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The impediment of health laws' values in the constitutional setting of the EU

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(...) account must be taken of the fact that the health and life of humans rank foremost among the assets and interests protected by the Treaty and that it is for the Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved. Since the level may vary from one Member State to another, Member States should be allowed a measure of discretion¹

In the above-cited Perez case, the Court of Justice of the EU (CJEU) refers to health and life of humans to rank foremost among the interests protected under EU law. Hence the EU is to leave discretion to the Member States to determine the level of health protection in each Member State. However, the involvement of the EU, through law and policy in the field of human health is vast, regardless of limited specific legal competence in the field (Article 168 TFEU). On the basis of an array of other legal competences, especially Article 114 TFEU on the functioning of the EU's internal market, the importance and authority of the EU in the field of human health is ever-growing.²

What is the relationship between the role of the EU and the values central in the field of human health? By such 'health values', I mean the guiding principles whereby a society in general ensures the merit of a health policy or law. When a topic goes to the core of the manner in which humans shape mutual relationships and obligations (in the current case with respect to human health), there is a good argument to make that we need more justification than law, or a democratic rule, may be able to provide.³ Health values are often articulated through law, but they are self-standing. In the context of bioethics, they are understood as having an intrinsic importance that gives expression to

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¹ Joined Cases C-570/07 and 571/07 *Blanco Pérez and Chao Gómez* ECLI:EU:C:2010:300, [2010] ECR I-4629, para 44. And see further references Case C-141/07 *Commission v Germany* ECLI:EU:C:2008:492, [2008] ECR I-6935, para 51, and Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others (Doc Morris)* ECLI:EU:C:2009:316, [2009] ECR I-4171 para 19.

² A de Ruijter, *The Expansion of EU Power in the Field of Human Health* (OUP 2016) (forthcoming). DS Martinsen, *An Ever More Powerful Court?: The Political Constraints of Legal Integration in the European Union* (OUP 2015).

³ O O'Neill, *Autonomy and Trust in Bioethics* (CUP 2002) 73 (who explains that 'political legitimation is not enough for an ethical justification of fundamental rights). But see S Bagatur, 'Toward a Democratic Conception of Human Rights' (2014) 2(1) *Theoria and Praxis* <<http://theoriandpraxis.journals.yorku.ca/index.php/theoriandpraxis/article/view/39372>> accessed 22 June 2016.

standards for conduct in individual cases and in the organisation of public health and healthcare.⁴ However, my focus here is not on bioethics specifically, nor the particular ethical questions on the basis of health values as they emerge in the EU. Rather, to achieve the objective of navigating the intricacies of ‘European Union Health Law’ and related policies, in their constitutional setting, the focus of this chapter is the relationship between health values, fundamental rights and health law and policy.

The central document that may immediately come to mind to EU health lawyers on these topics is the 2006 ‘Council Conclusions on Common Values and Principles in health care’.⁵ These conclusions were adopted when Member States agreed that the domestic healthcare systems were highly affected by the CJEU case law affecting the individual access to medical care, and the core values of ‘universality, access to good quality care, equity and solidarity’ needed safeguarding.⁶ Noting the links between values and ethics, I propose a somewhat wider scope for ‘EU health values’, and thus include human dignity, which is a central value of health law in the Western world generally.⁷ Hence, my focus is the values of solidarity, universal access, equality and human dignity.

The chapter argues that due to the EU’s current constitutional setting – which refers generally to the legislative limitations on the exercise of EU public authority of its institutions for adopting health law, including the protection and promotion of fundamental rights in that respect – EU health law and policy is not able to promote and protect the values that are embedded in Member States’ national health law and policy fully. The chapter will proceed as follows: first, the chapter turns to the place of values in (EU) health law and policy. Second, the chapter looks at the manner in which these values are expressed in the context of specific EU fundamental rights that have particular bearing on EU health law and policy. Third, the chapter addresses the place of EU health law in the EU constitutional setting and how EU health law affects values. By way of conclusion the chapter proposes a new research agenda on the constitutional embedding of values in health law in the EU.

I. VALUES IN (EU) HEALTH LAW AND POLICY

In health law, values and human rights play an important role. Together they make up the central aspects that form the fabric of most health laws in the Western world, and beyond. By contrast, according to most accounts, EU health law developed as a side issue of internal market law. Furthermore, EU health law came about as national health laws and regulations became exceptions to the creation of the EU internal market (deregulation). A relevant famous and foundational CJEU decision is the *Cassis de Dijon* case, in which the CJEU ruled on the extent of national power to adopt health-related alcohol laws.⁸

⁴ TL Beauchamp and JF Childress, *Principles of Biomedical Ethics* (7th edn, OUP 2012).

