

# *The Dynamic Potential of European Union Health Law*

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*Some understandings of European Union health law are based on a presumption of law as a static and closed system. This approach to the Union as a legal entity has important ramifications. The Union is a political system created by and subject to the rule of law. Its successes (and failures) are attributable to the legalisation of solving externalities and ensuring Member State solidarity to gain benefits from integration. Member States, which create and sustain the Union by repeated acts of sovereign choice, choose to subject themselves to the rule of (Union) law. This protects both the Member States and the Union institutions (imperfectly, but nonetheless) from charges of illegitimacy. While recognising the benefits of such an approach to European Union integration and law-making, we take the view that law also has an important dynamic potential. That dynamic potential is inherent in all law, for law is embodied in text, and always open to interpretation, as the external contexts that give legal text meaning in the real-world change through time. We trace the dynamic potential of Union health law by looking at its legal basis to its foundational Treaties, and we plot its trajectory going forward.*

## I. INTRODUCTION

There is a caricature of European Studies conversations that goes something like this:<sup>1</sup>

*Intergovernmentalist:* European Union integration is simply driven by political preferences as a vehicle for the move of the Member State governments towards integration and its benefits.

*Neo-functionalist:* No, seriously, European Union integration in one policy area creates a drive towards more integration in surrounding policy areas that are functionally related – that is the true dynamic of European Union integration.

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<sup>1</sup> This is an obvious simplification of these theories and explanations of European Union integration. Our understanding of the European Union’s involvement in health is greatly indebted to these understandings. See, seminally, B Rosamond, *Theories of European Integration* (Basingstoke, Macmillan 2000).

*Institutionalist*: No, it isn't. The Union's unique institutional structures create political preferences that drive the integration process independently of the political will or whims of Member State governments.

*Multi-level governance scholar*: No, it isn't. The integration process happens through interactions between national and European institutions and their political preferences.

*Legal scholar*: Excuse me . . . what about the law? The Union is founded on the rule of law, and political integration only takes place where it is legally permitted or mandated. The Union's successes are attributable to the legalisation of preventing free-rider behaviours, so as to secure the benefits of integration. Member States, which create and sustain the Union by repeated acts of sovereign choice, choose to subject themselves to the rule of (Union) law. Union law mandates that health policy is a *national* matter.

*All, except the legal scholar*: The law? That isn't relevant at all!

In this caricature, the main characters may disagree with each other, but they all agree that *law* is only one factor in explaining the European Union and the integration processes for which it is responsible. As legal scholars, we (perhaps surprisingly) *agree* with the main characters, if law is understood as a closed and inflexible factor in the structures of the Union and the integration processes for which the Union is responsible. But we *disagree* with this type of understanding of law as a fixed feature in the amalgam of political, institutional and social processes that shape European integration. For us, (Union) law is far from a static or closed system that gets meaning through text and context. It is imbued with *dynamic potential*. This dynamic potential is important when we consider the future of Union health law and policy.<sup>2</sup>

In this commentary, by understanding law as "situated" and having a dynamic potential, we both explain the history of Union health law and policy (Section II) and project its trajectories into the future (Section III). We mainly recount these as stories of some success and opportunity: Union health law and policy, though far from perfect, has done much to contribute to the health of Europe's people(s) and to protect European ways of organising both public health and national health systems. But Union law's dynamic potential also has a dark side, which we explore in Section IV. This leads us to our conclusion that the dynamic potential of Union health law is a necessary, but not sufficient, condition of a future European health Union that genuinely and legitimately protects and promotes good health.

For the purposes of this commentary, we define the scope of Union health law and policy as follows: it is a body of legal rules and policy provisions that mandate, incentivise or otherwise regulate certain actions, or the refraining from certain actions,

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<sup>2</sup> In this commentary, we were asked to provide a broad-stroke analysis of the past and future of Union law and policy. For full details of the legal instruments to which we refer, please see A de Ruijter, *EU Health Law and Policy: The Expansion of EU Power in Public Health and Health Care* (Oxford, Oxford University Press 2019); TK Hervey and JV McHale, *European Union Health Law: Themes and Implications* (Cambridge, Cambridge University Press 2015); and TK Hervey and JV McHale, *Health Law and the European Union* (Cambridge, Cambridge University Press 2004).

in the provision of human healthcare and the protection of public health.<sup>3</sup> This is a wide definition. It encompasses many fields of governmental activity that overlap with, or can be conceptualised as, other policy or legal fields. But it owes its coherence to the fundamental nature of human health and its relationship with human flourishing and well-being. Without health protection, other human activities, be they economic, social or cultural, simply cannot take place.

