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Principles of Medical Law, JUDITH LAING and JEAN MCHALE, Oxford University Press, 2017, 4th edn., hardback, 1344 pp., £225.00, ISBN: 9780198732518

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More than a decade ago, Alexander McCall Smith observed that in the 1980s, 'medical law, the discipline, in the United Kingdom at least, was in its infancy. There had been pioneering work by Ian Kennedy in London, Sheila McLean in Glasgow, and Peter Skegg in Oxford, but there were relatively few textbooks and a tiny literature in the academic journals'. McCall Smith contrasted this disciplinary infancy in the 1980s with a recognisable and respected maturity in the new millennium. Medical law had by then come of age and established itself as a cognate discipline, secure in its position as a unified field and replete with academic contributions. Examining the discipline in 2018, one might declare that it has not only come of age, it has actually become rather corpulent. Each medical law student, teacher and practitioner faces a tyranny of choice rather than a dearth of material. Anecdotally, on my office bookshelf, I tally six recently published textbooks of UK medical law – and this only a sliver of what is available on the market.² Each of these textbooks aims to educate the intrepid reader through an examination and thorough analysis of the legal and ethical issues in medicine and bioscience. These textbooks, covering the fundamental areas of the discipline (for example, the structure of the National Health Services, medical negligence, consent, confidentiality, end of life, abortion, organ donation, and biomedical research), are primarily written for those situated in academe, viz. students and teachers. The arrangement and tone of these books may vary in style,³ as might the coverage of the law in the four nations,4 but it is increasingly difficult to spot differences in substance and therefore settle upon (or recommend) one that reigns primes inter pares.

This assessment, however, does not extend to *Principles of Medical Law*, now in its 4th edition. When first published in 1998, under the editorship of Ian Kennedy and Andrew Grubb, it was apparent that this was not just another medical law textbook for those in the academe. On the contrary, it would constitute a comprehensive statement of the law, a *compendium*, with Kennedy and Grubb's primary intended audience 'the courts, legal

¹ A McCall Smith, 'Ken Mason – An Appreciation' in S McLean (ed), First Do No Harm: Law Ethics and Healthcare (Ashgate 2006) xv.

² See e.g. S Pattinson, *Medical Law and Ethics*, 5th ed (Sweet & Maxwell 2017); M Brazier, E Cave, *Medicine, Patients and the Law* 6th ed (MUP 2016); J Herring, *Medical Law and Ethics*, 7th ed (OUP 2018); E Jackson, *Medical Law: Text, Cases, and Materials*, 4th ed (OUP 2016); G Laurie, S Harmon, G Porter, *Mason and McCall Smith's Law and Medical Ethics*, 10th ed (OUP 2016); J Samanta, A Samanta, *Medical Law*, 2nd ed (Palgrave Macmillan 2015); M Stauch, K Wheat, *Text, Cases and Materials on Medical Law and Ethics*, 5th ed (Routledge 2015); N Hoppe and J Miola, *Medical Law and Medical Ethics* (CUP 2014); T Hope, J Savulescu, J Hendrick, *Medical Ethics and Law, Second Edition: The Core Curriculum*, 2nd ed (Churchill Livingstone 2008); J Montgomery, *Health Care Law*, 2nd ed (Oxford: OUP 2002).

³ Included in the category of stylistic difference is the choice of what to label this discipline, viz. medical law, healthcare law, and health law. I do not share the opinion that the latter labels are necessarily broader than the former. Indeed, the subject matter appertaining to all three labels considerably if not fully overlaps.

⁴ Most UK medical law textbooks focus largely or exclusively on the law in England and Wales.

practitioners, academic lawyers and others'. On the cusp of the new millennium, they gleefully remarked that medical law was metamorphosing from a tedious accumulation of medical negligence actions and professional disciplinary cases to treatment decisions cases, judicial review within the NHS, and guidance and guidelines from the Royal Medical Colleges. In other words, a new era in medical law was beginning to emerge; the discipline was both maturing and diversifying. These were 'times of genuine excitement for medical lawyers as the law has yet to fulfil its potential'. And in these exciting times, a different corpus of text was needed; 'not a book about the practice and process of litigation', but one that would 'expound the principles of law that govern medical practice and which form the corpus of medical law'. Unlike a textbook written primarily for the academy, which provides an overview of the principle areas of the subject - enough to enlighten but not enough to overwhelm - Kennedy and Grubb's book undertook a distinctly different aim. It would provide 'as comprehensive and, it is hoped, as authoritative an account as possible of the developing law in England and Wales'.8 Size is a rough but not unfair measurement of comprehensiveness. The first edition of *Principles of Medical Law* stood at over 900 pages; the 4th edition, published in 2017, has expanded to over 1,300 pages. At such a daunting mass, it is advisable to consult and cautiously dip into this compendium and not to deep dive or attempt to digest all chapters in one sitting.