⁵ Council Conclusions on Common values and principles in European Union health systems [2006] OJ C146/1.

⁶ *ibid.*

⁷ M Frischhut, “‘EU’: Short for “Ethical” Union, the Role of Ethics in European Union Law’ (2015) 75(3) *Heidelberg Journal of International Law* 531; C Foster, *Human Dignity in Bioethics and Law* (Bloomsbury 2011). TK Hervey and JV McHale, *European Union Health Law: Themes and Implications* (CUP 2015) 40, 95. The authors outline in the EU context: ‘The most we might expect is a change to the way courts express the discussion in such cases – a certain suppression of explicit consideration of ethical questions, replaced by a discussion of trade in goods or services.’

⁸ In Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon)* ECLI:EU:C:1979:42, [1979] ECR 649, the public health exception for goods in the Treaty (currently Article 36

EU health law and policy have also been a means to re-regulate the EU market in areas where national regulatory barriers to trade were removed to create the internal single EU market. In the *Tobacco Advertising I* case it is established that the European legislator cannot create legislation with health as a central and single objective. There must be an internal market connection as a legal basis for most EU health law (Article 114 TFEU, but see certain paragraphs in Article 168 TFEU).⁹ There are numerous examples here in the area of food safety, medicines and access to medical benefits in another Member State, where the market connection is the basis for EU regulation. However, over the past half-century in the Member States, health law developed on rather different foundational bases.

Generally, in the Member States health law regulates relationships of solidarity, of ethics, professional trust and the protection of human physical dignity, in the face of shared risks and opportunities related to life, disease and mortality.¹⁰ Health laws in the Member States on the whole express the values of solidarity, universal access, equality and human dignity. These values are translated in national public health programmes and healthcare systems in various ways.¹¹ The values of equality and solidarity are expressed in the general rule that all citizens have ‘universal access’ to medical treatment.¹² Human dignity is expressed in rules regarding the protection of informed consent in medical research and medical treatment or in national laws that guarantee a ‘right to know and not to know’ and the right to inviolability and physical integrity. In a public health sense human dignity is expressed in rules about eugenics and other research-related regulations. Besides the general national laws and policies that express the values and principles of health law, these values are expressed in constitutional law and the application of (EU or Council of Europe ECHR) human rights.¹³

Hence, national health laws largely protect a number of specifically health and human dignity-related rights,¹⁴ 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.¹⁵ The shared foundational basis of rights and objectives that can be found in national health laws, are the ‘values’ of health law. Given the EU’s constitutional order and the setting in which the growing role of the EU in human health regulation is taking place, the question is to what extent the EU is able to facilitate health values as EU values, or are they left behind at Member State level? One

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.

⁹ Case C-376/98 *Germany v European Parliament and Council (Tobacco Advertising I)* ECLI:EU:C:2000:544, [2000] ECR I-8419.

¹⁰ Hervey and McHale (n 7).

¹¹ ED Kinney and BA Clark, ‘Provisions for Health and Health Care in the Constitutions of the Countries of the World’ (2004) 37(2) *Cornell International Law Journal* 285. B Toebes, ‘Introduction: Health and Human Rights in Europe’ in B Toebes and others (eds), *Health and Human Rights in Europe* (Intersentia 2012).

¹² Nobody can be denied access to medical care.

¹³ Kinney and Clark (n 11). HJ Leenen, ‘Health Law in the Twenty-First Century’ (1998) 5(4) *European Journal of Health Law* 341; HJ Leenen, JKM Gevers and G Pinet, *The Rights of Patients in Europe* (WHO; Kluwer 1993); J Legemaate, ‘Integrating Health Law and Policy: A European Perspective’ (2002) 60(2) *Health Policy* 101; TK Hervey, ‘We Don’t See a Connection: The “right to Health” in the EU Charter and European Social Charter’ in G De Búrca and B De Witte (eds), *Social Rights in Europe* (OUP 2005); JV McHale, ‘Fundamental Rights and Health Care’, in E Mossialos and others (eds), *Health Systems Governance in Europe: The Role of EU Law and Policy* (CUP 2010).

¹⁴ Frischhut (n 7).

¹⁵ A de Ruijter, ‘EU Integration in the Field of Human Health, Review Article’ (2016) *Journal of European Integration* (forthcoming).

strategy for protecting the values of solidarity, equality, universal access and human dignity generally could be through the above indicated legal expression in fundamental rights. In the next section the relationship between values and fundamental rights, and the role of fundamental rights in EU health law is addressed.