Our approach and method is socio-legal in a broad sense and cross-disciplinary: we are interested not only in the relevant legal texts (which for us occupy a central methodological space), but also in their actual and potential effects in practice. We draw on and refer to knowledge of appropriate qualitative and quantitative social science research. But our key methodological departure point is that legal texts are situated and context-specific. When it comes to the health law and policy space, legal texts create opportunities for limiting and expanding policy and legal developments that are not obvious if looking only at the literal or previously understood interpretations of legal texts.<sup>4</sup>

## II. HISTORY OF UNION COMPETENCES IN HEALTH

From the inception of the Union in the Coal and Steel Community and then the European Economic Community, there was no formal legislative basis for health law and policy.<sup>5</sup> And yet, there was European health law and policy. In the context of the common agricultural policy – which was fundamentally concerned with ensuring that (Western) Europe did not starve again, as it had in the 1940s – communicable disease control was implemented to ensure that milk that was traded across borders was free of bovine tuberculosis. Furthermore, there was access to cross-border health benefits for steel workers, and the European-level rules on pharmaceuticals marketing were adopted to avoid a repeat of the thalidomide tragedy. But there were also “Europe against Cancer” and then “Europe against AIDS” programmes initiated to tackle the some of the most serious non-communicable and communicable diseases facing its populations at the time. Legally dubious,<sup>6</sup> as the Union then lacked formal power to establish such programmes of training, information exchange and research, these programmes could be understood as based on Article 2 EEC, establishing “the raising of the standard of living” as a Union objective, and Article 235 EEC, giving competence to meet objectives where no more specific power was given in the Treaties. However, rather than law-makers per se, it was also the health elites that would find linkage on health-related issues where cross-border exchange of expertise was seen as an advantage for health-related objectives. Union law and institutions, whether there was a legislative basis or not, provided a framework that was flexible enough to give some formality to these interactions without making them more

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<sup>3</sup> See de Ruijter, *supra*, note 2.

<sup>4</sup> For an example of the method, see TK Hervey, “Re-Judging social rights in the EU” in G De Burca, C Kilpatrick and J Scott (eds), *Critical Legal Perspectives on Global Governance* (Oxford, Hart 2014) p 347.

<sup>5</sup> For simplicity, we use “Union” throughout this article, although it is not legally correct.

<sup>6</sup> Hervey and McHale, 2004, *supra*, note 2, 73.

binding than any law-maker at the time would have felt comfortable with vis-à-vis its own electorate. This is an example of one feature of the dynamic potential of Union law: if there is no political opposition mobilised, then Union action can be based on very loose and surprising interpretations of the relevant legal texts, with scant judicial oversight of those interpretations.

The year 1993 saw the entry into force of the first formal Union health competence under the Treaty of Maastricht. Then Article 129 EC provided power for the Union to “contribute towards a high level of human health protection by encouraging cooperation between Member States, and, if necessary, lending support to their action”. Health here is a prime example of the paradox that epitomises EU integration when it comes to legislative competence. Some Member States felt that a specific legal basis for Union health law would be good in order to limit the increasing activity and interest by Union (supranational) law-makers in the topic, while other Member States felt that a formal legal basis would create a good platform for intensifying some of the activity that was already taking place in the field.<sup>7</sup> Action of the Union institutions was to be focused on specific areas, particularly major health scourges, research into those diseases and health education and information.

Substantively, the focus here was collectively determined health (public health) rather than individual protection of health (healthcare) or governance of healthcare systems. Most importantly, Union action was to be limited to the coordination and incentivisation of national action, and the harmonisation of national laws with respect to public health was explicitly excluded in the legal text. The specific prohibition on the harmonisation of national laws in the legal text that attributes legislative powers to the Union underlines the paradox that was part of the health competence from its inception. In addition, at the time, the attribution and subsidiarity principles were well enshrined within Union law. Hence, a health-specific recitation of a prohibition on harmonising national laws would seem excessive. However, it is exactly that push and pull that forms the basis for the further dynamics that became the breeding ground for the development of Union health law and policy.

