David Orentlicher and Tamara K. Hervey (eds), The Oxford Handbook of Comparative Health Law, Oxford University Press, 2021, Hardback, 1116 pp, £, ISBN 978-0-19-084675-6.

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Health Law and Comparative Law are two areas which receive continuing attention about their respective scope, and while policymakers and academics alike routinely draw on insights from other countries and systems in analysing and developing health law and policy, defining "comparative health law" is no mean feat. This may be explained in part by healthcare (provision and access) remaining "peculiarly and tenaciously local in its character",[1] as distinct even from ancillary fields (such as the pharmaceutical sector) which may be global in nature.

The sheer reach of "health law" - encompassing in very broad terms assisted reproductive technologies to assisted dying - indicates its universal nature, as does its common interdisciplinary pairing with bioethics. Once it is accepted that health is subject to myriad considerations across the world, then comparison becomes not just useful, but essential both for academic research and policy learning. Indeed, one of the many insights from the Covid-19 pandemic is surely how multifaceted "health law" can, and should be: encompassing not only the potential for re-evaluating ethical underpinnings of healthcare access, but also the influence and effects of supranational legal systems, as well as questions of healthcare system organisation at a national level.

In the past decade alone, comparative studies have engaged with issues as diverse as compelled obstetric intervention and competition reforms in predominantly European countries,[2] and justice and access to healthcare from an Anglo-Saxon perspective encompassing North America and the UK.[3] These studies are developed, to varying degrees, against the wider evolving backdrop of EU health law, global health law, and health and human rights emerging as disciplines in their own right[4] which can also help inform national and comparative analysis.[5] A related further literature sees encyclopaedic framings of how different countries respond in legal terms to health and medical issues.[6]

The existence of the level of interest in learning from others' experiences shifts the emphasis from *whether* to compare, to the key questions of *what* and *how* to compare, and the aforementioned various recent literature engage with these questions to varying degrees. The latter question of *how* to compare is perhaps the most difficult: framings such as the triangular

[1] Timothy Stoltzfus Jost, 'Comparative and International Health Law', 14 Health Matrix 141 (2003).
[2] Samantha Halliday, *Autonomy and Pregnancy – A Comparative Analysis of Compelled Obstetric Intervention*, Routledge 2016; Mary Guy, *Competition Policy in Healthcare – Frontiers in Insurance-Based and Taxation-Funded Systems*, Intersentia 2019.
[3] Eleanor D. Kinney, *The Affordable Care Act and Medicare in Comparative Context*, CUP 2015; Sabrina Germain, *Justice and Profit in Health Care Law: A Comparative Analysis of the United States and the United Kingdom*, Hart 2019.
[4] See, for example, Tamara K. Hervey and Jean V. McHale, *European Union Health Law – Themes and Implications*, CUP 2015; Lawrence O. Gostin, *Global Health Law*, Harvard University Press, 2014; Brigit Toebes, Mette Hartlev, Aart Hendriks, Katharina O Cathaoir, Janne Rothmar Herrmann, Henriette Sinding Aasen, *Health and Human Rights* (2nd Edition), Intersentia, 2022.
[5] See, for example, Irehobhude O. Iyioha and Remigius N. Nwebueze (eds), *Comparative Health Law and Policy – Critical Perspectives on Nigerian and Global Health Law*, Ashgate 2015.
[6] Notably the International Encyclopaedia of Laws (IEL) Medical Law collection edited by Professor Herman Nys. https://kluwerlawonline.com/Encyclopedias/IEL+Medical+Law/724

relationship between patient, healthcare provider and healthcare financer[7] (alternatively, the 'macro', 'meso' and 'micro' levels), or between the systemic and individual levels[8] have both benefits and limitations. Common understandings of comparative law methodology which draw on concepts such as 'functional equivalence' or 'transplants' of law also provide useful frameworks, but comparison which offers scope for learning from other countries and healthcare systems may be influenced less by the type of legal system (civil/common law), and more by factors such as the type of financing underpinning healthcare provision (with the classic distinction drawn between insurance-based and taxation-funded systems). This also merits consideration when seeking to understand the effects of transnational legal systems at a domestic level with regard to healthcare reform. Thus comparative health law can be considered to extend beyond questions of how a particular issue is addressed at a national level because this distinction (e.g. between common and civil law) may, or may not, be the determining aspect; factors such as healthcare system type, or the interaction between national, regional and transnational levels may be equally instructive.

