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Conceptualising European Union Health Law

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Abstract

A collectively authored article, which (unusually in legal scholarship) makes explicit the processes and methodologies by which 'European Union health law' is conceptualised; the implications; and the strengths and weaknesses of the approach taken. Strengths include implied structural and systemic coherence; and the breadth of analysis that having a large team of authors permits, through holding their positionalities in creative interplay with each other. The authors argue that European Union health law — defined as transversal and distinctively European Union law that either directly or indirectly affects human health, in a broad sense — should be understood through a metaphor of growth and connectedness, specifically a 'tree'. The article seeks to initiate a discussion not only about European Union health law, but also about European law and health law.

Keywords

collaboration – European Union – legal method – legal methodology – legal taxonomy

1 Introduction

Readers of the *European Journal of Health Law* will be aware of the Max Planck Encyclopaedias of International Law published by Oxford University Press (OUP). These are long-established, peer-reviewed and comprehensive sources of legal analysis written by scholarly experts on every aspect of international law. Drawing inspiration from the latter, and spotting a key gap in extant scholarly discussion, in 2019, a project to create the *Oxford Encyclopaedia of EU Law* (the Encyclopaedia) was launched. Readers of the journal may perhaps be a little surprised[1] that, even at this pre-COVID-19 time, 'European Union health law' was included as one of the 22 organising structures for that Encyclopaedia. The lead author of this article, Tamara Hervey, was appointed as 'section Editor' for that section of the Encyclopaedia. She set about recruiting a team of authors (including the co-authors of this article, as well as others) to both write the entries for the Encyclopaedia, and to collaborate on determining how the entries should be structured.

In this article we report and reflect on our collective endeavours. We first describe and attempt to delineate the boundaries of European Union (Union) health law, as part of the knowledge domains of Union law and health law. We accept that such a description, as is the case with every knowledge domain, will always be evolving, and hence provisional and contested. Indeed some authors of this article contest that Union health law has (yet) established itself as a knowledge domain. Such descriptions and boundaries are continually changing, as the (legal) scientific community (rightly) engages with and discusses them. In our discussion, we highlight the central role of a 'tree' metaphor as a way of thinking about, growing and developing the section on Union health law in the Encyclopaedia as a whole. From there, we consider the implications of that categorisation, and use of the metaphor, and why it matters. We draw out key consequences for Union health law, and broader implications for legal scholarship, particularly collaborative legal scholarship in and of the Union, and (comparative) health law, and discuss strengths and weaknesses of our approach.

The discrete category of Union health law may eventually become a widely-recognised knowledge domain in itself. However, at present we think it is better understood as emerging from the far more widely recognised and accepted knowledge domains of Union law and health law. Although the idea

1 T.K. Hervey and J.V. McHale, *Health Law and the European Union* (Cambridge: Cambridge University Press, 2004); T.K. Hervey and J.V. McHale, *European Union Health Law: Themes and Implications* (Cambridge: Cambridge University Press, 2015).

of health law being a component part of Union law is not new,[2] at this point in time, few general scholarly text books on Union law, nor indeed the law of the European Economic Area,[3] represent health law as a free-standing category. Key exceptions include Blumann, Dubouis and Rubio's *Droit matériel de l'Union européenne*, where 'la protection de la santé' has been a chapter in the part on 'people' since at least 2004; and Barnard and Peers' OUP textbook on *EU Law* which has included a free-standing chapter on 'EU health law' since its first edition in 2014. In terms of encyclopaedias of Union law, the two existing European (Union) law encyclopaedias in France[4] include entries on healthcare.[5] As far as we are aware, no general Union law German or Spanish language literature covers Union health law, other than as coordination of social security and/or patient mobility.[6] One Spanish language text just offers a collection of papers on the EU approach to certain healthcare topics.[7]

Equally, national treatises on health law (either in monograph, textbook or encyclopaedia form) tend not to include Union law explicitly: instead, they often embed discussion of Union law implicitly in discussion of national law,

2 E. Mossialos, G. Permanand, R. Baeten and T. Hervey (eds), *Health Systems Governance in Europe: The Role of EU Law and Policy* (Cambridge: Cambridge University Press 2010); A. de Ruijter, *EU Health Law and Policy* (Oxford: Oxford University Press, 2019); S.L. Greer, N. Fahy, H. Elliott, M. Wismar, H. Jarman and W. Palm, *Everything You Always Wanted to Know About European Union Health Policies but Were Afraid to Ask* (Brussels: European Observatory on Health Systems and Policies, 2014); S.L. Greer, S.L. Greer, N. Fahy, H. Elliott, M. Wismar, H. Jarman and W. Palm (eds), *Everything You Always Wanted to Know About European Union Health Policies but Were Afraid to Ask*, 4th edn. (Brussels: European Observatory on Health Systems and Policies, 2024).

3 M. Frischhut, 'Gesundheitsdienstleistungen im EWR' in A.T. Müller and W. Schroeder (eds), *25 Jahre Europäischer Wirtschaftsraum: Ein Integrationsszenarium auf dem Prüfstand* (Baden Baden: Nomos 2020).

4 F. Picod (ed.), *JurisClasseur Europe Traité* (New York, NY: LexisNexis, 1989), updated quarterly; F. Kessler, 'Sécurité sociale: Coordination des régimes de base — Champ d'application — Principes généraux', in D. Simon and S. Poillot-Peruzzetto (eds), *Répertoire de droit européen* (Paris: Dalloz, 2025).

5 E. Brosset, 'Soins de santé: principes généraux', in F. Picod (ed.), *JurisClasseur Europe Traité* (New York, NY: LexisNexis, 2025); E. Brosset, 'Soins de santé: patients, professionnels de santé et produits de santé', in F. Picod (ed.), *JurisClasseur Europe Traité* (New York, NY: LexisNexis, 2025); N. de Grove-Valdeyron, 'Santé publique', in D. Simon and S. Poillot-Peruzzetto (eds), *Répertoire de droit européen* (Paris: Dalloz, 2025); N. de Grove-Valdeyron, 'Médicament', in D. Simon and S. Poillot-Peruzzetto (eds), *Répertoire de droit européen* (Paris: Dalloz, 2025).

6 R. Streinz, *Europarecht*, 12th edn. (Hannover: C.F. Müller, 2023).

7 J.F. Pérez-Gálvez and R. Barranco-Vela (eds), *Derecho y salud en la Unión Europea* (Granada: Comares, 2013).

without acknowledging its original source.[8] This is of course in the nature of Union law, in that it becomes part of the national legal order.[9] Discussion of Union law on cross-border healthcare, patients' rights, medicines and medical devices, SoHO and so on tend to be found in publications on 'traditional' areas of national law such as administrative or commercial law. Alternatively, Union health law has sometimes been dealt with under a broader umbrella (European health law), which therefore includes both Union and Council of Europe law.[10]

It is precisely because of the rather precarious position of the category of Union health law in legal studies, and cognate disciplines and fields, that inclusion in the OUP Encyclopaedia gains importance. By developing a discrete section on it in the foundational text of the Encyclopaedia, the category of Union health law derives authority and legitimacy, as an integral part of the larger, taken for granted and accepted, category and knowledge domain of Union law. As we explain throughout the following, the technical entries in the section, and the section as a whole, have normative import for the category of Union health law itself (not least that it *ought* to count as and is deserving of wider recognition as a discrete category or emerging knowledge domain).

Our common project also highlights both the important *methodological choices* involved in any engagement with a knowledge domain, especially in its foundations, and their outworkings. Those choices relate to methodology, which we broadly understand as comprising the underpinning theoretical framework and rationale for the work involved in creating the Encyclopaedia section, and its composite entries, *and* also to our specific methods, by which we mean the tools chosen, consistent with the methodology, to undertake the

8 A.-M. Farrell and E. Dove, *Mason and McCall Smith's Law and Medical Ethics*, 12th edn. (Oxford: Oxford University Press, 2023); M. Brazier, E. Cave and R. Heywood, *Medicine, Patients and the Law* (London: Penguin, 2023); G. Genicot, *Droit médical et biomédical* (Antwerp: Larcier, 2016); F.E. Fonseca-Ferrandis, 'La asistencia sanitaria transfronteriza en la Unión Europea: análisis de la doctrina del TJCE en relación con el reembolso de los gastos producidos por la atención dispensada en otros Estados Miembros', in J. Cantero-Martínez and A. Palomar Olmeda (eds), *Tratado de Derecho Sanitario* (Cizur Menor: Thomson Reuters Aranzadi, 2013) pp. 597–634.

9 Article 288 TFEU.

10 A. den Exter (ed.), *European Health Law* (Antwerp: Maklu, 2017); J.M. Sánchez-Patrón and A. Bautista-Hernáez (eds), *Bioderecho internacional y europeo: desafíos actuales* (Valencia: Tirant lo Blanch, 2014); J. Cayón-de las Cuevas, 'European Health Law and Human Rights at the Crossroads: Exploring Tensions Between Harmonisation and Heterogeneity', in K. Fierlbeck and J. Cayón-de las Cuevas (eds), *Health Law and Policy from East to West: Analytical Perspectives and Comparative Case Studies* (Madrid: Thomson Reuters Civitas, 2022) pp. 55–84.

work. Principal among those tools — alongside doctrinal legal method — is the use of a metaphor to enable our discursive collaboration.

