

Hidden lawmaking in the province of medical jurisprudence¹

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Abstract: Judges articulate their role in controversial cases of medical ethics in terms of deference to Parliament, lest their personal morality be improperly brought to bear. This hides a wide range of law-making activities, as Parliamentary sovereignty is diffused by ‘intermediate law-makers’, and judicial activity is more subtle than the deference account implies. The nature of litigation raises questions about the contributions of other legal personnel and also the nature of the parties’ interests in test-cases. While judges demonstrate an awareness of some of these issues and anxiety about the constitutional legitimacy of their work, a more nuanced account is needed of their proper role. This may be built on Austin’s theory of tacit legislation. It may draw from human rights law. However, considerable work is required before the complexities of hidden law-making can be properly incorporated into the province of medical jurisprudence.

¹ This paper is drawn from the preparation for and reflection on a workshop held by the Health Ethics and Law research group of the University of Southampton in May 2011. We are grateful for the funding generously provided by the *Modern Law Review* for this key event, and especially to the workshop participants for their contributions to our thinking.

Introduction

This paper is concerned with some questions about the constitutional legitimacy of judicial law-making in the context of medical and health care law.² It draws attention to a range of problems that are created by the way in which the law is developed outside of Parliamentary processes and identifies questions for further consideration if this fuller picture of law-making processes is acknowledged. The issues that it addresses may be more general ones, concerning the role of litigation and other forms of ‘hidden’ lawmaking in the development of law on issues that are controversial in a pluralist society. We consider in our conclusions whether there are reasons to think the context in which we have examined them is unusual.

Medical and health care lawyers have long seen the law as a tool for promoting their interpretations of the requirements of bioethics and patients’ rights - and hence their focus has often been on what the law ‘should’ be – but, in contrast, they have shown comparatively little interest in whether it matters that reform is introduced via the judiciary rather than through the legislature, despite the constitutional issues raised by judicial ‘lawmaking’. Indeed, the dominance of legal positivism in Anglo-American jurisprudence in the latter half of the Twentieth Century led to considerable discomfort over the role of judges in making law.³ The development of Ronald Dworkin’s influential account of adjudication as the expression of deep principles, on which the integrity of law is based,⁴ can be seen as an attempt to rescue judges from the criticism that they lack constitutional legitimacy. Rather than ‘legislating’ in such cases, as H.L.A. Hart suggested (because they concern issues on which the voice of Parliament is silent), Dworkin argued that they use the resources of the law to determine the solutions that best fit the authority of the legal tradition that has been handed to them. Hence, the legitimacy of judicial pronouncements is derived from the authority of law, not from that of the individual judges, and adjudication is based on the application of legal principle rather than development of political policy.⁵ As we show below, judicial anxiety about the possibility that they might go beyond their legitimate role in dealing with controversial medico-legal issues indicates that the Dworkinian thesis has clear resonances with the thinking of judges in this area.

In practice, the process by which medical law is made is far more complex than can be accounted for by this distinction between legislative and adjudicative functions. Penney Lewis has shown how legal change can be achieved without formal legal interventions that can be neatly analysed as the action of an authorised legislator, even a constitutionally problematic law-maker such as a judge.⁶ She traces the process by which contraceptive sterilisations moved from being considered unlawful prior to the 1960s to being retrospectively acknowledged as being lawful in the National Health Service (Family Planning) Amendment Act 1972. She shows how by 1968 ‘a substantial medico-legal

² For the purposes of this paper, we use the term ‘medical law’ as a convenient label to encompass the subset of health care law that is usually understood to be concerned with issues of ethical rather than political or organisational significance. Health care law is more concerned with the relationship between citizens and the organisations that provide health services. For discussion of these ways of subdividing the law, see J. Montgomery *Health Care Law* (2003) pp 1-2; T. Hervey and J. McHale, ‘Law, Health and the European Union’, (2005) LS 25(2) 228-259.

³ A classic account of the positivist approach is J. Austin, *The Province of Jurisprudence Determined* (Cambridge: Cambridge University Press 1995, original edition published 1832), and for a Twentieth Century restatement, see H.L.A. Hart, *The Concept of Law* (Oxford: Oxford University Press 1961).

⁴ R. Dworkin, *Law’s Empire* (Fontana 1986).

⁵ For this distinction, see R. Dworkin, ‘Hard Cases’ in *Taking Rights Seriously* (Duckworth 1977), 81-130.

⁶ P. Lewis, ‘Legal Change on Contraceptive Sterilisation’ *J Leg Hist* (2011) 32:3, 295-317.

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consensus had emerged' that sterilisation operations for contraceptive rather than therapeutic purposes was lawful. This view supplanted the contrary consensus that had existed at the beginning of the decade, illustrated by the notorious (and controversial, even at the time) view of Lord Denning that:

Take a case where a sterilisation operation is done so as to enable a man to have the pleasure of sexual intercourse, without shouldering the responsibilities attaching to it. The operation then is plainly injurious to the public interest. It is degrading to the man himself. It is injurious to his wife and to any woman whom he may marry, to say nothing of the way it opens to licentiousness; and, unlike contraceptives, it allows no room for a change of mind on either side. It is illegal, even though the man consents to it.⁷

The way in which this legal change was brought about included a range of social, ethical and legal activities. The fact that the contemporary acceptability of eugenic concerns was thought to legitimise some non-therapeutic sterilisations assisted the consideration of other social reasons for performing sterilisations. The British Medical Association and the Medical Defence Union obtained counsels' opinions on various issues, which gained influence through publication in medical professional journals and annual reports.⁸ When the advice that supported the legality of the procedure went unchallenged, it was suggested that this gave it the status of an established view.⁹ This was reinforced by debate in the *Lancet*, *British Medical Journal*, and the lay press.¹⁰

Lewis notes Ian Kennedy's description of this process as 'one of the wonderful examples of the fudge-and-nudge development of English law. There was no town crier. It was not really written up in the books. The whole legal attitude towards sterilization simply had changed.'¹¹ However, as she shows this does not mean that the process was accidental. A substantial campaign was undertaken by a non-government organisation, the Simon Population Trust, to achieve its desired outcome. Also significantly, the issue was deliberately kept away from formal legal processes because it was thought that a test case might lead to an adverse decision.¹² The possibility of influencing the law in this way raises very significant concerns about the constitutional legitimacy of informal law-making that has received insufficient attention.

This paper uses examples from medical law to explore the complexities of contemporary law-making and seeks to refine the issues that need to be resolved in order to explain the constitutionality of the process. The broadly Austinian, positivist, assumptions on which the judges rely when they explain their role breaks down on at least two counts. First, the complexity of the processes by which legal norms are established. This requires careful consideration of the nature and identity of the 'sovereign' legislator who is assumed by Austin's account of the separation of powers. Second, a much richer understanding is needed of the various forces at play in 'test case' litigation in which judicial decisions come to establish legal principles rather than merely apply them. These are not limited to the choices made by judges in adjudicating on ambiguities in the law. The framing of their

⁷ *Bravery v Bravery* [1954] 1 WLR 1169, at 1180.

⁸ Lewis notes this being done in 1925, 1939, 1949, 1960; see especially n 6 above, 305-6.

⁹ Lewis particularly notes this assertion by Philip H. Addison (secretary, MDU) in 'Voluntary Sterilization in the Male', [1968] 2 BMJ 702 (15 June 1968).

¹⁰ Lewis, n 6 above, 310-131.

¹¹ I. Kennedy, 'Emerging Problems of Medicine, Technology, and the Law', in I. Kennedy, *Treat Me Right: essays in medical law and ethics*, Oxford, 1988, 10-11.

¹² Lewis, n 6 above, 315-6.

choices is a crucial element in their decision and the ‘process of production’ by which cases come to be selected and brought before the court also serves to shape the legal possibilities in a way that can be seen as a component of law-making with constitutional implications. The seeds of a constitutional solution may be found in Austin’s account, but it will require considerable development to take account of modern law-making processes.

Part 1: The changing shape of Parliamentary Sovereignty

Arguably, one reason why judicial and informal law-making have been under-explored by medical and health care lawyers is that over the last few decades this area has become increasingly dominated by legislation, and therefore subject to the oversight of Parliament. In some areas, case law has been superseded by statute. The foundations of mental health law were radically re-orientated around the requirements of the European Convention on Human Rights (ECHR) in the early 1980s, following a series of test cases, and reviewed again in 2007.¹³ Somewhat belatedly, the law relating to capacity to consent to treatment and the care of adults who are unable to consent was codified in the Mental Capacity Act 2005. Broadly speaking, this Act gave Parliamentary authority to principles that had been created in the courts and, in doing so, obviated the need to consider whether or not the judges *should* have developed them. The promise of legislation had been held out for fifteen years through various consultation processes,¹⁴ and it made sense to look to Parliament rather than the judges to take the law forward.

In other areas of medical and health care law statutory regulation has long been the norm, although the extent of *continuing* Parliamentary oversight has proved variable. By way of example, the Human Fertilisation and Embryology Act 1990 (amended in 2008) provided a reasonably comprehensive framework, based on broadly consistent principles, under which medically assisted reproduction and embryo research could take place. Concerns over the terms of the law were raised within and without the courts, but it was reasonably anticipated that reform would be made by Parliament when a number of reviews were sponsored by Government (signalling an intention to

¹³ The Mental Health Act 1983 consolidated the law following the Mental Health (Amendment) Act 1982; it in turn was amended by the Mental Health Act 2007.

¹⁴ Prompted by a discussion document produced by the Law Society (*Decision Making and Mental Incapacity: A Discussion Document*, 1989), the Law Commission launched a series of consultations on various aspects of (in)capacity (*Mentally Incapacitated Adults and Decision-Making – An Overview*, Consultation Paper No. 119, 1991; *Mentally Incapacitated Adults and Decision-Making: A New Jurisdiction*, Consultation paper No. 128, 1993; *Mentally Incapacitated Adults and Decision-Making: Medical Treatment and Research*, Consultation Paper No. 129, 1993; *Mentally Incapacitated and Other Vulnerable Adults: Public Law Protection*, Consultation Paper No. 130, 1993). Their research culminated in the Report on *Mental Incapacity* (Law Com Report No. 231) in February 1995. In response the (then) Lord Chancellor’s Department published a Green Paper ‘*Who Decides? Making Decisions on Behalf of Mentally Incapacitated Adults*’ (Cm 3803, 1997), followed by a White Paper entitled ‘*Making Decisions: The Government’s Proposals for making Decisions on Behalf of Mentally Incapacitated Adults*’ (Cm4465, 1999). In June 2003 the draft Mental Incapacity Bill (Cm 5859-I & II) was produced. A Joint Committee of both Houses scrutinised it and reported in November 2003 (HL Paper 189-I & HC 1083-I), the Government responded in February 2004 (Cm 6121); the renamed Mental Capacity Bill was introduced in Parliament on 17 June 2004; and eventually received Royal Assent on 7 April 2005.

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make changes via the legislature).¹⁵ An expectation of democratic oversight had been built into the statutory framework, which required the Human Fertilisation and Embryology Authority (HFEA), the regulatory body established under the 1990 Act, to produce an Annual Report to be laid before Parliament, thereby enabling intervention should its activities be found inappropriate.¹⁶ Thus, Parliament may have permitted the HFEA to develop the detail of the law but it also provided its democratic legitimacy. In 1990, it was content to delegate significant discretion over policy to the HFEA.¹⁷ However, the political acceptability of this delegation became problematic in the 2000s and the legislature reclaimed *some* responsibility for the oversight of this contentious area, albeit following some initial reluctance.¹⁸ We shall return to some of the issues around such ‘intermediate’ law-makers later in this piece.

Further examples of Parliamentary intervention include the Human Tissue Act 2004, which saw a comprehensive response to the regulation of transplant services, codifying and reforming the previously fragmented law based on private members’ bills;¹⁹ and also the ‘Clinical Trials Regulations’ (2004) which have given a more robust and comprehensive legal foundation to the work of research ethics committees.²⁰ The consolidation (with little reform) of a century of public health law into the Public Health (Control of Disease) Act 1984 has been revisited and modernised in the Health and Social Care Act 2008; and the fragmented legislative provisions that governed the National Health Service were comprehensively consolidated in 2006, only to be substantially amended once more under the Cameron administration with the passing of the Health and Social Care Act 2012. Finally, the bodies that regulate the Health Professions have had their constitutions, powers and procedures revisited under section 60 of the Health Act 1999.²¹ While the revisions are

¹⁵ *Surrogacy: Review for Health Ministers of Current Arrangements for Payment and Regulation* (1998) Cm 4068 and *Consent and the law: review of the current provisions in the Human Fertilisation and Embryology Act 1990 for the UK Health Ministers* (1997) *Human Reproduction Update* Vol. 3, No. 6, 593–621. The latter was prompted by the decision of the Court of Appeal in *R v Human Fertilisation and Embryology Authority, ex p Blood* [1997] 2 All ER 687 which condoned an apparently illegal harvesting of sperm on the basis that it would not reoccur; but note *L v HFEA and Secretary of State for Health* [2008] EWHC 2149 (Fam), [2009] 1 FCR 138.

