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European integration in the field of human health

European Union health law themes and implications, Law in Context Series, by Tamara K. Hervey and Jean V McHale, Cambridge University Press, 2015, ISBN 978-1-107-01049-9

Regulating Lifestyle RisksThe EU, Alcohol, Tobacco and Unhealthy Diets, by Alemanno, Alberto, and Amandine Garde, Cambridge University Press, 2015, ISBN 978-1-107-06342-6

Trade, Health and the Environment: The European Union Put to Test, by van Asselt, Marjolein, Michelle Everson, and Ellen Vos, Routledge, 2014, ISBN 1849713626

European Union Public Health Policy, Regional and global trends, Routledge Advances in European Politics, by Greer, Scott L., and Paulette Kurzer, Routledge, 2013, ISBN 0415516641

Introduction

In a time where the European Union (EU) project is politically more contested than ever, integration in the field of health continues, not faltered by the current ‘constraining dissensus’ (Hooghe and Marks 2009). This paradoxical continuing development, has been explained by a ‘permissive dissensus’, where the neo-functional integration mechanism seems to be at work as it was before (Greer and Kurzer 2013; Haas 1958). In the light of the steadily growing role of the EU in the field of human health (de Ruijter *forthcoming*), what to make of its legal imprint?

Health law in the EU is a *by-product*, and health considerations are the *exception* to the creation of the EU internal market. As a *by-product*, health can form an obstacle to the creation of a market for goods, services or persons. Numerous examples here can be found in the area of food safety, medicines and access to medical benefits in another Member State. As the *exception*, health is a legal ground for allowing derogations to internal market law when Member States are safeguarding the health of their population. Some famous and foundational cases from the Court of Justice of the European Union (CJEU) in this respect are the *Cassis de Dijon* and *Tobacco Advertising* case.¹ In the *Tobacco Advertising* case establishes that health considerations are a by-product of internal market law. The Court in this case determines that no regulation can be created by the European legislator that has health protection as a central and single objective, there has to be an ‘internal market hook’ in terms of legal basis (Alemanno and Garde 2015, Art. 114 TFEU).

The books discussed in this review each take a closer look at the way the EU is involved in the protection and promotion of human health. The co-authored monograph by Hervey & McHale, a major rewriting of their 2004 book, asks how through EU law and regulation, the very foundations and our assumptions about health law as an objective in itself, have changed, and how this change affects who we are in the face of health problems; from patients to consumers – how EU law alters

health systems into markets; and populations into (economic) risk-pools. The edited volume of Alemanno & Garde basically asks what currently is done, and in the future can be done through EU regulation and policy to make Europeans healthier. The edited volume of Van Asselt, Everson & Vos turns these questions around and asks how the science of health and environmental risks in trade are, or should be affecting the nature and the procedures of EU regulation. Last, the book edited by Greer & Kurzer maps European integration in the field of human health from a public health perspective. As a general theme these contributions give us an opportunity to view the EU from another perspective; a perspective where human health law and policy and its intrinsic and specific connections with science, risks, values and fundamental rights forms the central focal point instead of a side issue, and through this perspective it shows us a different view on the nature of the European legal order and its legitimacy problems.

What is EU health law about?

In developing an initial map of the dynamics of EU integration in the field of health, Greer & Kurzer's book highlights some of the major conundrums of the EU's involvement in the field of public health. In various chapters it shows how despite ongoing integration, Member States have not been willing to create a stronger health competence at EU level, nor create a tax system whereby the EU could be involved in redistributing health entitlements, which has perpetuated the current constitutional place of health regulation in the EU as an exception and a by-product of internal market law (Marks 1996). At the same time, legally health considerations ought to be taken seriously across EU public policy (Article 9 TFEU and 168 TFEU), and there are a number of ways the EU is expanding its authority in the field of human health other than through formal legislation and with a direct impact for European citizens (de Ruijter forthcoming).

The most notable contribution in this series of books is that of Hervey and McHale (2015) and this is not simply because it not an edited volume, unlike the other contributions. More importantly, it is the first comprehensive contribution to the scholarship on EU and human health that addresses the nature of Union health law. It describes how, over the last half century, health law in EU Member States developed on agreed foundational basis. This basis is that health law is the field of law that regulates relationships of solidarity, of ethics, professional trust and the protection of human physical dignity, in the face of shared risks and opportunities to do with human life, disease and mortality. Health law is not centrally based on commercial relationships. National health law across the EU Member States largely protects a number of specifically health-related (fundamental) rights, such as informed consent, the protection of medical and health data, secrecy and professional medical standards, medical liability, and the right to equal 'universal' access to medical care.