Such assumptions and processes are often left unspoken. This journal article is rare in focusing on and illuminating them. It does so by working in as granular, analytical and self-reflexive way as possible, within the constraints of a single article, to promote dialogue on the kinds of collaborative and reflexive work necessary to shape knowledge domains such as that of Union health law. In that regard, this article represents a relatively unusual mode of (Union) (and) (health) legal scholarship.

In some contexts across Europe, the kind of work on which we reflect in this article (writing legal encyclopaedia entries) is well regarded. The reputation of Oxford University Press contributes here. But in other contexts, this kind of work is probably often underappreciated in its significance, for both research and teaching purposes. One explanation relates to the kind of work: it is technical, and so undeniably far from one sense of 'innovative' or 'exciting' scholarship. Or, more charitably, it is not at all easy to make it so. In some parts of the legal academy across Europe, such technical work is hardly thought of as worthwhile at all. Another explanation is that, given the contemporary value placed on 'innovation' in scholarly work, such 'un-innovative' work is unattractive in many scholarly environments. It is often thought, as reflected in, for instance, access to funding or promotion criteria, that names are 'made' through monographs,[11] and research articles in top-flight journals. This is especially so where such articles are open access and therefore readily accessible to a broad global audience. Those other kinds of more innovative work (articles and monographs) tend to be seen as more salient contributions to the knowledge domain (here of Union law or health law more generally) than encyclopaedia entries.

In our view, this is a deeply unfortunate mis-valuation of the intellectual labour that goes into entries in a legal encyclopaedia. In this article, we show how encyclopaedia-related work both reveals and interrogates the wider knowledge domain within which it sits. Such work is therefore not only *highly original* per se, since it is by definition *foundational* to the wider knowledge domain of Union law. It is also both *vital* (in the sense of necessary to make sense of a knowledge domain) and *vitalising* (in the sense of driving an

11 Monographs are a key format for rendering the authorial voice authoritative, and animating scholarly discussion, unsurprisingly given the common origins of authority as referring to a knowledgeable person or a reliable and valid source, and an author as someone who writes confidently in light of their knowledge and expertise.

intellectual enquiry and scholarly engagement). We invite others to join the discussion that we initiate with this journal article.

2 Describing the Evolving Contours of European Union Health Law

The practical organisation of the Encyclopaedia has conceptual and principled consequences. From the beginning, the Encyclopaedia's General Editors, Sacha Garben and Laurence Gormley, encouraged us to consider Union health law as a 'tree'. In this metaphor, the main 'trunk' is represented by a general encyclopaedia entry outlining the whole topic in brief, and then several 'branches' growing from that trunk, and smaller 'twigs' and even 'leaves' from each branch. The question of what should comprise the main branches was therefore our first practical — but also analytical and conceptual — concern.

Through an iterative and highly-interactive collaborative discursive process, we have (currently) settled on eight main branches.[12] These begin with (1) people; then (2) substances of human origin and (3) health data; followed by (4) health products (both those which are used to treat ill-health or prevent illness, and those which are responsible for ill-health); and (5) other public health issues. Thereafter, (6) national and (7) Union health institutions, bodies, entities or agencies each have a branch. Finally (8) health in Union external relations law completes the tree.

The categories are incommensurable, reflecting the nature of Union health law itself, and the ways in which it affects health regulation across the Union in direct, and less direct, ways. A taxonomy based on commensurable categories, such as values, principles, competence provisions or (types of) legal instrument (expected structures for legal knowledge domains), would not capture the indirect impacts of Union law on health, a topic which is at least as important as, if not more important than, its direct impacts.[13] In this regard, we see

12 For a visualisation of these 'branches', particularly designed for pedagogical purposes, *see* https://research.mci.edu/en/jean-monnet-chair/eu-health-law-en.

13 T.K. Hervey, 'Telling Stories about European Union Health Law: The Emergence of a New Field of Law', *Comparative European Politics* 15(3) (2016) 352–369; T.K. Hervey and A. de Ruijter, 'The Dynamic Potential of European Union Health Law', *European Journal of Risk Regulation* 11(4) (2020) 726–735, doi: 10.1017/err.2020.70; T.K. Hervey (interview by A Mahalatchimy), 'EU Health Law in the UK: from the Past to the Present and into the Future', *Confluence des droits: La Revue* (2024), available at https://confluencedesdroits-larevue.com/?p=3591.

Union health law as 'transversal',[14] cutting across established taxonomies of Union law, reflected in competence provisions, the structure of the Treaty on European Union (TEU)[15] and Treaty on the Functioning of the European Union (TFEU),[16] or indeed in the majority of Union law textbooks or commentaries.

Our 'people' category (1) immediately branches into patients and healthcare professionals. Migrating patients, both Union citizens and 'third country nationals', enjoy rights in Union law, and these are covered here. The practical migrating patients' right to cross-border prescriptions also grows as a 'twig' within this branch. Healthcare professionals are considered both as migrants (their key touchpoint with Union law) but also otherwise, with an entry on access to medical education, which has been affected significantly by Union internal market and citizenship law.

Substances of human origin entries (2) follow, covering human blood, tissues, cells and human organs. Union law here covers only some aspects of their regulation, and interfaces with national law and law emanating from the Council of Europe are important. Union law mainly covers safety and quality, but some provisions protect donors, recipients and offspring born from donations. Next, a branch on health data (3) reflects the significant impacts of Union data law in general on the regulation of human health and especially biomedicine, and specific Union law on health data (including the 'European Health Data Space'). We consider Union regulation of health data when deployed for the purposes of health of the donor and others (for instance, in health research); and when used for non-health purposes, such as insurance. Again, the driver for the conceptualisation is human health, rather than the categories or instruments of Union law.

Substances of human origin and health data are neither 'people' nor 'things' in our classification. This reflects their relatively protected position in Union law generally, and is a key example of the specificities of Union health law. Moving to 'things', we have branches on 'health products' and on 'public health'. The health products (4) branch is the one with the most twigs and leaves. A significant body of Union legislation on medicines and medical devices is elaborated in detail. We consider definitional matters, including the special categories of paediatric and orphan medicines, and advanced therapy medicinal products,

14 T.K. Hervey, 'EU Health Law', in C Barnard and S Peers (eds), *EU Law* 4th edn (Oxford: Oxford University Press, forthcoming 2026).

15 Consolidated Version of the Treaty on the Functioning of the European Union' [2016] OJ C 202/13.

16 'Consolidated Version of the Treaty on European Union' [2016] OJ C 202/47.

in Union law;[17] then follow the 'regulatory life cycle' for medicines, with entries on clinical trials, marketing authorisation, manufacturing and batch control, packaging and labelling (including protection of Union populations from falsified medicines), distribution, advertising, pharmacovigilance, and medicines pricing (including health technology assessment and links with Union intellectual property law). Medical devices entries cover definitions, certification, risk management and obligations of economic operators. We consider joint procurement of medicines and medical devices, and product liability for medical harms.

Our 'public health' branch (5) covers non-communicable diseases, with entries on tobacco, food, alcohol and gambling, as the areas where Union law has had the most influence on public health, via its regulation of the internal market. The law on public health protection through air, water and waste regulation belongs outside our 'tree', in Union environmental law. Communicable diseases are covered in entries on cross-border health threats, where we also consider Union law on emergency medical countermeasures, like vaccines, linking to joint procurement. Again, these are areas where Union law (as opposed to Union policy) has had the greatest effects.

Two branches cover institutions, bodies, agencies and other similar entities (6 and 7). We first consider Union law as it has affected national healthcare institutions, bodies, entities or agencies (6), considering how Union internal market law on goods, establishment and services provision, Union competition law and Union state aids law operates in the context of healthcare institutions. Here is another place where the distinctiveness of Union health law is strongly apparent, as the 'ordinary' Union rules are modified when it comes

17 European Commission, 'Proposal for a Directive on the Union Code Relating to Medicinal Products for Human Use' COM (2023) 192 final; European Commission, 'Proposal for a Regulation Laying Down Union Procedures for the Authorisation and Supervision of Medicinal Products for Human Use and Establishing Rules Governing the European Medicines Agency' COM (2023) 193 final; K. Perehudoff, 'Global "Side Effects" of the EU's Pharmaceutical Reforms and Their Impact on Access to Medicines in LMICs', *BMJ Global Health* 10(4) (2025) e017789; S. Gamba, L. Magazzini and P. Pertile, 'The 2023 European Commission Proposal and the 2024 European Parliament Proposal for the EU Pharmaceutical Legislation: Policy Content Analysis', *Health Policy* 161 (2025) 105408; V.L. Raposo, 'A Room with a View (And with a Gene Therapy Drug): Gene Therapy Medicinal Products and Genetic Tourism in Europe', *European Journal of Health Law* 29(3–5) (2022) 504–520, doi: 10.1163/15718093-bja10083; V.L.Raposo, 'A Room with a View (And with a Gene Therapy Drug): Gene Therapy Medicinal Products and Genetic Tourism in Europe', in S. Slokenberga, T. Minssen and A. Nordberg (eds), *Governing, Protecting and Regulating the Future of Genome Editing* (Leiden: Brill Nijhoff, 2023) pp. 183–199, doi: 10.1163/9789004526136.

to healthcare. Entries on the law governing Union health institutions, bodies, entities or agencies (7) (for example, the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC), the Health Emergency Preparedness and Response Authority (HERA)) and health databases (for example, the Union's Clinical Trials Information System) complete these branches.