Article 129 EC and its successors gave the basis for further action programmes, which eventually became the Union’s various public health programmes,<sup>8</sup> and, most recently the proposed EU4Health programme.<sup>9</sup> The provision in Article 129 EC was amended, and renumbered at Article 152 EC, by the Treaty of Amsterdam, which entered into force in 1999; and again renumbered at Article 168 TFEU, by the Treaty of Lisbon, which entered into force in 2009. Several textual changes strengthened the Union’s powers in the field of health. Union activities were no longer limited to the prevention of disease, but expanded to include

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<sup>7</sup> *ibid.*

<sup>8</sup> *ibid.*, 74 et seq.

<sup>9</sup> “Proposal for a Regulation of the European Parliament and of the Council on the Establishment of a Programme for the Union’s Action in the Field of Health – for the Period 2021–2027 and Repealing Regulation (EU) No 282/2014 (‘EU4Health Programme’) (COM(2020) 405 Final)” <[https://ec.europa.eu/info/sites/info/files/com\\_2020\\_405\\_en\\_act\\_v11.pdf](https://ec.europa.eu/info/sites/info/files/com_2020_405_en_act_v11.pdf)>.

promotion of good health. Arguably, all Treaty changes in the field of health are related to constitutional moments and public health crises. In 1992, the tobacco advertising litigation saga and the HIV/AIDS pandemic formed important backdrops of the discussion during the Maastricht Treaty amendments. At the time of the Amsterdam amendments, the bovine spongiform encephalopathy (BSE) crisis had just put enormous political pressure on Member States to come up with a “Union” answer. By 2008, there had been the anthrax scare in 2001, followed by the bird flu, severe acute respiratory syndrome (SARS) and a number of other public health scares.

Hence, in the Lisbon Treaty amendments in 2008, the obligation on the Union institutions was strengthened from merely “contributing” to a high level of human health protection to an obligation to “ensuring” a high level of human health protection in all Union activities. This “mainstreaming” obligation, now reflected in Articles 9 and 168 TFEU, is a key aspect of the dynamic potential of the competence provisions of Union health law and policy. It has been understood as a response to the argumentation of the UK government in Case C-180/96/R *UK v Commission* concerning the emergency measures taken by the Union against the UK to stop the spread of BSE.<sup>10</sup> The UK argued that the measures, which restricted export of British meat, were adopted on the basis of protecting the beef market and did not take account of actions taken by the UK to eliminate risk, or of products for which the risk of BSE was not at the time established, and hence were unlawful. The essence of the Court’s reasoning was that the protection of public health is a duty of all Union institutions, which cannot be disregarded in the pursuit of other Union policies such as free movement of goods or the common agricultural policy. The Court in this case implicitly recognised the centrality of human health to all Union activity on the basis of its reading of the Treaty texts as a whole. The revised Treaty included this provision in its account of Union competence. This is an example of a second feature of the dynamic potential of law: in this case, the tensions implicit in legal texts meant that the law got “ahead” of the politics. Consequently, this paves the way for Member States to embody a “catch-up” in a Treaty revision.

The BSE case also serves as an example of the dynamic potential of Union law in its amenability to use by litigants seeking to secure market access in another or even their home Member State, or otherwise to challenge domestic law or policy. The direct effect and supremacy of the provisions securing free movement of the factors of production in the internal market has led to de facto Union health law-making in a wide range of aspects of national health systems. These include cross-border access of patients to medical treatments, sometimes because of waiting times or costs in the home Member State, or occasionally because of ethical or other differences in the “basket of care” available at home, resulting in changes to domestic practices or provision.<sup>11</sup> Union law has also been used to challenge restrictions on pharmaceutical sales conditions that *inter alia* have an effect on pharmaceutical pricing or on ready access to

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<sup>10</sup> R Geyer, *Exploring European Social Policy* (Cambridge, Polity 2000) p 175.