Now edited by Judith Laing and Jean McHale, *Principles of Medical Law* remains the leading comprehensive and authoritative medical law book in England and Wales. As the discipline evolves and expands, so too, it seems, do the volume and number of chapters. If the first edition reflected the nascent ascendance of human rights in medical law, as reflected in the Human Rights Act 1998, treatment decision cases and judicial review within the NHS, it also reflected the relatively narrow definition of what medical law encompassed. Chapters in the first edition were divided into four parts covering 1) the health care system, 2) consent to treatment, 3) medical negligence, and 4) some 'specific issues' such as confidentiality and medical records, abortion, and ending life. By contrast, the 4th edition is divided into seven parts ('The health care system', 'Clinical negligence', 'Patients' rights', 'The law and reproduction', 'Medicinal products and devices', 'Regulating human material', and 'The end of life') and contains 22 chapters that comprehensively cover the field, from the beginning to the end of human life, from torts to patents, and confidentiality to mental health.

Given such breadth and depth, the reviewer of a compendium like this would be remiss in attempting to offer a whistle-stop tour of each chapter. Instead, I will assess this book based on what I think are the criteria for an *excellent* legal compendium, illustrating the criteria through discussion of several of the exemplary chapters. An excellent legal compendium should satisfy at least five criteria, and two points are worth stressing. First, a compendium does not have to make an original contribution to the field – that is the role of a monograph and article. If anything, a compendium should be complementary or supplementary to what already exists in other form. Secondly, while there may be some overlap between these criteria, they are nonetheless distinct standards that speak to different aspects of an editor's and contributing author's joint role and responsibility in the careful construction of a

⁵ I Kennedy, A Grubb, 'Preface' in *Principles of Medical Law* (OUP 1998) viii.

⁶ Ibid, vii.

⁷ Ibid.

⁸ Ibid.

compendium. As to criterion, the first is *coverage*. A compendium should comprehensively cover information about a particular subject such that the reader can gain satisfactory understanding of the principles, and indeed details, at issue. This said, a fine balance must be struck between coverage and concision. The reader must learn the applicable principles and receive intelligent analysis of the key issues without becoming overwhelmed by the intricacies of minute matters. Equally, a compendium must cover important developments in the law. As the readers of this journal well know, medical law does not suffer from stasis. The third edition of *Principles of Medical Law* was published in 2010. In an age where law textbooks are updated every three years, a seven-year gap suggests that each edition must be carefully and liberally seeded with fresh material.

This book certainly succeeds in covering the corpus of medical law. One is hard-pressed to think of a topic in the discipline that is not covered (discounting public health law, which is arguably a separate cognate discipline). Keith Syrett's opening chapter, for example, delves into the organisation of the NHS in England through consideration of its structure (including the general duties of the Secretary of State, the commissioning and provision of NHS services, and the NHS Constitution) and governance (for example, NHS priority setting, public and patient involvement in the NHS, governance of standards and performance).9 Syrett pays particularly close attention to the implications of the Health and Social Care Act 2012, which represents one of the biggest reorganisations of England's NHS in its history. Similarly, Christopher Hodges' chapter on 'The Regulation of Medicinal Products and Medical Devices' provides a superbly nuanced discussion of products and devices that are utilised in the medical context.¹⁰ Separate coverage is required for each of these domains. As Hodges observes, 'Many product types are regulated by specific, vertical regulatory provisions. Thus, medicinal products and medical devices are each subject to specific, and different, regimes' (p 890). His chapter deftly describes and analyses each of the regulatory systems, noting, for example, how the regulatory system for medical devices does not involve the pre-marketing assessment of a product by a medicines agency or the granting of a marketing authorisation by a competent authority, but instead puts the onus of ensuring and declaring that a product conforms to the legal essential requirements on the manufacturer itself. In brief, these two chapters exemplify the coverage criterion because they expand the traditional confines of how we think and write about the discipline of medical law. By drawing on both organisational and regulatory dimensions, they deepen our understanding of law.

