

Introduction

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The domains of medical law and ethics are distinct, yet inextricably connected. Whereas the law delimits the scope of activities permitted in a liberal society, ethics forms the basis whereby these activities subscribe to the values and moral principles society constructs. Social norms find their expression in ethics and often subsequently in the law (Posner 2000). Understanding the ways in which both shape the structure and function of the medical enterprise is the cornerstone of good professional practice, not to mention central to the humanitarian care of patients.

The societal and individual moral applications manifested in the law and ethics respectively, have together guided the practice of medicine since ancient times.¹ It would be naive to assume, however, that their relationship has always been a symbiotic one (Beauchamp 2004). Capron (1979) argues that law and ethics give rise to different forms of rights that can be used to make apparent a distinction between the two. He asserts that from the study of ethics in a medical context there emerge *moral* rights attributed to users of healthcare systems, which can be defended using philosophical paradigms such as Aristotelian virtue ethics, utilitarianism and Kantianism, to name a few, whereas from the law emerges *legal* rights, which assign enforceable duties and responsibilities 'among the competing, and often conflicting, interests of its citizens' within a legal system (Hodge and Gostin 2001).

Eras of rapidly evolving innovation within medicine – and within other scientific and technology disciplines to be sure – continue to underscore the immediacy of iterative reevaluation, reconceptualization and reform in the law in order to keep apace with medical progress. In this way, ethics provide a theoretical and conceptual framework for clarifying – but also problematizing – emergent laws that are both jurisdiction-specific and international in outlook in the wake of contemporary controversies. Such laws, therefore, become useful elements of scholarship and offer a methodology for contextualizing medical advancement in conversation with its ethical implications (DeGrazia 1999). This book enters into these discussions by exploring the application,

¹ The first documented medical law was written in the Code of Hammurabi in 1772 BC, which read: 'If a physician make a large incision with the operating knife, and kill him, or open a tumor with the operating knife, and cut out the eye, his hands shall be cut off.' Discussions of ethics and value principles in medicine were largely coincident with the emergence of medical science itself, particularly in Ancient Greece (see Jones 1924).

scope and role of medical law and its regulatory norms in laying the groundwork for ethical policy and practice in healthcare. It attempts to find cohesion between medical law and ethics, debating new practical approaches to theoretical problems. Though the study of medical ethics is multidisciplinary by nature, this book unifies the otherwise incredibly diverse perspectives of interlocutors in the field under the auspices of medical law. It sets out to bring the complexities of this intersection to the fore of novel modalities and systems of care made possible by, *inter alia*, the genomic revolution and data-intensive sciences. Engaging with such themes is, we suggest, critical to navigating an increasingly data-driven healthcare system (Ozdenir *et al.* 2011), while preserving the ethos of rights-based medicine and optimizing health outcomes for populations globally. The Handbook, therefore, offers rich discussions of classical and novel ethical issues in medical jurisprudence from authors with a variety of theoretical perspectives, approaches and expertise. This diversity intentionally seeks to represent the key emerging domains of the field of medical law, and the breadth of ethical approaches purposefully addresses the many challenges of these new domains.

The authors of each chapter present the fundamental ethical and legal aspects, as well as discuss key international and national documents governing the activities in their field. Many offer an overview of the legal history and evolution of legal thinking, verifying their influence on the current legislative climate in which these issues are being examined. The chapters offer relevant case analyses, illustrating the practical applications of theoretical and normative ethics within a range of national and supra-national jurisdictions. The emergence of case law and precedence – as well as the formation of public opinion in response – alert us to the significance of legal processes in redefining socioethical norms and standards. Finally, each chapter carves a space for forward thinking and reflection. Authors provide critical commentary on some of the newest developments in their respective fields, elucidating the ways in which medical law governs advances in healthcare and clinical practice. It is called a Handbook not to put forth protocols or procedural guidance in deploying the law to resolve ethical conflicts. Rather it serves as a detailed compendium of legal instruments and ideas, both current and historical, in responding to matters of pressing ethical import in healthcare.