In their first edition Hervey and McHale described the impact of Union law on domestic health law and policy. The approach of this new edition goes beyond the perspective of Europeanisation and basically assumes EU health law exists, whether we like it or not (Hervey and McHale 2015, 8). Their book carves out an understanding of the nature of EU health law through distinguishing four themes: consumerism, protection of (human) rights, and interactions between equality, solidarity and competition, and risk regulation. Within these themes the writers outline an individual perspective and a collective perspective. Each of the four themes creates the backdrop for the description of particular areas of EU health law, drawing out how the balance is struck in EU health law between solidarity and market-based solutions for protecting and promoting human health. On the one hand these themes structure the book in accordance with the different policy areas in which EU health law developed. On the other hand, the themes create an immediate analytical frame for determining to what extent the nature of EU health law is predominantly a matter of economic, or social values.

In the first part of the book the concept of health law and its origins are defined abstractly, while heavily drawing on UK literature. Health law is conceptualised around an engineering model of 'health': the human body as a defective machine that needs to be fixed when broken. One may question if this abstract exercise as to what we mean by 'health', is still needed in this revised edition of the book, given the changed perspective on the very existence of EU health law. In other words, is this abstract concept of health relevant for the EU legal context; is it reflected in its regulation or case-law? Is there a EU concept of 'health'? However, the concept of health as adopted by the authors in the end neatly frames their further discussion on the conceptualisation of health law, which outlines the scope the book uses on EU regulation and law in this field.

Health law in the book is conceptualised rather broadly with on the one hand 'health care' which relates to the relationships between doctors and a wide range of health professionals; a central concern for individual human rights, liability and disciplinary regimes, the health care institutions, including health insurance. On the other hand, 'public health' is identified as relating to the role of public authority in promoting and protecting the health of the population. The following discussion of the recent scholarly literature on EU health law and policy will follow a similar division between 'health care' and 'public health'.

EU health care law: horizontal relationships

The first part of Hervey and McHale's book addresses what I would call *EU health care law* in that the focus is on predominantly individual, horizontal legal relations that are affected by this area of regulation in the field of health.² The book here describes the manner in which the EU regulates relationships between health professionals and their patients and the legal duties and powers of health care institutions. The writers describe how the EU regulates health products and services as comparable to any other consumer product. They address how the patient that chooses to receive health care across the border in another Member State in the context of EU health law is essentially regarded as any other consumer of services. Moreover, EU health law facilitates the commercialisation of health care for instance by being a driving force in the availability of over the counter medicines, and the blending of social and private health financing schemes. Accordingly Hervey & McHale's assessment is that EU health law with respect to *health care* moves away from the basic solidarity assumptions that are found in national health care law. Furthermore the book shows convincingly that EU law creates a tension between the individual consumer of services and the social priorities of the Member States' health care systems. Also with respect to the legal understanding of the relationship between patients and health professionals, EU law couches these as founded on economic contract rather than solidarity.

Another aspect of EU health care law is the manner in which the CJEU has given way to the application of internal market law in this field. In that regard Hervey & McHale note (47) that when it comes to health care systems the more recent case law of the CJEU seems to recognise the need to sustain the financial viability and solidarity of health care systems. At the same time, they note that the vast majority of the litigants are market actors, companies and professionals challenging national rules that divide the health care 'market' but protect the solidarity-based systems for equal access to medical care. Competition law in this regard also plays an important role in the 'systemic' aspect of health care law. In the assessment of Hervey & McHale, Union law has had an impact on national health systems as it has a 'sticky' quality and its effect has slowly built up. Interestingly, regardless of its slowly increasing importance, competition law has not had a directly neoliberalising effect, and in some areas has reduced the price of health care according to the authors (Hervey and McHale 2015, 289). Moreover, it is their assessment that competition law in the field of health care is not necessarily closed off for including welfare or ethical goals.

In sum, the contribution of Hervey & McHale convincingly shows that while with regard to individual access to health care, EU health law has a more market-based approach than the Member States, when it comes to the protection of the health systems specifically EU health law does not impose a singularly economic paradigm and to some extent even protects the discretion of the Member States. Nonetheless, EU health law challenges national values embedded in their approach to facilitating access to medical care and these values do conflict with the creation of the EU single market generally. At the same time EU health law has gone virtually unchallenged in the CJEU on the basis of fundamental rights, even with regard to highly ethically salient aspects. Hence, where at national level health law is sometimes even viewed as a species of fundamental rights law, at EU level the protection of human health through regulation is a market discourse, rather than a rights discourse.