¹⁶ Human Fertilisation and Embryology Act 1990, s 7(3).

¹⁷ J. Montgomery, ‘Rights, Restraints and Pragmatism: The Human Fertilisation and Embryology Act 1990’ (1991) MLR 54(4) 524-534.

¹⁸ The Parliamentary review of this Act was initially prompted by the House of Commons Science and Technology Committee in October 2003, when it announced its intention to undertake an inquiry into this field, in light of the ‘limp response’ of the Department of Health to its earlier Report on this area. See further House of Commons Science and Technology Committee, *Human Reproductive Technologies and the Law*, HC 7-1 2004-5, and C. Jones, ‘Exploring the Routes from Consultation to (In)forming Public Policy’, in M. Freeman (ed) *Current Legal Issues: Law and Bioethics*, (OUP, 2008), 257-285.

¹⁹ Human Tissue Act 1961, Human Organs Transplant Act 1989. In 2013, the Government announced its intention to revisit the 2004 Act; see Department of Health, *Government response to the report of the independent review of the Human Fertilisation and Embryology Authority and the Human Tissue Authority by Justin McCracken*, London 2013, para 11.

²⁰ Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, which transposed into domestic law the EU Clinical Trials Directive (2001/20/EC); see H. Biggs, *Healthcare Research Ethics and Law: Regulation, Review and Responsibility* (Routledge 2009), especially chapter 4.

²¹ See also the NHS Reform and Health Professions Act 2002, which created what is now the Professional Standards Authority (originally entitled the Council for the Regulation of Health Care Professionals, then known as the Council for Health Care Regulatory Excellence).

approved by statutory instrument, rather than primary legislation, Parliamentary oversight is nevertheless maintained.²²

Intermediate authorities and the making of ‘soft-law’: ‘authorised’ law-makers?

A common feature of many of these legislative interventions is the creation of intermediate authorities, such as the Human Fertilisation and Embryology Authority, the Human Tissue Authority, Research Ethics Committees (now under the umbrella of the Health Research Authority, a position to be fully regularised under the Care Bill 2013), and the various professional regulators. These intermediate authorities have important functions and powers to establish legal norms. Such ‘soft law’ has come to play a very important role in health care law. Indeed, it has been suggested that the subject cannot be fully understood without appreciating that it is a combination of hard law and collegiate norms.²³ This is partly because the National Health Service creates its own internal norms to support staff in both legal compliance and meeting good practice standards.²⁴ It is also a consequence of the fact that professional regulatory bodies have statutory responsibilities to issue guidance on ethics and practice,²⁵ coupled with the tendency of the judges to integrate that guidance into their analysis of the law.²⁶ Finally, many of the bodies established to license and oversee areas of health care practice have developed guidance and codes of practice to assist those within their jurisdictions. The processes by which such ‘soft law’ has been made deserve analysis, and it is not always clear who the key influencers are. Once again, there is a process of law-making that is not easy to place within the traditional accounts of how law is created and the conditions that legitimise its production.

The authority and responsibility of these law-makers is recognised in law, but it is not always so clear how to assess whether they have carried out their tasks appropriately. Some assistance can be found in the public law principles used to regulate discretionary power, litigated via actions for judicial review, such as the doctrine of ultra vires. However this gives only a partial account of the legitimacy issues. A brief consideration of how these intermediate authorities have carried out their lawmaking functions gives some insights into the questions that need to be addressed.

‘Law-making’ by interpretative elaboration

The HFEA is the regulatory body responsible for providing guidance and elaboration on the meaning of statutory provisions pertaining to the use of gametes and embryos in fertility treatment and research, under the auspices of the Human Fertilisation and Embryology Acts of 1990 and 2008. It is

²² The Law Commission was asked to consider this area, and consulted on the Regulation of Health and Social Care Professionals between 1 March and 31 May 2012. See further http://www.justice.gov.uk/lawcommission/areas/Healthcare_professions.htm (last visited 26 July 2013).

²³ J. Montgomery, ‘Time for a Paradigm Shift? Medical Law in Transition’ in Freeman, M (ed) *Current Legal Problems 2000* (Oxford: Oxford University Press, 2000) 363-408.

²⁴ See for example Department of Health, *Reference guide to consent for examination or treatment* (Second edition London DH 2009); *Confidentiality: NHS Code of Practice* (London DH 2003); *Confidentiality: NHS Code of Practice Supplementary Guidance: Public Interest Disclosures* (London DH 2010).

²⁵ See, for example, the Medical Act 1983, s 35.

²⁶ See J. Montgomery, ‘Law and the Demoralisation of Medicine’ (2006) 26(2) LS 185-210 for a sympathetic account of this tendency, and for a more critical one, J. Miola ‘Medical law and medical ethics – complementary or corrosive?’ (2004) 6 Med L Int 251-274, and J. Miola, *Medical Ethics and Medical Law* (Hart 2007).

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required by law to develop a Code of Practice issued to licensed clinics working in these fields,²⁷ but this does not explain the processes and choices that are made in developing the guidance. The interpretation of the welfare principle contained within the Act serves by way of example. The statute originally stipulated that “A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment, (including the need of that child for a father), and of any other child who may be affected by the birth”;²⁸ and further specified that the Code of Practice shall include guidance on child welfare matters.²⁹ Although the welfare aspect proved to be a contentious provision,³⁰ the HFEA’s role was (and remains) to provide guidance on what clinics must do in order to meet the statutory requirements. Hence, in the first Code of Practice, it was stated that clinics ought to ‘take a medical and social history from each prospective parent’, each of whom should be seen separately and together, and enquiries should be made with their GP to ensure there were no further factors which might render them unsuitable for treatment, and a list of relevant factors to be considered was provided.³¹ While some changes were made to this text over the course of the next few editions, up to and including the sixth version of the Code, the mandated approach largely remained the same.

In the summer of 2004 the HFEA began work on developing new guidance on the child welfare provision. The consultation phase was launched in January 2005 by Dame Suzie Leather, (then) the Chair of the HFEA, who noted that it ‘was drafted more than a decade ago and has not been properly reviewed since. The time to review this guidance is now long overdue.’³² This review was undertaken in the knowledge that the Department of Health would soon launch its own review of the legislation, with the expectation that it would include consideration of the welfare provision.³³ Although the document clearly stated that the HFEA could not amend the statute, and that the ‘primary purpose’ of the consultation was not to ‘solicit suggestions on how the Act might be amended’, nevertheless there was an invitation to comment on the welfare principle (‘we welcome views on the welfare principle itself’).³⁴ The consultation posited a range of positions for most questions, from the least interventionist, ‘minimum’ threshold where only risks of serious medical harm should be protected against (including, interestingly, the option that ‘no welfare of the child enquiries should be made’, question 2a – clearly in contravention of the statutory language); to a ‘maximalist’ threshold with follow ups to GPs and other agencies *routinely* (question 2e), and consideration of physical, medical, psychological harms *and* social circumstances to be taken into account (question 4c).

²⁷ HFEA 1990, s 25(1); to be approved by the Secretary of State under HFEA 1990, s 26.

²⁸ HFEA 1990, s 13(5).

²⁹ HFEA 1990, s 25(2).

³⁰ E. Jackson, ‘Conception and the Irrelevance of the Welfare Principle’ (2002) MLR 65(2) 176-203; J. Wallbank ‘The Role of Rights and Utility in Instituting a Child’s Right to Know Her Genetic History’ (2004) S & LS 13(2) 245-264; A. Alghrani and J. Harris ‘Reproductive liberty: should the foundation of families be regulated?’ (2006) CFLQ 18(2) 191-210. For a contrary view see J. A. Laing and D. S. Oderberg ‘Artificial reproduction, the “welfare principle”, and the common good’ (2005) Med L Rev 13(3) 328-356.

³¹ HFEA, *Code of Practice*, First Edition, Part 3, para 3.18-3.19. The full child welfare guidance can be found in Part 3, 3.i-3.x. All previous editions can be found on the HFEA website, <http://www.hfea.gov.uk/2999.html> (last visited 27 July 2013).

³² HFEA, *Tomorrow’s Children: A consultation on guidance to licensed fertility clinics on taking in account the welfare of children to be born of assisted conception treatment*, (2005), foreword.

³³ *Ibid*, para 1.1.

³⁴ *Ibid*; see also question 9, 22.

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In November 2005, the HFEA announced the outcome of its review,³⁵ signalling a clear shift to a ‘presumption’ in favour of treatment, unless there was evidence that the child to be born, or any existing child of the family, was likely to suffer serious harm, in language akin to the threshold criteria for child care cases;³⁶ and accordingly the revised guidance saw the removal of the requirement for clinics to consult patients’ GPs.³⁷ This paradigm shift in the interpretation of the statute³⁸ was grounded on the views expressed by respondents, which the HFEA classified into four categories; two of which (its removal, or fortification into the paramount consideration) would require legislative amendment and were therefore simply noted and left aside.³⁹ Of the remaining categories, the pivotal point was the typification of the level of responsibility of the medical team – either ‘some’ or ‘significant’ responsibility towards the child(ren) in question (whether those to be born, or already in the family). The former approach favoured patient autonomy, with refusals only occurring where serious physical or psychological harm was likely to occur. The latter focused greater attention on the clinics being satisfied that the child’s welfare would not be negatively impacted, and was considered by the HFEA to be too similar to the (then) current guidance, and said to have ‘placed too much emphasis upon the interests of the prospective child at the expense of patient choice’.⁴⁰ Noting only that ‘the experience of the past 14 years suggests that’ children conceived through licensed treatment do not appear to be more likely to be ‘disadvantaged’ than their peers, the HFEA concluded that a shift in favour of a presumption of treatment was justified and appropriate.

The key point for our purpose is that the law in this area was changed as a result of the HFEA’s ‘interpretive elaboration’, in the absence of any statutory amendment. It is clear that the HFEA exercised choice in developing the guidance, and that this was a *law-making* choice. It altered the substantive rules by which the conduct of fertility services were governed, rules that were backed by regulatory sanctions.

‘Law-making’ by regulatory decision

Regulatory decision-making, with regard to both the determination of the ambit of an authorised body’s remit and the outcome of applications for licences (or permission) to develop novel techniques for use in research, also has the potential to establish principles pertinent to future applications and may prove influential in subsequent legislative amendments by Parliament. Hence,

³⁵ HFEA, *Tomorrow’s Children Report of the policy review of the welfare of the child assessments in licensed assisted conception clinics*, (November 2005), http://www.hfea.gov.uk/docs/TomorrowsChildren_report.pdf (last visited 27 July 2013). For further discussion see C. Jones *Why Donor Insemination Requires Developments in Family Law: the need for new definitions of parenthood*, (Edwin Mellen Press 2007), 211-216.

³⁶ Children Act 1989, s31.

³⁷ The HFEA 1990, s 13(5) (as amended by the HFEA 2008), now makes reference to ‘need of that child for supportive parenting’ rather than to ‘a father’, but the presumption in favour of treatment is similarly evident in the current Code of Practice, 8th edition, as amended, para 8.11, which states: ‘It is presumed that all prospective parents will be supportive parents, in the absence of any reasonable cause for concern that any child who may be born, or any other child, may be at risk of significant harm or neglect.’ See further J. McCandless and S. Sheldon, ‘“No Father Required?” The Welfare Assessment in the Human Fertilisation and Embryology Act (2008)’ (2010) *Fem LS* 18(3) 201-225.

³⁸ Evident in the language adopted in the 7th edition of the Code of Practice, n 31 above, G3 - G3.5.1.

³⁹ HFEA, n 35 above, 6.

⁴⁰ *Ibid.*

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such decisions can also be viewed as a form of law-making. Again illustrative examples can be found within the work of the HFEA.⁴¹

The first relates to the regulation of sex-selection in assisted conception. Despite significant debate of this issue before and during the passage of the HFEA 1990, no statutory provisions were made. The HFEA first consulted in 1993, and ultimately decided not to license sex-testing for ‘social reasons’, but did permit the use of PGD and sex selection for medical reasons.⁴² In 2002 the Minister for Public Health requested a review of sex selection techniques and regulation, and following public consultation the HFEA reiterated its 1993 stance.⁴³ This issue was raised in the House of Lords decision in *R (on the application of Quintavalle) v HFEA*⁴⁴, wherein the appellant Josephine Quintavalle (on behalf of Comment on Reproductive Ethics (CORE)) sought to challenge whether the HFEA had the power to license the use of PGD together with HLA typing. Although this case was not about sex-selection *per se*, Lord Hoffmann utilised it as a useful illustration for his conclusion that the absence of statutory prohibition(s) implied that ‘Parliament intended to leave the matter to the [HFE] authority (sic) to decide’.⁴⁵ The HFEA’s policy was subsequently placed on a statutory footing by the 2008 amendments to the HFEA 1990;⁴⁶ hence its stance was retrospectively authorised by Parliament. This raises the possibility that the legitimisation of the regulatory law-making lay in the Parliamentary oversight, but it needs to be recognised that the position was already ‘law’ before the 2008 Act was passed - as a result of the regulatory decision.