II. THE EXPRESSION OF HEALTH VALUES IN EU FUNDAMENTAL RIGHTS

II.i Health Values and Fundamental Rights

Values in bioethical research and analysis have a separate meaning from fundamental rights or human rights. ‘Fundamental rights’, rather than the term ‘human rights’ does not define one body of rights as more ‘fundamental’ than the other, but it refers to rights with a similar meaning, applicable as EU law. It is the term used in EU law to describe these types of rights. ‘Fundamental rights’ in the jurisprudence of the CJEU refers to the legal *praxis* that is used in balancing the legitimacy of the EU’s policies, legal rights claims against the Member States, against institutions of the EU or in some cases even in horizontal, private relationships.¹⁶ Human rights usually have a broader (international) or more abstract connotation.¹⁷ In this more abstract connotation, human rights can also refer to what is understood here as ‘values’.

Bioethics and the human rights discourse in many ways grew up together after the Second World War, where particularly the Nuremberg Trials had an important and contested role to play.¹⁸ In the literature there are different approaches to the relationship between bioethical values –both in an individual health context, and with regard to population health – and rights. On the one hand, it has been argued that to speak of values or human rights in legal terms provides a universal language for ‘the development of international legal standards for biomedicine’.¹⁹ Values in this respect provide a normative basis for specific fundamental health-related rights. George Annas even refers to bioethics and law as ‘estranged twins’ in this respect.²⁰ On the other hand, there is also criticism of the immediate relationship between values and fundamental or human rights. Bioethicists have argued that rights have their own legitimacy problems and that it limits the moral concepts that are used and

¹⁶ Commission, ‘2013 Report on the application of the EU Charter of Fundamental Rights’ COM (2014) 224 final; C Mak, *Fundamental Rights in European Contract Law: A Comparison of the Impact of Fundamental Rights in Contractual Relationships in Germany, the Netherlands, Italy and England* (Wolters Kluwer 2008) 6. See further Chapter 3 in this book.

¹⁷ R Alexy, ‘Discourse Theory and Fundamental Rights’ in AJ Menendez and EO Eriksen (eds), *Arguing Fundamental Rights* (Springer 2006) 17.

¹⁸ E Fenton, ‘Bioethics and Human Rights’ in JD Arras, E Fenton and R Kukla (eds), *The Routledge Companion to Bioethics* (Routledge 2014).

¹⁹ R Andorno, ‘Human Dignity and Human Rights as a Common Ground for a Global Bioethics’ (2009) 34 *Journal of Medicine and Philosophy* 223, 224. Also see LP Knowles, ‘The Lingua Franca of Human Rights and the Rise of a Global Bioethic’ (2001) 10 *Cambridge Quarterly of Healthcare Ethics* 253.

²⁰ GJ Annas, ‘Human Rights and American Bioethics: Resistance Is Futile’ (2010) 19 *Cambridge Quarterly of Healthcare Ethics* 133.

relevant when referring to broader values that have a self-standing importance. Moreover, a rights-based approach is only one of the many perspectives in this regard.²¹

The innate plurality of the EU legal order and the growing importance of fundamental rights (CFREU) and the underlying ‘ethical’ (naturalistic) implications of rights, makes their impact controversial in the European context. Rights are increasingly used to legitimate important decisions that affect the autonomy of the Member States.²² In a political conception, rights in the EU are also controversial, given the absence of a formal EU constitution.²³ Furthermore, rights in the deeper sense of common humanistic values are particularly controversial in the health context.²⁴ The different underlying reasons for the regulation of abortions across Member States, is a striking example. It is therefore important to reconcile the ‘legal’, ‘political’ and the ‘ethical’ conceptions of values and human rights, for instance through democratic notions or on the basis of other theories.²⁵ This is particularly the case for the EU, where an actual ‘fundamental rights policy’,²⁶ including Article 2 TEU itself presupposes a preconceived idea of shared values, an idea in which direction to take the EU in this respect,²⁷ rather than merely taking the status quo of fundamental rights protection as a matter of social practice, and thus dependent on place and time, as implied by a political conception of human rights.²⁸ What remains is the expression of values in EU health law. In this respect, as will be outlined below, there are different aspects of EU health law that express various degrees of values of health law, yet EU fundamental rights and EU values and principles are the primary locus whereof EU values in health law are expressed.

II.ii Health Values in EU Fundamental Rights

In the context of health law, each Member State itself has formulated the values and principles that underlie its national healthcare system or systems.²⁹ When the Council adopted its Conclusions on

²¹ O’Neill (n 3). Other approaches could be the classical utilitarian or deontological approaches, or a capabilities perspective etc. M Freeman, *Law and Bioethics* (OUP 2008).