Finally, we have a branch on the Union's externally-facing health law (8), covering health in Union trade and development law, considering topics of global health law[18] such as global markets in substances of human origin, and access to essential medicines, but from the point of view of Union law.

The OUP Encyclopaedia also structures its entries by means of links (in practice, hyperlinks) between entries. In this regard, the metaphor of a tree with branches may seem less useful, but we can think of root systems, and the ways in which trees in a forest share the light, soil and water, including by careful tending to ensure each individual tree and its branches have enough light and space.[19] What is created is more of a complex and dense web of connections between legal topics and categories, both within Union health law, and beyond into other areas of Union law, for example Union environmental law and Union internal market law. This is how we indicate linkages between our separate entries, such as how joint vaccine procurement links with external health law, or how Union cartel law and Union law on freedom of establishment protect the solidarity-based structures of national healthcare systems within Union Member States.

From this description of our 'tree' and 'web' of entries, what can we deduce about our conceptualisation of Union law? We are both inspired by and depart from 'classical' conceptualisations of (Union) (and) (health) law. The classification by Gaius of law into 'persons' 'things' and 'actions', familiar to

18 L.O. Gostin and B.M. Meier (eds), *Global Health Law and Policy: Ensuring Justice for a Healthier World* (Oxford: Oxford University Press, 2024); L.O.Gostin, *Foundations of Global Health and Human Rights* (Oxford: Oxford University Press, 2020); N J Hassoun, *Global Health Impact: Extending Access to Essential Medicines* (Oxford: Oxford University Press, 2020); L.O. Gostin, *Global Health Law* (Cambridge, MA: Harvard University Press, 2014); G.L. Burci and B. Toebes (eds), *Research Handbook on Global Health Law* (Cheltenham: Edward Elgar, 2018); C. O'Neill, C. Foster, J. Herring and K. Tingle (eds), *Routledge Handbook of Global Health Rights* (Abingdon: Routledge, 2021); M. Freeman, S. Hawkes and B. Bennett (eds), *Law and Global Health* (Oxford: Oxford University Press, 2014); J. Cayón, 'Global Health Law', *South Eastern European Journal of Public Health* (Special Volume) (2016) 288–303, https://doi.org/10.4119/seejph-1828.

19 P. Wohlleben, *The Hidden Life of Trees: What They Feel, How They Communicate — Discoveries from a Secret World* (translated by J. Billinghurst) (Saltspring Island, BC: David Suzuki Institute, 2016).

us as a foundation of civil law systems, is to some extent reflected in our division between people, products and institutions.[20] But we do not divide our branches according to the 'public' and 'private' law categories which have structured legal science and the legal system across Europe, and about which there is long-standing and extensive doctrinal and theoretical debate.[21] In this regard, we follow the ways in which the Union itself may have deliberately blurred the public/private law divide.[22]

Although we follow to some extent others who have conceptualised Union health law (and several among us have done so in previous projects), we depart from previous conceptualisations.[23] We cover more topics than several authors of book-length treatments of Union health law,[24] especially in our inclusion of national and Union health(care) institutions, bodies, entities or agencies, and in our consideration of the Union's external-facing health law. We do not see our subject-matter as a sub-category of another legal category within Union law, such as 'social law',[25] or 'social security law'.[26] We incorporate many topics

20 W.M. Gordon and O.F. Robinson (eds), *The Institutes of Gaius* (London: Duckworth, 1988); R. Zimmermann, *The Law of Obligations: Roman Foundations of the Civilian Tradition* (Oxford: Oxford University Press, 1996) 25.

21 D. Kennedy, 'The Stages of the Decline of the Public/Private Distinction', *University of Pennsylvania Law Review* 130 (1982) 1349–1357; M. Rosenfeld, 'Rethinking the Boundaries between Public and Private Law for the Twenty-First Century', *International Journal of Constitutional Law* 11 (2013) 125–128.

22 N. Reich, 'The Public/Private Divide in European Law', in H.-W. Micklitz and F. Cafaggi (eds), *European Private Law* (Cheltenham: Edward Elgar, 2010) chapter 4.

23 Hervey and McHale (2015), *supra* note 1; de Ruijter, *supra* note 2; den Exter, *supra* note 10.

24 de Ruijter, *supra* note 2; Hervey and McHale (2015), *supra* note 1; T.K. Hervey, C.A. Young and L.E. Bishop (eds), *Research Handbook on EU Health Law and Policy* (Cheltenham: Edward Elgar, 2017); E, Brosset, *Manuel de droit de l'Union européenne de la santé* (Brussels: Bruylant, 2024); N. De Grove-Valdeyron, *Droit européen de la santé* (Paris: LGDJ, 2018); H. Nys, *European Union Health Law* in *International Encyclopaedia of Medical Law* (Alphen aan den Rijn: Wolters Kluwer, 2024).

25 M. Fuchs and C. Janda (eds), *NomosKommentar. Europäisches Sozialrecht* (Baden Baden: Nomos. 2025); T.K. Hervey, *European Social Law and Policy* (New York, NY: Longman, 1998); P. Rodière, *Droit social de l'Union européenne* (Paris: LGDJ. 2022); M. Del Sol, S. Hennion, M. Le Barbier and J.-P. Lhernould, *Droit social européen et international* (Paris: PUF, 2021).

26 F. Pennings, *European Social Security Law* (Antwerp: Intersentia, 2022) chapter 11; G. Strban, 'Cross-border Healthcare and Social Security Rights', in F. Pennings and G. Vonk (eds), *Research Handbook on European Social Security Law* (Cheltenham: Edward Elgar, 2023) pp. 332–352; J. Paju, *The European Union and Social Security Law* (Oxford: Hart/Bloomsbury, 2019) chapter 5; J.-M. Servais, *International Social Security Law* (Alphen aan den Rijn: Wolters Kluwer, 2022) part IV, chapter 3; R. Blanpain and F. Hendrickx, *Code de droit européen du travail et de la sécurité sociale* (Brussels: Bruylant, 2002); G. Huteau, *Le droit de la sécurité sociale* (Rennes: Presses de l'EHESP, 2021); M. Borgetto and R. Lafore, *Droit de la sécurité sociale* (Paris: Dalloz, 2023).

of Union health law that have been the subject of book-length works themselves, including medicines law,[27] law on novel health technologies,[28] food law,[29] and the impacts of Union competition law on health and healthcare.[30]

In terms of relationships with other legal orders, our central concern is Union health law, but we see that relationally and not as wholly independent or free-standing from other jurisdictions. We demonstrate its impact and effects by reference to many Union Member States, particularly through case-law of the Court of Justice of the European Union and particularly, but not only,[31] through the preliminary reference procedure.[32] We go much further than single-country studies of the implications of Union law for national healthcare systems, whether embedded within comparative law studies,[33] single-jurisdiction books on national health law,[34] or in whole-book treatments

27 V.L. Raposo, *Danos Causados por Medicamentos — Enquadramento Jurídico à Luz do Ordenamento Europeu* (Coimbra: Almedina, 2018); E. Jackson, *Law and the Regulation of Medicines* (Oxford: Hart, 2012); C. Maurain and M. Bélanger (eds), *Traité de droit pharmaceutique* (New York, NY: LexisNexis, 1963) (regularly updated); P. Feldschreiber, *The Law and Regulation of Medicines and Medical Devices* (Oxford: Oxford University Press, 2021); M.-A. Frison-Roche (ed.), *Concurrence, santé publique, innovation et médicaments* (Paris: LGDJ, 2010); A. Mendoza, *Médicament et droit: droit français et européen* (Paris: Larcier, 2017); N. de Grove-Valdeyron (ed.), *Santé et produits de santé: Regards de la jeune doctrine Chaire DESAPS (2017–2021)* (2021), available at https://hal-03359349.

28 M. Flear, T. Hervey, A.-M. Farrell and T. Murphy (eds), *European Law and New Health Technologies* (Oxford: Oxford University Press, 2013); C. Castets-Renard (ed.), *Droit du marché unique numérique et intelligence artificielle* (Brussels: Bruylant, 2020); N. de Grove-Valdeyron (ed.), *Espace européen des données de santé et IA: Enjeux juridiques et défis de mise en œuvre* (Toulouse: Presses de l'Université Toulouse Capitole, 2025).

29 H. Schebesta and K. Purnhagen, *EU Food Law* (Oxford: Oxford University Press, 2024).

30 M. Guy, *Competition Law, Inequalities and Healthcare: Insights from EU and National Frameworks* (London: Bloomsbury, 2022); Á. Amadá, *Patentes Farmacêuticas na União Europeia — Estratégias (Anti)concorrenciais e Aplicação do Direito da Concorrência* (Coimbra: Almedina, 2023); L. Hancher and W. Sauter, *EU Competition and Internal Market Law in the Healthcare Sector* (Oxford: Oxford University Press, 2012); M.M. Bellanger, 'L'introduction des mécanismes de marché dans des systèmes de santé européens: un langage commun et des pratiques parfois différentes' in P Hassenteufel and S Hennion-Moreau (eds), *Concurrence et protection sociale en Europe* (Rennes: Presses Universitaires de Rennes, 2004) pp. 233–244.

31 Articles 258 and 263 TFEU.

32 Article 267 TFEU.

33 Fierlbeck and Cayón-de las Cuevas, *supra* note 10; D. Orentlicher and T.K. Hervey (eds), *Oxford Handbook of Comparative Health Law* (Oxford: Oxford University Press, 2021).

