines that we have seen in other sectors (such as those that we saw in the assisted conception cases); but, they might find that there are deep anxieties about automation, about humans no longer being in the loop, about the possibility of unlawful (indirect) discrimination, about a lack of transparency, about the insecurity of data and records (even with blockchain), and about a willingness to subordinate individual fairness to general utility. Moreover, where new technologies are used to make economies or to exclude persons from important legal services, then (unless the ground has been prepared extremely carefully) resistance and push-back must be expected.

6.2.2.3 Advisory

The idea of the regulatory sandbox, although developed for financial services, seems to present regulators of legal service provision with an important opportunity to pilot new technologies and new applications in the legal sector. What matters here are not the particular features of the sandbox as used by regulators of financial services but the idea of a test vehicle that informs regulators, that supports innovators, and that protects consumers.

Given that there is no standard operating procedure for assessing new technologies, and given that there is no central hub for gathering and synthesising regulatory best practice in engaging with new technologies, it makes sense for the regulators of legal services to look to other sectors—most obviously, in this particular case, the financial sector—for guidance in employing sandboxes.

6.2.3 Compliance and sustainability

The general lessons to be taken in relation to compliance are that regulators need to be smart (in the sense of choosing the right instruments), they need to anticipate how regulatees are likely to react, and they need to be alert to the risk of their interventions having unintended consequences. In relation to connection and sustainability, the challenge is one of timing and, again, finding the right mix of hard prescription and softer guidance. In both respects, compliance and sustainability, there are perhaps lessons to be taken from the regulation of genetics and insurance (1.2), where the joint ABI and Government Code seems to have satisfactorily managed a potentially serious risk to both individual consumers of insurance (with high-risk genetic profiles) and even to the viability of important insurance pools.

More specifically, with reference to new technologies in the legal services sector, one aspect of smart regulation is to be careful about mantras such as the need for human-centric applications of AI, for transparency or explainability where AI and machine learning tools are used, and for a regulatory approach that respects technological neutrality. Regulators need to ask what these common calls mean and whether (and how) they make sense for the sector.

With regard to compliance in the sector, regulators should understand that legal service providers have their own priorities and plans and that, where regulation cuts across the grain of these priorities and plans, this militates against compliance. In such circumstances, regulatory experience in other sectors indicates that there is likely to be an adverse reaction and resistance. That said, where regulators judge that the interests of consumers or the larger society need to be protected, this has to be the priority and resistance by regulatees simply has to be anticipated and managed.

Finally, financial regulators in several parts of the world have adopted the idea of a regulatory sandbox for innovative products and, in the UK, it now seems that health regulators are ready to borrow this idea. As we have said, the idea of a ‘sandbox’ (with regulators working with both innovators and consumers) is, in principle, applicable to all service sectors. Accordingly, it should be seriously considered by regulators in the legal services sector as a vehicle that expedites innovation and facilitates both compliance and sustainability.¹⁵⁰

7. Concluding remarks

What are the ‘take home’ messages that we might draw from the foregoing analysis and discussion? How should we begin to answer the general questions that we posed in our introductory remarks about the cross-sectoral relevance of, and the technological specificity of, regulatory experience?

First, some regulatory experience is relevant across all professional service sectors and in relation to all technologies. In all domains, there are a number of generic regulatory challenges. These are the challenges of connection, effectiveness/compliance, and acceptability. Where new technologies are the subject-matter of the regulation, these challenges are especially demanding. Although there is some sense in entrusting sector-specific regulation to sector-specific regulators, it is important that sectoral regulators maintain channels of communication across the professional service sectors so that cross-sectoral lessons can be learned.

Secondly, not only do the generic regulatory challenges apply across all professional service sectors, the sectoral regulators are all likely to find that their own regulatory success is conditioned on the performance of upstream legislatures and regulators. Insofar as it is possible to do so, sectoral regulators should maintain channels of communication with upstream legislative and regulatory bodies.

Thirdly, we have suggested that it is hard to compare, in general terms, the importance of legal services relative to the services provided in either the health or the financial sector. Nevertheless, we can say that, in the health services sector, physical safety and well-being is a distinctive regulatory concern—hence, new medical devices and (especially) drugs are subject to extensive ex ante regulatory checks for their safety. Moreover, health technologies have tended to provoke a certain kind of dignitarian ethical concern that we would not expect to find in either financial or legal service provision.¹⁵¹ That said, reliance on AI, which is likely to be

¹⁵⁰ Compare the insightful discussion in Zetzsche, Buckley, Barberis, and Arner (n 112).