Orentlicher and Hervey engage with these considerations and more in the *Oxford Handbook of Comparative Health Law*, both in their clearly delineated and well-defined Editors' Introduction, and with the effective structure throughout which incorporates "paired" and joint, co-authored chapters by US and European experts on an extensive range of topics. Orentlicher and Hervey modestly acknowledge the limits of the transatlantic focus, but given the scope for the US and European countries to serve as comparators in a variety of health contexts, this can be seen more as a pragmatic scoping decision rather than a limitation of this impressive volume.

Consistent with the wider Oxford Comparative Law Handbooks series, this Handbook offers a range of important original research by acknowledged experts in the field, so provides insights for a range of scholars, both within law and beyond. Many – if not all – contributors will be familiar names to a health law audience (broadly defined), but their combined expertise indicates the breadth and depth of the discipline of *comparative* health law.

Accordingly, the structure in overview offers an accessible way in to the diverse topics via parts which encompass paradigms of healthcare systems, as well as topics such as preventing and treating ill health; regulating medical treatments; and healthcare at the beginning and end of life. This structure is not only familiar to health lawyers, but provides an accessible way into the wider subject for readers across law and other disciplines.

Part I of the Handbook opens with a transatlantic conversation about paradigms of healthcare systems, law and regulation by Alceste Santuari and William Sage. This relatively informal format is structured around six paradigm concepts – quality versus accessibility; individual liberty, "health citizenship" and the right to health; market competition and economic productivity; "health justice" and integrated social services; regulation and provider governance and federalism and healthcare regulation. This enables the authors not only to move beyond more "simplistic caricatures" of the state predominating in European healthcare systems and the market in US healthcare, and also to highlight profound differences between the approaches, but also to consider how both groups have addressed the COVID-19 pandemic. Concerns about attempting to conceptualise a "European" healthcare system are addressed by

[7] See, for example, André Den Exter (eds), *European Health Law*, Maklu 2017.
[8] See, for example, Hervey and McHale (2015) above n4.

discussions of federalism, and examples representing different healthcare system types (e.g. Italy and the UK).

Part II, "Preventing ill health", comprises a comprehensive overview of public health law. This section comprises a carefully-curated array of topics across the US (well-represented by Wendy Parmet) and Europe, both in terms of the EU (by Markus Frischhut and Amandine Garde) and the wider sense of the European human rights context (by Brigit Toebes). A useful introductory chapter sets out the structure of the section across three paired, but distinct US/European-focused paired chapters addressing the topics of communicable diseases (Parmet / Frischhut), non-communicable diseases (Parmet / Garde) and social determinants of health / socioeconomic health inequalities (Parmet / Toebes). The introduction is useful for not only providing a signpost for the section, but also in acknowledging not only "public health law", but also "European" (as including the EU, WHO Europe, the Council of Europe and the European Court of Human Rights).

Part III, "Treating ill health", offers an ambitious coverage of four diverse broad topics: access to the healthcare system; regulation of health care services, facilities and transactions; the treatment relationship: confidentiality, consent, and conflicts of interest; and medical malpractice. This section again adopts the structure of introduction and paired chapters on specific themes, which is particularly helpful in navigating the diversity of topics in this area.