EU public health law: vertical relationships

EU regulation in the field of public health affects the protection and promotion of the health of the whole EU population, rather than that it is aimed at the health of specific individuals. Hence, EU public health law generally impacts vertical public law/public authority protecting the population vs. individuals/legal relationships. The book by Hervey & McHale also takes public health to cover, what in EU legal context is usually termed as ‘risk regulation’ (van Asselt, Everson, and Vos 2014), which in health law terms is nothing new under the sun, in the sense that health law usually regulates the basic task of public authority’s responsibility to protect the population from the inherent health risks of a market economy. Moreover the book also focuses on several aspects of EU policy in the field of lifestyle risks. This is a relatively new field of study in terms of the research on the law and regulation that has been adopted in the field over the last decade (Alemanno and Garde 2015). Regardless, the health community itself for some time now has criticised the impact of EU policies, for instance that the Common Agricultural Policy is bad for health (Elinder 2005; Loyd-Williams et al. 2008).

Alemanno and Garde take up this aspect of EU public health law forcefully in their edited book. Their central focus is on EU policy with regard to Non Communicable Diseases (NCD’s), which relates to e.g. diabetes, cardiovascular disease, cancer, chronic respiratory diseases and mental disorders. The EU in this respect has linked up its efforts with a global public health agenda together with the World Health Organisation (WHO). According to the WHO–EU regional office 86% of deaths and 77% of the EU disease burden can be accounted for by NCD’s. Central causes of NCD’s are the harmful use of alcohol, smoking and unhealthy diets and lifestyles.

The questions that Alemanno and Garde take up in their edited book are much closer to the type of questions that were previously only asked in the EU public health community rather than in the EU legal community. They basically ask, what is the EU doing to regulate healthier lifestyles and could regulatory solutions that may work in one area, also work in another area - and in a bio-ethical sense, whether these policies are too paternalistic or not. The first part of the book in several contributions researches the information paradigm in public health, which refers to the simple assumption that solid health information will guide consumers to healthy choices. The second part of the book addresses the constitutional limits of public health regulation regarding the promotion of healthy lifestyles, and the last part of the book surveys regulatory possibilities for improving the role of EU regulation in the fight against NCD’s.

Highlighting the above cited ‘golden-oldie’ case law in the field of tobacco advertising, the chapter by Amandine Garde & Marine Friant-Perrot on the discussion of tobacco advertising targeted at children, illustrates exceptionally well the marked difference when a public health perspective is used for looking at a field of regulation that has been the bread and butter of EU lawyers discussing EU competences. The chapter convincingly exemplifies how a ‘health law’ lens, immediately puts into frame – as they do – the fundamental rights perspective in order to

safeguard human health by restricting the marketing of unhealthy goods. The general argument that runs through the book is that the EU has not done enough and that action needs to be taken at EU level to curb the proliferation of NCD's because currently the EU is restricting Member State actions; if Member States would act on their own this would fragment the EU internal market.

The limitations of the EU's central objective of establishing an internal market, brings the conundrum of EU health law back at Fritz Scharpf's thesis: the EU does not have any competence for the paternalistic policies that in this case would need to be adopted in order to protect the health of Europeans with respect to the aggressive marketing of alcohol and unhealthy foods, which also brings us to the lingering question of EU competence in the field. The editors conclude that the lack of EU competence for regulation for NCD's leaves us with an inherently fragmented landscape in the public health field. This is particularly the case in the light of the paradox that in order to mainstream health protection in establishing an internal market (Article 168 TFEU) health protection measures may need to restrict the creation of these very markets themselves, such as the markets for alcohol and tobacco.

Public health: the health risks- and market dichotomy

In the EU law literature, public health has usually been treated on the basis of a Union law logic (Alemanno and Garde 2015; Majone 1999; Vos 1999; Weimer 2014). However, risks to public health are generally not a new phenomenon, also not in the context of the creation of a market economy (Rosen 1958). As outlined by Hervey & McHale, in the literature, there are two strong claims regarding risk regulation and health in the EU. The first claim is that the EU under-regulates for health risks, which has a detrimental impact on the protection of health, but that EU is unwholesomely regulatorily limited given that if the EU would regulate for public health risks more strictly this may create obstacles for the internal market (tobacco advertising case law). The second, opposing claim is that the EU over-regulates for risk, which is detrimental to the development of new cures and health technologies and bad for the economy as a whole (Hervey and McHale 2015, 212).