<sup>11</sup> See the case study of *Watts* in T Hervey, “EU Health Law” in C Barnard and S Peers (eds), *European Union Law* (Oxford, Oxford University Press 2020 forthcoming), ch 21.

pharmaceuticals for patients. And Union law has been used by health professionals such as dentists, ophthalmologists or pharmacists seeking access to markets in other Member States (or even in their home Member State), opening up cartels based on professional exclusion, as well as by aspiring medical professionals to secure access to training opportunities. Union law on equality or non-discrimination has been relied upon to challenge national rules about blood donation, Union competition law has been relied upon to challenge hospital mergers, and so on. The logics of Union law reach deep into the logics of national health systems, disrupting their territorial bases and creating new efficiencies and opportunities.

The standard response in Union law to the deregulation inherent in such internal market or other litigation is to re-regulate at the Union level by adopting harmonised law. Here, in Union health law, we run against a classical constitutional tension that is amplified in health as a result of the legal text in Articles 168(5) and (7) TFEU. The key constraints to the Union's competence provisions in health reiterate that there is no Union power to harmonise national law or policy in order to protect or improve human health or directly to protect public health.<sup>12</sup> But this apparent "no harmonisation in health policy" rule does not mean what it seems to mean. In fact, this apparent constraint upon Union action is not reflected in Union health law and policy as it developed through the 1990s, 2000s and 2010s. The Union has adopted many harmonising measures in health law and policy, deploying other legal bases within the Treaties, principally the power to create and sustain the Union's internal market.<sup>13</sup> Safety of medicines, medical devices and equipment, blood and human organs and other substances of human origin;<sup>14</sup> clinical trials regulation; protection of privacy of medical data; liability for harm from novel health technologies; recognition of medical qualifications; intellectual property in biotechnological inventions; food safety, labelling and traceability; and, infamously, tobacco regulation and advertising are all subject to harmonised Union law.<sup>15</sup> Such law-making based on creative interpretations of the Union competences does not take place without at least the possibility of judicial oversight, either because parties are dissatisfied with process (eg as in the case with the Directive on the Legal Protection of Biotechnological Inventions, which was adopted only with parliamentary consultation) or outcome (eg as in the case with the Tobacco Advertising Directive, which prohibited advertising services where there was no link to creating or sustaining the internal market). But judicial review does not necessarily mean asserting narrow or literalistic readings of legal texts – another feature of law's dynamic potential.

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<sup>12</sup> Note the exceptions for substances of human origin (Art 168(4)(a)), public health protections in veterinary and phytosanitary rules (Article 168(4)(b)) and medicines and medical devices (Article 168(4)(c)).

<sup>13</sup> S Garben, "Competence Creep Revisited" (2019) 57 *Journal of Common Market Studies* 205. Garben describes at least six forms in which competence creep may take place, which all take place in areas where Member States have retained authority (Arts 2–6 TFEU).

<sup>14</sup> For a broad discussion and case references, see Hervey and McHale, 2015, *supra*, note 2, 364.

<sup>15</sup> We refer here to an intricate regulatory space with intensive legal developments within EU case law. See eg. Case C-376/98 *Germany v Parliament and Council (Tobacco Advertising)* [2000] ECR I-8419. And for further discussions, see, eg, Hervey and McHale 2015, *supra*, note 2, 71–124, including the patients and the medical products cross-border dynamics. Also see de Ruijter, *supra*, note 2, 63–90.

### III. THE DYNAMIC POTENTIAL OF THE CURRENT LAW

Those features of law's dynamic potential (its contextualised, constructed, interpreted nature; the phenomenon of politics "getting ahead" of the law; its amenability to strategic litigation; an open approach to judicial review) pertain today. The legal texts in the Treaty for health law and policy look restrictive in terms of the Union's competence to create a European health Union, but actually they are amenable, if the political will is present. The Union powers to incentivise, encourage, support, coordinate and resource activities in the health field are significant in this regard. Most laws are intended to incentivise particular behaviour. Although in most understandings the power to create "incentivising" legislation in Article 168 TFEU might have been seen as relatively non-binding and inconsequential, who is to say that "incentivising" cannot entail carrot-and-stick-type laws. In the context of COVID-19, for example, the Union may lawfully support work towards collaborative research into vaccines, treatments and new medical equipment; epidemiological research into the spread of the disease; and social sciences research into its economic, political, social, cultural and other consequences. The Union has the power to pool medical professional capacities, to develop capacities in regions or specialisms that are lagging, to secure the benefits of digital technologies in health fields or to bargain with the pharmaceutical industry in procuring vaccines or medicines. Many of these ideas are part of the European Commission's proposal on an EU4Health Programme 2021–2027.