34 M. Neumayr, R. Resch and F. Wallner (eds), *Großkommentar. Gmundner Kommentar zum Gesundheitsrecht* (Vienna: MANZ, 2022); R, Resch (ed.), *Handbuch Medizinrecht* (LexisNexis 2020); V Saalfrank (ed.), *Handbuch des Medizin- und Gesundheitsrechts* (Vienna: MANZ, 2022); T. Mattsson, K. Zillén and S. Slokenberga (eds), *Medicinsk rätt,* 3rd edn (Stockholm:

of the subject.[35] Similarly, we cover a wider scope than single-jurisdiction case studies of the Union and its law embedded within comparative or global health law books are able to cover.[36]

In other respects in terms of relations with other legal orders, our focus is more narrow than that of others. We cover European *Union* health law only, not *European* health law more generally, which includes the law of the Council of Europe and other European-level law-making entities.[37]

The edges of the branches, twigs, and leaves of our 'tree' are not always as distinct as the discussion so far implies. We see them as intertwined with other branches of Union and health law, in such a way that the distinction might be difficult to discern at times. As already alluded to above, measures of Union health law may also be seen as within Union citizenship law; internal market law; competition law; external relations law; environmental law; consumer law (including food law); human rights law; bio-law (if seen as distinct from health law, a point upon which we do not agree); labour law; social security law; family law; digital law; data protection law; criminal law, and so on. The point is not that we do not recognise these other 'trees'. It is that there is value in considering Union health law as a 'tree' in its own right, as part of a legal 'forest', so to say.

Norstedts Juridik, 2025); L. Rönnberg, *Hälso- och sjukvårdsrätt* (Lund: Studentlitteratur, 2020); S. Slokenberga and S. Olsena (eds), *Medicīnas tiesības* (Riga: Tiesu namu aģentūra, 2022); A.K. Befring, *Helseretten* (Oslo: Cappelen Damm Akademisk, 2022); B. Apollis and D. Truchet, *Droit de la santé publique* (Paris: Dalloz, 2024); D. Duval-Arnould, *Droit de la santé: Prise en charge des patients et réparation des dommages liés aux soins* (Paris: Lefebvre Dalloz, 2023); A. Laude, B. Mathieu and D. Tabuteau, *Droit de la santé* (Paris: PUF, 2012); A. Leca and B. Legros, *Petit dictionnaire de droit de la santé et de bioéthique* (Bordeaux: LEH Éditions, 2017); J.-P. Markus, D. Cristol, J. Peigné and E. Autier, *Code de la santé publique 2024, annoté commenté en ligne* (Paris: Dalloz, 2024); H Gaumont-Prat (ed.), *Mélanges en l'honneur de Claude Grellier: Droit de la santé, responsabilité et réparation* (Bordeaux: LEH Éditions, 2018); M. Brazier and E. Cove, *Medicine, Patients and the Law* (Manchester: Manchester University Press, 2023).

35 R. Stankiewicz, *Krajowe systemy ochrony zdrowia a Unia Europejska: Przykład Polski* (Alphen aan den Rijn: Wolters Kluwer, 2016); E. Mondielli, F. Vialla and E. Cadeau (eds), Mélanges en l'honneur de Michel Bélanger: Modernité du droit de la santé (Bordeaux: LEH Éditions, 2015).

36 B. Toebes, M. Hartlev, A. Hendriks, K. O Cathaoir and J.R. Herrmann, *Health and Human Rights* (Antwerp: Larcier Intersentia, 2022).

37 M. Bélanger, *Droit européen général de la santé* (Bordeaux: LEH Éditions 2019); G.G. Sander, *Internationaler und europäischer Gesundheitsschutz* (Baden Baden: Nomos, 2004); A. den Exter, *European Health Law* (Antwerp: Maklu 2017).

How do we capture the scope of Union health law (the edges of our 'tree')? In one sentence, for us, it is transversal and distinctively European Union law that either directly or indirectly affects human health, in a broad sense.

To unpack that sentence a little, the transversality of Union health law, and its direct[38] but also indirect[39] impacts, blossom from the range of Union competences from which Union health law is grown. Union health law is law 'about' health, but also law that impacts health. It is Union law that affects human health, in a broad sense, but not such a broad sense as to be removed from healthcare institutions and practices, or public and preventative health. So, for example, even though poverty is a key indicator of good human health, we do not include Union law aimed at tackling poverty within our conceptualisation of Union health law. Some parts of Union health law are seen by us as more 'central' (bigger branches of the tree, perhaps); while others are more 'peripheral' as smaller branches or twigs: although again we may not all agree which belong in which category. We agree that Union law that explicitly *seeks to protect* or *promote* health is in the former category. Most of us think that Union law that only has 'effects' on health[40] is in the latter category. Equally, we agree that Union law that has *detrimental* effects on health is covered; as is Union law that affects health to a certain degree without intending to do so.

Union health law is found in Union hard law, including harmonising law, but also in Union soft law. The sources of Union health law are primary, secondary or tertiary Union law/legislation, Union soft law, CJEU case-law, and international agreements entered into by the Union or the Union and its Member States. Its sources also include relevant legal acts of the Member States when they are 'implementing' Union law.[41] Union health law is substantive Union law, but also the law that relates to relevant Union — and national — institutions, bodies, entities or agencies, such as law regulating power horizontally at Union level, setting out and controlling acts of Union entities such as the ECDC, European Medicines Agency (EMA), Health Emergency preparedness and Response Authority (HERA), Health Security Committee, and so on. Further, Union health law also regulates relations between the Union level and the Member States (vertical relations); and beyond, through the Union's external legal relations with other countries, most closely the European Economic Area (EEA) and Switzerland; but beyond where the Union has entered into

38 Articles 168, 2(5), 4(2)(k) and 6(a) TFEU.

39 Article 114 TFEU.

40 Case C-426/13 P(R) *Commission v Germany* EU:C:2013:848, para 75.

41 Article 51(1) Charter of Fundamental Rights of the European Union [2012] OJ C 326/391.

international agreements that affect human health.[42] One such evolving relationship is the Union's relationship with the Council of Europe.[43]

Union health law's distinctiveness derives from the way that it is rooted in European conceptions of human rights, common values,[44] and principles which embody a particularly 'European' approach to health and healthcare.[45] This rootedness in human rights, principles and values gives health law — not only Union health law — its own authority, linking it to deontological (bio-)ethics[46] for at least some of us.

In common with others who came before us, we recognise that the delineation of the scope of Union health law is an ongoing dynamic process.[47] Union health law evolves through a double-dynamic: not only because Union law is constantly expanding as the process of European integration unfolds, but also because health law develops along with bio-science, medicine and technology more generally.

3 Consequences and Implications

Having explained our delineation and categorisation of Union health law, we turn to broader questions. What normative — or other — claims underpin it or

42 EU–UK Withdrawal Agreement [2020] OJ L 29; *Trade and Cooperation Agreement* [2021] OJ L 149; P.A. Villarreal, A. Gross and A. Phelan, 'The Proposed Pandemic Agreement: A Pivotal Moment for Global Health Law', *Journal of Law, Medicine & Ethics* 53(S1) (2025) 55–58.

43 S. Schmahl, 'EU and Council of Europe', in S Garben and L Gormley (eds), *Oxford Encyclopaedia of EU Law* (Oxford: Oxford University Press, 2024); L.M. Guerra Lopez, *Strengthening Cooperation with the Council of Europe: Study Requested by the European Parliament's Committee on Constitutional Affairs* (PE 689.275 2021); H. Gaudin, 'L'adhésion de l'Union européenne à la Convention européenne des droits de l'homme: Le Big Bang des droits de l'homme en Europe est-il pour bientôt ?', *Revue trimestrielle des droits de l'homme* 4(140) (2024) 845–886.

44 M. Frischhut, *The Ethical Spirit of EU Values: Status Quo of the Union of Values and Future Direction of Travel* (Berlin: Springer, 2022).

45 T.K. Hervey, 'Health Law' in in S Garben and L Gormley (eds), *Oxford Encyclopaedia of EU Law* (Oxford: Oxford University Press, 2024).

46 M. Fartunova-Michel and B. Nabli, *Droit de l'Union européenne de la bioéthique* (Brussels: Bruylant, 2021); N. Coghlan, 'Health Union and Bioethical Union: Does Hippocrates Require Socrates?', *European Journal of Risk Regulation* 11(4) (2020) 766–780, doi: 10.1017/err.2020.89; European Group on Ethics in Science and New Technologies, *Reports*, available at https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/scientific-support-eu-policies/european-group-ethics_en.

47 Hervey and McHale (2015), *supra* note 1, 19.

are implied by it? Why does it matter how we determine its (evolving) boundaries? What are the more immediate consequences: what does it mean for scholarship of Union health law (including, but also going beyond, our own)? What are the broader implications of that determination, that go beyond a consequence for Union health law, but resonate elsewhere in the legal academy or indeed beyond? What are the strengths — and weaknesses — of our approach? This section explores those questions.

3.1 *Why It Matters and the Consequences and Broader Implications*

Why does it matter whether Union health law is a free-standing and distinct category of Union law? And, relatedly, why does it matter how we — the authors of this article — systematise and structure that category? There are five overlapping and interacting reasons: principled; legal analytical and philosophical (or jurisprudential); pedagogical; political; and practical. We discuss each in turn.

