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**Telling stories about European Union Health Law: The emergence of a new field of law**

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**Abstract**

The ideational narrative power of law has now solidified, and continues to solidify, 'European Union health law', into an entity with a distinctive legal identity. EU health law was previously seen as either non-existent, or so broad as to be meaningless, or as existing only in relations between EU law and health (the 'and' approach), or as consisting of a body of barely or loosely connected policy domains (the 'patchwork' approach). The process of bringing EU health law into being is a process of *narration*. The ways in which EU health law is narrated (and continues to be narrated) involve three main groups of actors: the legislature, courts and the academy.

**Keywords**: EU law, healthcare

**Introduction**

When Jean McHale and I began working on European Union (EU) health law in the mid 1990s, we were counselled by a senior colleague against our choice of research agenda. 'European Union health law – there isn't any,' he mused. Then he paused. 'Actually, I beg your pardon, it's huge, isn't it?'

These responses – the non-existence or vast and imprecise scope of EU health law – remain pertinent today and show that the very object of inquiry in this paper is contested. Are EU health policies represented in, supported by, and implemented through specific and distinct legal arrangements? In simpler words, does EU health law exist? In 2004 (Hervey and McHale 2004) and as recently as 2010 (Hervey and Vanhercke 2010), the implicit assumption, in my work and that of others (Hatzopoulos 2002; Newdick 2006, 2009; Lamping and Steffen 2009; Mossialos et al 2010; Flear et al 2013, but see concluding chapter thereof), was that EU health law could be understood only in the interface between EU law and health (the 'and' of Hervey and McHale 2004), or in a patchwork of legal provisions 'that constitutionally "belong" to different policy domains, principally those of the internal market, social affairs, public health, enterprise, and economic policy' (Hervey and Vanhercke 2010: 85). But Hervey and McHale (2015) develops a thematic analysis of EU health law. In other words, the assumption underpinning that monograph is that it is now the case that EU

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health law should be seen as a distinct field of law or at least of legal enquiry (Hervey and McHale, 2015: 6, 8, 30-70). But if it is now tenable that EU health law 'exists', how did it come into being?

Discovering how EU health law came to be matters for several reasons. The structures and assumptions underpinning a body of law have consequences for the meanings and applications of legal rules. Legal rules determine obligations and entitlements in both private relationships, and, importantly in this context, relationships between individuals and public authorities, including bodies such as the institutions within national health systems, and those of the European Union. Legal rules may be 'constitutional', such as the Treaty on the Functioning of the EU (TFEU), or the EU Charter of Fundamental Rights (CFR); legislative, such as the Data Protection or Patients' Rights Directives; or administrative, such as a Commission Decision to grant European marketing authorization to a controversial new medical technology. To understand legal rules as part of a self-referencing entity thought of as 'EU health law', with its own specific logics, is to understand them differently from rules that are understood as part of 'internal market law', 'human rights law', 'privacy law', 'innovation law' and so on. It also matters if an entity such as 'EU health law' becomes institutionalised into various settings, including policy, legal, and academic institutions, at EU and national levels (De Ruijter, 2016; Vollaard and Martinsen, 2016 in this issue). If we take seriously the idea that the rule of law is a key explanatory factor in European integration (Schiengold 1965; Stein 1981; Weiler 1991; Burley and Mattli 1993; Stone Sweet 2010; Greer and Loblova 2016 in this issue), then the rule of law in EU health policy is no exception.