The Handbook takes up a number of these compelling issues and arranges them in four categories. *Rights of Persons* comprises chapters that interrogate the protections and freedoms of patients in their interaction with the healthcare system, including the traditionally more vulnerable categories of persons such as children (Chapter 5) and the mentally disabled (Chapter 7). It touches upon long-standing principles of bioethics, including consent (Chapter 3) and confidentiality (Chapter 4) and brings to light the contemporary challenges of preserving these traditional fixtures in the doctor–patient relationship. To this point, an entire category of the Handbook is dedicated to the *Professional Relationship*. Ries investigates the organizational infrastructures and healthcare mandates that guarantee adherence to, and maintenance of, professional standards of practice (Chapter 10). Moreover, the chapters in this section make clear that protecting patient safety is the focal point of professional standards. Khoury (Chapter 11), for example, puts into sharp relief the serious ethical and legal consequences when healthcare professionals fail to meet such standards in preventing nosocomial infections, and contextualizes the emergence of patient safety legislation in the aftermath of the tort frenzies that followed.

As its name suggests, *Medical Interventions and Emerging Technologies* highlights some of the frontiers of medical science, and the ways in which researchers and policymakers alike are attempting to chart their sociotechnical futures. From creating online clinical interfaces through telemedicine (Chapter 15), to developing high-precision techniques in assisted reproduction (Chapter 13), novel technologies and machines are transforming the landscape of healthcare delivery (Kahvejian *et al.* 2008). In turn, the law and regulatory mechanisms are challenged to evolve in parallel with

the technological sophistication witnessed in recent years. As life expectancies and quality of life are projected to increase with greater adoption of technology – though almost exclusively in countries able to invest in costly research and development – the need for international dialogue on access and policy harmonization has never been more immediate.

Likewise, multidisciplinary collaboration is required to translate research discoveries into routine medical practice. Our ethicolegal engagement with the increasingly genome-oriented objectives in research and care is reflected in *From Bench to Bedside*. In Chapter 17, Chalmers argues that the regulatory and legislative governance of medical research must adapt ethical frameworks better suited to preserve scientific freedom, and minimize risks unique to research participation in the ‘genome era.’ He underscores the fact that little more than a decade after completion of the Human Genome Project, diagnostics and treatment strategies are chiefly centering on a patient’s genomic profile, most notably in rare genetic diseases (Ng *et al.* 2010; Bamshad *et al.* 2011) and cancer (Lander *et al.* 2001; Roychowdhury *et al.* 2011; Curtis *et al.* 2012). Sequencing techniques and an explosion in computational power have blossomed into entirely new research and clinical subfields, such as pharmacogenomics (Chapter 11), nutrigenetics (Fenech 2014; Mutch *et al.* 2005) and bioinformatics (Ouzounis 2012).

Where legal apparati purported to regulate new technologies often face issues of classification and applicability, the role of the law in safeguarding public health can raise questions of scope and competing notions of rights. ‘The crux of public health,’ Gostin maintains, ‘is a public or governmental entity that harbors the power and responsibility to assure community well-being ... perhaps the single most important feature of public health is that it strives to improve the functioning and longevity of populations’ (2008). In *Public Health and International Health Systems*, authors provide an international take on models of public health law, and its purpose and permanence in augmenting a human right to health. Through a rights-based lens, Munyi canvasses the issue of access to essential medicines in the developing world (Chapter 22), where international instruments expand such access. Because public health *practice* is concerned with optimizing the health of populations, it is fitting that good public health *policy* recognizes the different sociocultural and regional constructions of health and wellbeing across the world. Kaan (Chapter 23) explores this complicated relationship by analyzing the protective capability of public health law between predominant medical traditions in the Global North and South.

Notwithstanding the plethora of legal structures and interpretations represented in this Handbook, a number of common motifs weave throughout the chapters. When examined together, they isolate the points of theoretical convergence that allow medical law and ethics discourse to complement each other toward the provision of effective and ethically sound healthcare.

1.1 Human rights and professional accountabilities in the law

Many contributors to this Handbook employ rights-based rhetoric to defend the vehicle of accountability espoused by medical law. December 10, 2013 marked the 65th anniversary of the 1948 Universal Declaration on Human Rights. An undoubtedly poignant moment in history, it was an opportunity to restore faith in humanity through collective agreement and codification of the inviolability of human life. For some, reference to human rights doctrines is implicit in the framing, formulation and protection the law offers its respective constituents. For others, these principles act as the starting point from which to assign legal accountability in facing ethical uncertainty. As was true at the time of its ratification, political will is necessary to actualize the Declaration’s principles in national laws governing medicine and healthcare.