The second and third examples concern the HFEA’s licensing decisions regarding the use of particular types of embryos in research (hybrid embryos and mitochondrial donation/replacement therapy). The HFEA identified hybrid or inter-species embryos as a ‘medium priority’ issue in its horizon

⁴¹ A similar analysis might also be applied to the regulation of the number of embryos or eggs that can be transferred during a single cycle. In 1987, in response to evidence that a number of centres had been replacing more than four eggs/embryos, the Voluntary Licensing Authority clarified its original guidance to make clear that no more than three, or exceptionally four, eggs or embryos should be transferred (Voluntary Licensing Authority for Human In Vitro Fertilisation and Embryology, 1987: 8, 12, 35: para 12). Morgan and Lee note that the transfer of up to 15 eggs had been ‘publicly acknowledged’ in GIFT (gamete intra-fallopian transfer) cycles (D. Morgan and R. G. Lee, *Blackstone’s Guide to the Human Fertilisation and Embryology Act 1990*, Blackstone, 1991: 135). GIFT remains outside the HFEA’s remit. Morgan and Lee indicate that ‘one forceful reason’ for this omission was to ensure the compliance of medical professionals with regard to other aspects of the legislation; if true, they argued, this would be ‘another example of the clinical profession dominating input into the legislative process (ibid: 135). There is at least one recorded suggestion of clinicians refusing to accept this policy (Ms Harman, *Human Fertilisation and Embryology, HC Deb 04 February 1988 vol 126 cc1198-256: 1249*) and the VLA withdrew their licence of approval (F. Price, ‘Establishing guidelines: regulation and the clinical management of infertility’ in R. Lee and D. Morgan (eds) *Birthrights: Law and Ethics at the Beginnings of Life* Routledge 1989: 37-54, esp 42-44). In its first Code of Practice, the HFEA set a limit of three eggs/embryos per cycle (para 7.6); a policy which remained unchanged when later – and unsuccessfully - challenged by Mr Taranissi in *R (on the app of the Assisted Reproduction and Gynaecology Centre and another) v HFEA* [2002] EWCA Civ 20, [2003] 1 FCR 266. In this example there were no legislative changes, but the regulatory decisions of the VLA and the HFEA both brought about a change in norms that proved difficult to challenge.

⁴² HFEA, *Code of Practice* (5th ed, 2001) para 9.9.

⁴³ HFEA, *Sex-Selection: Options for regulation*, at www.hfea.gov.uk/docs/Final_sex_selection_main_report.pdf (last visited 27 July 2013).

⁴⁴ [2005] UKHL 28.

⁴⁵ *Ibid*, at [29]. Under HFEA 1990, Schedule 2, s.1(1)(d).

⁴⁶ HFEA 1990 (as amended), Schedule 2, s. 1ZA(1)(c).

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scanning process during 2004-05.⁴⁷ In November 2006, a month before the DH's proposals for reform of the HFEA 1990 were published,⁴⁸ the HFEA received two research licence applications from researchers wishing to use hybrid embryos for specific projects. The HFEA released a statement indicating that this type of research 'would potentially fall with(sic) the remit of the HFEA to regulate and licence and would not be prohibited by the legislation';⁴⁹ but prior to deciding whether or not to grant the requisite licences it undertook an extensive public consultation, summarised in the resulting report.⁵⁰ Almost simultaneously, and reportedly as a consequence of these developments, the House of Commons Science and Technology Committee decided to undertake an urgent inquiry into this issue and its Report was published on April 5 2007,⁵¹ followed shortly by the Draft Bill in May 2007. On January 17 2008 the HFEA announced its decision to grant licences to Newcastle University and King's College London, prior to completion of the passage of the relevant Bill through Parliament. This raises an issue of sequencing in the law-making process – a reflection which formed an aspect of the (unsuccessful) application for judicial review by CORE and the Christian Legal Centre, that 'it was irrational to grant the licence before waiting to see what the will of Parliament was; [and] that to do so, was usurping legitimate debate and the decision of Parliament'.⁵²

The final example is mitochondrial donation/replacement therapy⁵³ involving human embryos. Here the licensing decision was taken much earlier (in 2005), but the amendments made by the 2008 legislation only provided for possible *future* permissive regulations under delegated legislation (akin to the removal of donor anonymity under the HFEA 1990). Since 2010 three key UK policy-advisors/makers, notably the Human Genetics Commission (HGC),⁵⁴ Human Fertilisation and Embryology Authority (HFEA)⁵⁵ and the Nuffield Council on Bioethics (NCOB)⁵⁶ have considered the policy implications of permitting the use of these techniques in treatment cycles. The NCOB reported its findings on June 12, 2012.⁵⁷ The HFEA, together with Sciencewise-ERC,⁵⁸ launched its public consultation on the ethical issues raised by these techniques in September, and made

⁴⁷ A full chronology is available: HFEA, 2007, *Hybrids and Chimeras: A report on the findings of the consultation*, Appendix A: 24-27, at www.hfea.gov.uk/docs/Hybrids_Report.pdf, (last visited 27 July 2013).

⁴⁸ DH, *Review of the Human Fertilisation and Embryology Act: proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos)*, Cm 6989, December 2006.

⁴⁹ www.hfea.gov.uk/474.html (last visited 27 July 2013).

⁵⁰ HFEA, n47 above, Chapter 4.

⁵¹ House of Commons Science and Technology Committee, *Government proposals for the regulation of hybrid and chimera embryos (Fifth Report of Session 2006-07)*, HC 272-1, para 1-3.

⁵² *R (On the application of Quintavalle and CLC) v HFEA* [2008] EWHC 3395 (Admin), [17]; but see [22], [33].

⁵³ The NCOB referred to these techniques as mitochondrial donation, whereas latterly the HFEA used the term mitochondrial replacement, and in the most recent coverage the phrase mitochondrial replacement therapy has emerged; see C. Jones and I. Holme, 'Relatively (im)material: mtDNA and genetic relatedness in law and policy' (2013) *Life Sciences, Society and Policy* 9(4) 1-14.

⁵⁴ HGC (2010) *Discussion of Ethical Issues in Human Reproduction Using Materials Containing DNA From More Than Two Sources*, HGC10/P07 Annex A.

⁵⁵ HFEA (2011) *Scientific review of the safety and efficacy of methods to avoid mitochondrial disease through assisted conception*, at www.hfea.gov.uk/6372.html (last visited 27 July 2013).

⁵⁶ NCOB (2012) *Emerging techniques to prevent inherited mitochondrial disorders: ethical issues*.

⁵⁷ NCOB (2012) *Novel techniques for the prevention of mitochondrial DNA disorders: an ethical review*, at www.nuffieldbioethics.org/sites/default/files/Novel_techniques_for_the_prevention_of_mitochondrial_DNA_disorders_compressed.pdf (last visited 27 July 2013).

⁵⁸ Sciencewise-ERC, the UK's national centre for public dialogue in policy making involving science and technology issues; <http://www.sciencewise-erc.org.uk> (last visited 27 July 2013).

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recommendations in support of the use of the technique in March 2013.⁵⁹ As noted by Dr Geoff Watts, Chair of the Nuffield Council on Bioethics' Working Party on this issue, the HFEA's decision to licence this technique 'fuelled' the pressure on the Government to put regulations before Parliament, in order to permit its use in treatment cycles.⁶⁰ As predicted, in 2013 the Government announced its intention to publish draft regulations, to be presented to Parliament in 2014.⁶¹

There is a complex interplay of actors and forces at play in this area which shapes the substantive regulation of fertility treatment. Between 1991 (enactment) and the 2008 amendments, most of the regulatory changes were made through licensing decisions and developments in the Code of Practice.⁶² Even with Parliamentary scrutiny, the resulting legislation mostly endorsed or ratified the standpoints developed earlier by the HFEA. Thus, it codified rather than changed the law and this raises questions as to who the law-makers really are in this field; at what points the legislative decisions are taken, and how the constitutional legitimacy of the process should be explained.

Legitimation by consultative processes

The HFEA has recognised the legitimacy problems facing an unelected body making policy under the umbrella of its statutory powers and has had to fight a number of cases in the courts where its legal authority has been challenged.⁶³ One of the strategies employed to address this concern, as with many of the regulatory bodies established to deal with matters of health care law, has been to legitimate decisions by preparing for them through public consultation. Thus, the HFEA has developed its policies in light of the feedback it gets from the public, although the processes set in place to elicit responses are not always optimal.⁶⁴ Interestingly, with regard to the child welfare consultation (explored above), although the HFEA noted that 265 responses were received from individuals and organisations, and it provided a breakdown of numbers and percentages as classified into 'patient', 'academic' categories and so on, there is no publicly available data provided on its website or in the Report as to how people responded, other than vague statements that 'some said', 'most argued' or that views were 'evenly balanced'. Further, in justifying the paradigm shift in the

⁵⁹ HFEA, at www.hfea.gov.uk/6896.html (last visited 27 July 2013).

⁶⁰ NCOB, n 57 above, vii.

⁶¹ Press release, 'Innovative genetic treatment to prevent mitochondrial disease' 28 June 2013, <https://www.gov.uk/government/news/innovative-genetic-treatment-to-prevent-mitochondrial-disease> (last visited 24 July 2013).

⁶² Exceptions include the Human Reproductive Cloning Act 2001, prohibiting cloning, and provisions regarding naming deceased fathers on their children's birth certificates in the Human Fertilisation and Embryology (Deceased Fathers) Act 2003; both subsequently incorporated by the HFEA 2008. Both developments were the result of judicial review applications, by Pro-Life Alliance in the former and Diane Blood in the latter instance (respectively *R (on the application of Quintavalle on behalf of Pro-Life Alliance) v Secretary of State for Health* [2001] EWHC Admin 918; and an unreported declaration in the High Court, outlined by Lord Lester HL Deb vol 650 col 1155-1156 04 July 2003).

⁶³ *R v Human Fertilisation and Embryology Authority, ex p Blood* [1997] 2 All ER 687, *R (on the app of the Assisted Reproduction and Gynaecology Centre and another) v HFEA* [2002] EWCA Civ 20, *R (Quintavalle) v Secretary of State for Health* [2003] 2 AC 687, *Quintavalle v Human Fertilisation and Embryology Authority* [2005] UKHL 28, *Human Fertilisation & Embryology Authority v Amicus Healthcare Ltd* [2005] EWHC 1092 (QB), *L v Human Fertilisation and Embryology Authority* [2008] EWHC 2149 (Fam),

⁶⁴ E. Blyth, M. Crawshaw, L. Frith, C. Jones, N. Martin, 'No "brownie points" for ill-conceived Donation Review', (2011) *Bionews* Issue 593, January 31 2011 at www.bionews.org.uk/page_87010.asp (last visited 27 July 2013).

interpretation of the meaning of child welfare, reference was made only to ‘the experience of the past 14 years’⁶⁵ and not to specific evidence from the consultation or other relevant research.

In a separate example, its public consultation on ‘Hybrids and Chimeras’⁶⁶ involved significant public dialogue activities, including deliberative group work in London, Manchester, Newcastle, Belfast, Glasgow and Swansea, of which a number of participants attended a subsequent full-day workshop with expert speakers present; an opinion poll of 2,000 GB residents and 60 Northern Irish residents; and a public meeting, attended by over 150 (self-selected) people. In addition, a written consultation and scientific literature review were undertaken, and a small number of stakeholders were consulted on specific scientific issues. However, the precise connection between the feedback such consultations elicit and the conclusions drawn by the HFEA is not always easy to explain. For example, 65 per cent of the 810 written responses to the consultation were against the use of *any* research on human embryos, yet the analysis regarding the possible creation of hybrid, cytoplasmic and chimera embryos initially focused on the 35 per cent in favour of such research;⁶⁷ with subsequent reiteration of the finding that the majority of those opposed to the development and use of such embryos were also opposed to embryo research *in toto*.⁶⁸ Thus, rather than engaging further with the potentially interesting differences among the reasons given for these respondents’ views (recorded in percentage terms in the final Report), they were placed together in a singular category of ‘opposition’, thereby marginalising exploration of the ethical and social reasons provided for their views – which at the very least is ironic given the title of the initial consultation (*A Consultation on the Ethical and Social Implications of Creating Human/Animal Embryos in Research*). Therefore, while there is an attempt to ensure that the ‘soft law’ that emerges from these processes is a matter of co-production with stakeholders, thereby extending considerably the cohort of law-makers - and potentially assuaging some concerns over the legitimacy of an unelected body driving policy in this (sometimes) contentious field - it is not easy to track the dynamics by which some views come to hold sway over others.⁶⁹

Summary

A substantial body of medical and health care law can now, therefore, make some claim to legitimacy through the authority of Parliament. However, the analysis shows an intertwined search for both constitutional and democratic legitimacy. The former concerns the proper place of those who seem to shape the law within the constitutional structures that confer law-making authority. It is clear that the traditional account of Parliament as the sovereign and sole law-maker, with other agencies being subordinate to its authority, needs considerable adaptation if it is adequately to capture the processes by which legal rules are created. This extension and delegation of law-making powers is not inadvertent, nor is it generally perceived as being a constitutional error (although

⁶⁵ HFEA, n 35, above, 6.