**Methodology**

This paper places *narration* at the heart of the processes that are understood to have led to the emergence of EU health law. The telling of stories (or 'cognitive scripts' (Hall and Taylor, 1996: 947)) that contribute to shared beliefs and understandings of the world, its problems, and how to fix them is a feature of social constructivist political science accounts of EU integration and governance (eg Rosamond, 2000, 2003; Hay and Rosamond 2002; Risse, 2004, 2009; Risse, Jorgensen and Wiener 2001). Narration is also a significant aspect of legal methodologies: both in the academy and in legal practice. The ways in which legal processes (or the threat of legal processes), in particular court proceedings, but also legislative processes, construct social facts into shared understandings, ideas, expectations, and truths (the 'constitutive power of law' (Feeley 2013: vi)) has long been reflected in sociological (eg Friedman 1977; Mnookin and Kornhauser 1979, Galanter 1983; Boyd White 1985; Cotterrell 1992: 102-36; Ewick and Silbey 1998; Gessner and Nelken, 2007), critical (eg de Sousa Santos 1985; Fitzpatrick 1997; Hunter, McGlynn, Rackley 2010) and traditional approaches to law. These include, for instance, those based on the common law inductive processes of deriving legal principles from the stories told in litigation, described in 'introduction to law' textbooks (such as Holland and Webb, 2013). As de Búrca and Walker (2007) and Cardwell and Hervey (2015) observe, this is also so in the case of EU law. Law here is understood not only as a mandate which guides behaviour, but also as a site for stories which give meaning to that behaviour. The two are interconnected in that, through processes of interpretation, the meaning determines the mandate. Hence the paper's mixed, 'law-in-context', approach.

The limits of this approach are the well-known limits of constructivist approaches in general. Constructivist accounts tend to suppress the relevance of agency, particularly the agency of non-state actors, as an explanatory factor. They discount the importance of rationalist interest-based decision-making. They have also been accused (for instance by neo-realists) of being inappropriately optimistic (Cowles 2003). In this paper, which adopts something of a 'mixed' methodology, some of these limits are mitigated by including elements of other approaches, in particular, a focus on three key groups of institutional actors, who interact through over-lapping networks of expertise.

The strengths of a mixed approach, combining interests, institutions and ideas (Bache, George, Bulmer 2011: 63-4) compensate for the weaknesses of a single approach. Law is above all things a text-based discipline, so in the context of a paper like this, a text-based approach is more appropriate than, for instance, a quantitative approach. For example, counting the numbers of rulings of the CJEU, or EU Directives and Regulations, 'on a particular subject' will not reveal much about the ways in which the particular subject is understood – the act of deciding what to count is an act of narration in and of itself. And – of course – law occupies a particularly powerful ideational narrative space. The scope for *legal* narrations to result in changes to 'real world' situations, relationships, obligations and entitlements differs from that for other narrations, because, ultimately, law is backed by the sanction of state-based power, for instance, to deprive of property or even liberty.

**The 'telling' of EU health law into existence**

The core argument of this paper is that EU health law has now been narrated into existence. Its agenda is to explore how this performative, discursive process unfolded and is unfolding. The narration has been, and continues to be, carried out by three key groups of narrators: those contributing to legislative processes but also determining law-making powers ("the legislature" as shorthand in this paper), the courts, and the academy.[i] Another group, legal professionals, are also relevant, although their narrative tools in this area (it would be different in, for instance, commercial transactions law) have been focused on interactions with the legislature and, in particular, the courts, so they are not dealt with separately here. The groups of narrators form a networked community of expertise, with (at least some/sufficient) shared beliefs in both how legal problems are framed ('told'), and consequently what legal solutions come to be understood as appropriate. The practical mechanisms of narration used by each of the three groups of narrators differ, contingent upon institutional constraints and dependencies. Their narratives may also differ to some extent.

The EU is not a state. It is a body of constrained competence, so its ***legislature*** can act only where empowered to do so. Although the politically determined preferences of the EU legislature are undoubtedly relevant to the question of whether EU health law exists, the legal and indeed quasi-constitutional opportunities and constraints under which those preferences are pursued are equally important. It follows that, for the purposes of this paper, the legislature is not understood solely through its formal legal meaning (the Commission, European Parliament and Council). It is also understood as including the governments of the Member States, which give the formal EU

legislature powers and competences through the legal basis provisions of the Treaties.[ii] The governments of the Member States acting through Council also play a role in determining the *interpretation* of EU health law, through their use of 'soft law' instruments, such as Declarations and Council Conclusions.