The opening subsection, "Access to the Healthcare System", sees André Den Exter and Keith Syrett covering Europe and Mark A. Hall and Allison K. Hoffman examining the US. In their introduction, the four authors acknowledge the magnitude of their task and the distinctions which emerge, notably between the underpinning of access to healthcare by private law doctrine in the US and by constitution and statute in Europe. Scope for divergence is highlighted as more instructive than similarity, although the commonalities of lawful residence (or "citizenship") determining eligibility for coverage and the challenge of increasing costs are also presented. Hoffman and Hill's chapter foregrounds inequity as characteristic of US healthcare by reference to developments in health insurance (via Medicare, Medicaid and the Affordable Care Act) and the implications of inequitable coverage. The treatment relationship is also examined in terms of its constituent parts: constitutional rights of access and common law and statutory duties to treat. Den Exter and Syrett structure their examination of access to healthcare in Europe around the key characteristics of Social Health Insurance systems (including examples from the Netherlands, Germany and Switzerland) and National Health Systems (such as Spain, but notably the UK (and specifically England within this). Further focus is given by questions of when healthcare can be accessed in the different system types, and the duty to provide healthcare, as well as eligibility – with identification of "pan-European" (and beyond) instruments such as the European Social Charter and the International Covenant on Economic, Social and Cultural Rights.

"Regulation of health care services, facilities and transactions" is an area which sees wide divergences within Europe and this sub-section comprises paired chapters on three discrete themes. Deidre Madden and Isaac D. Buck address the regulation of professionals and facilities in, respectively, Europe and the US. Overlaps between the two can be seen with the distinction drawn between the ex ante focus on quality in regulating professionals and facilities and ex post medical malpractice regimes, the definitional limitations around the practice of medicine and the need to balance appropriate and cost-effective regulation to protect patients while

maintaining public trust and confidence. In contrast, distinctions can be seen with the greater regulatory structures for (private) hospitals in the US and the lesser scope for "consumerism" in Europe. Leading on from this comes Okeoghene Odudu's and Thomas Greaney's analysis of markets, and specifically, respectively, how EU competition law and US antitrust law operate in the healthcare context. Greaney and Odudu's introduction outlines common challenges, notably, the sharp increase in healthcare provision costs, and tackle issues such as the "prevalent but misleading" caricature of markets as the exclusive driver of US healthcare, and an anathema in Europe. The sub-section concludes with Tracey A. Elliott's and Joan H. Krause's examination of healthcare fraud and abuse in, respectively, Europe and the US. Having acknowledged the universality, dynamism and persistence of healthcare fraud, issues such as definitional variation of "fraud" and "abuse" with distinctions existing across different European countries (such as the UK and France), as well as between Europe and the US. In addition to outlining the relevant legal frameworks, the authors also examine ethical and operational issues, offering a further dimension to their comparison.

"The treatment relationship: confidentiality, consent, and conflicts of interest" combines the "paired chapter" approach to conflicts of interest with standalone chapters on medical information and patient autonomy, capacity and consent in connection with children and vulnerable adults co-written by authors based in the US and Europe. Sharona Hoffman and Jean Herveg's examination of privacy and integrity of medical information compares major regulatory initiatives – the US Health Insurance Portability and Accountability Act (HIPAA) privacy rule and the EU General Data Protection Regulation (GDPR) and Council of Europe law to frame analysis including of distinctions between privacy, confidentiality and data security, as well as contemporary legal challenges. Jessica Berg and Emma Cave's analysis of patient autonomy, capacity and consent for children sees an overview of children's rights in the US and a focus on England and Wales as representing Europe alongside international and regional human rights law to consider particular issues such as the best interests standard and advance directives. Mary Donnelly and Jessica Berg's examination of vulnerable adults highlights the country-based approaches to determining capacity in Europe (with reference to wider EU and ECHR frameworks) and the state-based US legal framework, and how these apply with regard to concepts such as informed consent and therapeutic privilege. Sunčana Roksandić and Richard S. Saver then introduce key elements in defining conflicts of interests and perceptions of undue influence before providing comprehensive analyses of, respectively, the position in Europe and the US.