⁶⁶ HFEA, *Hybrids and Chimeras A Consultation on the Ethical and Social Implications of Creating Human/Animal Embryos in Research*, April 2007 at: www.hfea.gov.uk/docs/Hybrids_Chimera_review.pdf (last visited 27 July 2013).

⁶⁷ HFEA, n 47 above, especially Appendix D.

⁶⁸ For a discussion of similar problems with regard to the Department of Health’s Review of the HFEA 1990, see C. Jones, n 18 above.

⁶⁹ For discussion of some early steps in this direction, in the Mental Health Act context, see P. Fennell, ‘The Mental Health Act Code of Practice’ (1990) 53 MLR 499–507 and M. Cavadino, ‘Commissions and Codes: A Case Study in Law and Public Administration’ [1993] PL 333–45.

there some hints of this in Parliamentarians' discussion of the need to take issues back from the jurisdiction of the HFEA and possibly in the more general rhetoric of the 'Bonfire of the Quangos').⁷⁰ Rather, it has become a normal method of making the law, for which we need to be able to give a proper constitutional account.

The response of 'intermediate law-makers' to their own anxieties about legitimacy is more concerned with democratic legitimacy than legal constitutionalism. The HFEA has been challenged on the basis of constitutional powers, but asserting that its decisions are *intra vires* has not been its main legitimisation strategy. Rather, that has come from public consultation and engagement. Bodies such as the NCOB and the HGC did not have legal constitutions to constrain them, but they also showed concern for grounding their recommendations on public opinion. For bodies such as the HFEA, the challenge of democratic legitimacy can partly be satisfied by reference back to the democratic legitimacy of Parliament, but direct engagement with the public is still carried out. Possibly, this is because formal constitutional legitimacy may not be enough, as there is a further set of issues about democratic legitimacy that are raised about the enforcement of particular moral positions in a pluralist society.⁷¹ It would, however, be a good start.

Part 2 Judge-made law and the challenges of legitimation

Although, as we have shown, Parliamentary authority lies behind a substantial part of medical law, judge-made law still dominates some crucial areas, including those concerning the position of patients (eg the standard of disclosure required for consent) and also matters of life and death (withholding and withdrawing life sustaining treatment). Further, the courts have been the place to which professional bodies,⁷² drug companies,⁷³ campaign groups,⁷⁴ and individuals,⁷⁵ have gone to test how far the legal rules are consistent with the policy positions that they promote. Hence, understanding how the judges react to invitations to make policy in the courts is an important part of explaining the ways in which medical and health care law is made. It is necessary, however, to go beyond this and to excavate a further set of processes that have remained largely hidden from constitutional and jurisprudential concern. Cases do not come before the courts wholly by chance.

⁷⁰ House of Commons Public Administration Select Committee, *Smaller Government: Shrinking the Quango State* HC 537 (2010-11).

⁷¹ See J. Montgomery, 'The Legitimacy of Medical Law' in In McLean, S (ed) *First do no harm: Law, ethics and healthcare* Aldershot: Ashgate, 2006, 1-16.

⁷² See eg *Royal College of Nursing of the United Kingdom v Department of Health and Social Security* [1981] AC 800 (legality of nurses' involvement in medical abortions).

⁷³ See eg *R v Secretary of State for Health, ex p Pfizer* [1999] Lloyds Medical Law Reports 289 (QBD) (availability of Viagra on the NHS).

⁷⁴ See eg *British Pregnancy Advisory Service v Secretary of State for Health* [2011] EWHC 235 (Admin) (trying to force the making of regulations permitting medical abortions at home), *R (Quintavalle) v Secretary of State for Health* [2003] 2 AC 687 (application of the Human Fertilisation and Embryology Act 1990 to cloning by cell nuclear replacement).

⁷⁵ See eg *Gillick v W Norfolk & Wisbech AHA* [1985] 3 All ER 402 and (young people's access to family planning without parental involvement), see also *R (On the Application of Axon) v Secretary of State for Health* [2006] EWHC 37 (Admin), [2006] 1 FCR 175; *Jepson v Chief Constable of West Mercia Constabulary* [2003] EWHC 3318 (Admin) (attempt to force the prosecution of doctors who carried out a late termination of pregnancy on the basis of bilateral cleft lip and palate).

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Although the opportunities open to the judiciary to shape the law depend substantially on what Munby LJ (as he then was) has described as the ‘happenstance’ of litigation,⁷⁶ it is not an entirely random process.

Rather, we suggest that there is a ‘typology’ of test cases in the medical and health care law context (and indeed more generally),⁷⁷ which can be illustrated by the development of mental health law in England and Wales. That is, some cases are *planned* as part of a litigation strategy designed to probe and change the law. Thus, test case litigation was one of the tools used by Larry Gostin when legal director of MIND to establish the ‘ideology of entitlement’⁷⁸ as a basis for mental health law.⁷⁹ The shape of the Mental Health Act 1983 was in part established by test case litigation before the European Court of Human Rights.⁸⁰ In such cases, the individual dispute can be said to be secondary to the issue of principle and it is likely that suitable cases are selected by the sponsors of the litigation to maximise the possibility that the case will lead to their preferred result. This selection process is rarely transparent and its ability to shape the opportunities presented to judges may be significant.

In contrast to this category, some cases that begin as an attempt to resolve an *individual* dispute are *made* significant in the development of the law due to the way they are treated by the judges or by the interventions made by third parties. The *Bournewood*⁸¹ litigation initially concerned the care given to an individual client, but prompted a reassessment of the gap left between mental health law and the common law relating to incapacitated patients that is still not fully plugged.⁸² Following the decision of the Court of Appeal, three interested groups who were concerned about the position that it created were permitted to become parties.⁸³ Thus, it became a test case only when it looked as though the way in which the dispute would be resolved had a wider significance with which policy

⁷⁶ Munby LJ, ‘Lost Opportunities: Law Reform and Transparency in the Family Courts’ (2010) CFLQ 22 273-289.

⁷⁷ For the purposes of this paper we provide only a brief overview here. The ‘typology’ analysis will be developed further in a separate paper.

⁷⁸ Eg *Collins v The United Kingdom*, application no. 9729/82; also, on the right to vote, MIND instigated two county court cases, namely *Wild and Others v Electoral Registration Officer for Warrington and Another*, County Court for Warrington, 15 June 1976; *Smith and Others v Electoral Registration Officer of Clitheroe Constituency*, Blackburn County Court, 16 September 1981 – cited in L.O. Gostin, ‘Perspectives on Mental Health Reforms’ (1983) 10 J Law & Soc 47, 54 (fn22) and 64 respectively.

⁷⁹ L.O. Gostin, *A human condition. The Mental Health Act from 1959 to 1975. Observations, analysis and proposals for reform* (MIND, 1975, volume 1). Also, L.O. Gostin, *A Human Condition. The law relating to mentally abnormal offenders. Observations, analysis and proposals for reform* (MIND, 1977, volume 2). For consideration of the assumptions that underpinned this strategy and some of its problems, see N. Rose ‘Unreasonable Rights: Mental Illness and the Limits of the Law’ (1985) 12 J Law & Soc 199-218.

⁸⁰ Eg *X v UK* (Application 7215/75) (1981) 4 EHRR 188; *Ashingdane v UK* application no. 8225/78, (1982) 4 EHRR 590, (1985) 7 EHRR 528. See also *Kynaston v UK* application no. 9480/81, cited in Gostin (1983, at 63).

⁸¹ *R v Bournewood Community and Mental Health NHS Trust, ex p L* [1999] AC 458 (HL); *HL v UK (also known as L v UK)* (2005) 40 EHRR 32.

⁸² See Pearce J & DJ Jackson, ‘The Deprivation of Liberty Safeguards Part 1: has the Mental Capacity Act 2005 bridged ‘the Bournewood Gap’? [2012] Fam Law 319-322; ‘Part 3: how the authorisation regime safeguards are working’ [2012] Fam Law 567-572; ‘Part 6 definition of deprivation of liberty’ [2012] Fam Law 999-1004. The continuing availability of the inherent jurisdiction to plug remaining gaps was confirmed in *A Local Authority v DL* [2012] EWCA 253.

⁸³ These were the Secretary of State for Health, the Mental Health Act Commission and the Registered Nursing Homes Association; *R v Bournewood Community and Mental Health NHS Trust, ex p L* [1999] AC 458 (HL), 475 and 481, [1998] 3 All ER 289, 294.

makers were unhappy. Here, interesting issues for ‘hidden lawmaking’ arise around the intervention process – that is, the process by which those not originally involved in the dispute become parties or make representations before the courts. This includes their decision to seek permission to intervene and also the response of the court to whether or not to give such leave. While applications will draw attention to this possibility, a decision not to seek to intervene will rarely be visible but may be highly significant.

In a third category, test case status can be *accrued* in the course of legal history by subsequent reflection on decisions. Thus, *Re C*⁸⁴ established the common law test for capacity and prompted its consolidation into what is now the statutory test under the Mental Capacity Act 2005 (via the work of the Law Commission, cited above), but was not seen at the time by the lawyers involved as an especially novel case.⁸⁵ In a different area of law, *R v Adams* was a celebrated murder trial but few can have predicted that a jury direction from a *puisne* judge (which was never properly reported) would provide the leading legal authority on medical euthanasia over half a century later.⁸⁶ The judge’s own account of the case concentrates on issues of evidence and the approaches taken by the police and lawyers.⁸⁷ One leading academic text of the time saw the direction as using the concept of causation when ‘necessity’ would capture the issues better and does not give it any priority over other approaches.⁸⁸ Another does not even refer to it in its account of recent mercy killing cases.⁸⁹ The legal sections of the contributions from the Church of England to the euthanasia debates in the 1960s and 1970s cover the issues but do not rely on the *Adams* case as authority.⁹⁰ In 1988, the British Medical Association regarded the issues as unclear but by 1992 it was relying on *Adams*.⁹¹ In the first edition of Mason and McCall Smith’s textbook on *Law and Medical Ethics*, published in 1983, there is a brief mention of the case as an example of ‘double effect’.⁹² By the second, only four years later, it has come to be described as ‘the seminal case in the United Kingdom’.⁹³ In the House of Lords in *Bland* Lord Goff regarded the rule as ‘established’.⁹⁴ However, it is far from clear by whom it was established and by what authority. In *R (Nicklinson) v Ministry of Justice* it was regarded as an accepted legal principle, although it was noted that it has ‘nowhere been the subject of a specific decision but seems to have been generally assumed to be the law by criminal

⁸⁴ *Re C (Adult: refusal of medical treatment)* [1994] 1 All ER 819.

⁸⁵ Andrew Grubb saw the test as a development of those set out in *Gillick*, and the Mental Health Act 1983; (1994) 2(1) Med L Rev 92-95.

⁸⁶ H. Palmer, ‘Adam’s Trial for Murder’ [1957] Crim LR 365.

⁸⁷ P. Devlin, *Easing the Passing: The Trial of Dr John Bodkin Adams* (Bodley Head, 1985).

⁸⁸ G. Williams, *The Sanctity of Life and the Criminal Law* (Faber & Faber, 1958) 283-291.

⁸⁹ N. St John Stevas, *Life Death and the Law* (Eyre & Spottiswoode, 1961) 263-4.

⁹⁰ Church Assembly Board for Social Responsibility, *Decisions about Life and Death: A problem in modern medicine* (Central Board of Finance of the Church of England, 1965) Appendix 2, by Chancellor E. Garth Moore. General Synod Board for Social Responsibility, *On Dying Well: An Anglican contribution to the debate on euthanasia* (Central Board of Finance of the Church of England, 1975) chapter 6, drafting led by Chancellor E. Garth Moore. In the second edition (Church House Publishing 2000), *Adams* is relied upon as the principal authority (drafted by Jonathan Montgomery).