The textual changes through time to legal provisions, such as (now) Article 168 TFEU, are thus an important element of the story (Hervey and McHale 2004: 72-81; McKee, Hervey, Gilmore, 2010: 235-240; Hervey and McHale 2015: 42-44, 61). The EU legislature's understandings of the meaning and significance of its adopted acts are recounted through the binding text of the acts themselves; the preambles to those acts, which explain their rationale and intentions; and the preparatory documents that form part of the legislative process. For instance, the text of early EU food labelling legislation refers only to the internal market as its rationale and aim. But more recent EU food legislation is understood as promoting public health through reducing obesity, as part of EU health law. The Patients' Rights Directive is more explicitly expressed as falling within an entity which is understood as EU health law. The preamble to the Patients' Rights Directive begins with Article 168 TFEU, it refers to the Council's 2006 Conclusions on Common values and principles in European Union Health Systems, and its stated aim is 'to establish rules for facilitating access to safe and high-quality cross-border healthcare … to ensure patient mobility … and to promote cooperation on healthcare between Member States' (Directive 2011/24/EU, recital 10).

The ways in which law is understood through national legislative, administrative and judicial implementation or compliance practices is also an important element in articulating EU health law (Obermaier 2009). Examples involving several EU Member States (Denmark, Spain, Netherlands, Belgium, Poland, Czech Republic, Bulgaria, France Germany) of implementation of EU law on migrant in patients' rights are elaborated in Martinsen and Diaz-Asensio 2016 in this issue, Vollaard 2016 in this issue, and Vasev, Vrangbæk, Křepelka 2016 in this issue.

The legal meaning and (practical or symbolic) significance of both the Treaty's legal basis provisions and EU legislation (Directives, Regulations) is a matter, ultimately, for ***courts***. The principal relevant court is the CJEU, using its interpretative jurisdiction under Article 267 TFEU and its power to determine validity of EU law under Article 263 TFEU. National courts and quasi judicial administrative authorities also play an important story-telling role (Martinsen and Diaz-Asensio 2016 in this issue), including in relationships of constructive cooperation with the CJEU (Vasev, Vragbæk, Křepelka 2016 in this issue. A dynamic interaction between the CJEU and the EU legislature, which is in part based on a notion of the relationships between courts and legislatures in democratic societies, founded on the rule of law, forms a key part of the process of narrating EU health law into existence (Vollaard 2015; Vollaard and Martinsen 2016; Martinsen and Diaz-Asensio 2016 in this issue). So, for instance, the texts circulating during the processes of adoption of the Patients' Rights Directive, even before it came into force formally, resulted in the CJEU 'seeing' or 'reading', and then 'retelling', its jurisprudence on free movement of patients in a different way from the way it recounts that jurisprudence in 'ordinary' internal market law (Hatzopoulos and Hervey, 2013).

In some ways, the ***academy*** is the least important narrator of EU health law. It has no formal power to issue legally binding interpretations of law. Where its narratives depart from those of legislature and courts, we might therefore expect processes of narration to be less successful. But in other

respects, the academy is the most important interlocutor here. The academy is *the* discursive and performative site for articulating what is (and is not) a topic or subject for study. Moreover, the way that the academy understands the world is not just 'academic'. It has important practical implications, not only for research funding, for learning and teaching, and for academic appointments. The views of the legal academy have a long history of informing and even constituting the definitive meanings of legal texts – in European contexts, dating back to medieval glosses on Roman law, and more recently where courts rely on academic interpretations of texts. Perhaps concrete material expressions of EU health law in the academy (Chair in EU Health Law; programmes in EU Health Law) would be the most convincing form of evidence for the argument made in this paper. The academy narrates EU health law through its dissemination activities (particularly its publications), and through its interactions with the legislature and the courts. For instance, the work of scholars who understand those aspects of EU law that apply to medical research as part of EU health law (see, eg, Flear et al 2013) 're-reads' legal instruments otherwise thought of as falling within areas of EU law such as internal market law, intellectual property or competition law (the Directive on Legal Protection of Biotechnological Inventions; the Clinical Trials Directive; the *Brüstle* and *International Stem Cell* cases).

To summarise. The ideational narrative power of law has now solidified, and continues to solidify, into an entity with a distinctive legal identity, an entity previously seen as either non-existent, or so broad as to be meaningless, or as existing only in relations between EU law and health (the 'and' approach), or as consisting of a body of barely or loosely connected policy domains (the 'patchwork' approach). The process has been executed (and continues to be executed) by three main groups of actors: the legislature, courts and the academy. What are the constituent features of the processes? How did EU health law come to be?