"Medical Malpractice" comprises a single chapter by Karl Harald Søvig and Barry Furrow on medical liability, in which they provide an overview and case studies of system differences. This is then supplemented with more in-depth analysis of, respectively, Europe (both in terms of wider EU/EEA/Council of Europe frameworks and a focus on Scandinavia) and the US.

Part IV, "Regulating the Development and Use of Medical Treatments", comprises four subsections: Human Experimentation and Research; Pharmaceutical and Medical Devices Law; Control, Use, and Allocation of Body Parts: Organs, Human Tissue, Blood; Ethical and Legal Implications of Advances in Genetics. Again, the analyses make use of both joint chapters and "paired chapters" to explore the US and European approaches.

Carl H. Coleman introduces research with human participants by considering common aspects such the tension between the benefits and ethical dilemmas emerging from such research,

before a more in-depth analysis of the US legal framework (comprising various federal and state regimes), with David Shaw and David Townend providing the European counterbalance with an examination of EU "hard" law in this area. This is further complemented by a joint chapter by Coleman and Graeme T. Laurie examining the US and European (both EU and national level) approaches to biobanks.

Erika Lietzan, Aurélie Mahalatchimy and Patricia J. Zettler introduce the broad grouping of "medical products law" and the distinction between US and EU approaches, while recognising the role of state law and individual Member State law. Their respective chapters focusing on the EU (Mahalatchimy) and US (Lietzan and Zettler) then provide a deeper dive into regulating medicines and regulating medical devices, including insights into innovative medical treatments (such as 3D printing and cell and tissue therapies) that challenge current paradigms to explore what the future may bring in this exciting and evolving area.

Justine Pila's discussion of property in human body parts sets the scene for the sub-section on control, use and allocation of body parts and introduces US, European and international frameworks governing this area.

Joaquin Cayon-De Las Cuevas and David Orentlicher examine organ transplantation, from universal concerns about shortages of organs for transplantation, via the European (EU/Council of Europe/national) and US governance approaches, to considering issues such as living and deceased donation and financial incentives associated with organ trafficking.

Natalie Ram and Stéphanie Hennette Vauchez make effective use of the "paired chapter" format to examine "incomplete commodification" in the development of markets in body parts and the marketization of, inter alia, gametes and blood. This enables a juxtaposition of common lived experiences with differences in legal frameworks between the US (Ram) and Europe (Hennette Vauchez), with the latter revealing a further dimension in the tension between the EU's market focus and the Council of Europe's human rights approach.

Maxwell Mehlman, Mette Hartlev and Sonia Suter's analysis of genetic analysis and genetic testing is introduced by considerations of the legal doctrine of informed consent in the US and Europe and how this may become more difficult to obtain amid the growing availability and complexity of genetic analysis. Further issues covered in examinations of the US (Mehlman and Suter) and Europe (including the EU and Council of Europe) (Hartlev) include the distinction between genetic analysis for adults and children, and the regulation of genetic testing in clinical and "direct-to-consumer" environments.

Part V, "Healthcare at the beginning and end of life", is framed around two discrete topics: reproductive rights, and the law of death and dying, and both the "paired chapter" and joint chapter formats are used.

I.. Glenn Cohen and Emily Jackson introduce their discussions of the right(s)[9] to procreate and assisted reproductive technologies (ART) by juxtaposing comparisons of the ECHR and US constitution forbidding involuntary sterilisation, and identifying issues such as most patients being "self pay" when accessing ART, and how to deal with cross-border travel for reproductive technology services. Both the Europe (Jackson) and US (Cohen) chapters are

[9] Cohen identifies rights (plural) to procreate based on differing parental identities – gestational, genetic and legal.

framed around differing approaches to regulating reproduction, the role of rights and rights-based legal claims regarding ART, the different ways in which professional self-regulation, tort law and detailed regulations in statute and "soft law" guidance in Europe and the US, increasing numbers of people engaging in cross-border reproductive care, and growth of markets in fertility.