²² E Muir, ‘The Fundamental Rights implications of EU Legislation: Some Constitutional Challenges’ (2014) 51 *Common Market Law Review* 219.

²³ AJ Menendez ‘Some elements of a theory of European fundamental rights’ in Menendez and Eriksen (n 17) 156.

²⁴ Menendez and Eriksen (n 17).

²⁵ Bagatur (n 3); *ibid.* P Gilibert, ‘Humanist and Political Perspectives on Human Rights’ (2011) 39(4) *Political Theory* 439; SM Liao and A Etinson, ‘Political and Naturalistic Conceptions of Human Rights: A False Polemic?’ (2012) 9(3) *The Journal of Moral Philosophy* 327 and see Alexy (n 17).

²⁶ P Alston and JHH Weiler, ‘An ‘Ever Closer Union’ in Need of a Human Rights Policy: The European Union and Human Rights’ (1998) 9 *European Journal of International Law* 658; A von Bogdandy, ‘The European Union as a Human Rights Organisation? Human Rights and the Core of the European Union’ (2000) 37 *Common Market Law Review* 1307.

²⁷ This also shows in some of the CJEU’s case law on the Charter where the interpretation is usually based on a preconceived idea of rights ‘that were already protected’ in the EU legal order, see on this point and a discussion of these cases, P Eeckhout, ‘The EU Charter of Fundamental Rights and the Federal Question’ (2002) 39 *Common Market Law Review* 945.

²⁸ R Forst ‘The Justification of Human Rights and the Basic Right to Justification: A Reflexive Approach’ (2010) 120 *Ethics* 711, 727, emphasising the ‘internal’ role (inside a political system) of human rights for assessing legitimacy and see further Bagatur (n 3) 9.

²⁹ Council Conclusions (n 5).

Common Values and Principles in EU Health Systems,³⁰ it referred to ‘common’ values and principles among the Member States. The legal status of those common values and principles, and their relationship to fundamental rights in the sense of EU law, depends on whether the Council was referring to these values and principles in the sense of Article 2 and 6 TEU.

Article 6(3) TEU holds that:

Fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms and as they result from the constitutional traditions common to the Member States, shall constitute general principles of the Union’s law.

The language of the Council’s 2006 statement of Common Values (referring to ‘values’, rather than principles of EU law) suggests that it is not intended to constitute a statement of general principles of EU law, that are on equal footing with fundamental rights. However, in combination with particular fundamental rights of the Charter of Fundamental Rights of the EU (CFREU),³¹ it could be argued that the Common Values in the 2006 Council Conclusions may help shape the interpretation of fundamental rights in the context of EU health law. The 2006 Common Values were a response to the CJEU line of case law at the time, in the field of cross-border healthcare. They were intended to feed into the legislative process that eventually resulted in the Patients Rights’ Directive.³² Therefore the 2006 Common Values represent an indication of the baseline of principles that are common to the Member States, and in that regard they could also at least be taken into consideration in the EU legislative process, although this is not legally required. At the same time, the 2006 Common Values were written so as to stress their importance in the context of the organisation of national healthcare systems, a matter over which the Treaty explicitly requires national competence. In the field of public health, where the EU enjoys greater competence, however, there is no explicit document that refers to for instance values of solidarity or equality. In the central legal provisions, Article 9 TFEU and Article 168 TFEU, the central objective is formulated as ‘a high level of human health’, which is difficult to determine.

The values of solidarity, equality, universal access and human dignity are addressed in the CFREU. For an outline of the importance and application of the CFREU, and also general principles of EU law, and how these different legal sources have gained importance in the EU legal order, readers are referred to Calum Young’s chapter.³³ The EU’s adherence to the protection and promotion of fundamental rights, on the basis of EU primary law, is expressed as a constitutional value. Article 2 of the Treaty on European Union (TEU) lays the foundation of the EU’s agreed ‘common values’ as the basis of the EU’s constitutional structure.

Article 2 TEU

*The Union is founded on the **values** of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities. These values are **common** to the Member States in a society in which pluralism, non-discrimination, tolerance, justice, solidarity and equality between women and men prevail. [emphasis added]*

³⁰ *ibid.*

³¹ Charter of Fundamental Rights of the European Union [2012] OJ C326/391.

³² European Parliament and Council Directive 2011/24/EU of 9 March 2011 on the application of patients’ rights in cross-border healthcare [2011] OJ L88/45 (Patients’ Rights Directive).

³³ Also see McHale (n 13); TK Hervey, ‘The “Right to Health” in European Union Law’, in TK Hervey and J Kenner (eds), *Economic and Social Rights under the EU Charter of Fundamental Rights* (Hart 2003); Hervey and McHale (n 7).