3.1.1 Principle

At the level of principle, our systematisation of Union health law places human beings first. We acknowledge the anthropomorphic and/or speciesist limitations of such an approach, and indeed the claims that ecosystems and planetary interconnectedness and climate crisis would justify a different approach, one that placed environmental, planetary and animal health higher in the categorisation.[48] But to us, health law exists fundamentally to serve human beings, who will all experience ill-health, ageing and death, and who will all need to be cared for at some time(s) in their lives. So, actually, we are interested in *human* health law; we take 'the human' focus of *health law* to be both implicit to the category, and indeed the very term or concept, and readily understood as implied by it, by you as the audience for this article. In a rather circular way, the main justification for this understanding, this limitation of the concept, in principle, is that humans and their physical and mental frailties and vulnerabilities[49] are foregrounded very prominently in *Union*

48 K. Woolaston and J. Kotzmann (eds), *The Cambridge Handbook of One Health and the Law: Existing Frameworks, Intersections and Future Pathways* (Cambridge: Cambridge University Press, 2025); S. Negri (ed.), *Environmental Health in International and EU Law: Current Challenges and Legal Responses* (Abingdon: Routledge, 2020).

49 M.A. Fineman, 'Vulnerability in Law and Bioethics', *Journal of Health Care for the Poor and Underserved* 30 (2019) 52–61; M.A. Fineman, 'The Vulnerable Subject: Anchoring Equality in the Human Condition', 20 *Yale Journal of Law & Feminism* 20 (2008) 1–23; J. Herring, *Vulnerable Adults and the Law* (Oxford: Oxford University Press, 2016); M.A.Fineman, 'Covid-19: Lessons for and from Vulnerability Theory', *International Journal*

health law, since it must value and respect *human* dignity above other rights and interests.[50] That said, some of us do not agree with that foregrounding in general, but agree with it as a working construct for the project, a point which we pick up in the conclusion. Some of us put greater emphasis on what unites humans and animals, the capacity to feel pain and, oftentimes, their self-consciousness, and therefore deny the existence of a specific *dignity* of humans if compared to other living beings.[51] Union health law, however, grows from the Union's legal texts, which — at least at the current stage of Union integration — acknowledge human dignity as different from any dignity or legal rights of animals, or indeed the environment or planet.

The broader implications of our approach are that Union law on planetary or animal protection does not belong in our 'tree', but in an alternative 'tree' in the systemisation of Union law, such as Union environmental law or Union animal law. We do not, for example, include within Union health law any *general* Union law on use of animals for research.[52] We cover only clinical trials of pharmaceuticals and uses of health data for research.

The centring of human beings is not the only reason of principle that matters to our delineation and systemisation of Union health law. Through our discursive process, we have considered the following non-exhaustive list of 'principles' or 'values' which inform the category: protection of human rights, both to health and healthcare, and rights central to their provision such as human dignity, integrity, privacy, autonomy and non-discrimination; solidarity and collectivisation in the provision of healthcare and protection of public health; proportionality, transparency and accountability; and precautionary public health protection. We find these principles or values reflected in Union primary law: in the EU's Charter of Fundamental Rights,[53] in provisions of the

of Discrimination and the Law 21 (2020) 181–183; M. Heikkilä and M. Mustaniemi-Laakso, 'Approaches to Vulnerability in Times of Crisis', *Human Rights Review* 24 (2023) 151–170; K. Sangsuvan, 'The Right to Health in COVID-19', 47 *Vermont Law Review* 47 (2023) 72–126; A. Broderick and J.A. Sellin (eds), *Socio-economic Rights, Inequalities and Vulnerability in Times of Crises: Building Back Better* (Cheltenham: Edward Elgar, 2024); É. Gennet, 'Introducing "Health Vulnerability": Towards a Human-Right Claim for Innovative Orphan Drugs?', *European Journal of Health Law* 27(3) (2020) 290–307.

50 Article 2 TEU; Article 1 Charter of Fundamental Rights of the European Union; Article 168 TFEU.

51 P. Singer, *Animal Liberation Now: The Definitive Classic Renewed* (New York, NY: Harper Perennial, 2023).

52 Directive 2010/63/EU of the European Parliament and of the Council on the Protection of Animals Used for Scientific Purposes [2010] OJ L 276/33.

53 Articles 1, 3(1)–(2), 7, 8, 21(1), 23, 34(1), 35, 36, 41 and 42 Charter of Fundamental Rights of the European Union.

Treaty on European Union and Treaty on the Functioning of the European Union,[54] and in 'general principles' of Union law.[55] They play both a normative and constitutive role, claiming the values and principles that justify and ground detailed legal rules. They also play an exegetical role: they provide a touchpoint when detailed and specific rules are interpreted. Such principal-based exegesis is a primary function of legal scholarship, and our project engages with it too.

3.1.2 Legal Analytical/Philosophical/Jurisprudential

From a legal analytical perspective, legal categories matter because they are key concepts, related to and containing other concepts and ideas, which are central to structuring how we think about, see, understand, and approach 'the law'. Central questions flow from and are framed by the very category. What are the 'rules' and what are the 'exceptions'? What is the personal scope of legal obligations? What is their material scope? And who enjoys which rights under each of them, when the personal and material scopes are considered together? The existence of a category of Union health law helps to counter a widespread and persistent belief that Union law is all about the rule of the 'market'.[56] Thinking in terms of Union health law validates other 'rules' (variously termed 'values' or 'principles' in both Union law and literature[57]), such as the solidaristic organisation of healthcare systems; human dignity and human rights protection in health and biomedical settings; and collectivisation of preventative and protective public health.

The category of Union health law also elucidates questions of constitutional significance, at both Union and national levels, and in the interactions among them. It helps to explain the fine balance between competences that the Union has,[58] and does not have,[59] to intervene in matters concerning the health, and health rights, of Union populations, and of those beyond the Union who are

54 Articles 2, 3(3), 5(1)–(4), 10(3), 11 TEU; Articles 10, 14, 16, 18, 19(1), 168(1)–(2), 191(2) TFEU.

55 Case C-221/00 *Pfizer Animal Health SA v Council* EU:C:2002:688, paras 123–160.

56 F.W. Scharpf, *Governing in Europe: Effective and Democratic?* (Oxford: Oxford University Press, 1999); C. Newdick, 'Citizenship, Free Movement and Health Care: Cementing Individual Rights by Corroding Social Solidarity', *Common Market Law Review* 43(6) (2006) 1645–1668; Hervey and McHale (2015), *supra* note 1; V. Delhomme and T.K. Hervey, 'The European Union's Response to the Covid-19 Crisis and (the Legitimacy of) the Union's Legal Order', *Yearbook of European Law* 41 (2022) 48–82; T.K. Hervey and M. Michalak, 'European Union Border Law during the COVID-19 Pandemic', *Common Market Law Review* 62 (2025) 747–796.

57 Frischhut, *supra* note 44.

58 Articles 4(2)(k), 114, 153(1)(a)–(b) and (f), 168(1)–(4), 182(1), 196(1), 207(1) TFEU; Article 21(2)(d) TEU; Article 35 Charter of Fundamental Rights of the European Union.

59 Articles 168(5) and 168(7) TFEU.

touched by Union law or (in)action.[60] Union intervention is possible through a plethora of tools or techniques that find their basis and aspects of their form and content through, inter alia, binding harmonising legislation, as well as coordinating and 'softer' laws (more or less binding, but not quite as 'hard' as the law per se, particularly in terms of bindingness and (legal) consequences, for instance, as regards accountability, mandating action or liability). To give just one example, a significant amount of Union COVID-19 law took the form of such 'softer' law.[61]

Legal categories are also central to broader questions and debates about 'the law'. These include whether the law is understood in a realist perspective as 'out there', that is, as an independent and objective part of reality, a thing that becomes understood through our senses and various tools (often of the classic scientific methods of observation and testing).[62] Or, indeed in a socially constructivist perspective, that is, as a thing that does not exist independently, but rather is the product of intersubjective relations or interactions and shared meanings *between* people (and indeed other components of reality, including science and technology, and the other elements making up the social milieus

60 K. Purnhagen, A. de Ruijter, M. Flear, T. Hervey and A. Herwig, 'More Competences than You Knew: The Web of Health Competences for Union Action in Response to the COVID-19 Outbreak', *European Journal of Risk Regulation* 11 (2020) 297–306; T. Hervey and S. Garben, 'Article 168 TFEU' in M. Kellenbacher and M. Klamert (eds), *The EU Treaties and the Charter of Fundamental Rights: Commentary*, 2nd edn, (Oxford: Oxford University Press, 2024); T.K. Hervey, 'Community and National Competence in Health After Tobacco Advertising', *Common Market Law Review* 38 (2001) 1421–1446; J. van de Gronden and M. Veenbrink, 'EHDS and Free Movement of Patients: What EU Intervention Is Needed?', *European Journal of Health Law* 31(3) (2024) 249–284.

61 Hervey and Michalak, *supra* note 56; T.K. Hervey, A. Fyfe and V. Delhomme, 'Management of the European Union's (Internal and External) Borders during the COVID-19 Pandemic' in C.M. Flood, Y.Y.B. Chen, R. Deonandan, S. Halabi and S. Thériault (eds), *Pandemics, Public Health and the Regulation of Borders: Lessons from COVID-19* (London: Taylor & Francis, 2024) 64–77; Delhomme and Hervey, *supra* note 56; V.L. Raposo, 'Que a Tecnologia Esteja Connosco Nestes Tempos de COVID-19 (Legitimidade da STAYAWAY COVID no Ordenamento Jurídico Português)', *Revista do Ministério Público* 164 (2020) 9–49; V.L. Raposo, "'I'm Right Behind You": Digital Contact Tracing Under European Law', *Maastricht Journal of European and Comparative Law* 29 (2022) 434–450.