**The processes of narration**

The processes through which EU health law has been (and continues to be) narrated include the following:

(a) Articulation of distinctive *principles* and *themes* of EU health law
(b) Expression of EU health law as *structurally coherent*
(c) Understanding of the body of EU health law as *special and distinctive*

These processes are not entirely separate, but overlapping and mutually reinforcing.

***(a) Discerning and Articulating Principles and Themes***

One of the already-noted principles of EU health law – the principle of constrained competence – is common to all areas of EU law. Every area of EU law, no matter how uncontested its existence, reflects the EU's constrained competences. It follows that the legal statement that 'the definition of their health policy and the organisation and delivery of health services and medical care and the allocation of the resources assigned to them' (Article 168 TFEU) are a matter for Member States, not the EU, is not evidence that EU health law cannot be understood as a meaningful field of law.

In spite of the EU's constrained formal competences, over time, the EU institutions have articulated common substantive values, which have become regarded as the underpinning principles of EU health law. The values (Article 2 TEU) and aims (Article 1 TEU) of the EU, as expressed in its founding treaties, include 'respect for human dignity', 'equality', 'respect for human rights', 'non-discrimination', 'solidarity', 'the well-being of its peoples' and respect for 'services of general economic interest'. All of these have a direct bearing on health, health systems, and health policy. These values, along with others such as individual (consumer) autonomy and regulatory protection from risk of harm, have also been articulated thematically (Hervey and McHale 2015).

In 2006, the EU's Council adopted *Conclusions on Common values and principles in European Union Health Systems*. The history of the *Common values and principles* lies in significant opposition to the proposed Directive on services in the internal market, contemporaneous with debates on 'social Europe' embodied through the (failed) Treaty establishing a Constitution for Europe. The revised Directive explicitly excluded health care, and eventually the EU adopted a separate Patients' Rights Directive. Council has reiterated the *Common values and principles* in the EU's growth strategy *Europe 2020*. In its 2011 *Conclusions: Towards modern, responsible and sustainable health systems*, Council calls on Member States and the European Commission to refocus health from being regarded as solely an expenditure, to being regarded as a contributor to economic growth (Kvist 2015). The *Common values and principles* have been endorsed by both the European Commission (2007) and the European Parliament (2008), although not yet by the CJEU.

The 2006 Council *Common values and principles* state that 'universality, access to good quality care, equity and solidarity' constitute a set of shared EU values that are applied to healthcare systems, and by implication, to health law. Although Council states that different Member States express these values differently in terms of practical reality, the *Common values and principles* go as far as to articulate a set of shared 'operating principles', that are expected to be found anywhere in the EU. These shared principles are 'quality of care', 'patient safety', 'evidence-based and ethically robust care', 'patient involvement', 'redress', and 'privacy and confidentiality'. Crucially for the purposes of this paper, Council not only expresses these values and principles as shared among *national* health care systems, and, implicitly, the law that underpins them, but also calls upon the European Commission to ensure that these principles are followed *when proposing health-specific EU legislation*.

As a measure of 'soft law', the *Common values and principles* are not binding, but they form a persuasive interpretative source on which the CJEU may draw (Senden 2004), in interpreting and applying measures of 'hard law'. Such hard law includes the TFEU's 'mainstreaming' provisions. They require the EU institutions, when defining and implementing their policies and activities, to take into account 'requirements linked to … a high level of … protection of human health' (Article 9 TFEU; Article 168 (1) TFEU. See also Article 35 EU CFR). The TFEU is binding on the EU institutions when they adopt EU Health Law.[iii] The *Common values and principles* are an interpretative guide as to the meaning of the mainstreaming duty, at least in the context of EU law pertaining to health systems, and arguably also pertaining to public health. Hence the *Common values and principles* are a credible expression of the principles and themes of EU health law.