The introduction to Janne Rothmar Herrmann and Elizabeth Sepper's discussions of the right to avoid procreation and the regulation of pregnancy outline the boundaries of abortion law and touch on diverse issues: autonomy, health and medicine, equality, family life versus private life, negative and positive rights, and foetal life. Rothmar Herrmann writes about the European perspective, encompassing ECHR case law and its wide margin of appreciation in this area, and national approaches to abortion, from the 'on-demand model' found broadly in Scandinavian countries and Italy, the 'illegal-unless model' of England and the Netherlands, and the 'strictly illegal model' associated with Poland and Malta. Further consideration of Council of Europe law is seen with the Oviedo Convention and the regulation of pregnant women. Sepper's analysis of the US perspective naturally includes *Roe*, and the constitutional and statutory law approaches protecting the right to avoid procreation, but also protections for, and the regulation of pregnancy.

The final chapter, "Decisions at the end of life", by David Orentlicher and Judit Sándor, frames analysis of European and US approaches around four types of decisions at the end of life: the right of competent patients to refuse medical care; withholding or withdrawing treatment from patients who lack decision-making capacity; medical aid in dying; and the authority to withhold desired medical care from patients on grounds of medical "futility". These decisions all attract sensitivities, and see a diverse range of legal responses, from prominent cases such as *Gard* and *Pretty* in the UK, *Cruzan*, *Glucksberg* and *Quill* cases in the US, ECHR cases such as *Haas v Switzerland*, and statute in the Netherlands and Belgium.

Overall, this Handbook is to be highly commended on various levels: from the impressive roll call of 46 leading contributors bringing diverse national insights as well as transnational expertise, via the sheer diversity of subjects covered, to the clear demonstration of differing approaches to comparative analysis.

The broad distinction in format – of "paired chapters" and joint chapters – is effective and avoids the risk of an artificially formulaic approach to comparison emerging across the book. While "paired chapters", by offering more space for detail, arguably offer a logical route for comparing and contrasting US approaches with a more specifically EU-level European approach to certain areas – notably medical products law – they also enable meaningful discussion of areas where state and national laws may be more in evidence, for example, with healthcare fraud and abuse. However, the joint chapter approach proves equally effective with comparison at different levels.

The insights gained from the contributors' differing interpretations of *how* and *what* to compare (and contrast) is also refreshing – for example, Søvig and Furrow's use of case studies is particularly distinctive, while Parmet's highlighting of gun violence as a public health issue is notable insofar as this may be less intuitive for health lawyers outside the US. Indeed, delineating the scope of "health law" is part of the challenge, including at different levels. This is acknowledged by the editors in referencing Toebes' observation about the extent of

considerations – poverty, education, housing, taxation to name a few – which make up "health law".[10]

The range of nationalities represented among the contributors, and the diversity of countries referenced in order to provide a true sense of "European" perspectives, is notable. While the UK in some ways occupies a distinctive space – geographically European, but in terms of legal systems and cultural identity perhaps more Anglo-Saxon and closer to the US, it nevertheless provides a useful reference point for comparison.

The Editors outline the ultimate aim of the project as being "…to learn from the diverse contexts in which health law is played out".[11] The Handbook achieves this and more – as areas covered continue to evolve, and some attract more or less political attention at a given time (abortion law providing a timely example), this impressive volume provides insights not only to benefit not only health lawyers, but scholars across diverse fields. It also offers a wide-ranging framework to enable further comparative work for yielding further insights at national levels, but also in terms of regions (such as North and South America, as well as the global north and south) and transnational legal systems.

[10] A similar insight has been applied in connection with the development of EU health law and policy insofar as health '…is either non-existent as an autonomous policy area, given that it is mainstreamed into all other policies, or that it is basically everything, in that all EU public policy is also health policy'. Anniek de Ruijter, *EU Health Law and Policy - The Expansion of EU Power in Public Health and Health Care*, OUP 2019. Page 52.

[11] Introduction, page 11.