⁹¹ Compare BMA, *Euthanasia* (BMA 1988) para 257-60 with BMA, *Rights and Responsibilities of Doctors* (2nd Ed BMA 1992) 76-77. The first edition of the latter book does not address the area.

⁹² J.K. Mason & R.A. McCall Smith, *Law and Medical Ethics* (Butterworths, 1983) 182-3.

⁹³ J.K. Mason & R.A. McCall Smith, *Law and Medical Ethics* (2nd Ed Butterworths, 1987) 238.

⁹⁴ See *Airedale NHS Trust v Bland* [1993] 1 All ER 821, 868.

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practitioners.⁹⁵ This is a process of law-making that begins and ends in judicial pronouncements, but whose intermediate steps remain extremely opaque.

A fuller understanding of the processes by which litigation emerges from amongst the various options for progressing disputes and campaigns for law reform will illuminate some key questions about test case litigation in the light of unequal access to justice. Our focus in this paper is on the ‘personnel’ aspect of hidden law-making: who is making law and how far is it beyond their explicit mandate to do so? While it is clear that alternative pressures and dynamics generated in and by the legal system itself will also prove influential - determining which cases might be brought, who has standing, funding and the like – these elements fall outside the focus of this article and will need to be explored elsewhere.

Judges: reluctant law-makers?

A broadly accepted account of both why judges have been generally sensitive to the higher authority of the legislature on policy matters, and also the difficulties of relying on case law as a source of legal development was expressed by Lord Browne-Wilkinson in the *Bland* case:

The position therefore, in my view, is that if the judges seek to develop new law to regulate the new circumstances, the law so laid down will of necessity reflect judges' views on the underlying ethical questions...

Where a case raises wholly new moral and social issues, in my judgment it is not for the judges to seek to develop new, all embracing, principles of law in a way which reflects the individual judges' moral stance when society as a whole is substantially divided on the relevant moral issues. Moreover, it is not legitimate for a judge in reaching a view as to what is for the benefit of the one individual whose life is in issue to take into account the wider practical issues as to allocation of limited financial resources or the impact on third parties of altering the time at which death occurs.

For these reasons, it seems to me imperative that the moral, social and legal issues raised by this case should be considered by *Parliament*. The judges' function in this area of the law should be to apply the principles which society, through the democratic process, adopts, not to impose their standards on society. *If Parliament fails to act, then judge-made law will of necessity through a gradual and uncertain process provide a legal answer to each new question as it arises.* But in my judgment that is not the best way to proceed.⁹⁶

In many respects, this expression of reticence articulates the Hartian concerns that judicial activism is based on personal rather than legal values and therefore legislation rather than adjudication. It also reflects concern that the courts do not have the full range of information that is relevant to determining policy before them. These anxieties were described in the High Court in *R (Nicklinson) v Ministry of Justice*, as issues of ‘competence’ (indicating wariness of determining conflicts of fundamental principles through specific cases), ‘constitutionality’ (deference to Parliamentary

⁹⁵ [2013] EWCA 961 at [26].

⁹⁶ *Airedale NHS Trust v Bland* [1993] 1 FLR 1026, 1051, emphasis added.

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sovereignty) and ‘control of the circumstances’ (the need for safeguards to be put in place rather than a general permission).⁹⁷ Approving this analysis, the Court of Appeal said:

Parliament as the conscience of the nation is the appropriate constitutional forum, not judges who might be influenced by their own particular moral perspectives; the judicial process which has to focus on the particular facts and circumstances before the court is not one which is suited to enabling the judges to deal competently with the range of conflicting considerations and procedural requirements which a proper regulation of the field may require; and there is a danger that any particular judicial decision, influenced perhaps by particular sympathy for an individual claimant, may have unforeseen consequences, creating an unfortunate precedent binding in other contexts.⁹⁸

However, the suggestion that judicial law-making may be reluctantly undertaken as a matter of *necessity* obscures the extent to which the judiciary has, in fact, taken the initiative in the development of legal rules. We would posit that judges are less reluctant to get involved in law-making than this account would suggest.

Judges certainly exercise more discretion over the way in which they develop the law than Lord Browne-Wilkinson’s statement implies. They can choose to deal with issues narrowly (dealing only with what is required to resolve the immediate dispute) or expansively (to contribute to the development of legal principles). This can be illustrated by reference to two controversial Court of Appeal decisions regarding adolescents who refused medical treatment.⁹⁹ In each case the court could have disposed of the issue on the narrow ground that the young women in question lacked the necessary degree of understanding to pass the legal test of competence.¹⁰⁰ That would have enabled those with parental responsibility to consent to the treatment, in their best interests. However, in both cases the judges went further and also noted that, even if the young women had been competent to give or withhold consent to the treatment, their competence would not have excluded the supervisory jurisdiction of the courts to act in their best interests, even when that meant overriding their choices. If, on the facts this step was, strictly speaking, unnecessary, there was even less need to go further still and consider whether the consent of a person with parental responsibility would remain valid if the young women had been deemed ‘Gillick competent’ – although it could be seen as giving a clear signal against further appeal by showing that the outcome of the case was unlikely to be changed. Nonetheless, the Court of Appeal did take this additional step, and in the second case Lord Donaldson expressed some irritation with commentators who had taken exception to the position that he had outlined in the earlier decision, making clear that he regarded it as an integral part of his reasoning that should not be marginalised in subsequent cases.¹⁰¹

A further example of the scope for a very different approach to the role of judges can be seen in the judgments in three cases concerning whether the ‘morning after pill’ should be classified as an

⁹⁷ [2012] EWHC 2381 (Admin) at [75-87].

⁹⁸ *R (Nicklinson) v Ministry of Justice* [2013] EWCA 961 at [60]. See also the trenchant comments on constitutionality from Judge CJ at [153-6] (which could possibly also be addressed to the approach of the House of Lords in *Purdy*).

⁹⁹ *Re R* [1991] 4 All ER 177; *Re W* (1992) BMLR 22.

¹⁰⁰ As set out in *Gillick v West Norfolk and Wisbech AHA* [1985] 3 All ER 402, discussed below.

¹⁰¹ *Re W* (1992) 9 BMLR 22, [1992] 2 FCR 785, 798. Arguably it was quietly ignored in *R (On the Application of Axon) v Secretary of State for Health* [2006] EWHC 37 (Admin), [2006] 1 FCR 175.

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abortifacient under the Offences Against the Person Act 1861 (and therefore only to be used within the provisions of Abortion Act 1967, which required certification by two doctors that the grounds were made out). In the first two decisions, the judges were content to give brief judgments citing the usage of common language and the assumptions of prevailing medical practice.¹⁰² Yet, in *R (Smeaton) v Secretary of State for Health* a very different approach was adopted by Munby J (as he then was).¹⁰³ His judgment ran to 398 paragraphs and included a discussion of the theory of statutory interpretation, a full review of the Nineteenth Century medical literature (to aid understanding of the use of language when Parliament had passed the original legislation), and examination of the relevant academic legal writings. This is different both to the pragmatism of the two earlier decisions, but also to the more flexible ‘purposive’ approach to statutory interpretation adopted by the House of Lords latterly in determining the application of legislation in the light of scientific advances.¹⁰⁴

The decisions taken by these different judges on how to approach cases seem to be driven by some deeper assumptions regarding the purpose of medical law. Thus, Lord Donaldson was concerned to ensure that the law did not intrude unduly into medical practice, stating his satisfaction with the result of his approach, that the ‘doctor will be presented with a professional and ethical but not a legal problem.’¹⁰⁵ In contrast, the approach taken by Munby LJ seems to be built on the view that legal scrutiny should be increased,¹⁰⁶ although in two later cases, the Court of Appeal indicated concern about the approach which he had taken.¹⁰⁷ These examples illustrate very different approaches to the responsibilities of judges, and also to the fundamental structure of medical and health care law.¹⁰⁸ The choice between them has fundamental implications for the future of the law, but the basis on which they are to be made is obscured by the traditional view that judges follow rather than make the law.

This judicial creativity is not, however, merely reactive to cases put before them. In the *Bland* case, the House of Lords endorsed the suggestion of the (then) President of the Family Division (Sir Stephen Brown) that cases of patients in a permanent vegetative state (PVS) should be brought to court for consideration prior to the withdrawal of treatment.¹⁰⁹ The reasons given for this

¹⁰² *R v Price* [1969] 1 QB 541, *R v Dhingra* (1991, unreported, Birmingham Crown Court).

¹⁰³ [2002] 2 FCR 193. See for discussion, J. Keown, ‘“Morning after” pills, “miscarriage” and muddle’ (2005) 25(2) LS 296-319.

¹⁰⁴ *R (Quintavalle) v Secretary of State for Health* [2003] 2 AC 687. See also *Quintavalle v Human Fertilisation and Embryology Authority* [2005] UKHL 28 on a different aspect of the same statute. It should also be noted that, prior to the *Smeaton* case, this was an area where a politico-legal consensus had led people to operate as if an authoritative ruling had been made. The Attorney General, Michael Havers, had made a statement to the House of Commons that the Abortion Act 1967 only applied post-implantation in answer to a Parliamentary Question on 10 May 1983, *Hansard* HC Vol 42 Cols 238-9 which had been widely regarded as settling the matter for practical purposes.

¹⁰⁵ *Re R* [1991] 4 All ER 177, 185.

¹⁰⁶ See in addition to *R (Smeaton)*, above, *R (Watts) v Bedford Primary Care Trust and Secretary of State for Health* [2003] EWHC 2228 (Admin), [2004] Lloyd’s Rep Med 113 and *R (Burke) v GMC* [2004] EWHC 1879 (Admin), [2004] 2 FLR 1121.

¹⁰⁷ See *R (Watts) v Secretary of State for Health* [2004] EWCA Civ 166, (2004) 77 BMLR 26 and *R (Burke) v General Medical Council* [2005] EWCA Civ 1003, [2005] 2 FLR 1223.

¹⁰⁸ See J. Montgomery, ‘Law and the Demoralisation of Medicine’ (2006) 26(2) LS 185-210, especially 202-205 for discussion.

¹⁰⁹ *Airedale NHS Trust v Bland* [1993] 1 FLR 1026, see for example, comments by Lord Keith at 856, and Lord Goff at 873-874, affirming the views of Sir Bingham MR at 815-816, and Butler-Sloss LJ at 824 (albeit Lord Goff

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requirement were that the nature of PVS was uncertain, and that there was therefore scope for disagreement amongst relatives and professional staff. Here, the judges seem to be promoting further litigation in order to give them the opportunity to develop legal principles. Thus, the picture is more complex than Lord Browne-Wilkinson's statement of deference to Parliamentary sovereignty would imply. There are also cases where the judges express the view that litigation was inappropriate; either by passing comment on the wisdom of the case being brought,¹¹⁰ or more harshly in awarding costs against a hospital that seemed reluctant to accept the legal position on the treatment of adolescents that had been established by the Court of Appeal.¹¹¹ Hence, the judges seem here to be taking steps to manage the production of law reform (or discourage it) through the courts.

A particularly stark example of the judges prompting changes in the law without reference to Parliament can be seen in the finding of the House of Lords in the *Purdy* case that the provisions of the ECHR required greater clarity on the prosecution policy adopted in relation to the crime of assisting a suicide.¹¹² Although the point had not been raised in, or by, earlier litigation on the implications of Article 8 of the ECHR for assisted dying,¹¹³ their Lordships regarded the current state of English law to be too imprecise to meet the requirement that interventions into private and family life needed to be 'in accordance with the law' before they could be compatible with the ECHR. They therefore prompted the Director of Public Prosecutions (DPP) to promulgate a detailed policy on the factors that will be taken into account in such cases.¹¹⁴ In a wider context, this raises challenging constitutional issues not least as, in the same month as the *Purdy* case was heard in the House of Lords, Parliament had expressly considered and rejected reform in the precise area of law with which the litigation was concerned. Their Lordships' approach could therefore be seen as an affront to Parliamentary sovereignty.¹¹⁵

In relation to 'hidden lawmaking', however, the main interest lies in the role of the DPP, who was given responsibility for developing the new 'law'. His guidelines for prosecution play an important part in shaping the legal rules as they operate in practice, but this role is poorly accounted for in constitutional accounts of how law is made. In a strong dissent in *R (Nicklinson) v Ministry of Justice*, Judge CJ drew attention to the way in which 'the process of necessary law reform has been subsumed in prosecutorial guidance. In short, prosecutorial guidance is in danger of expanding into

indicated his hope that the President of the Family Division might, in future, relax this requirement and limit it to those cases where a 'special need' for the procedure was present).