The EU's human rights instruments also express the principles and themes of EU health law. Originally EU law was devoid of explicit recognition for human rights. They first appeared as 'general principles' of EU law. The EU now has its own Charter of Fundamental Rights, which has 'the same legal value as the Treaties' (Article 6 (1) TEU). The EU CFR protects human dignity (Article 1), the right to life (Article 2), integrity of the person (Article 3), private life (Article 7), protection of personal data (Article 8), right to marry and found a family (Article 9), freedom of thought, conscience and religion (Article 10) all of which have significance for EU health law (McHale 2010). In addition, the EU CFR provides for the rights of children (Article 24), the elderly (Article 25), and persons with disabilities (Article 26), three groups whose vulnerabilities mean that their rights need special attention in health contexts. The EU CFR states that 'everyone has the right of access to preventive health care and the right to benefit from medical treatment' in accordance with national conditions (Article 35). The CJEU, and in particular its Advocates General, has referred to the EU CFR's provisions, such as that on the right to health care, when it interprets EU health law (Hervey and McHale 2015: 160-164; 169-176; 185-189; 202-210). In so doing, the CJEU narrates those principles as expressing the framework within which it understands the relevant litigation – expressing it as something distinct from other, more established, areas of EU law.

Some commentators, including me, have expressed significant reservations as to the practical fulfilment of these principles, particularly those of solidarity and equity, but also those of human rights protection, within EU health law (Hervey 2003, McHale 2010). In particular, there is concern about the extent to which the free movement and fair competition provisions of EU internal market law, when they form part of EU health law, can ever support such principles (Hatzopolous 2002; Newdick 2006, 2009; McHale 2010; Hervey 2011). There is also concern over whether the quality of care principle is sufficiently fulfilled where EU health law seeks to support technological innovation (Flear et al 2013, Hervey and McHale 2015). Some of these concerns reflect the EU's constrained competences in health. However, in the context of this paper, whether these *Common values and principles*, and the human rights expressed in the EU CFR, are honoured in every specific instance is not the point. What matters is the thematic 'telling' of those instruments as an expression of the underlying principles of EU health law. The articulation and acceptance of the principles of EU health law, as comprising human rights protection, quality of care, patient safety, evidence-based and ethically robust care, patient involvement, redress, and privacy and confidentiality, within the context of constrained EU competences, is one process of narration of EU health law. It is an expression of the existence of EU health law, distinct from (although interacting or even overlapping with) other fields of EU law, or national health law, or global health law.

### *(b) Expressing Structural Coherence*

However one measures its scope (for an inclusive approach see Hervey and McHale 2015), although EU health law is a body of law based on constrained EU competences, it nonetheless represents a sizeable body of legal texts. But mere volume is insufficient as evidence of the existence of EU health law. What is needed is an account that makes sense of that body of legal texts in accordance with some kind of internal and self-referring structural coherence. The articulation of the principles of EU health law (see above) goes some way to expressing such structural coherence.

However, as we already noted, the dominant metaphor, historically, for describing EU health law, and especially EU health policy, has been that of a 'patchwork' (Ashcroft 2013; Greer 2011; Hervey and Vanhercke 2010; Lamping and Steffen 2009). For instance, some of the earliest EU health legislation and court rulings consist in 1965 rules on marketing authorisation for pharmaceuticals, a 1971 Regulation on the access of mobile workers and their families to health care in the Member State to which they have migrated for work, CJEU decisions from the mid 1970s on the question of whether intellectual property rights could justify restrictions on importation of pharmaceuticals, and 1975 Directives on mutual recognition of doctors' qualifications. If articulated in that way, the implication is that EU health law is nothing more than elements of law and policy that 'belong' in different domains, in a way that makes no sense as a coherent story.[iv] An argument against the existence of EU health law is that the 'fabric' of each aspect thereof is distinctive, and the effect of putting together the total is of a not-quite-complete and not-terribly-coherent whole: hence the 'patchwork' metaphor.