Article 3 TEU

(1) The Union's aim is to promote peace, its values and the well-being of its peoples.

Importantly, the *respect for rights* in itself is taken to be a foundational value of the European Union, which is assumed to be a value that is *common* to the Member States. Arguably, given that the values in Article 2 TEU are taken to be common to the Member States,³⁴ this means that reference to national identity (Article 4(2) TEU) cannot be used in the case of infringements of the values held in Article 2 TEU.³⁵ Furthermore, Article 2 TEU refers to 'human rights' and not 'fundamental rights', which are protected under Article 6 TEU by reference to, for example, the CFREU. As mentioned 'human rights' as a term is usually used to connote a deeper meaning that goes to underlying, deeper values when speaking in terms of 'rights'. These deeper values are sometimes also referred to as 'rights' but rather in a particular ethical sense.

The fundamental rights in the CFREU that express the EU health law values of solidarity, equality, universal access and human dignity can be found as follows in Table 19.1.

Table 19.1 Overview of the health topics potentially affected by European fundamental rights

Value/human right	Fundamental right	European provisions	EU Health topics involved
Human dignity	Human dignity	1 CFREU	End of life issues, access to health care, long term care
Human dignity (Respect for human life/autonomy)	Right to life	2 CFREU	Access to abortion in another Member State End of life issues, euthanasia Protection of life through public health measures Environmental health threats
Human dignity	Informed consent	3 CFREU	Bodily integrity, inviolability of the human body, autonomy in medical decisions, the right to refuse medical treatment

³⁴ Article 49 TEU on membership to the Union also refers to adherence to its values in Article 2 TEU

³⁵ LFM Besselink, 'The Bite, the Bark and the Howl: Article 7 TEU and the Rule of Law Initiatives' in A Jakab and D Kochenov (eds), *The Enforcement of EU Law and Values: Ensuring Member States' Compliance* (OUP 2016). (Although given the status of the right to health as a principle in the CFREU it is unlikely that Article 7 TEU as an enforcement mechanism will easily be evoked in the case of health rights' violations in Member States.)

Human dignity	Prohibition of torture and inhuman and degrading punishment	4 CFREU	Confinement of persons with mental disabilities Rape, sexual abuse Undue delay of access to health care
Human dignity	Privacy and family life, data protection	7, 8 CFREU	Medical research Protection of personal data, confidentiality of medical files (ehealth) Medical files/psychological background Union civil servants
Human dignity	Information and participation	11 CFREU	Access to health-related information to services and public health. Informed consent
Dignity, equality, solidarity	Education	14 CFREU	Education as a social determinant of health Sex education as public health
Equality	Protection of mothers, children and of the family	24 CFREU	Paid and sufficient maternity leave Social and family benefits Equality directive, disabilities, gender etc.
Equality, solidarity and universal access	Non-discrimination	20-26 CFREU	Non-discrimination in access to health care services and preventive care
Equality, solidarity	Employment	32 CFREU	Occupational health Employment as a social determinant
Solidarity and Equality	Social security	33 CFREU	Social security as a social determinant of public health
Equality, universal access	Right to health Right to access health	35 CFREU	Access to health care and other (public) health services, Access to preventive care Protection of public health

care	Reproductive Health
	Protection of environment as it affects public health
	Occupational health
	Regulation of services of general interests
	Pharmaceuticals and medical devices

Yet, the fact that these shared and common values can be distinguished at EU level in the field of health, does not solve the puzzle of what effect the constitutional nature of the EU has on the protection and promotion of these values within EU health law. The values that underlie EU health law as common values are difficult to balance on their own, when they are competing – and losing – to other values or principles of the EU’s free market.³⁶ It is at least arguable that the internal market freedoms form the very reason for the EU health law’s existence.³⁷ The four freedoms as constitutional principles are even stronger than the EU constitutional principle of subsidiarity in the field of health, which explains the recurrent paradox that the internal market legal basis (Article 114 TFEU) forms the legislative ground for many aspects of EU health law, where Member States at the same time have limited EU powers (Article 168(5) public health and (7) healthcare TFEU).

III. HEALTH LAW IN THE EU CONSTITUTIONAL SETTING

The question regarding the role of the EU’s constitutional order brings into perspective a classical thesis by Fritz Scharpf. Scharpf proposes that the EU’s limited legislative competence in areas outside the internal market objectives create a constitutional asymmetry.³⁸ The institutional and legal constraints for the EU to adopt ‘market-correcting policies’ favour economically liberal interests and policies, which in turn constrain Member States at national level to pursue welfare goals. At the same time, as recently argued by Dieter Grimm, the EU’s legal order is ‘over-constitutionalized’. In most political systems, constitutions function to legitimise and limit political power. Constitutional rules form the ‘framework for politics, not the blueprint for all political decisions.’³⁹

The ‘over-constitutionalisation’ of the EU refers to the notion that the four freedoms and the

³⁶ See particularly Chapter 11 in this book which refers to the competing values of the common market in EU competition law.