¹¹⁰ See the comments in *R (Burke) v General Medical Council* [2005] EWCA Civ 1003, [2005] 2 FLR 1223, eg per Lord Phillips at [13-14], [19], [21], [82]. See further below.

¹¹¹ *Northamptonshire HA v Official Solicitor and Governors of St Andrew's Hospital* [1994] 1 FLR 162. Similarly, in the context of advance directions, see *Ms B v An NHS Hospital Trust* [2002] EWHC 429 (Fam), per Dame Butler-Sloss at [99].

¹¹² *R (Purdy) v DPP* [2009] UKHL 45, see Lord Phillips at [16]; Lord Hope at [56]; Baroness Hale at [86-87], and Lord Neuberger at [101].

¹¹³ *Pretty v UK* [2002] 2 FCR 97.

¹¹⁴ For a discussion of this policy, the consultation and some of its flaws, see P. Lewis 'Informal legal change on assisted suicide: the policy for prosecutors' (2010) LS 31(1) 119-134.

¹¹⁵ See J. Montgomery, 'Guarding the gates of St Peter: life, death and law making' (2011) LS 31(4), 644-666.

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a method of law reform (if only by way of non-enforcement of the criminal law) which is outside the proper ambit of the DPP's responsibilities.¹¹⁶

Nonetheless, we have already seen that 'soft' law instruments, such as codes of practice and guidance notes have played a significant role in the making of medical and health care law. They have been incorporated into judicial decisions, as in the use of medical guidance on the management of PVS cases in *Bland*,¹¹⁷ and have also been mandated by Parliament as a means to translate legal provisions into practice guidance.¹¹⁸ This area of law thus relies heavily on a body of 'law-makers' who sit neither in the legislature nor the judiciary, but whose existence is recognised in the process by which legal norms are formed.

Deliberative engagement

Statutory bodies such as the HFEA are not the only organisations that seek legitimacy in deliberative engagement. The process adopted by the DPP to develop his policy for prosecutors¹¹⁹ following the *Purdy* case was an open one. It involved the publication of a consultation document (also serving as an interim policy), consideration of responses, and then the issue of a final policy, which included 16 factors that tend in favour of prosecution and six against. More factors were included in the interim policy, but those relating to the medical condition and perceived vulnerability of the assisted person (termed the 'victim' in the policy) were removed after the consultation.

The published policy insists that the law has not changed and assisting or encouraging the suicide of another continues to be a criminal offence that is open to prosecution.¹²⁰ Yet, as Mullock points out, this may not be entirely true, as the policy has 'the effect of sanctioning compassionately motivated assisted suicide, with compassion as the key determining factor which potentially places an act which remains criminal beyond the reach of the criminal courts.'¹²¹ Further, some commentators regard the process by which the policy was developed as unconstitutional, even dangerous.¹²² The fact that the DPP was required by the judiciary to develop the prosecutorial policy in order to provide clarity is in itself somewhat unusual.¹²³ Consequently, it is perhaps not the policy itself that should be criticised but rather the questionable *processes* which led to the ruling in *Purdy*.

Since the first reported case in 2003¹²⁴ there have been many instances of British nationals being helped to travel to the Dignitas clinic in Zurich for an assisted suicide. In *R (Nicklinson) v Ministry of*

¹¹⁶ [2013] EWCA Civ 961 at [169], considering wider developments in prosecution guidelines to draw attention to the dangers he saw in the *Nicklinson* and *Purdy* cases.

¹¹⁷ *Airedale NHS Trust v Bland* [1993] 1 FLR 1026.

¹¹⁸ See for example the role of Codes of Practice under the Mental Health Act 1983, the Human Fertilisation and Embryology Act 1990, the Human Tissue Act 2004 and the Mental Capacity Act 2005.

¹¹⁹ CPS, *Policy for Prosecutors in Respect of Cases of Encouraging or Assisting Suicide* at www.cps.gov.uk/publications/prosecution/assisted_suicide_policy.html (last visited 29 July 2013).

¹²⁰ *ibid* at para 6.

¹²¹ A. Mullock, 'Overlooking the Criminally Compassionate: What are the implications of prosecutorial policy on encouraging or assisting suicide?' (2010) *Med Law Rev* 18(4) 442-470.

¹²² For example, J. Keown, 'Dangerous Guidance' (2009) 159 *New Law Journal* 1718.

¹²³ Although not unique, as discussed by Judge CJ in his dissenting judgment in *R (Nicklinson) v Ministry of Justice* [2013] EWCA Civ 961 at [168].

¹²⁴ BBC News, 24th January 2003, 'Suicide man's 'dignified' death' <http://news.bbc.co.uk/1/hi/england/2688843.stm> (last visited 29 July 2013). See also H. Biggs and C. Jones,

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Justice, the court was told that approximately 25 British citizens had travelled each year between 2008 and 2010 to make use of its services.¹²⁵ Nobody has been prosecuted, partly because of decisions taken in the office of the DPP that prosecution would not be in the public interest.¹²⁶ Whilst it has always been the case that prosecution requires the consent of the DPP,¹²⁷ this seemingly systematic approach to a particular crime smacks of a normative response. The judgment in *Purdy* represents clear evidence that the court saw it in this light, with Lord Brown accepting previous prosecutorial reluctance to prosecute as ‘sensitive, thoughtful and principled’,¹²⁸ and calling for a ‘custom built policy statement indicating the various factors for and against prosecution ... designed to distinguish between those situations in which, however tempted to assist, the prospective aider and abetter should refrain from doing so, and those situations in which he or she may be, ... forgiven rather than condemned’.¹²⁹

Nowhere within this statement, or anywhere in the *Purdy* judgment, are concerns expressed about the potential to undermine the independence of the office of the DPP by requiring the publication of such a policy even though it was premised upon the notion that it is legitimate, in some circumstances, not to prosecute those who assist suicide. Nevertheless, alongside the extensive public consultation, the intervention of the Law Lords does lend legitimacy to the policy making process. It certainly renders visible a process that might otherwise be obscured. This may, however, be at the expense of constitutional theory about the separation of powers. In *R (Nicklinson) v Ministry of Justice*, the Court of Appeal held that further clarity was still required, but did recognise that there was a constitutional issue to be considered. The Lord Chief Justice dissented precisely on the point that the DPP was being asked to do something that was constitutionally inappropriate.¹³⁰ It is expected that the Supreme Court will have the opportunity to consider this issue.

Litigation and obscured law-making

In one sense the leading players in test cases are highly visible. The parties are identified in the law reports along with the judges, counsel and solicitors. However, there are a number of senses in

‘Tourism: A Matter of Life and Death in the United Kingdom’ in I. G. Cohen (ed), *The Globalization of Health Care* (New York: OUP, 2013).

¹²⁵ [2013] EWCA Civ 961 at [129].

¹²⁶ The DPP considered such 8 cases in the ten years up to 2008, a small proportion of those thought to have travelled to Switzerland, of which none were prosecuted (mostly because of evidential problems); see http://www.cps.gov.uk/consultations/as_keyfacts.html (last visited 1 August 2013). Since the *Purdy* decision the DPP has published reasons for five non-prosecution decisions taken in 2010, involving seven defendants. In respect of three of those defendants the non-prosecution was because of insufficient evidence. In respect of the other four it was based on public interest considerations; see DPP, ‘Assisted Suicide cases - published decisions’ at http://www.cps.gov.uk/publications/prosecution/assisted_suicide.html (last visited 1 August 2013). Latest figures are reported on this webpage and updated every six months. From 1st April 2009 up to 1 March 2013 there were 68 cases referred to the CPS by the police, 7 of which were still under investigation, Only two charges are being brought, which were for murder or manslaughter rather than assisted suicide.

¹²⁷ Suicide Act 1961, s 2(4).

¹²⁸ *R (on the application of Purdy) v DPP* [2009] UKHL 44 at [81].

¹²⁹ *R (on the application of Purdy) v DPP* [2009] UKHL 44 at [86].

¹³⁰ See the concerns expressed by Judge CJ in his dissenting judgment in *R (Nicklinson) v Ministry of Justice* [2013] EWCA Civ 961.

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which the law-making process is obscured by the apparent transparency of the record that is set out in the decisions of the courts.

Legal personnel – concentration of expertise

Some of these relate to the personnel of the law, where there are patterns that need to be recognised as influencing the development of the substantive law. Thus, where there has been a tendency to instruct the same specialist barristers, known to be supportive of particular views, this can lead to a consistent approach to advice and argument. Similarly, there are patterns of solicitors specialising in certain types of cases. These processes of concentrating the preparation of litigation on a limited group of lawyers can also be seen as a form of law-making in the shadow of the court process (and therefore drawing its legitimacy from the adjudication in the case), but it is a process that is not necessarily explicitly validated by the judges (not least, because it may be hidden from them). The role of lawyers beyond the judiciary therefore requires further consideration.

In some areas, this can be seen quite easily. The fact that medical law cases have frequently involved vulnerable and incapacitated persons has meant that the Official Solicitor has often been involved in the key cases, and has played a consequential role in codifying practice, and to some extent thereby codifying the substantive law too. Practice Notes indicating the understanding that the Official Solicitor has reached of the implications of judicial decisions serve the function of drawing together the disparate comments of judges into a coherent guide to practice. This was done in relation to the string of decisions exploring the sterilisation of incapacitated women and the withdrawal of life sustaining treatment from those in a vegetative state, initially as separate notes which were subsequently codified into a single note covering those unable to consent for themselves.¹³¹ Under the Mental Capacity Act 2005, this role has become a more formal one, and moved into the jurisdiction of a recognised legal authority, through the issue of Practice Directions by the President of the Court of Protection, supplementary to the Court of Protection Rules 2007.¹³² The initial foray of the Official Solicitor in this quasi-legislative role in medical law was made in response to the decision of the House of Lords in *F v West Berkshire Health Authority*.¹³³ In subsequent litigation, Thorpe J (as he then was) raised some concerns about its content, observing that it was ‘issued for the guidance of practitioners and was not intended to be a mandatory code’, and suggesting various points at which it failed to reflect the position as he saw it.¹³⁴ As he recognised, advice from the Official Solicitor has a more significant impact on the conduct of the litigation than the personal opinion of a lawyer, and commands a degree of informal authority that is properly seen as a form of law-making.

One of the interesting consequences of the consistent involvement of the Official Solicitor is that it led to a tendency to instruct the same counsel. Thus, Allan Levy and James Munby were regularly instructed in the major medical law cases of the 1980s and had an opportunity to develop their own

¹³¹ *Practice Note (Official Solicitor: Sterilisation)* [1989] 2 FLR 447, amended [1990] 2 FLR 530, *Practice Note (Sterilisation: Minors and mental health patients)* [1993] 3 All ER 222 and *Practice Note (persistent vegetative state: Withdrawal of treatment)* [1994] 2 All ER 413, then *Practice Note: Official Solicitor: Sterilisation* [1996] 2 FLR 111, *Practice Note (Vegetative State)* [1996] 2 FLR 375, and subsequently *Practice Note (Official Solicitor: Declaratory Proceedings: Medical and Welfare Decisions for Adults Who Lack Capacity)* [2001] 2 FLR 158.

¹³² SI 2007 No. 1744, see *Practice Direction 9E – Applications Relating to Serious Medical Treatment* at <http://www.judiciary.gov.uk/publications-and-reports/practice-directions/cop-practice-directions> (last visited 5 August 2013).

¹³³ [1990] 2 AC 1, see *Practice Note (Official Solicitor: Sterilisation)* [1989] 2 FLR 447.