If one articulates the pieces of this 'patchwork' in the terms of categories of EU law with a longer pedigree, as in Hervey and McHale 2004, there is little evidence of structural coherence. Multiple areas of EU law are involved. For instance, and non-exhaustively, provisions on the recognition of health care professionals' qualifications, and their ability to practise across borders within the EU; on access to health care of mobile workers and their families in another EU Member State; on patients accessing health care services across borders; on restrictions on health care providers setting up and offering their services in another Member State, fall within various areas of EU free movement law. Measures on the marketing and advertising of pharmaceuticals and medical devices fall within EU free movement, consumer protection and innovation law. Perhaps counter-intuitively, legislation on data protection also falls within EU free movement law. Special arrangements for the provision of health care services paid for by the public purse, through for instance granting exclusive licenses, authorisations or other restrictive measures to hospitals, clinics and other health care providers, at least potentially fall within EU competition law. Legislation on working conditions in hospitals falls within EU labour law. Provisions on development, authorisation and marketing of novel health technologies fall within EU innovation and free movement law. International treaty provisions and EU legislation on access to essential medicines across the globe fall within EU external relations law. Measures ensuring safety of food, as a major disease vector, or the regulation of sale, labelling and advertising of food, tobacco and alcohol, major contributors to 'life-style' diseases, fall within EU external trade law, agricultural law, free movement law and consumer protection law. Air or water quality regulation falls within EU environmental law, as does road safety, which also falls within EU transport law. In addition, as already noted, provisions of EU 'constitutional' law, on allocation of competences, 'mainstreaming' duties, and the place of human rights in EU law, are also important, in terms of their implications for how the more detailed legislative provisions are both adopted and interpreted.

Each of these different areas of EU law, through which EU health law has been developed historically, has its own trajectory, its own rationales and principles, as well as formal legal basis, and its own communities of expertise, with shared understandings of problems and their (legal) solutions. The pedigree of EU health law, as emerging from these areas and solidifying into a structurally coherent area relatively recently, forms part of the distinctive quality of EU health law, as opposed to health law in any of the EU's Member States, or indeed global health law.

The key group of actors articulating EU health law as structurally coherent is the academy. Increasing numbers of legal academics interested in the EU and health, and those from other disciplines, have sought to express EU health law through its increasing structural coherence. One way in which the academy has told this story is to see EU health law as a new combination of one or more of these recognised areas. As the list above indicates, even the 'already recognised' areas of EU law blur into one another, as is the case for free movement law and consumer protection law. The academy creates 'EU health law' as a new blending of existing areas of EU law. It has 're-read' some early EU health law texts, with hindsight, to understand them as part of this new field of legal enquiry, as well as of the pre-existing 'accepted' categories of EU law. Thus, for instance, the 1984 CJEU ruling of *Luisi and Carbone*, to the effect that restrictions on currency movement, where the currency was to be used to pay for medical treatment, are *prima facie* contrary to EU law, or its 1991 *Grogan* ruling, to the effect that restrictions on abortion advertising are *prima facie* contrary to EU law, although may be justified, are now understood as embodying the EU's approach to its health law, through principles of human rights protection, quality of care, patient safety, evidence-based and ethically robust care, patient involvement, redress, and privacy and confidentiality, all within the context of constrained EU competences (Hervey and McHale 2015: 62-63, 161, 194). At the time the decisions were taken, they were understood within the fields of EU internal market and constitutional law (eg Phelan 1992).

Admittedly not every area of health law (either nationally or globally focused) is significantly covered by EU health law. If we take the main areas of health law, as for instance understood by key health law texts from European countries (Westerhäll 1994; Nys 1994, 2012; Kennedy and Grubb 2000; Montgomery 2002; Mason and Laurie 2010; Rynning and Hartlev 2011; Brazier and Cave 2011; Madden 2012; Jackson 2014, Herring 2014; Pattinson 2014), we see some areas where EU law has no, or very little, relevance. These include, for instance, consent to treatment, end of life decision-making, and resource allocation within national health systems. An objection to the argument that I am making in this paper is thus that EU health law is not sufficiently structurally coherent to constitute a distinct legal area, because it does not cover these areas on which the structural coherence of health law rests.

But two observations may be made in response. First, in each of the areas of health law where EU law appears to have no relevance, there is some relevance. For sure, the prospects of *harmonized* EU level legal rules are remote. But the EU level is no longer entirely absent from legal structures. For example, questions of consent to treatment, or of beginning or end of life decision-making (Nys 2001) may fall within the scope of the EU CFR, and are covered by EU law on biomedical research and human organ and tissue regulation. Questions of resource allocation within national health systems are covered by EU law on transparency of pharmaceuticals pricing, as well as indirectly by EU law on free movement of patients. Rather than EU law being irrelevant, the EU's legal order has become one of the areas in which conflicting rights claims, or claims to resources, are adjudicated, even if those processes give significant 'margin of discretion' to national preferences. Second, much of the substantive content of health law *is* covered by EU health law, and increasingly so. As we suggested in 2004, the pattern or trajectory is for EU law to have relevance in ever more areas of health law. The argument I am making here is that the trajectory has reached a stage of sufficient structural coherence to evidence the existence of 'EU health law'.