Annas (Chapter 2) describes this translational process in the context of leveraging the triad of bioethics, law and medicine to devise effective healthcare legislation. He argues that not to acknowledge how the three in fact coexist and inform each other is to create irresponsible law at best. Nowhere is this potential incongruity between the principles of human rights and the law starker than in drafting antidiscrimination legislation for communities of people with disabilities. Indeed, Hendriks (Chapter 6) affirms the frequent violations of human rights within this population, where patients are largely devalued and disregarded by the healthcare system.

Health professionals personify the actualization of rights through practice, and mediate the triangulated relationships Annas identifies. The role of the health professional, therefore, as both a specific technology user and care deliverer, is a centerpiece in ethics discourse on professionalism. Rothstein explores this theme in Chapter 4. He examines the unique transformations in the uptake and dissemination of health information through online networks and social media platforms such as Facebook and Twitter, and how the connectivity they allow are in fact reshaping standards of patient interaction. Moreover, with greater online presence comes enhanced privacy risks and the need to develop advanced information storage platforms. Others share this view, identifying the added ethical implications for healthcare professionals whose online presences have, more than ever, broadened their visibility and ready accessibility to patients (DeCamp *et al.* 2013).

Freckelton and Bennett's discussion of the migration of healthcare professionals and patients across national borders (Chapter 9) raises new questions in the way of redefining a professional ethic of care. They chronicle recent trends in the regulation of medical practice, charting a move from professional self-regulation through to contemporary (read external) models of oversight and accountability.

Similar transitions dare us to consider *quis custodiet ipsos custodes?* or, 'who will guard the guardians?'² Do our professional codes of ethics – like the law, purported to be reflections of the values and virtues society deems essential to the realm of professional practice – indeed protect healthcare users from abuses of the system or clarify legal accountability where ethical ambiguity dominates?

The authors in this Handbook do not resolve these pending questions *per se*. Perhaps more ambitiously, what resonates from their analyses is a demand for reconsidering the basic notions of professionalism and revisiting the fundamental purpose(s) of medicine. In doing so, the authors offer grounded perspectives on the extent to which the law ought to build on these foundational concepts so as to draw legal theory and clinical practice into healthier confines.

1.2 Reevaluating foundations

Implied above is how the law serves as a practical instrument to ground bioethical and human rights principles in the realities of healthcare delivery. It is from this practical standpoint that the conception of professionalism and a professional ethic of care emerge. In a healthcare context, there are three spheres of ethical priority setting that (ideally) converge on patients' best interests: that of the patient, the professional and the institution. Gastmans and Nys confirm this in Chapter 8. Through exploring the ethical tensions of end-of-life care in neonates, they validate

² Though not directly quoted in his volumes, this question first appeared in Book Three of Plato's *Republic* before the Roman poet Juvenal includes it in his *Satires*. Plato's Socratic disciples ponder who will oversee the authority of those charged with overseeing everyone. It is often interpreted as musings on ending political corruption, but in the text it is deliberately referring to ensuring marital fidelity within the polis. They ultimately conclude, 'it would be absurd that a guardian should need a guard.' (See Besley and Robinson 2010; Book III, XII, 403E, p. 264 (Greek) and p. 265 (English), in Plato, *The Republic*, vol. 1, trans. P. Shorey. New York: G. P. Putnam's Sons 1930).

the true challenges in determining the moral permissibility of withdrawing care, at what point, and to what end. The authors contend that medical prognosis – and the courses of action it inspires – is but consideration as part of the ethical analysis that determines the child's best interest. Tensions arise when healthcare professionals find they must allow assessments on quality of life to become the province of, in the case of neonates, parental expertise. Oftentimes, these views can denounce Western medicine's obsession with curative rigor and rigid definitions of futile treatment.

That sophistication of medical technology, namely in genetics/genomics, can convert modalities of care and professional norms is key to Thorogood and Knoppers' thesis in Chapter 18. They argue how the notion of best interests can be problematic for healthcare professionals hoping to offer preventative care through genetic surveillance to pediatric patients and their families. Until recently, searching for particular biomarkers known to predispose patients to disease had been the hallmark and promise of genetic testing. Increasingly, the discovery of secondary or incidental findings using whole genome sequencing in clinical research (discussed in terms of professional duties to inform in Chapter 12) fuels widespread debate on the meaning and application of the respect for persons principle as it relates to a patient's or participant's best interest. The lack of professional guidance in disclosing such findings prompted a number of recent guidelines from the United States (Green *et al.* 2013; United States Presidential Commission for the Study of Bioethical Issues 2013) and abroad (Viberg *et al.* 2014).