¹³⁴ *Practice Note, J v C* [1990] 3 All ER 735.

thinking and regular lines of argument. The latter argued as counsel that treatment should not be withdrawn or withheld from children unless their lives were “so full of pain and suffering’ as to be ‘intolerable’ and so ‘demonstrably awful’ that the child must be ‘condemned to die’. However, this suggestion was rejected by the courts in favour of an undifferentiated welfare test.¹³⁵ This did not stop Munby J (as he had then become) adopting the same approach on the bench in the *Burke* case.¹³⁶ The Court of Appeal overturned his decision and was specifically critical of his suggestion that intolerability was a legal test,¹³⁷ a position it confirmed in its decision in the *Wyatt* litigation.¹³⁸ Nevertheless, the debate has continued. One Court of Appeal judge has suggested that it is open to a Court of Protection judge to have regard to whether life is ‘tolerable’ in the best interests assessment,¹³⁹ but most judges have avoided it as unhelpful.¹⁴⁰

A brief analysis of Munby J’s (as he then was) reasoning in *Burke* is nevertheless instructive. It shows the continuity between his work as counsel and later judicial rulings, indicating that the process of law-making has roots outside of individual case decisions, which need to be brought into detailed consideration. It also illustrates the relative invisibility of this history to all but the most informed student of this area of law. The argument’s legal pedigree ranged through a series of cases; *Bland*¹⁴¹ (counsel Munby QC alongside Robert Francis QC acting for the Health Authority, and who was also counsel in *Burke*), *Re J*¹⁴² (counsel Munby QC), the ‘classic case’ of *Re B*¹⁴³ (counsel Munby QC), *Re C*¹⁴⁴ (counsel Munby QC), *Re R*¹⁴⁵ (counsel Munby QC), and *NHS Trust v D*.¹⁴⁶ This might be said to be a selective history of welfare cases, and it could also be argued that Munby J’s treatment of Taylor LJ’s judgment in *Re J* as the dominant one is less common than taking Lord Donaldson’s as the leading judgment. However, this is apparent on the face of his argument and open to scrutiny and challenge (as indeed it was scrutinised and challenged before the Court of Appeal). Slightly more obscurely, in his judgment Munby J notes the analysis set out in the relevant sections of the standard practitioner text, Kennedy and Grubb’s *Principles of Medical Law*.¹⁴⁷ Few readers were likely to appreciate that these were in fact sections that he had authored himself. Munby J therefore offered what seems like an account of cumulative and independent authority for his interpretation of the welfare principle that in fact was the repetition of a case that he had personally been promoting over a long period. This neither enhances nor decreases the validity of his position, but it is not quite the simple story of a developing line of authority that it might seem to be to a reader who was ignorant of this history. It suggests that a comprehensive account of how the law is being

¹³⁵ *Re J* [1990] 3 All ER 930.

¹³⁶ *R (Burke) v GMC* [2004] EWHC 1879 (Admin) at [98-113].

¹³⁷ *R (Burke) v GMC* [2005] EWCA Civ 1003 at [62-3].

¹³⁸ *Portsmouth NHS Trust v Wyatt* [2005] EWCA Civ 1181 at [58-91], see most explicitly [62].

¹³⁹ *Aintree University Hospitals NHS Foundation Trust v James* [2013] EWCA Civ 65, at [49] (Sir Alan Ward).

¹⁴⁰ E.g. *Portsmouth NHS Trust v Wyatt* [2004] EWHC 2247 (Fam) (Hedley J); *Re L (A Child) (Medical Treatment: Benefit)* [2011] EWHC 2443 (Fam) (Butler-Sloss P); *NHS Trust v D* [2005] EWHC 2439 (Fam) (Coleridge J); *NHS Trust v MB* [2006] EWHC 507 (Fam) (Holman J); *Re K (A Child) (Medical Treatment: Declaration)* [2006] EWHC 1007 (Fam) (Potter P); *NHS Trust v H* [2013] Med. L.R. 70 (High Court, Fam Case No: FD11P02589) (Jackson J).

¹⁴¹ *Airedale NHS Trust v Bland* [1993] 1 FLR 1026.

¹⁴² [1991] Fam 33.

¹⁴³ [1981] 1 WLR 1421.

¹⁴⁴ [1990] Fam 26.

¹⁴⁵ [1996] 2 FLR 99.

¹⁴⁶ [2000] 2 FLR 677.

¹⁴⁷ *Burke*, n 136 above, at [104], I. Kennedy and A. Grubb, *Principles of Medical Law* (Oxford: OUP, 2nd ed, 2004).

made would need to have regard to his personal contribution prior to being appointed to the bench and in his extra-judicial writings.

This pattern of developing expertise around a small number of legal practitioners can also be seen at work in a campaigning context in the contribution of Gerard Wright QC, who acted in a number of significant cases promoting views consistent with the Roman Catholic faith. He appeared for Mrs Gillick in all levels of her litigation, a case in which the DHSS did not instruct silks.¹⁴⁸ Similarly, he appeared in all levels of the *Janaway* case, in which a secretary sought to use the conscience clause to avoid typing correspondence connected with the arrangements of terminations¹⁴⁹; and represented an Oxford student who sought to intervene to prevent his former girlfriend terminating her pregnancy, instructed by the same firm of solicitors as in *Janaway*.¹⁵⁰ Further, he published on medico-legal matters from a Roman Catholic perspective, providing counsel's opinion on the legal status of the IVF embryo for the Society for the Protection of the Unborn Child as part of its submission to the Warnock Inquiry,¹⁵¹ and giving a talk on his concerns over legal aspects of dying to a symposium of the Guild of Catholic Doctors.¹⁵² It seems clear that some legal practitioners have more influence on how law develops than others, and that this is an area for further study.

Parties

A second sense in which the lawmaking processes are obscured concerns the parties to litigation. In some cases disputes seem to be concerned solely with the issues affecting individuals, in others the parties seem to represent particular moral positions. We showed above that some cases only emerge as significant through their subsequent interpretation. In those cases, the parties involved play little part in their cases becoming an important event in the making of the law. However, where cases are planned as 'test-cases' or become such cases through the intervention of third parties, it is important to consider how to assess the legitimacy of their actions in bringing matters to court. It may be an idea that this does not cause constitutional anxieties because the judges provide legitimacy for the law-making consequences of test-cases. However, this is an area that deserves some consideration.

Bob Lee and Derek Morgan developed the idea of a 'stigmata' case to capture the way in which some litigation raises questions that require the courts 'to develop a social, even a moral vision with which to respond to the dilemmas created by the social and cultural revolution of contemporary medicine'.¹⁵³ In their first discussion of this idea, they focused on two cases that have the

¹⁴⁸ *Gillick v West Norfolk and Wisbech AHA* [1984] QB 581 (QBD), [1985] 1 All ER 533 (CA), [1985] 3 All ER 402 (HL).

¹⁴⁹ *R (Janaway) v Salford AHA* 1988] 1 FLR 17 (QBD), [1988] 2 FLR 370 (CA), [1988] UKHL 17, [1989] AC 537 (HL).

¹⁵⁰ *C v S* [1987] 1 All ER 1230.

¹⁵¹ Gerard Wright QC, 'Legal Status of the IVF Embryo: Counsel's Opinion' in J. Lejeune, P. Ramsey & G Wright, *The Question of In Vitro Fertilization: Studies in Medicine, Law and Ethics* (London, SPUC Education Trust 1984) 47-52. See also 'The Legal Implications of IVF' in Order of Christian Unity, *Test Tube Babies – a Christian view* (London, Unity Press, 2nd ed 1985).

¹⁵² Gerard Wright QC, 'The Culture of Death' Talk given at the Symposium of the Guild of Catholic Doctors, Southport, 24 April 1999; http://www.cmq.org.uk/CMQ/1999/culture_of_death_g_wright.htm (last visited 5 August 2013).

¹⁵³ R. G. Lee & D. Morgan, 'Regulating the Risk Society; stigmata cases, scientific citizenship and biomedical diplomacy' (2001) 23(3) *Syd LR* 297-318, 298.

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characteristics that they describe but which began as highly personal legal problems.¹⁵⁴ In *Airedale NHS Trust v Bland* the matter became a legal problem because the treating consultant had been warned by the local coroner that withholding treatment from his patient could expose him to risk of prosecution for murder.¹⁵⁵ Consequently, he brought the matter to court in order to ensure that his legal position was clear. In the litigation brought by Diane Blood, she was seeking the opportunity to have a child by her deceased husband, a campaign that took her court twice and then to Parliament to secure recognition for the child's status.¹⁵⁶ While these cases have proved to be important for the development of the law, they appear to have been prompted by personal tragedies rather than a campaigning desire to change the rules.

In other cases, it has been clear from the outset that the issues have a broader significance than the immediate dispute. When Mrs Victoria Gillick brought her case about family planning advice for young people, it was expressly stated that the issue was hypothetical and that there was no suggestion that her daughters were actually seeking such advice at the time.¹⁵⁷ Few doubted that the principal reason for bringing the case was to establish the principle of parental control over their children's upbringing prompted by Mrs Gillick's views on family life, drawn from her faith as a Roman Catholic. In subsequent litigation, she sought to protect her reputation in further campaigning activities.¹⁵⁸

In many cases, the motivation of a litigant is unclear, but there is occasional judicial disapproval of the use of the courts for campaigning without a pressing personal interest. Thus, Lord Phillips MR stated:

Had Mr Burke been well advised he would and could have sought reassurance from the GMC as to the purport of their guidelines and from the doctors who were treating him as to the circumstances, if any, in which ANH might be discontinued. Mr Burke did not take that course. The manner and circumstances in which these proceedings were commenced suggest that he was persuaded to advance a claim for judicial review by persons who wished to challenge aspects of the GMC guidance which had *no relevance* to a man in Mr Burke's position.¹⁵⁹

Implicit in this comment is disquiet about the use of the law in this way, prompting consideration of whether there are some criteria (beyond the formal rules about standing) against which it is possible to judge the propriety of litigants raising general issues through the courts. This can be seen as a recognition of the need to legitimise this, currently obscured, aspect of law-making through test case litigation.

¹⁵⁴ D. Morgan & R. G. Lee, 'In the Name of the Father? Ex p Blood: Dealing with Novelty and Anomaly' (1997) 60 MLR 840-856.

¹⁵⁵ [1993] 1 FLR 1026.

¹⁵⁶ *R v Human Fertilisation and Embryology Authority, ex p Blood* [1997] 2 All ER 687. The second case is unreported, but see D. Blood, *Flesh and Blood: The Human Story Behind the Headlines* (Edinburgh: Mainstream Publishing, 2004), 263-264, 273-274, 279-281, 288-293. The legislation was the Human Fertilisation and Embryology (Deceased Fathers) Act 2003, whose provisions were incorporated into the Human and Fertilisation and Embryology Act 2008.

¹⁵⁷ *Gillick v W Norfolk & Wisbech AHA* [1985] 3 All ER 402.

¹⁵⁸ *Gillick v BBC* (1996) EMLR 267 (in which Mrs Gillick succeeded); *Gillick v Brook Advisory Centres* [2002] EWHC 829 (QB) (in which Mrs Gillick lost).

¹⁵⁹ *R (Burke) v General Medical Council* [2005] EWCA Civ 1003, at para [13]-[14], emphasis added.

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If the characters and circumstances of the individuals involved in cases have an impact on the way in which the substantive law develops, then test case litigation, in its various senses, is not entirely random. Further work is necessary to trace the patterns and consider their implications. One of those patterns concerns how test case litigation is connected to other efforts to promote reform of the law.

Litigation and the politics of campaigning

Two recent examples of test case litigation provide instructive examples. In both cases it is possible to see where the court cases come in the sequence of legal steps and allow discussion of how far such cases reinforce the orthodox expectations of the separation of powers doctrine, or whether they require some further revision of the traditional judicial account of deference to Parliament while subjecting the Executive to the Rule of Law. In the first example, concerning the Abortion Act 1967, litigation was a step taken after other attempts to get the legal issues examined had failed. It could plausibly be described as a step of last resort. The second example, around death and dying, shows a more complex interplay between courts and Parliament.

In February 2011, Supperstone J ruled in a case brought by British Pregnancy Advisory Service (BPAS) for a declaration on the meaning of the provisions of the Abortion Act 1967 relating to where abortions could take place.¹⁶⁰ The case concerned ‘medical’ abortions, where the woman’s miscarriage is caused by a drug and in particular early medical abortions where miscarriage takes place in the first nine weeks of the pregnancy. There are safeguards in the Act that require pregnancies to be ‘terminated’ by a registered medical practitioner in an approved place.¹⁶¹ These make sense in relation to surgical abortions, but seem less clearly logical in relation to medical abortions. The court was told it was possible for women to take the drugs and then return home, expecting to have the miscarriage there but risking it occurring while they were travelling.¹⁶² BPAS contended that it would be preferable if women were able to obtain the drug from their doctor and self-administer it at home and that the legislation permitted this because the phrase ‘treatment for the termination of pregnancy’ in section 1(3) of the Act, which could only lawfully occur in an ‘approved place’, covered the act of prescription not administration.¹⁶³ The court did not accept that construction and held that the course of action that terminated the pregnancy, both the prescription and administration had to be in a place approved by the Secretary of State.

If the dynamic of policy development is to be understood, it is important to place this case in a broader context. Litigation was not the preferred route for BPAS.¹⁶⁴ Rather, it followed a prolonged series of attempts to raise the policy issue for decision. Discussions between BPAS and the

¹⁶⁰ *BPAS v Sec State for Health* [2011] EWHC 235 (Admin).

¹⁶¹ Abortion Act 1967, s 1(3), (3A).

¹⁶² At [10-11] of the judgment.