Despite the apparent restriction on harmonisation, the Union has the power to adopt binding laws that have the effect of improving health, so long as those measures remove obstacles to trade or prevent appreciable distortions of competition. Union laws in many policy areas, including trade, consumer protection, agriculture and security, must protect and promote health. And as outlined, the Union's powers to incentivise Member State action "to protect and improve human health and in particular to combat the major health scourges" is untested. The Union has a range of incentives under its control and can offer access to resources, collectively held equipment, human resources, pooled expertise or knowledge, administrative capacity or information or the Union's geopolitical capital. Taken together, as a "web of competence",<sup>16</sup> these powers will go a long way to creating a European health Union.

### IV. THE "DARK SIDE" OF UNION HEALTH LAW'S DYNAMIC POTENTIAL

So far, we have considered the dynamic potential of Union health law as a benefit – a positive and a force for improving human health in the Union, and potentially beyond. Deployed creatively, the Union's legal powers in health domains have been, and can be, used in this way. The Union has developed its health laws and policies in ways that include all stakeholders, including patients, health professionals, the biomedical research community, public health specialists, health system institutions

<sup>16</sup> KP Purnhagen et al. "More Competences than You Knew? The Web of Health Competences for Union Action in Response to the COVID-19 Outbreak" (2020) 11 European Journal of Risk Regulation 297.

and governmental bodies. Where “many eyes” are on legal or policy proposals, particularly where that scrutiny represents expert knowledge from the logics of human health, rather than the logics of trade relations, we increase the chances of beneficial policy outcomes.

Two constitutional problems arise from using the opportunities that are offered by the primary legal text in the Treaty for the creation of health law and policy. The first is procedural and the second is substantive. Procedurally, as a result of health being a side issue to other policies, competence creep can create a democratic problem, which has been well described in Union (legal) studies.<sup>17</sup> But substantively, for health specifically there is a constitutional problem, where a competence to act in other policy areas (indirect legislation), such as the internal market or agriculture, is used to create public health protections of healthcare entitlements. The tobacco advertising saga and the Cross-Border Health Care Directive are prime examples of this phenomenon.<sup>18</sup> In health, then, the problem for legitimacy is not so much the democratic safeguards, but rather that there are no limits to Union competence, as these are formulated in Article 168(5)(7), when legislation is based on wider, more undetermined areas of legal competence such as Article 114 TFEU (internal market).<sup>19</sup>

For the content of Union health law and policy, this presents a “dark side” when the dynamic potential for health law and policymaking is fully exploited without a sense for the constitutional stakes at play: using indirect legislation constrains the consideration of the full spectrum of rights and values that are involved in health law and policy generally at the Member State level.<sup>20</sup> Furthermore, it changes the institutional actors around the table, who might not have a full grasp of the substantive issues and health-related fundamental rights at stake. Health law and policy represent highly complex systems of regulated markets, self-organisation and expert policy at the Member State level. Furthermore, this is a politically sensitive policy area, so putting another policy expert on the table can have the effect of the proverbial “bull in a china shop”, as the negotiations around the Patient’s Rights Directive exemplified.<sup>21</sup>

Furthermore, its legally loose base may turn Union law and policy into a tool for political capture. The tobacco industry, for example, has used (Union) law to seek to secure access to new markets, particularly of young people, and particularly for novel

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<sup>17</sup> There is a long line of scholars working on the Union’s democratic deficit – we name a few: D Curtin, “‘Civil Society’ and the European Union: Opening Spaces for Deliberative Democracy?” in *Collected Courses of the Academy of European Law*, Volume 3, Book 1, European Community Law (Alphen aan den Rijn, Kluwer 1997); A Moravcsik, “In Defence of the ‘Democratic Deficit’: Reassessing Legitimacy in the European Union” (2002) 40 *Journal of Common Market Studies* 603; M Bartl, “The Way We Do Europe: Subsidiarity and The Democratic Deficit” (2015) 21 *European Law Journal* 23; D Grimm, “The Democratic Costs of Constitutionalisation: The European Case” (2015) 21 *European Law Journal* 460.