The touristic undertone with which Sipp describes emerging stem cell therapies (Chapter 24) begs questioning whether medicine is in peril of becoming overly commoditized by for-profit entities. Patients in pursuit of the fountain of youth or a miracle cure need not look any further! Popular marketing campaigns boast the (dubious) regenerative promises of their stem cell products, many of which fall through the cracks of federal licensing and safety regulations. Stemming the tides of clinical and direct-to-consumer (Chapter 16) genetic testing likewise accentuates the law's dual responsibility for delimiting the availability of health services from private companies, and safeguarding autonomous rights to information concerning one's genetic material or health status. However, the difficulty of establishing clinical validity and utility for many of these new tests means that the information generated from them can sometimes cause more harm than good (Dickensen 2014; Cornel *et al.* 2014).

Beak and Isasi highlight similar challenges in product classification for new drugs and therapeutics in Chapter 14 on regenerative medicine. In a detailed examination of the regulatory pitfalls facing developers – including enormous time constraints and costs – they show how uncertainties in classification have a corresponding effect on the required scientific evidence to approve novel therapeutics for patient use. The failure of such classification schemes under current regulatory frameworks illustrates the dissymmetry between the law and new technologies, as the former 'attempts to govern [technologies] with an antiquated grasp of their meaning' (Askland 2011).

1.3 A brave new framework

The analyses presented in this Handbook mount increasing evidence of the need for more coherent legal frameworks that better reflect the ethical dimensions at the intersection of clinical research, healthcare and the law. Authors contend a more reflexive and versatile legal gaze is needed, one that takes into account history as either a cautionary tale – which Lobato de Faria and Cordeiro tell with respect to the public health initiatives and the economy in Chapter 20 – or an optimistic indication verifying the successes of anticipatory governance and 'norm entrepreneurship' that Aginam promotes in Chapter 21. Implicit in his arguments, and others, is the importance of regulatory harmonization and the interagency collaboration

among policymaking bodies (e.g. the World Health Organization (WHO)) that play a key role in its negotiation. Often, these bodies serve as collaborative grounds for the shared ideals and principles of the international community to inform jurisdiction-specific regulation. Thorogood and Knoppers make this connection in describing the ways in which micro and macro levels of governance frame the ethical issues that demand legal scrutiny. Indeed, online health information privacy presents us with one such realm where micro and macro governance must complement one another if patients are to receive equal protection under law. In Chapter 13, Ravitsky and Dupras-Leduc likewise cite reproductive tourism as an example of the possible consequences for maintaining varying levels of regulatory stringency between these micro and macro domains of governance.

1.4 Conclusion

The particular scope of legal frameworks established to respond to emerging issues in medicine and healthcare are a key focus for many chapters in the Handbook. It is through the use of effective yet nuanced and harmonized legal frameworks to justify legislation that we can ensure patients are cared for in an ethically responsible manner. Whether calling for the development of a new framework, or revisiting the foundational aspects of preexisting ones, the authors testify to the significance of frameworks for grounding medical law in normative ethical theory. Yet the law remains conceptually distinct from ethics. Healthcare professionals, institutions, and legal scholars need, therefore, to embrace opportunities for multidisciplinary collaboration on what constitutes ethical healthcare and research if for no other reason than to acknowledge the many facets and moving parts of providing it to patients, their families, and research participants. The sheer complexity and significance of the ethical issues identified through the various chapters of this Handbook speak to the need for building international consensus rather than working in jurisdictional silos.

In an increasingly globalized and connected world, the Internet has created a technological frontier for the masses that can be harnessed to improve healthcare delivery everywhere and enable mobilization around these efforts. Though the possibilities seem infinite, ethicolegal discourse is critical to constructing a morally permissible utilization path. This Handbook advocates that to better understand the role of medical law and ethics in the promotion of health, we must be able to recognize where our professional commonalities and differences lie. Only then can we begin to imagine a society that prioritizes public health as a global public good, for example, and ensure the continued relevance and legitimacy of international policymaking bodies. The array of ethical discussions that comprise this Handbook uniquely attest to the regulatory harmonization that is possible when efforts to enact legal reforms mirror the degrees of innovation and creativity witnessed in technology development.

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