Secondly, clarity of writing is essential because a compendium constitutes a comprehensive statement of a particular subject, but it must not be a repository of academic jargon or dense text that muddles the subject or befuddles the reader. A compendium must aim to enlighten through clear writing that avoids clutter. Mark Taylor's chapter on 'Confidentiality and Data Protection' exemplifies clear writing that enlightens. He investigates two questions in his chapter: first, when does the law allow a health professional to disclose information that is personal to the patient?, and, when does the law require a health professional to disclose information that has been generated through the provision of a

⁹ 'The organisation of health care', ch 1.

¹⁰ Chapter 17.

¹¹ Chapter 12.

patient's medical treatment? Through exploration of, *inter alia*, section 251 of the National Health Service Act 2006 and the Health Service (Control of Patient Information) Regulations 2002, the Health and Social Care Act 2012, the Data Protection Act 1998 and relevant case law, Taylor expertly and elegantly contours the private and public interests at stake in ensuring patients can trust their doctor to keep secrets safe, have confidence in speaking frankly to them, whilst at the same time recognising the social value in making patient data available to others in a regulated manner to improve care. The question, of course, becomes when, how, and for whom should patient data be made available. What are the contours of this regulated environment? Taylor explains:

Consideration of the law of confidentiality and data protection shows that a respect for confidentiality and privacy does not mean that data should not be used. It means that data should be used, but used *only* in ways that are consistent with a person's reasonable expectations. [...] The challenge is to identify the appropriate 'norms of exclusivity' that *permit* access to data under conditions that persons have reason to expect, accept, and are respectful of fundamental rights and freedoms: both their own and those of other members of the community. (pp 710-11, emphasis in original)

The third criterion is *specificity*. A compendium is not an academic treatise; it is a statement of the law. Readers foremost desire precise accounts of the principal cases and positions or arguments about the subject matter. There is no room for speculation. Specificity implies that the text faithfully records statements and facts, interwoven with analysis and intelligent opinion when warranted. Rachael Mulheron's chapter on 'Duties in Contract and Tort' is a prime example of precise legal analysis. ¹² She focuses her chapter on breach of contract (for example, treatment under the NHS and private treatment) and negligence and the duty of care (specifically to patients, third parties, and doctors engaged by others). Mulheron states that:

[w]ithin the NHS today it is generally accepted that there is no contractual relationship between a doctor (whether general practitioner or hospital doctor) and the patient. Equally, there is no contractual relationship between the patient and the hospital [...] where the patient is cared for. Any claim for damages based upon a breach of a duty lies only in tort and, in particular, in an action for negligence. (p 104)

Yet Mulheron does not stop there. She supplements this statement with a rich contrary argument to this 'orthodoxy' for why a breach of contract claim could still apply in the NHS context. For example, she argues that the statutory context within which a GP functions is not necessarily inconsistent with a contractual arrangement, and that 'in the case of a GP consideration may indirectly be provided by the patient since his inclusion upon the doctor's medical list will result in remuneration being paid by the relevant Local Authority to the doctor' (p 106). Mulheron's chapter also includes analysis of the topical issue of duties of care owed by doctors to genetic relatives, focusing on the *ABC* case.¹³ This is a live issue in

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¹² Chapter 3.

¹³ ABC v St George's Healthcare NHS Trust [2015] EWHC 1394 (QB), [2017] EWCA Civ 336.

UK law, with no settled position yet on whether healthcare professionals owe a legal duty of care to genetic relatives when healthcare professionals receive a patient's predictive genetic information and that information may have relevance to the genetic health of members of the patient's family.

Fourthly, all compendiums should *accurately* record information about a particular subject, but this is especially crucial in law. Inaccurate statements of the law are fatal. A legal compendium must, as of the date of its writing, faithfully and accurately record the law. In medical law, this imperative extends beyond law to policy and regulatory matters as well. Additionally, a legal compendium should underline the current topics or recent changes that impact the legal domain. In medical law, recent events have included ongoing structural changes to the NHS and the Supreme Court's decision in *Montgomery v Lanarkshire Health Board*, which endorsed the patient-centred approach to consent for treatment that had long been reflected already in most medical practice. Jean McHale's chapter on 'Consent to Treatment: The Competent Patient' is an exemplary recording and assessment of the law relating to consent, covering both the nature of consent and the elements of consent as it relates to adult patients with capacity. Consent to treatment forms the bedrock of medical law. McHale informs us that:

Under the common law, the legality of a medical treatment or procedure will largely turn upon whether the patient has given a valid consent to it. Treatment without consent may amount to the tort of battery or the crime of assault. Failure to provide information in relation to the risks of a treatment procedure may give rise to liability in negligence. (p 419)

She also reminds us that consent is:

the legal reflection of the primacy of the principle of respect for autonomy which takes precedence over the duty of care owed by clinicians to their patient. In this particular context, this notion might be better expressed as respect for a person's bodily integrity stemming from a right of self-determination. It is a "fundamental principle, now long established, that every person's body is inviolate". ¹⁶ (pp 419-20)

Consent, we learn, is 'a state of mind personal to the patient whereby he agrees to the violation of his bodily integrity' (p 433). McHale carefully distinguishes actual and inferred consent as forms of express consent, and details the steps to make a consent to treatment, or a refusal of treatment, legally valid. She also considers the impact recent changes in the law have had on consent, and she perceives that the law has evolved 'significantly over the last two decades' (p 450). While 'the broad parameters remain untouched—the idea that consent itself is protected through criminal and civil law and, moreover, that consent in law has its limits', we have witnessed broader and deeper 'engagement of patients and health care professionals with consent as a concept, both as a right and as a process' (p 450). Significantly, English law is increasingly aligning expectations of information disclosure with

¹⁴ [2015] UKSC 11.

¹⁵ Chapter 8.

¹⁶ Re F (Mental Patient: Sterilisation) [1990] 2 AC 1, [1989] 2 All ER 545, 563 (HL) per Lord Goff.

respect for human rights. McHale thus concludes that 'The implications of *Montgomery* for informed consent are still to be worked through by academic commentators and subsequently by the courts' (p 451).

Finally, a compendium must be *accessible* for its intended audience. In the case of *Principles of Medical Law*, this means that the editors and contributing authors are both 'perceptive and able navigators' (p vii), carefully imparting their knowledge and wisdom to medical law practitioners such that they can all adequately comprehend the law. Neil Allen's chapter on 'Care and Treatment of Those Lacking Decision-making Capacity' is a prime illustration of accessibility.¹⁷ It provides, in equal parts, information and wisdom regarding the law pertaining to patients who lack the capacity to consent for themselves and are, therefore, unable to exercise their right to self-determination. Allen records that there are three classes of such patients: children, adults who have impaired or disturbed functioning of the mind or brain, and young persons (aged 16 to 17) who, because of immaturity or mental impairment, lack the legal and/or the mental capacity to give consent (pp 484-5). He plumbs the depth of the law covering each of these classes, charts the meaning and value of best interests, and investigates the application of specific contexts to those lacking decision-making capacity (for example, abortion, and organ and tissue donation). In his expert analysis of the Mental Capacity Act 2005, Allen observes that:

The Mental Capacity Act 2005 has already been influential in modernizing the law [regarding the care and treatment of the incapacitated patient] ... But with regard to welfare, the Act expressly enables others to make best interests decisions for those lacking mental capacity. At some level, health and social care requires a legal mechanism for co-decision-making; otherwise the most vulnerable risk being subjected to harm, either by act or omission, which would make for a perverse kind of equality ... Cultures of paternalism in health and risk-aversion in social care prevail and its empowering ethos has not been delivered. (pp 561-62)

In the overall assessment, this fourth edition of *Principles of Medical Law* fulfils the criteria of an excellent legal compendium. It maintains its position as the most comprehensive one-volume text of medical law in the UK, and as the 'go-to' resource for academic medical lawyers and practitioners. I encourage the British readers of this journal, therefore, to keep a copy next to their desk for periodic consultation. As a brief coda, Kennedy and Grubb remark in their Foreword with strong understatement that the uncertainty of Brexit clouds the law (p vii). If it is to maintain its superior mark of distinction in the field, a 5th edition of *Principles of Medical Law* will necessitate careful attention to the legal consequences of Brexit through faithful adherence to the five criteria listed above. Moreover, as we enter these unchartered waters, we may need additional criteria in the compendium assessment matrix – conceivably 'Navigating regulatory uncertainty' and 'Monitoring emerging trends'.

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¹⁷ Chapter 10.