62 B. Bix, *Law, Language and Legal Determinacy* (Oxford: Oxford University Press, 1995); R. Dworkin, 'Law as Interpretation', *Critical Inquiry* 9(1) (1982) 179–200; J. Raz, *Between Authority and Interpretation: On the Theory of Law and Practical Reason* (Oxford: Oxford University Press, 2009); B. Tamanaha, *Realistic Socio-Legal Theory: Pragmatism and a Social Theory of Law* (Oxford: Clarendon Press, 1997).

within which these occur, are produced and perpetuated).[63] Or, finally, somewhere between these two positions.[64]

But whatever the position, and it is fundamental, the very concept of legal categories has vital consequences for the nature of the thing to which we are paying attention, including what falls within and outwith the category (ontology); and, relatedly, how we come to know and understand law and legal meaning, and communicate it to others, including through 'the law' and 'legal procedures' (epistemology). To be upfront about it, the authors of this article share a more 'middle position' in these debates. These are important because it is a point that is implicit to the notion of boundary disputes between legal categories, and the idea that their boundaries are very much the products of scholarly and formal legal dialogue and contestation, making them both 'out there', but at the same time the products of social construction in very particular ways.

Further, the explanatory power of a legal category, and its underpinning ontological and epistemological assumptions (for us, a mix between realist and social constructivist perspectives), here, Union health law, helps to elucidate the category's inherent peculiarities. And that in turn justifies their distinction from other competing legal categories, such as 'administrative law', 'civil law' or 'public versus private law', all of which centre and privilege other, albeit often closely related, concerns. Indeed, the identification and naming of legal categories has normative implications. That is, legal categories do not simply describe 'the law', and bring order, clarity and coherence to what may otherwise be disparate and unseen (rules ordered in accordance with principles across a gamut of areas or examples). The latter process also helps to bring the very category into being as part of the knowledge domain of Union law, where further scholarly discussion and wider reflection leads to the accretion of 'taken-for-grantedness' or naturalness, stability and authority of the category (of Union health law, and indeed Union law) over time. The evolution of legal categories in this way is not new: see, for example, the split of labour law

63 P. Ewick and S. Silbey, *The Common Place of Law: Stories from Everyday Life* (Chicago, IL: University of Chicago Press, 1998); R. Ellickson, *Order Without Law: How Neighbours Settle Disputes* (Cambridge, MA: Harvard University Press 1994); N. Creutzfeldt, 'Traditions of Studying the Social and the Legal', in N. Creutzfeldt, M. Mason and K. McConnachie (eds), *Routledge Handbook of Socio-Legal Studies* (Abingdon: Routledge, 2019).

64 A. Riles, 'A New Agenda for the Cultural Study of Law: Taking on the Technicalities', *Buffalo Law Review* 63(4) (2005) 973–1033; M. Valverde, 'Jurisdiction and Scale: Legal "Technicalities" as Resources for Theory', *Social & Legal Studies* 18(2) (2009) 139–157; D Cowan and D Wincott (eds), *Exploring the "Legal" in Socio-Legal Studies* (Basingstoke: Palgrave Macmillan, 2016).

or consumer law from the original construct of civil law;[65] or the construction of medical/health law and ethics. Indeed, this latter is now taken for granted, but actually grew out of attempts to rationalise what had previously been seen as a mish-mash of various other areas of law. These attempts involved looking across and assembling instances where private law and public law engage with medical practice, through interaction between scholarly discourse and those promulgating the law, especially judges.

Thus Union health law is something beyond or greater than simply the study of relationships between law and health, seen through the lenses of national criminal law, tort law, constitutional law, and so on. And it is something beyond or greater than the study of relationships between Union law and health, seen through the lenses of Union internal market and competition law, Union consumer protection law, Union institutional law and so on.

3.1.3 Pedagogical

Pedagogical reasons for defining and defending a category of Union health law, within the circuits of scholarly knowledge and understanding, include providing a comprehensive overview to enable learners to navigate its ever-expanding complexities. The (perceived) complexity arises in part from the history of Union health law as comprising a merger of two lesser-known areas of law among national lawyers: Union law and health law, which is itself an assemblage of different legal categories such as administrative law, civil law and so on. Complexity arises also from the proliferation of Union legislation and case-law elaborating the meaning and effects of Union legislation and Treaty provisions, both in areas that explicitly concern health, and in areas that have indirect, but profound, effects on the provision of healthcare to Union populations, and to public health.

In this context, 'learners' are not only the students we teach. Our audience also includes our colleagues (in Union law and health law, among others), as well as national (and Union) law and policy-makers and administrators, who need to navigate the intersections of Union law with national health law and policy, and indeed those real and legal individuals (patients, companies, foundations, and so on) who may wish to demand and contest decisions relating to their health or wider health-related public interests.[66] The category of Union health law, and the way that we systemise it, thus has useful functional effects for relevant actors in the world outside of the academy.

65 L. Lessig, 'The Law of the Horse: What Cyberlaw Might Teach', *Harvard Law Review* 113(2) (1999) 501–546.

66 Article 267 TFEU; Article 263 TFEU.

3.1.4 Political

For some of us — and again, we are not all in agreement here — articulating a category of Union health law has an important political implication: it supports the contention that the Union institutions should (be empowered to) do more in the field of human health. While the descriptive/analytical activity of writing legal encyclopaedia entries is far from the mode of legal scholarship that argues for greater Union competences and/or activities, we acknowledge that the identification of Union health law as a distinct 'tree' (an 'is') may also bolster a political argument to the effect that Union health law *should be*. Conversely, for some of us, at least in some circumstances, analysis of Union health law may be carried out for the opposite purpose — to argue that the Union has over-stepped legal boundaries in the health law domain, and acted beyond its competences.[67] The particularities of Union health law — as apart from other 'trees' in the Union law 'forest' — may help us to navigate difficult political decisions about where the responsibilities and powers for human health flourishing in the Union — and indeed beyond — should lie.

3.1.5 Practical

At the more mundane and practical level, Union health law as a category matters for the allocation of resources in the academy and beyond. If Union health law is understood as distinct from other categories of law, funding for projects and salaries, publications, pedagogical courses, Chairs, and so on, will follow. For example, the existence of a free-standing category of Union health law has consequences for academic careers. Across at least 10 Member States (Austria, Croatia, France, Germany, Greece, Italy, Poland, Slovenia, Spain and Sweden), a consistent institutional pattern appears in which courses on Union law are embedded in public-law Chairs or departments, whereas courses on medical law or health law are located in civil-law streams, optional electives or interdisciplinary centres that bridge civil, criminal and administrative law. This structural separation confirms that much of European legal education (and research) continues to classify Union law as quintessentially 'public', whereas health law is treated as a specialised, practice-oriented domain that is either treated as '(mainly) private law', or straddling or lying outside the traditional public/private divide, sitting uneasily in the structures of European university law departments. This historical bifurcated classification of law is foundational in the organisation of law schools, and hence careers. A career in 'Union health

67 V.N. Delhomme, 'Emancipating Health from the Internal Market: for a Stronger EU (Legislative) Competence in Public Health', *European Journal of Risk Regulation* 11(4) (2020) 747–756.

law' is structurally very tricky in that context, but our continued insistence that Union health law exists may make it easier as time passes.

There are also consequences for professional associations such as the European Association of Health Law, and indeed for this journal, which has published many articles on topics in the European health law 'tree'. It is odd that the category has gone largely unremarked in the general scholarly textbooks on either Union or (comparative) health law. This article is, therefore, a way to partially correct the treatment of the category of Union health law, by inserting it more centrally within the very foundations of the knowledge domain of Union law — and health law — as a whole.

The practical utility of the tree also becomes evident when we trace recent Union initiatives that began as twigs and are now thickening into distinct branches. The ways in which we understand such initiatives are affected by their location in a distinct category of Union health law. Two examples illustrate the point. First, the Union's joint procurement of COVID-19 vaccines. As a matter of technical Union law, this was carried out under the competence provision for solidaristic action between Member States in times of natural disaster or severe economic difficulties such as energy supply.[68] Before the pandemic, it was probably not considered to be relevant for healthcare provision or preventive health. Seen it in this light, it looks as if joint vaccine procurement should be understood as an aspect of Union economic law, necessary for the economic (re)flourishing of the Union, and one that was specific to the pandemic, not an approach to be used into the future. But seen as a medical counter-measure, one of the three key legal approaches to responding to a pandemic,[69] we can make better sense of the continued use of collective Union funding to secure vaccine-readiness, not only in the 2020 joint purchasing contracts, but also for example in the establishment of a standing Union-wide vaccine capacity[70] under the auspices of the EU4Health programme.[71] The

68 Article 122 TFEU; Council Reg (EU) 2016/369 [2016] OJ L 70/1; Council Reg (EU) 2020/521 [2020] OJ L 1173.

69 The others being (i) limiting the spread of a virus through public health measures, such as social distancing; and (ii) organising the healthcare system to respond, in particular, securing space in hospitals with intensive care units.

70 European Commission, *Framework Contract Signed under EU4Health to Guarantee Fast Response to Future Health Crises* (2023), available at https://hadea.ec.europa.eu/news/framework-contract-signed-under-eu4health-guarantee-fast-response-future-health-crises-2023-06-30_en (accessed 4 September 2025).