³⁷ For an alternative position, see Hervey and McHale (n 7); TK Hervey, ‘Telling stories about European Union Health Law: The emergence of a new field of law’ (2016) *Comparative European Politics* DOI 10.1057/cep.2016.4 <www.palgrave-journals.com/cep/journal/vaop/ncurrent/full/cep20164a.html> accessed 1 June 2016.

³⁸ A de Ruijter and TK Hervey, ‘Healthcare and the Lisbon Agenda’ in P Copeland and D Papadimitriou (eds), *The EU’s Lisbon Strategy: Evaluating Success, Understanding Failure* (Palgrave 2012); see F Scharpf, ‘The Asymmetry of European Integration or why the EU cannot be a “Social Market Economy”’ (2010) 8(2) *Socio-Economic Review* 211.

³⁹ D Grimm, ‘The Democratic Costs of Constitutionalisation: The European Case’ (2015) 21 *European Law Journal* 460.

objective of the creation of an internal market overrides all other legitimate policy objectives, due to their constitutional status in the Treaties and their function as constitutional review standard for the CJEU. The field of health in the EU exemplifies Grimm's thesis, given that the CJEU has had a central role in reaffirming the recasting of national public health considerations as 'exceptions' even beyond those exceptions that are mentioned in the Treaties.⁴⁰ Importantly, however, in the field of human health, Member States' health law is directly impacted by EU inroads into this field.⁴¹ Liberalisation and privatisation, together with the effects of globalisation and the constitutional context of the EU make it difficult for the Member States to uphold their standards of social welfare in order to retain their economic competitiveness.⁴²

Furthermore, the EU does not have a budget that can be used to alleviate these effects in light of values such as equality, solidarity and universal access. The European public health programme only has a small budget that pales in comparison to the national budgets for public health and healthcare services and programmes.⁴³ Nevertheless the EU public health programmes are an example of positive integration at EU level that actually redistributes funds in the area of social welfare. And although the public health programmes over the years have had to make do on very low budgets,⁴⁴ they have links with the much larger budget of the EU research programme that allocates more than six billion Euros for health. The priorities defined in the Programme Committee for the public health programme filter through in the funding priorities that are chosen in the Programme Committee of the health programme under the heading of DG Research.⁴⁵ Moreover, much of the public health budget is distributed through co-funding, which means any activity or action usually needs at least 40 per cent funding from other sources. Another aspect that plays into this is that the EU public health programmes play a role in the distribution of EU structural funds, in that objectives of the public health programmes are mirrored with respect to the budget for health priorities in the structural funds.⁴⁶ However, EU macroeconomic policy has had a much deeper impact on the protection of values of health in the Member States.

In Chapter 12 Sokol and Mijatović outline how the EU facilitated the existence of the European Stability Mechanism (ESM), which is the governance structure established by (or for) the Eurozone countries. With regard to the countries that received financial aid during the Euro crisis, the ESM established Memorandums of Understanding (MoU), monitored by the European Commission. Non-compliance with these MoUs can result in sanctions. As a result, the healthcare systems of these Member States, and particularly the ability of Member States to determine their own budgets for healthcare spending, were immediately affected. Given that the ESM is outside the EU legal realm, the first question is whether EU law on fundamental rights even applies. Furthermore, Member States

⁴⁰ See *Cassis de Dijon* (n 8), 'The Rule of Reason'.

⁴¹ TK Hervey and JV McHale, *Health Law and the European Union* (CUP 2004). In this first edition, this dynamic is meticulously mapped.

⁴² Grimm (n 40); see further Chapter 12 in this book.

⁴³ See de Ruijter (n 2).

⁴⁴ Averaging 300 to 500 million Euros.

⁴⁵ This link with research and health at EU level goes back to the 1950s since the ECSC funded research programmes in the area of occupational diseases. Over the course of the 1970s and especially in the 1980s, research into communicable diseases was also funded by the Community – this was mainly in the context of the common market and agriculture. However, also in the field of research and technology biomedical research became funded at the European level in the area of biotechnology. Commission, 'Biology and Health Protection Programme: Research Programme 1976–1980' (Proposal) COM (75) 351 final. See de Ruijter (n 2).