### *(c) Understanding EU Health Law as a Distinctive Body of Law*

At least until the 2000s and 2010s, EU health law occupied at best an uncertain position vis-à-vis EU internal market law. EU law's 'constitutional asymmetry' (Scharpf 1996) – the (contested) idea that social policies are constitutionally subservient to EU internal market law – is at the heart of this uncertainty. The logical consequence of the constitutional asymmetry position, as applied to EU health law, is that freedom of movement and competition are the rule; health protection or health promotion are at best exceptions. Some take the view that the EU's internal market law is the central organising area of law, and that EU health law is not conceptually distinct from internal market law, but rather national health law is subservient to it (Hatzopoulos 2002, 2005; Montgomery 2005, Newdick 2006, 2011; Gekiere Baeten Palm 2010; Davies 2011). But others (Hervey and Vanhercke 2010; Hervey 2011; Hervey 2008; (to some extent) Hancher and Sauter 2012) see the relationship with internal market law as more complex than 'rule-exception', and hence express EU health law as more coherent and distinctive than before the 2000s. EU health law is no longer understood as comprised of a series of unrelated exceptions to free trade rules, but rather as a distinctive legal area, with its own underlying principles and structural coherence.

Some of the broader contexts within which the emergence of EU health law as a distinctive body of law has taken place include the EU's 'Lisbon agenda' for growth and development (Copeland and Papadimitriou 2012, de Ruijter 2015); a revitalisation of the discussion about 'governance' (new and old) of the internal market (Hatzopoulos 2012); and the idea of health and other social capital not only as a matter of social rights or welfare, but also as a factor in a productive economy (Greer 2014, Kvist, 2015) or an element of macroeconomic conditionality (Baeten and Vanhercke 2016 in this issue). Many of these ideas are reflected in the Lisbon Treaty, most prominently in the statement that the EU's internal market is based on a 'social market economy' (Article 3 (3) TEU). The CJEU has increasingly articulated the idea that health systems occupy a distinctive position in internal market law (Hervey and McHale 2015, 227-246; 247-268; 269-291 elaborating the multiple ways in which the CJEU has given weight to the solidarity that underpins health systems rather than narrating health systems' place in internal market law within concepts of free trade and fair competition) – to the extent that that position can be said to be part of the principles or structural coherence of EU health law. The 'objective public interest' in protecting the organisational structures and capacities of national health systems, and their financial viability, has been increasingly recognised by the CJEU, in cases concerning migration of patients, but also concerning migration of professionals, and novel business structures delivering aspects of health services, such as internet pharmacies, privately owned biomedical laboratories, and multinational hospital chains. In doing so, the CJEU built on earlier jurisprudence which recognised the need to protect the financial viability of social security systems; rules about the organisation of health care professions, qualifications, and professional ethics; or consumer protection. National courts, competition authorities and the CJEU have expressed the idea that health occupies a special place in EU competition law, as a 'service of general economic interest'. Similarly, both the CJEU and the EU legislature have explicitly recognised in public procurement law that health systems do not operate entirely within ordinary markets.

Internal market legislation that itself protects 'non-market' interests has existed since the foundation of the internal market. Obvious examples are legislation covering pharmaceuticals, medical devices, and products that are harmful to health (in particular tobacco, but also food and alcohol). Again, the way that this legislation is understood to fit within the scheme of EU law has changed over time. The European Commission's 2001 review of its pharmaceuticals regulation, involving stakeholders from health policy communities, not only from industry, and involving DG Sanco and DG Markt, led to a significant amendment of the EU pharmaceuticals legislation in 2004. The 're-telling' of pharmaceuticals regulation as not merely a matter of internal market law is a strong example of the emerging greater distinctiveness of EU health law. The proposed amendments to EU medical devices regulation are another example; as is EU regulation of tobacco and alcohol.