71 Regulation (EU) 2021/522 of the European Parliament and of the Council Establishing a Programme for the Union's Action in the Field of Health (EU4Health Programme) [2021] OJ L 107/1.

need to protect human health — not merely the Union's economy — better explains the ongoing collectivisation of risk by vaccine capacity procurement at Union level.

Second, the 'European Health Data Space' Regulation[72] has emerged from Union data privacy law as a distinctive response to the need to balance interests in collective use of health data for the improvement of human health and interests in privacy, autonomy, and data protection in health domains. Looking only at its legal basis, Articles 16 and 114 TFEU concerning data protection and the internal market respectively, it is hard to make sense of its provisions, especially those concerning secondary use of electronic health data. There would be no reason why existing Union law, especially the General Data Protection Regulation, would not be perfectly adequate for regulation of the European market in electronic health data. But seeing it through the frame and principles of Union health law explains the need for a *lex specialis*: it takes account of the particular issues that arise in health domains.

This 'empirical rooting' of Union legal developments in the health 'tree' thus serves to elucidate both reasons behind the evolution of Union law, and how Union law should be understood. It offers both practical explanatory analysis and hermeneutical framing.

3.2 *Strengths and Weaknesses of Our Approach*

Drawing from the analysis above, we consider the following three elements to be the key strengths of our approach in defining Union health law, as a free-standing legal category, with its own organising structures and concepts (such as health values and principles), which are not only distinct from those of Union law and from those of health law, but are also more than the sum of their two parts. We also note one key weakness.

First, our approach insists that there is an implied structural and systemic coherence to Union health law, as least as an object of legal science, if not as a set of legal rules found in Union legislation and case-law. In other words, we strengthen a claim to the scientific autonomy of Union health law. We see as belonging together, for example, cartels law applied to hospitals and free movement of patients; competence to regulate food and medicines advertising; health professional regulation and vaccine procurement; the list could go on … By considering linkages and relationships (the 'web' of roots) between what may otherwise appear to be wholly distinct elements of Union law, and by considering them as parts of a whole (the 'tree'), we are elucidating patterns

72 Regulation (EU) 2025/327 of the European Parliament and of the Council on the European Health Data Space [2025] OJ L 327/1.

and legal logics that not only explain norms but also perpetuate values and principles-driven legal reasoning about how those norms should properly be interpreted. This is a central concern for and practice of the legal academy, and we place ourselves firmly within that tradition of (European) legal scholarship.

For example, our insistence on non-commodification of human beings as a fundamental value or principle of Union health law not only inspires the structure of our 'tree' with the placement of the branches concerning people first, and then substances of human origin and human health data next. It also explains and justifies our analysis of the intersections of Union market law (movement of goods and services, establishment, competition and state aids law) with health professionals and institutional practice. It shows that where Union law meets national health law, policy or practice, Union health law does not consider health services as simply another market commodity to be regulated in accordance with the logic of market freedoms and Union market integration. Union health law is not alone in this logic of non-commodification; it may also be found, for example, in Union citizenship law.[73]

Another example is that our approach to Union health law as having an underpinning value or principle of solidarity and collectivisation of the organisation of healthcare provisions means that Union health law considers both national and Union health institutions, bodies, entities or agencies to be a distinctive type of structure, with commitments to underpinning those values. Union health law is committed to the ordering of health services provision at a community (national, regional) level, through national or sub-national healthcare systems, funded through some form of collective mechanism (taxation, social insurance, a blend of both) and in principle providing healthcare on the basis of medical need. Again, the way that Union law engages the powers of the Member States, and the Union, in the provision of healthcare and the protection of public health, is understood through Union *health law's* organising principles, not those of 'ordinary' Union law. But it is also understood through *Union* law's organising principles, not those of 'ordinary' health law, whether that is national or global.

Second, both a possible weakness but also at least arguably actually a strength of our approach is the divergence of our views. We do not all agree on the precise modalities of the conceptual underpinnings of Union health law. Specifically, we do not agree on a hierarchy of its underpinning 'values' or 'principles', nor where 'human rights' (and which human rights, precisely) belong in such a hierarchy. Our discursive interactions and the process by which we have

73 Case C-181/23 *Commission v Malta* (*Citoyenneté par investissement*) EU:C:2025:283.

pursued our collective project have revealed that each one of us would define that hierarchy at least slightly differently. Indeed, some of us are not particularly interested in whether there is a hierarchy of such normative underpinnings, or what it is, but are more interested in the practical consequences of different legal framings in the worlds of medical practice, healthcare provision, and policy. This divergence of views may be seen as a weakness: we are not agreed on what might be seen as the normative fundamentals of our object of inquiry — how then can we proceed?

But this divergence of views is not a surprise. We are independent scholars. Each of us has different formative experiences in legal science, and we have been subject to different legal pedagogies in our learning journeys. We speak different languages. We come to Union health law from different routes: from (bio)medical or health law, from Union law, from human rights law …; and we are branching out from it in different directions too, to Union AI law, competition law, global health law … Yet we are able to work together by holding in tension our disagreements and making them sufficiently provisional so as to do the practical work of a collaborative academic enterprise like this one, with all the benefits that flow from that. Indeed, the very make-up of our group seeks to reflect the different 'Europes' that encapsulate the legal and other traditions that flow into European Union law. We work in the north, south, west and (not quite) east, but at least in the centre of Europe. We include scholars from Anglophone, Francophone and Germanic traditions of legal science. Between us, we speak at least 10 languages and are trained in and teach within at least 20 national legal systems, including by invitation as guests in legal systems within which we are not employed. In that sense, we embody the best of comparative law as a mode of European Union law.[74] We are early, mid- and late-career scholars. Holding our positionalities in creative interplay with each other is, we would argue, a *strength* of our approach, not a weakness.

Third, a strength of our approach in using a metaphor of a living entity — a 'tree' — through which to understand our work is that it allows for a conceptualisation of Union health law as a dynamic category, which changes over time, and which interacts with other 'trees' in the 'forests' or 'ecosystems' of Union

74 M. Kiikeri, *Comparative Legal Reasoning and European Law* (Alphen aan den Rijn: Kluwer, 2001); R. Nielsen, 'The Role of Comparative Law in EU Legal Method', *Scandinavian Studies in Law* 61 (2015) 71–86; R. Deplano, G. Gentile, L. Lonardo and T. Nowak (eds), *Interdisciplinary Research Methods in EU Law: A Handbook* (Cheltenham: Edward Elgar, 2024); J. Gruber, 'Methodische Besonderheiten des Unionsrechts', in M. Niedobitek (ed.), *de Gruyter Handbuch Europarecht* (Berlin: de Gruyter, 2020) pp. 775–802; R. van Gestel and H.-W. Micklitz, 'Why Methods Matter in European Legal Scholarship', 20(3) *European Law Journal* 20(3) (2014) 292–316.

law and health law. Rather than ordering our discursive activity through metaphors that imply fixed or static creations — for example, metaphors of architecture such as 'building' or of geography such as 'mapping' or 'surveying' — our collective commitment to the idea of a 'tree' serves as a constant reminder of the ever-changing nature of the category, and also its organic and (partially) self-sustaining nature. We do not only bring the tree into being by 'planting' it (for example, establishing a category in the OUP Encyclopaedia). We tend to its growth, in 'pruning' or 're-directing' branches so that branches around may flourish (setting the parameters of our encyclopaedia entries so that each is distinctive, and changing their focus over time). We allow for the sharing of 'nutrients' around the trunk, branches and twigs, for example, by determining general values or principles which are shared points of analysis in multiple Encyclopaedia entries. We acknowledge Union health law's 'rootedness' within a 'forest' of other categories of Union and health law.

Thinking of Union health law as a tree also allows us to conceptualise moments in the history of Union health law, where hoped-for growth does not occur (shoots that do not grow; buds that do not become flowers or leaves), or even where growth is arrested (broken branches). To focus just on recent events, for example, despite the post-pandemic opportunities for linking Union competitiveness with health, the Draghi Report on Union competitiveness[75] barely mentions health;[76] and the Letta Report's[77] title (*Much More Than a Market*) suggests something different, but the content is essentially more of the same. Health finds a place in these conceptualisations of the Union and its upcoming future aspirations only as 'innovation', not as a free-standing value or human right in itself. Another example is the Commission announcement in February 2025[78] which withdrew many legislative proposals. These include withdrawing the proposal for a directive[79] which would have protected against discrimination based on religion, disability, age and sexual orientation, also in the field of 'goods and services', which would have included health services;

75 M. Draghi, *The Future of European Competitiveness* (Brussels: European Commission, 2024).

76 M. McKee, A. de Ruijter and T. Hervey, 'Health, the Missing Chapter in the Draghi Report on Europe's Future', 48 *The Lancet Regional Health — Europe* 48 (2024) 101150.

77 E. Letta, *Much More Than a Market: Speed, Security, Solidarity* (Brussels: European Commission, 2024).

78 European Commission, 'Commission Work Programme 2025: Moving Forward Together' COM (2025) 45 final.

79 European Commission, 'Proposal for a Council Directive on Implementing the Principle of Equal Treatment between Persons Irrespective of Religion or Belief, Disability, Age or Sexual Orientation' COM (2008) 426 final.

and withdrawing the proposed AI liability directive,[80] which would have had important implications in health domains.