<sup>18</sup> A de Ruijter, “The Impediment of Health Laws’ Values in the Constitutional Setting of the EU” in TK Herve, CA Young and L Bishop (eds), *Research Handbook on EU Health Law and Policy* (Cheltenham, Edward Elgar 2017); A de Ruijter, “EU Integration in the Field of Human Health” (2016) 38 *Journal of European Integration* 837.

<sup>19</sup> Garben, *supra*, note 13.

<sup>20</sup> G Davies, “Subsidiarity: The Wrong Idea, in the Wrong Place, at the Wrong Time” (2006) 43 *Common Market Law Review* 63. Subsidiarity as a tool for EU integration is a matter of assessing the effectiveness of law in view of a particular (legislative) objective, rather than balancing values.

<sup>21</sup> de Ruijter, *supra*, note 2.



products. The pharmaceutical industry has sought to undermine European pharmaceutical pricing approaches deployed by Member States to keep negotiated prices relatively low for their national health systems. For sure, it remains important to pay attention to who might deploy law to challenge Union competence to act in the creation of a European health Union, as well as to how they might do so. The locus for bringing judicial review claims before the Court of Justice of the EU (CJEU) is quite restrictive (although privileged applicants such as the European Parliament or Member States enjoy such a locus); but judicial review may also be brought by private actors before national courts, and from there a preliminary reference to the CJEU is possible. And the direct effect of Union law means that it can be relied upon in litigation by private actors.

At the same time, much of the detail of Union health law and policy lies in technocratic decision-making at the agency level through committee processes or through private standards bodies. Here is where decisions about the safety of medicines, devices and equipment, chemicals and other components, about the permissibility of clinical trials, about food safety, contents and labelling, about environmental effects on health and a host more are made. Much more than the high-profile, broad-brush legislation, these areas are where the specifics about the European ways of thinking about health – especially public health – are embedded into dense regulatory structures. These areas are where, for example, the Union’s precautionary principle is instrumentalised in practice.

Union law and policymaking have not always been successful in protecting and promoting human health through such processes and mechanisms, partially given that its hands were tied legally, but also due to a lack of political will, capacity and knowledge.<sup>22</sup> The decision-making under the Common Agricultural Policy did not prevent the BSE scandal. Oversight by standards bodies did not prevent the Poly Implant Prothèse (PIP) breast implants scandal. The European Centre for Disease Prevention and Control (ECDC) failed to protect Italy and other Union countries from the ravages of COVID-19. One of the key roles of law in the Union’s constitutionalised structures is to secure the accountability and legitimacy of decision-making. This can be through compensation for harm, mandating transparency and accounting for decisions made, perhaps with political consequences including being relieved of public office. This is the case as much for technocratic decision-making as it is for high-level legislative decision-making.

To be sure, matters related to human health are rarely *only* technocratic matters. Technocratic decision-making may be appropriate where a matter is truly only technical, but not so much for matters where there are ethical or other similar dimensions. In such matters, constitutional legitimacy requires parliamentary or other representative and/or stakeholder oversight, as well as consistency with fundamental human rights. The dynamic potential of the Union’s constitutional and institutional legal frameworks hides a “dark side”: the possibilities for political and/or technocratic decision-making without any real reference to legal oversight.

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<sup>22</sup> *ibid.*

## V. CONCLUSION

The dynamic potential of law represents an opportunity for creating a European health Union, if the political will is there to do so. We have argued that such competence is necessary, but not sufficient, to create the kind of European health Union that is consistent with the Union's self-proclaimed values and the human rights it promises to protect.<sup>23</sup> Health law and policy are areas of human order that are highly tied into specific bioethical values related to disease, the beginning and end of life and even human identity itself. These are values such as human dignity, equality and solidarity, which are protected at the Member State level and the Union and Council of Europe level in various legal documents and in European case law. It is this sensitivity of the particular nature of health law and policy that should give us even more caution. For the Union, we need to ensure that, moving forward, we avoid the risks associated with relatively unfettered powers. We must make sure that legitimacy mechanisms including stakeholder scrutiny, parliamentary oversight and access to justice are also in place.

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<sup>23</sup> See, eg, Art 2 TEU; The Charter of Fundamental Rights of the European Union OJ 2012 C 26/391; European Council Conclusions on Common values and principles in European Union Health Systems OJ 2006C 146/01.