⁴⁶ J Watson, 'Health and Structural Funds 2007–2013 (2013): Country and regional assessment' (Report for DG SANCO, 2009) and see *ibid.*

are subject to the European Semester, which is an EU governance mechanism for national macroeconomic and fiscal policies based on the Stability and Growth Pact. Also in this regard the Member States have been pushed towards cutting public spending in the field of health.⁴⁷

Aside from deregulation, (EU) macroeconomic policies and their impact on the Member States' abilities to sustain national health policies in accordance with the values of solidarity, equality and universal access, re-regulation of human health law and policy at EU level is a third factor to consider in terms of its effect on the upholding of health values. Particularly in the field of public health, a massive regulatory effort has been undertaken in the EU to create markets by ensuring health and safety. However, also in this respect as the tobacco advertising saga foretold, the EU has only a limited legislative basis for recreating health protection regulation at EU level. As Marjolein van Asselt, Ellen Vos and Michelle Everson have argued persuasively, the manner in which the EU re-regulates in the field of public health is also depoliticised through what Sheila Jasanoff calls the 'constitutional role of' science.⁴⁸ Their central thesis is that the EU obfuscates political disagreement about balancing health risks with economic aims, through science.⁴⁹ Moreover the EU constitutional order – similar to Dieter Grimm's observations – puts executive actors in the lead, particularly also in politically sensitive policy issues.⁵⁰ Van Asselt, Vos and Everson have shown how the EU regulators use public health regulation as a tool to enhance the EU's legitimacy. In their research they establish that for public health regulation, science is needed to align economies in order to limit market forces. However, the EU – in so doing – excludes the value or ethical considerations that are actually at play. Ethics, specifically bioethics, are formally still largely determined at Member State level.⁵¹ In some specific areas of EU secondary regulation, ethics committees are involved, however their contribution is fragmented and in a recent overview of the EU's approach to ethics it was outlined that many gaps remain at EU level, also in areas affected by EU internal market regulation.⁵²

Human dignity as a value lies at the basis of all elements of law and involvement in health, and can thus be taken as the foundation for a number of specific patients' rights.⁵³ At EU level, however, what human dignity requires is essentially left up to the Member States.⁵⁴ But the question of human dignity could also become a EU issue – in this regard Article 3 CFREU on the integrity of the person is closely related to the principle of human dignity.⁵⁵ Human dignity can refer both to the individual in terms of personal integrity and to protecting the society at large. The principles outlined in Article 3

⁴⁷ See Grimm (n 40). R Baeten and B Vanhercke, 'Inside the Black Box: The EU's Economic Surveillance of National Healthcare Systems' (2016) *Comparative European Politics* DOI: 10.1057/cep.2016.10 <<http://link.springer.com/article/10.1057/cep.2016.10>> accessed 7 July 2016.

⁴⁸ See S Jasanoff in M Weimer and A de Ruijter, *The Co-Production of EU Expert and Executive Power in the Field of Public Health and the Environment* (Hart) (forthcoming).

⁴⁹ Hervey and McHale (n 7). M van Asselt, M Everson and E Vos, *Trade, Health and the Environment: The European Union Put to the Test* (Routledge 2013). M van Asselt and E Vos, 'The Precautionary Principle and the Uncertainty Paradox' (2006) 9 *Journal of Risk Research* 313. See also Chapter 6 in this book.

⁵⁰ See Grimm (n 40). Also see D Curtin, *Executive Power of the European Union, Law, Practices and the Living Constitution* (OUP 2009).

⁵¹ Frischhut (n 7).

⁵² *ibid.*

⁵³ See McHale (n 13).

⁵⁴ See Case C-36/02 *Omega* ECLI:EU:C:2004:614, [2004] ECR I-09609 and see S Douglas-Scott, 'The European Union and Human Rights after the Treaty of Lisbon' (2011) 11 *Human Rights Law Review* 645.

⁵⁵ Case C-377/98 *Netherlands v Parliament and Council* ECLI:EU:C:2001:523, [2001] ECR I-7079, see paras 77 and 78 on the basis of human dignity for not allowing patentability of elements of the human body.