New shoots — such as in Union resilience law;[81] biomanufacturing;[82] cybersecurity of hospitals and healthcare providers;[83] review of HERA[84] — at present do not require us to change our overall conceptualisation of Union health law and its structure. But we remain open to the possibility that they may do in the future, particularly if there is a Treaty reform, or a reinterpretation of Union competences as articulated in the Treaty as it stands. It may be that future determination of Union health law may move away from thinking of Union health law as a 'transversal' field of Union law towards thinking of Union health law as being a 'vertical' field, with its own major competence provisions, for example, like Union environmental law.

Finally, what may be perceived as a weakness of our approach is the way in which our structure (the 'branches' of our 'tree') puts 'inward-facing' Union health law first, and adds 'external' health law thereafter. We might argue that the attention to inward-facing law is a logical consequence of Union law-making. Much effort has been devoted to building the Union's internal market for health (most recently, for example, in the 'European Health Data Space'[85]) and shaping the internal market's engagement with health, and to Union public health law (for example, through Union pandemic preparedness law). Union external law-making in health domains is more recent, less sustained, and less cohesive. Nonetheless, the choice to place Union internal-facing health law first among the branches of our tree is a choice that we make, not a naturally occurring phenomenon.

Hence, the claim that there is simply more Union health law that is inward-facing is not enough to counter the objection that our model of Union health law (our 'tree') implicitly values internal Union health law more highly than external Union health law. And it is but one step from there to an implicit

80 C. Frattone, 'Anatomy of a Fall: On the Anticipated Withdrawal of the AI Liability Directive Proposal', *Verfassungsblog* (2025), available at https://verfassungsblog.de/anatomy-of-a-fall-ai-liability-directive/.

81 European Commission, 'Proposal for a Regulation Establishing a Critical Medicines Act' COM (2025) 102 final.

82 European Commission, 'Building the Future with Nature: Boosting Biotechnology and Biomanufacturing in the EU' COM (2024) 137 final.

83 European Commission, 'European Action Plan on the Cybersecurity of Hospitals and Healthcare Providers' COM (2025) 10 final.

84 European Commission, 'Review of the Implementation of the Operations of the Health Emergency Preparedness and Response Authority (HERA)' COM (2025) 147 final.

85 Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space [2025] OJ L 327/1.

valuing of 'European' human beings above others, elsewhere in the world. This is not just a point about the personal scope of Union health law, most instruments of which are indeed limited to human beings present within (or at the borders of) the Union. That may be true, and much health law (not just Union health law) is jurisdictionally-based. But our articulation of the 'tree' incidentally and by implication gives a particular place and respect to 'European' human beings (those present within the Union, whether as citizens, residents, asylum seekers, or visitors). It thereby implies that their health and healthcare should be valued more highly than that of people elsewhere in the world. By contrast, the focus of global health law scholars, especially those within health and human rights traditions, is the inherent and equal value of health of every human being on the planet.[86]

This is a 'dark side' of Union law more generally, which is only more recently being explored,[87] including in this paper, in that we acknowledge here that much of Union health law is inward-facing. This 'dark side' applies both to Union law based on 'internal' competences and that based on 'external' competences. For example, Union resilience law (and policy), (such as the proposed Critical Medicines Act[88]) is about securing health and healthcare (for example critical medicines supply) *for European populations*. It has little regard for the health of people elsewhere in the world. While Union external trade and development policy has aspects engaged with global health,[89] the legal instruments

86 L.O.Gostin and B.M.Meier (eds), *Global Health Law and Policy* (Oxford: Oxford University Press, 2024); J.P. Ruger, *Global Health Justice and Governance* (Oxford: Oxford University Press, 2018); A.E. Yamin, *Power, Suffering and the Struggle for Dignity: Human Rights Frameworks for Health* (Philadelphia, PA: University of Pennsylvania Press, 2016); Committee on Economic, Social and Cultural Rights, *General Comment No 14: The Right to the Highest Attainable Standard of Health* (11 August 2000) UN Doc E/C.12/2000/4; *Constitution of the World Health Organization* (1946) 14 UNTS 185 (Preamble).

87 H. Eklund (ed.), *Colonialism and the EU Legal Order* (Cambridge: Cambridge University Press, 2025); J. Silga, 'From Political to Migration-based Conditionality in the EU Development Policy', in H. Eklund (ed.), *Colonialism and the EU Legal Order* (Cambridge: Cambridge University Press, 2025) pp. 202–228; D. Ashiagbor, 'Decentring Europe in EU Social Law Scholarship', *European Law Open* 2(3) (2023) 479–483; I. Solanke, 'Embedding Decoloniality in Empirical EU Studies', in M. Rask Madsen, F. Nicola and A. Vauchez (eds), *Researching the European Court of Justice* (Cambridge: Cambridge University Press, 2022) pp. 343–353; P. Neuvonen, 'A Way of Critique: What Can EU Law Scholars Learn from Critical Theory?', *European Law Open* 1 (2022) 60–88.

88 European Commission, 'Proposal for a Regulation Laying a Framework for Strengthening the Availability and Security of Supply of Critical Medicinal Products' COM (2025) 102 final.

89 European Commission, 'EU Global Health Strategy: Better Health for All in a Changing World' COM (2022) 675 final.

underpinning it are few and far between. Whether, and if so the extent to which, important aspects of Union trade and other external relations law, such as 'the Brussels effect', whereby Union regulatory standards are de facto imported to the rest of the world;[90] or reciprocity in trade agreements;[91] foster and protect human health elsewhere in the world is a subject that deserves greater investigation than we can undertake here.

4 Conclusions

In explaining our collective project, we have first outlined what counts as Union health law, distinguishing it from neighbouring fields of legal enquiry. We do not claim to have reached a static delineation for perpetuity which over time would stunt the growth of our field of expertise. Rather, we rely on a metaphor of a 'tree' to convey an adaptive framework or evolving taxonomy: a living, growing entity, through the double-dynamic of legal facets of changing Union integration and bioscience, that interacts both within itself and with other 'trees' around it. We use this to organise current legislation and case-law, anticipate future growth, and invite further discussion and inquiry.

We have shown how creating a section in a legal encyclopaedia is a process through which a knowledge domain comes into being, grows and develops. The section on Union health law in the OUP Encyclopaedia of European Union Law, both in itself and through the wider knowledge domains of Union law and health law, ultimately helps to co-constitute law, regulation and governance, and potentially (dis)enables a whole range of other social, economic and political relations, ways of knowing and (self)understanding(s). As it grows ever more branches (perhaps whole new areas of Union legislation?), twigs (perhaps secondary and tertiary legislation building on primary law?), buds (perhaps proposals for new law?), flowers and leaves (perhaps specific interpretations of provisions of law in cases?), ever more of the intricacies and nuances of Union health law emerge. This growth has implications for both the Member States, in the pursuit of provision of healthcare and protection of the health of their populations; and for the Union as a global health actor vis-a-vis others, such as the World Health Organisation.

90 A. Bradford, *The Brussels Effect: How the European Union Rules the World* (Oxford: Oxford University Press, 2019).

91 M. Cremona, 'Mix or Not to Mix? Non-Trade Objectives in EU Trade Agreements', *EUI RESPECT Project Report* (2022), available at https://respect.eui.eu/wp-content/uploads/sites/6/2022/02/to_mix_or_not_to_mix.pdf.

Further, we have sought to render more transparent the process, its consequences and broader implications, and its strengths and weaknesses, than is usually the case for legal scholarship. Our taxonomy reveals the normative weight of the category Union health law, in that it aligns with a cluster of Union primary law principles, values, human rights; solidarity commitments; and precautionary obligations. These show that Union health law is not merely derivative of Union internal market, citizenship, or external relations law, but rooted in primary law values and principles. Our approach sheds light on constitutional questions, especially of Union competence, and supports our claim that Union health law is currently best understood as 'transversal' but may be moving in the direction of a (more) 'vertical' competence category as the European Union project continues. We offer a way to understand whether forthcoming measures such as digital health governance, One-Health integration, or external pandemic agreements will consolidate or contest this movement toward verticalisation.

We show how we understand (Union) (health) law through a 'middle way' between realist and social constructivist perspectives. There are implications for legal learning, for the politics of Union involvement in health, and for a range of practical matters such as legal academic careers, disbursement of resources, journals and learned societies, and policy making.

One such consequence/implication, and both strength and also weakness, not so explicitly drawn out in the above, is that our approach is a deep form of *collaborative* legal scholarship. We have shown how a method like ours surfaces tensions (or even inaccuracies) that are invisible to single-author accounts. We are a group of scholars with different views, yet we are able to co-create a project like this one, while at the same time having even quite profound disagreements among ourselves. This type of collaborative (legal) scholarship involves constant discursive processes and compromises: there were times when we felt that we perhaps would not succeed in even writing this journal article.

On the upside, though, together, we are able to make claims across legal scholarly works in different languages, and rise above assumptions that might arise from being rooted in one (or just a couple of) scholarly tradition(s). This is particularly valuable in the context of a topic — health law — that tends to be jurisdictionally based, and which has a long comparative law history. After all, Union law is a law with many different authoritative languages; and it is law that is equally valid, equally applicable, and has (or should have, according to its own normative claims) the same legal effects in each of its Member States. A scholarly endeavour within Union/health law will be more effective if it can understand Union/health law (if we can tend the tree of Union health

law) from many perspectives. Our tree is strong because it is tended by many gardeners.

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