The idea of health as a factor in a productive economy (Greer 2014), related to internal market law, the Lisbon Agenda and now *Europe 2020*, is reflected in various aspects of EU law. A particularly good example is EU law on pharmaceuticals and medical devices, which seeks to promote industry innovation (Flear et al 2013). EU law and policy on health-related research involves investment in research into novel health products or processes, as well as into health system reform. The EU invests in health infrastructure through its cohesion funds (Clemens et al 2013). Some aspects of this element of the distinctiveness of EU health law may at least appear to run against some of its underlying principles, such as equality. Whether that is the case or not (Hervey and McHale 2015), the underlying idea of health as a productive factor has the effect of enhancing the cohesiveness of EU health law as a distinctive body of law.

**Conclusions**

Perhaps the ultimate evidence that 'EU health law' now exists would be the impossibility of publishing this paper(!). In other words, if the academy and the legal profession (broadly understood, as including legislatures, courts and those who practise law), were sure that the notion of 'EU health law' were beyond dispute, we would be pretty confident that specific and distinct legal arrangements support EU health(care) policies. A body of law is understood as autonomous and distinct as a consequence of the performative effects of the discourses of relevant actors who consider it to be so. Very few people would now seriously dispute that 'EU law' or 'health law' (or for that matter, 'contract law', or 'family law') is a meaningful concept. There are disputes about the *scope* of those entities (see, eg, Barnard and Odudu 2009; and the discussion in Hervey and McHale 2015: 10-29; 53-55), and about their intellectual trajectory (see eg, re EU law, Cardwell and Hervey 2015; de Witte 2009; Arnull 2008; Walker 2005; Shaw 1996) but very rarely about their *very existence*. (There is a thoughtful discussion of exceptions to that rule concerning health law in Ruger 2008, Hall 2008). That is not the case for EU health law. Its very existence remains contested.

But the argument advanced in this paper is that those who are sceptical should no longer be so. Through their narrative accounts, the EU legislature, courts and the legal academy have created/constructed EU health law. They have done so, and continue to do so, through articulation of principles and themes of EU health law, and expression of EU health law as structurally coherent, special and distinct from other areas of law. The distinctive features of EU health law include a weak

(but not a strong, as is sometimes claimed) consumerizing effect on health policies; a rhetorical attention to (human) rights, with some consequences for procedural entitlements; respect for the solidarity and equality bases of national health systems; and context-specific approaches to risk (Hervey and McHale 2015, summarized at 544-546).

Telling stories about EU health law matters in academic contexts; in the ways in which legal texts are enacted, adopted, and implemented; and in the ways courts interpret them. Whether a body of law such as EU health law is understood to exist in a meaningful sense also matters in the non-legal world. Law not only has narrative power; it also has material power, to alter relationships between human beings and institutions. The stories we tell about law affect its very meaning, in that they inform the interpretative acts of applying legal texts to concrete situations, determining obligations and entitlements, powers and constraints. The important questions now are not so much about how EU health law came to be – they are about its meaning and significance.

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[i] I note the self-reflexive nature of this paper, in that I am very much part of the academy on which the paper reflects.
[ii] In this regard, the notion of 'legislature' departs from its traditional meaning of a network of actors constitutionally empowered to adopt laws within a legal system.
[iii] Technically, if the EU institutions were to adopt legislation or take decisions contrary to the mainstreaming principle, those measures would be subject to judicial review under Articles 263 or 267 TFEU. In fact, the CJEU has never held a measure to be contrary to the public health 'mainstreaming' duty, and I am unaware of any judicial review claim brought against the EU's institutions, agencies or bodies, on the basis that an EU law or policy failed to ensure a high level of health protection. One staff case, Case F-64/06 *S v European Parliament* OJ C 199 from 25.08.2007, p.53; removed from the register OJ C 223 from 30.08.2008, p.63, which settled out of court, included the argument that a reassignment in the place of work from Rome to Brussels of an ill person constituted a breach of Article 35 EUCFR.
[iv] This might well be the case for many other areas of EU law, for instance EU external relations law.