¹⁵¹ On the dignitarian concern, see Deryck Beylveid and Roger Brownsword, *Human Dignity in Bioethics and Biolaw* (Oxford: Oxford University Press, 2001); Roger Brownsword ‘Stem Cells, Superman, and the Report of the Select Committee’ (2002) 65 *Modern Law Review* 568, and ‘Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the “Dignitarian Alliance”’ (2003) 17 *University of Notre Dame Journal of Law, Ethics and Public Policy* 15.

characteristic of all service sectors, might present some common regulatory issues in both the health and legal service sectors and, although human dignity is not a value that has a strong resonance in UK debates, it might connect to concerns about the compromising of the conditions for human accountability and respect.¹⁵²

Fourthly, the generic regulatory challenges notwithstanding, the hotspots of concern can vary from one technology to another. While some of the technologies that immediately evoke concerns about catastrophic risks—for example, nuclear technology, synthetic biology, nanotechnologies, and the like—are probably not going to be relevant to the provision of legal services, we know that the technologies upon which legal service providers will rely are far from risk-free. For example, the famous denial-of-service attack on the Estonian critical cyber infrastructure in 2007¹⁵³ as well as the many more recent hacks, viruses and security breaches serve to remind us that reliance on information technologies creates risks for individuals as well as sector and society-wide vulnerabilities; and, although we do not yet know just how risky AI might be, we should certainly proceed with care.

Fifthly, following on the last point, it is worth emphasising that we really do not know how risky AI might be. As the late Stephen Hawking remarked, ‘the advent of super-intelligent AI would be either the best or the worst thing ever to happen to humanity.’¹⁵⁴ As the best thing, AI would contribute to ‘[the eradication of] disease and poverty’¹⁵⁵ as well as ‘[helping to] reverse paralysis in people with spinal-cord injuries.’¹⁵⁶ However, on the downside, some might fear that, in our quest for greater safety and well-being, we will develop and embed ever more intelligent devices to the point that there is a risk of the extinction of humans—or, if not that, then a risk of humanity surviving ‘in some highly suboptimal state or in which a large portion of our potential for desirable development is irreversibly squandered.’¹⁵⁷

Sixthly, the insistence on new technologies being developed and applied in ways that respect humanity or human dignity or that are human-centric is well-intended but it needs to be interpreted in a way that is sensitive to the full range of human interests. It is not enough that new technologies do not cause direct and obvious physical harm to humans. New technologies (such as surveillance and identification technologies) can change the context in which humans operate, impacting on autonomy and self-development as well as the opportunity for moral development and the building of relationships based on trust and personal responsibility. Moreover, some of the most insidious impacts might arise from technologies (such as AI-enabled digital devices) that are designed to assist humans but which, in human hands, lead to

¹⁵² Compare, Roger Brownsword, ‘From Erehwon to Alpha Go: For the Sake of Human Dignity Should We Destroy the Machines?’ (2017) 9 *Law, Innovation and Technology* 117.

¹⁵³ See, https://en.wikipedia.org/wiki/2007_cyberattacks_on_Estonia (last accessed June 21, 2019).

¹⁵⁴ Stephen Hawking, *Brief Answers to the Big Questions* (London: John Murray, 2018) at 188.

¹⁵⁵ *Ibid.*, at 189.

¹⁵⁶ *Ibid.*, at 194.

¹⁵⁷ See, Nick Bostrom, *Superintelligence* (Oxford: Oxford University Press, 2014), 281 (note 1); and, Martin Ford, *The Rise of the Robots* (London: Oneworld, 2015) Ch. 9.

an over-reliance that is corrosive of human responsibility and that expose humans to new vulnerabilities.

Seventhly, insofar as it is possible and practical to do so, regulators of legal service provision would do well to learn from the mistakes of the past—such as the mistakes associated with the unsatisfactory consultation on GM crops, and the lack of consultation and communication (coupled with an under-estimation of public resistance to the commercialisation of NHS patient records) that derailed care.data. To introduce a new technology without consultation, without preparation of the regulatory space, and without an appreciation of likely resistance is a recipe for problems.

Eighthly, insofar as it is possible to do so, regulators of legal services would also do well to learn from the successes of both the past and the present—such as the soft law approach to genetics and insurance and the innovative idea of a regulatory sandbox. In general, working with regulatees seems to improve the chances of regulatory success (although, as we have noted on several occasions, the particular characteristics of the legal services sector set the parameters within which cooperation with regulatees can work).