A more critical analysis, in parallel to the health risks-economy dichotomy of EU regulation in the field has been developed in the literature, particularly after the Bovine Spongiform Encephalitis outbreak in the EU. This literature centrally puts into view the role of science. The thesis is that the EU obfuscates political disagreement about balancing health risks with economic aims, through science. The book by Asselt, Everson and Vos makes an important contribution to this literature. Their edited volume in various ways analyses how the EU uses the public health regulation as a tool to enhance its own legitimacy. In doing so they turn the previously discussed questions around: they do not ask what the EU is doing for the regulation of human health, but rather, what is human health regulation doing for the EU? In several contributions the book illustrates how the current EU regulatory model has not solved the balance between regulation of the public health and environmental risks to trade and other societal values in situations of uncertainty. In their estimation, in various ways the current regulatory model privileges processes of depoliticisation and scientification, which is used in turn to legitimate the EU's regulatory role in these politically sensitive policy areas.

The first part of the book edited by van Asselt, Everson and Vos addresses the role of science in the EU precautionary approach to regulating health and environmental risks caused by trade. The second part of the book looks at the regulatory practice and case studies of pharmacological regulation, nanotechnologies and climate change targets in trade. The last section looks at accountability mechanisms, in particular the role of the courts and the involvement of stakeholders. The last chapter of the book provides a practitioner's perspective in the form of an interview with an MEP involved in the regulation of health risks. Although it was not emphasised explicitly,

except in one of the last chapters, a red thread that runs through the book is the link between what the writers call the ‘uncertainty paradox’ and issues of trust. The uncertainty paradox refers to the situation where *science* can merely determine an uncertain risk to health, but *not provide any certainty* about the possibility of the dangerous events’ occurrence, while at the same time policy-makers increasingly use *science for more certainty* and conclusive evidence for the legitimacy of their policies (Asselt and Vos 2006). The related trust issue brings into play questions of the trustworthiness of science itself.

The interchanging relationship between science, uncertainty and trust is of pivotal importance in health law generally. In public health, regulation and science have dynamic relationship with the levels of trust at population level. However, the situation that Van Asselt, Everson and Vos describe in the field of public health in this regard is mirrored by the centrality of trust in the patient–health professional relationship at the level of individual health care. Health law as a legal field is characterised by intertwining legal principles, fundamental rights and trust in professional and scientific expertise, both in the individual setting and also in a public setting, where the EU has a large role to play.

EU health law coming into being

The edited volume of Greer and Kurzer explains the role of the EU in the field of human health as being driven by the logic of a ‘permissive dissensus’. Thus its development remains in flux, even when we do not agree on its desired contents. However, surveying the other more recent contributions to the literature in discussing European law and public policy from a human health perspective, we may perceive of an EU that could pursue objectives that go beyond its primary internal market paradigm. At the same time, it seems to me that as long as Fritz Scharpf is right and there is no regulatory pathway for pursuing human health perspectives simply for their own sake or for the sake of solidarity, the limited competence for the EU to regulate health should remain firmly instated.

What does the European integration in the field of human health tell us about the EU itself? Human health, addressing one of the most important aspects of human well-being (Article 2 TEU) by its very nature, brings the EU closer to Europeans. In doing so, studying the EU’s role in human health shows that as long as the market paradigm remains the predominant legitimating factor for EU policies, EU legitimacy will remain problematic; not only on the basis of democratic considerations (Greer and Kurzer 2013) but also in terms of the *type of policy* the EU is able to produce. In the field of public health, science is needed to align economies in order to limit market forces, however the EU in doing so excludes the value or ethical considerations that are actually at play (van Asselt, Everson, and Vos 2014). With respect to major lifestyle risks the EU is unable to produce the paternalistic policies that are needed to protect Europeans from debilitating diseases such as obesity, diabetes, heart disease and cancer.

These books each in their own way show that in matters of human health there is no fair competition, and that the EU market paradigm is unfit for accommodating the value of well-being in terms of human health as an intrinsically valuable objective. Yet, in giving us the most comprehensive picture, Hervey & McHale’s book paints a hopeful picture for EU integration in the field of human health, in that their meticulous accounts show that there are many areas where regardless of the market forces at play, the EU is developing its own health law paradigm. A paradigm that includes the protection of the health values and health-related fundamental rights, also encompassing the protection of those rights and values under national laws, and in doing so, the legal discipline of European health law is coming into being.

Notes

1. In *Cassis de Dijon*, the public health exception for goods in the Treaty (currently Article 36 TFEU) as broadened through the establishment of a Rule of Reason-doctrine that applies only to national measures that treat products from another Member State equally. Case C-376/98 Germany v Parliament and Council (Tobacco Advertising) [2000] ECR I-8419 1998; Case 120/78, Rewe-Zentrale AG v Bundesmonopolverwaltung für Branntwein [1979] ECR 649 1978.
2. Although the precise nature of these relationships depend on the nature of the respective health care system (more or less centralised).

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