CFREU generally are also part of the Council of Europe's ECHR, except for informed consent, which has only been developed in the case law of the ECtHR on the basis of Article 8 ECHR.⁵⁶ The second paragraph of Article 3 CFREU specifically outlines that informed consent must be respected in the field of medicine and biology, and that eugenic practices, particularly those aiming at the selection of persons, making the human body and its parts a source for financial gain and reproductive cloning of human beings, are prohibited.⁵⁷ The prohibition of reproductive cloning reflects the value of human dignity at population level, for instance with regard to the regulation of clinical trials at EU level or even with the appropriation of funds for medical research from the EU.⁵⁸

Human dignity also plays a role in the context of EU regulation of medicines. For instance, take the authorisation of gene therapy with respect to the regulation of pharmaceuticals at EU level. In 2013, the European Commission approved the medicine Glybera. This medicine uses a virus to deliver DNA encoding a lipid-processing enzyme to patients that lack this gene mutation. Gene therapy alters the human genetic code; the question is how this is different from a 'eugenic practice' and to what extent this (should) affect the authorisation of these therapies at EU level.⁵⁹

The constitutional setting of the EU, where economic objectives (i.e. the policy content itself) is protected as constitutional values, affects the place and protection of values in EU health law, that are central to the health law of the Member States – values such as human dignity, equality and solidarity. At Member State level, the EU law also affects health law, as it is approached as a barrier to trade, whereas at EU level, health law is recreated, but its inherent values are depoliticised through science. The constitutional balance between the economic 'values of efficiency' as outlined in the chapter by van de Gronden and Rusu, and health values is – because of the constitutional setting of health law in the EU – more likely to favour economic aims rather than health values. However, these values are not always opposing. For example, as Hervey and McHale outline, EU competition law has likely contributed to consumer benefits and a lowering of prices in the healthcare sector, which is important in ensuring universal access and upholds the values of solidarity and equality.⁶⁰

IV. CONCLUSION: FUTURE RESEARCH

Comparing the status of health values in the Member States and at EU level would substantiate the claim that the EU impedes health values through EU health law. However, the argument is not that simple. On the one hand, Member States to a large extent retain their own competences in the field of

⁵⁶ See, eg, *Tysic v Poland* App No 5410/03 (ECtHR, 20 March 2007); *KH and others v Slovakia* App No 32881/04 (ECtHR, 28 April 2009); and *RR v Poland* App No 27617/04 (ECtHR, 26 May 2011), which are some of the more recent cases of the ECtHR on the forced sterilisation of Roma women and in the context of abortions for medical reasons.

⁵⁷ CFREU, Article 3(2)(d), this is also prohibited in the UN declaration on the Human Genome and Human Rights and in European Parliament and Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L213/13. See extensively Chapter 9 in this book.

⁵⁸ An example here is *Netherlands v Parliament and Council* (n 56), where although an appeal to human dignity is accepted, nevertheless the plea with respect to informed consent is rejected given that: 'The purpose of the Directive is not to replace the restrictive provisions which guarantee, outside the scope of the Directive, compliance with certain ethical rules which include the right to self-determination by informed consent;' see para 80.

⁵⁹ See n 59, to interpret this provision as an individual right would probably involve reference to human dignity.

⁶⁰ Hervey and McHale (n 7) 229.

health in the EU as the Court of Justice clearly outlines in the above-cited *Perez* case. On the other hand, deregulation, macroeconomic policies and reregulation also affect the values that are part and parcel of health law at national level. Member States' health law has not remained unchanged in the past decade, and this is in a large part due to EU health law and regulation.

EU health law has a bearing on the same health values that form the foundations of national health law and its backbone is formed not only by internal market law, but also by EU fundamental rights law. Yet the impediment of EU values underlying health law is arguably stronger at national level due to the constitutional setting at EU level. Given the constitutional order of the EU, in which the policy content is determined at constitutional level, mostly by competition law and economic free movement principles and values, EU health law is lacking in terms of its protection and promotion of the values of solidarity, human dignity and the protection of the plurality of Member States.

Besides the importance of the 'EU economic constitution' in this respect, another factor to consider is the role of science. Science in the EU has the important role of depoliticising and taking the discussion on its innately related values such as human dignity out of the political equation. Health law and policy related to science or new technologies and aspects such as the commodification of human body parts etc. are often not presented as political choices at EU level, but rather presented as necessary for competitiveness or innovation. The argument as put forward by many scholars is that the EU needs a more lively and real democratic debate. However also in this respect, the economic values and aims being a central connecting factor in the EU constitutional structure could prove to be problematic. As Mark Flear exemplifies in the field of citizens science,⁶¹ even when participative democratic procedures are used in order to politicise and legitimise political choices on values that are made in the field of science, also here democratic participation is captured by the dominant economic constitution in which the objectives of science have been predetermined (knowledge economy, competitiveness, innovation).

These problems are constitutional because they address the manner in which the EU is able to create health law. This is an inherently democratic problem, but also a problem of the nature of EU health law itself. Hence, it is up to future research in the field of EU human health law, legal scholars and political and social science to ask whether the constitutional order of the EU can be changed or set up in a manner in which EU health laws' values will not have to compete so hard with EU economic values.

⁶¹ See further Chapter 6 in this book.