Finally, a degree of humility is in order. Law, regulation and technology is still a relatively young field of legal scholarship and it is a field in which little stands still. We think that we know some things about this field—for example, about what works and what does not; but there is a lot that we do not know—for example, about the acceptability of today's emerging technologies and about the longer-term impact of their use; and there is probably even more that we do not know we do not know.

Appendix A: the general guiding principle—a check list for regulators

Lawfulness

- Are you satisfied that practice and provision in the sector is in line with the law (especially with those laws that regulate the collection and processing of personal data)?
- Does background law clearly cover the particular application of the relevant technologies? If not, why not? Are legislators aware of any problems with the interpretation or application of the law? Is this a matter to be resolved by either judicial or legislative clarification?
- Are there any tensions between background legal provisions and regulatory policy for the sector? If so, how are these tensions to be resolved? Are there channels of communication with general regulators and lawmakers to try to resolve whatever difficulties there might be?
- Are the particular problems or tensions also being experienced in other professional service sectors? If so, is this a case for concerted action by sectoral regulators?
- Are there any problems or concerns arising from the activities of new and alternative service providers in the sector? If the activities are unlawful, has appropriate enforcement action been taken? If the providers are outside the jurisdiction, have all enforcement options been considered? Where provision is lawful, should it be supported and encouraged? If so, have appropriate steps been taken? In any case, have appropriate steps been taken to protect consumer welfare and/or to communicate to consumers whatever risks might be involved in dealing with such providers and to assist consumers to make informed choices?

Social acceptability

- Are you satisfied that the regulatory environment in the sector is socially acceptable?
- Does the regulatory environment strike an acceptable balance between, on the one hand the interest in beneficial innovation and, on the other, the management of risk? Are you confident that you are neither over nor under-regulating?
- Have you consulted to ensure that no red lines are being crossed by provision and practice in the sector?
- Have you consulted to check the range and depth of interests and preferences implicated by the application of the particular technology?
- In particular, have you assessed views on (the acceptability or unacceptability of) automation, not knowing whether one is talking to a human or a machine, humans no longer being in (or on) the loop, (indirect) bias, transparency, insecurity of data and records, false positives, and fair treatment of individuals versus promotion of the general utility?
- Where technologies are being used to make decisions about access to legal services, are you confident about your understanding of the ‘transparency’ and ‘explainability’ of the process?

- What do consultees think about the importance of access to legal services? How would consultees view a legal provider's refusal to take on a case or to decline to pursue a particular service option? Do these views change where new technologies are employed in making decisions about such refusal or denial?
- Was your consultation inclusive, open, respectful of conflicting and competing views, and adequately resourced?
- Are you confident that particular technologies, such as AI, present no existential or catastrophic threat? If not, should there be a moratorium on their use until such doubts have been removed?
- How do you understand the principle that technologies should respect 'humanity' or be designed to function in a 'human-centric' way? Are you satisfied that the technologies that are implicated in the provision of legal services satisfy this principle?
- Where the risk profile of a particular technology is uncertain, have steps been taken to 'pilot' it?
- Have steps been taken to 'de-risk' a particular technology? Has the idea of a regulatory sandbox been properly considered?
- Are the technologies in question assessed as being 'zero-risk'? If not, what contingency plans are in place should 'something go wrong'? Are there satisfactory arrangements for compensation and/or accountability?
- Have you talked to regulators in other service sectors from whom lessons might be learned about the use of particular technologies as well as about particular regulatory approaches/mechanisms?

Compliance and sustainability

- Is your regulatory intervention geared for compliance and sustainability?
- Before responding to the possible use of a new technology, have you considered the full range of your regulatory options (from hard-wired rules to softer standards and guidance)? Where intervention is required, have you thought about the best mix of regulatory instruments to serve your purposes?
- Have you thought about the best time at which to take regulatory action? Is there a risk that early intervention might miss the target or otherwise fail to engage with the technology in the desired way?
- Have you considered that there might be a degree of resistance by regulatees? What steps have you taken to mitigate this risk?
- Have you considered the possibility that regulatory intervention might lead to unintended negative consequences? What steps have you taken in order to minimise this risk?
- What steps have you taken to improve the chances of the regulatory intervention being sustainable?
- Have you allowed for the rapid development of a technology and the possibility that its future applications might be different to those that are contemplated initially?