¹⁶³ It is important to distinguish the provisions relating to the place of termination from the question whether the termination in question was carried out by a doctor under s 1(1) so that the defence against the 1861 Act was available. In *RCN v Department of Health and Social Security* [1981] AC 801 it had been established that the administration of the drugs by a nurse was acceptable providing it was under the authority of a doctor. Similarly, self-administration could be under the authority of the doctor for the purposes of s 1(1). However, the RCN case concerned medical abortions in hospital and did not therefore address the scope of s 1(3).

¹⁶⁴ This summary of the background, as seen by BPAS, is based on a presentation by Dorothy Flower to the Modern Law Review Seminar, ‘Hidden Law-makers’ held at the University of Southampton in May 2011.

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Department of Health had been initiated in 2000, but had not led to any resolution. An attempt had been made secure Parliamentary consideration when, in 2007, BPAS, along with a number of other groups pushing for reform of the law (on all sides of the policy debates) sought to raise the matter within the review of the human fertilisation and embryology legislation. Representations on the issues were made to the Science and Technology Committee. However, when the Human Fertilisation and Embryology Bill 2008 was debated, Parliamentary time was not available for amendments to the abortion law. Consideration was then given to whether litigation might assist and BPAS obtained counsel's opinion, which was favourable. Even at this stage, they hoped that clarification of the legal position might prompt policy consideration. The opinion was shared with the Department of Health hoping that it would promote the debate, at least by identifying the contrary legal arguments so that they could be explored. The BPAS saw the litigation as a last resort, not least because of the risks that it raised, rather than one of a number of alternative strategies.

It may be that the Department of Health's resistance to the case being brought by BPAS was driven by its concern to avoid abortion policy being made by and through the courts.¹⁶⁵ Certainly, counsel for the Department placed considerable store on the fact that the drafting of the legislation made it clear that the decision whether to license particular classes of place, potentially including the woman's home, was a matter for the Secretary of State through regulations.¹⁶⁶ Both this approach and also the strategy adopted by BPAS seem to accept the position set out by Lord Browne-Wilkinson in *Bland* that is preferable that Parliament should address the issues and the courts should only step in if there has been no opportunity for it to debate them. Thus, BPAS sought first to get Parliamentary consideration, and only sought a judicial ruling once it became clear that this would not happen. This sits comfortably with a constitutional theory in which Parliament is sovereign in matters of social and ethical controversy.

The second example seems to show a different approach to constitutional legitimacy. This is the series of cases around death and dying since 2009. We have already noted the difference between the judicial approach in *Purdy* to that articulated in *Bland* about the relationship between parliamentary sovereignty and judicial law-making and the discussion of this in *Nicklinson*. It can be argued that there is a similar difference in approach to be seen in the litigation strategies. The Director of Campaigns & Communications for 'Campaign for Dignity in Dying' has expressed a preference for Parliamentary law-making that seems to fit the same model as that expressed by BPAS:

The law will change on assisted dying, and it is in everybody's interests, both those sympathetic to change and those sceptical, that this comes about via Parliament and not the courts.... Until Parliament gets a grip on this issue the law will continue to be challenged in the courts and practice on the ground will evolve. There is an irony in this: if the vocal minority opposed to change continue to block legislation in Parliament, we could well end up with a more permissive system c/o (sic) the courts.¹⁶⁷

¹⁶⁵ We are grateful to David Lock QC for raising this question at the seminar. Penney Lewis makes a similar observation about the informal legal change in relation to non-therapeutic sterilisation, see n 6 above.

¹⁶⁶ *BPAS v Sec State for Health* [2011] EWHC 235 (Admin), at [20], discussing the Abortion Act, s 1(3A). This point was reiterated by Supperstone J at [30], [33] and [37].

¹⁶⁷ James Harris, 'A change in the law on assisted dying – it's not a question of if but how', 8 August 2013, at www.campaignfordignityindying.org.uk/pages/blog/580/a_change_in_the_law_on_assisted_dying_it_s_not_a_question_of_if_but_how_.html (last visited 23 August 2013).

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However, it should be noticed that, unlike the issue being raised by BPAS, there has been extensive Parliamentary debate of the issue on which this group campaigns. In a House of Lords debate, one Anglican bishop suggested the continuing campaign was ‘the old business of holding the referendum again and again until people give the right answer.’¹⁶⁸ It seems not so much a litigation strategy with a constitutional hierarchy of deference to Parliamentary sovereignty as a campaign on all available fronts. This may require a different understanding of the constitutional legitimacy of test-case litigation.

The judicial deliberations in the *Nicklinson* case indicate that one basis for such an understanding may lie in the role of the courts in relation to fundamental human rights. The Court of Appeal seems to have accepted the argument that deference to Parliamentary sovereignty did not absolve the courts of their obligations to consider the proportionality of interferences with human rights under Article 8 of the ECHR. As counsel for the applicants contended:

Since the Article 8 right is engaged, it is always necessary for the court itself to carry out the proportionality exercise even where the circumstances fall within the margin of appreciation. The Divisional Court was obliged to carry out that exercise and was wrong to leave the field to Parliament. Even if that is a legitimate stand for the court to take when considering whether or not to develop the common law, it is not appropriate where fundamental Convention rights are in issue because it is the court’s job to protect them.¹⁶⁹

Test case litigation on the basis of fundamental human rights might be seen as more easily legitimated than campaigns based on a sense of moral outrage. The courts may be understandably more reluctant to wait for parliamentary action in cases where the applicants’ personal situation is very pressing than in those where it is less directly affected. The application of rules of standing, the exercise of discretion to give or withhold permission to intervene in cases may all be influenced by this sort of consideration of how parties are connected with the issues before the court. Given the proliferation of test-case litigation in the health care context, developing an account of their constitutional legitimacy seems an important task.¹⁷⁰

Conclusion

We have shown that law-making in the context of health care and medical ethics is far more complex than the constitutional theory on which judges draw would suggest. Parliamentary sovereignty has become diffused through the authorisation of intermediate law-makers. Although the idea of deference to the jurisdiction of Parliament is attractive as an explanation of their role, it does not adequately explain the range of law-making decisions that we have identified. Further, we have identified a number of features of litigation that suggest that there are patterns within the work of legal personnel that influence the development of substantive law. There are also variations in the nature of the parties’ connections with the issues being placed before the courts that bear careful consideration. Each of these features needs to be accommodated in a more subtle account of constitutional legitimacy than has generally been articulated by the judges. The split in the Court

¹⁶⁸ Hansard, House of Lords, 3 February 2010, Col GC72. See also Lord Carlile at GC74.

¹⁶⁹ *R (Nicklinson) v Ministry of Justice* [2013] EWCA Civ 961 at [69]. The Court goes on to undertake the examination that is suggested, so seems to accept the force of the point even without express approval.

¹⁷⁰ To be examined in a paper ‘Interferors and Intervenors’ currently in preparation.

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of Appeal in the *Nicklinson* case demonstrates that this issue is still of current concern to the judiciary.

Our analysis has identified ‘tiers of relative invisibility’ in law-making. At one end of the spectrum lies Parliament; in its capacity as the legislature it is the most visible lawmaker. Nonetheless, there are some ‘hidden’ aspects to the development of legislation, including the role of democratic lobbying.¹⁷¹ John Kingdon’s work in the US suggests that this needs to be placed in the wider context of agenda-setting and public policy formation.¹⁷² Our analysis has shown that law-makers demonstrate a desire to secure democratic as well as constitutional legitimacy, and suggests that such a wider context is integral to providing a satisfactory account of the proper approach to law-making on the sort of controversial issues with which we are concerned.

Further along the spectrum of visibility, judges might be considered ‘partially hidden’ law-makers inasmuch as their rulings are set out in judgments and there are clearly recognised constitutional issues raised by *explicit* judicial law-making. Of course, judges must determine the application of law to the facts of the case before them. However, *how* they go about addressing specific cases is instructive, and some judges appear keener than others to push the law in particular ways, or directions. Next we have placed ‘intermediate authorities’, which have a defined legal role, (eg regulatory bodies such as the General Medical Council (GMC) and HFEA discussed in Part 1) but where the processes by which they develop legal norms are not necessarily transparent.

The players in litigation can be placed at the furthest end of the spectrum. It is not always clear whether litigants are seeking simply to resolve their own disputes or are litigating in order to further a particular agenda, perhaps as part of a sustained campaign by a particular organisation or group of interested parties. Sometimes such organisations (e.g. CORE or Campaign for Dignity in Dying) form the missing link between intermediate authorities and litigants, whereby ‘good’ cases might be sought by interest groups in furtherance of a strategic campaign. This is an area for further study.

Our consideration of litigation has also led us to conclude that there are patterns that emerge from the way in which the legal profession is organised that deserve closer scrutiny in order to see whether it has an influence on the substantive law. We suggest that a number of activities that can properly be said to ‘make’ law are obscured in the course of litigation and deserve to be uncovered. The contributions of counsel and instructing solicitors to the evolving shape of the law are often under-estimated, as we have shown through illustrative examples. This information can perhaps be drawn out from readily available sources, but a considerable knowledge of the field will be required to identify any patterns.

It seems clear, therefore, that the account given by the judges when explicitly addressing their role needs to be refined (at the very least). Our examples suggest that it may be possible to rely on an aspect of the Austinian theory that is rarely discussed, but could certainly be used to explain the judges’ understanding of their role; the idea of ‘tacit’ legislative commands. Here the argument is

¹⁷¹ Eg the Society for the Protection of Unborn Children (SPUC), whose campaigns have included sending plastic model fetuses, postcards and videos to MPs during the passage of relevant legislation, including the Human Fertilisation and Embryology Act 1990, as noted by Ms Short, *Hansard*, HC, Vol 171, col 257, and Ms Gordon, Vol 171, col 259, 24 April 1990. More recently, the Commission on Assisted Dying might be considered an example of a privatised form of lobbying, www.commissiononassisteddying.co.uk (last visited 05 August 2013).

¹⁷² J. W. Kingdon, *Agendas, Alternatives and Public Policies*, (Longman, 2011, updated 2nd ed).

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that where Parliament could intervene but chooses not to, then it can be assumed to legitimate judicial law-making by its acquiescence:

The rules that he [the judge] makes derive their legal force from authority given by the state: an authority which the state may confer expressly, but which it commonly imparts in the way of acquiescence. For, since the state may reverse the rules which he makes, and yet permits him to enforce them by the power of the political community, its sovereign will ‘that his rules shall obtain as law’ is clearly evinced by its conduct, though not by its express declaration.¹⁷³

This approach avoids the potential clash between Parliament and the judiciary over legislative sovereignty and is echoed in the language used by judges.¹⁷⁴ However, it is not clear how realistic it is to expect Parliament to exercise this oversight. It seems from the examples we have examined that the frustration of those campaigning around the ‘right to die’ with their failure to secure legislation has evinced some sympathy from the judges. It is also clear from our analysis of the law on human fertilisation and embryology that frequent Parliamentary intervention is unlikely. Arguably, the potential for this approach to provide a satisfactory constitutional account is dependent on some form of Parliamentary mechanism to keep the need for law reform under review.

We have also seen that an alternative, or perhaps complementary, way forward would be a constitutional account based on the principle that deference to Parliament is limited by the proper role of the courts in protecting fundamental human rights. However, this too is problematic. Partly because the European Convention Human Rights is not specifically designed to deal with health care issues, and the UK is not a signatory to the Oviedo Convention on Human Rights and Biomedicine (which does). Partly, this is because the contested issues with which we are concerned fall within the scope of the margin of appreciation and arguments about the limits of this doctrine bring judges into precisely the constitutional problems that the approach is trying to explain. The European Court of Human Rights (ECtHR) has shown similar anxieties about being drawn into a pro-life or pro-choice position in relation to abortion and right-to-die cases, as we have drawn out in our discussion of the English cases.¹⁷⁵ As noted in the *Nicklinson* case, the activity before the ECtHR around positive rights in relation to the ‘right-to-die’ is currently significant, but to date it continues to be reluctant to override democratic debate on this issue by resolving it as a matter of human rights.¹⁷⁶

Both a human rights model and a theory of democratic oversight through the idea of tacit legislative approval are worth further examination. Our study of hidden law-making has shown there is a very significant range of such activity in an area that is highly contentious. In our pluralist society it needs to be more soundly rooted in constitutional and democratic theory. Considerable work is required before the complexities of hidden law-making can be properly incorporated into the province of medical jurisprudence.

¹⁷³ J. Austin, *The Province of Jurisprudence Determined* (London: John Murray 1832), 28.

¹⁷⁴ n 96-98, above.

¹⁷⁵ See eg *Vo v France* [2004] 2 FCR 577 and *Pretty v UK* [2002] 2 FLR 45.

¹⁷⁶ *Haas v Switzerland* (2011) 53 EHRR 33; *Koch v Germany* (2013) 56 EHRR 6; *Gross v Switzerland* (application No 67810/10), 14 May 2013.

