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Fundamental rights and humaneness in European private Law

The case of health care

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1 Introduction

EU legislation, along with the European Court of Justice (CJEU) interpretative intervention, has directly[1] and indirectly[2] influenced substantive private law.[3] This chapter questions the 'humaneness' of this influence on the provision of health care.[4]

'European private law' is understood broadly in this chapter: it embraces 'all legal rules concerning relationships between private parties regardless of the nature of the law, public or private, in which they have been included in national legal systems'.[5] This definition echoes the regulatory nature of the *acquis communautaire* in the field of private law.[6] In a similar vein, Mak labels European (regulatory) private law as

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[1] For example, in the effort to address consumer, labour, anti-discrimination, and business law matters.

[2] For example, in the effort to liberalise markets, such as telecommunication, postal services, energy, transport, and health care.

[3] This chapter only deals with substantive private law. It does not consider rules of civil procedure.

[4] We define 'health care' herein the same way as it is defined in Article 3(a) of the EU's Patient's Rights Directive: as 'health service provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medical products and medical devices'.

[5] O Cherednychenko, 'Fundamental Rights, European Private Law, and Financial Services' in H-W Micklitz (ed) *The Constitutionalization of European Private Law* (Oxford University Press, 2014) 171.

[6] See H-W Micklitz, 'The Concept of Competitive Contract Law' (2005) 23 *Penn State International Law Review* 549; C U Schmid, 'The Instrumentalist Conception of the Acquis Communautaire in Consumer Law and Its Implications on a European Contract

the rules laid down by the EU that seek 'to facilitate private law relationships whilst also pursuing specific policy goals, such as consumer protection or the integration of the EU internal market'.[7]

'Private law relationships' involve natural or legal persons other than a public authority. Private parties can be individual citizens, commercial undertakings not predominantly owned by public authorities, non-governmental organisations, associations, foundations, trade unions, or even political parties.[8] Typical categories of legal relationships between private parties include contractual relationships, tortfeasor–victim relationships, relationships concerning rights on movable/immovable property, family relationships, and succession relationships.[9]

In line with the above mentioned broad understanding of European private law, Grundmann demonstrates that EU law seeks to protect private law relationships in three instances:[10] protection against state power (e.g. by subjecting national legislation to the demanding case law on fundamental freedoms), protection against cartels and dominant

Law Code' (2005) 1 *European Review of Contract Law* 210; F Cafaggi, 'Introduction', in F. Cafaggi (ed), *The Institutional Framework of European Private Law* (Oxford University Press, 2006) 1; H Collins, 'Governance Implications for the European Union of the Changing Character of Private Law' in F Cafaggi and H Muir-Watt (eds), *Making of European Private Law: Governance Design* (Edward Elgar, 2008) 269; F Cafaggi and H Muir-Watt (eds) *The Regulatory Function of European Private Law* (Edward Elgar, 2009); H-W Micklitz, 'The Visible Hand of European Regulatory Private Law. The Transformation of European Private Law from Autonomy to Functionalism in Competition and Regulation' (2009) 28 *Yearbook of European Law* 3.

[7] V Mak, 'The Consumer in European Regulatory Private Law' (2015) 5 *Tilburg Private Law Working Paper* 2.

[8] See A Colombi Ciacchi, 'European Fundamental Rights, Private Law, and Judicial Governance', in H Micklitz (ed), *The Constitutionalisation of European Private Law* (Oxford University Press, 2014) 102 at 103. For an insight to the different concepts of 'private law relationships', see the chapters by Leczykiewicz and Weatherill, Claes, Reich, Dougan, Hesselink, Mak and Freedland in D Leczykiewicz and S Weatherill (eds), *The Involvement of EU Law in Private Law Relationships* (Hart Publishing, 2013).

[9] Confer the four pillars 'Contract', 'Tort', 'Property' and 'Family' in G Brüggemeier, A Colombi Ciacchi and G Comandé (eds), *Fundamental Rights and Private Law in the European Union. Volume 1: A Comparative Overview* (Cambridge University Press, 2010). See in particular G Brüggemeier, A Colombi Ciacchi and G Comandé, 'Introduction', ibid, 4.

[10] S Grundmann, 'The Concept of the Private Law Society: After 50 Years of European and European Business Law' (2008) 4 *European Review of Private Law* 580. Grundmann evidences how these aspects of EU law are largely in line with Böhm's seminal concept of a *Private Law Society*. In this respect, see also: A McCann, 'The CJEU on Trial: Economic Mobility and Social Justice' (2014) 22(5) *European Review of Private Law* 729–768.

positions (e.g. by applying competition rules and the horizontal effect of fundamental freedoms), and protection against other structural imbalances between private parties (e.g. by developing anti-discrimination rules and consumer protection measures).

The discussion in this chapter embraces this progressive understanding of European private law. The focus here, however, is on a relatively small yet politically salient part of the said field. It relates to four instances of EU law that regulate private law relationships concerning health care: (1) the relevant CJEU judgments on cross-border healthcare and the Patient Rights Directive; (2) the consumer law Directives applicable also to health-related contractual relationships; (3) EU legislation on safety standards for products, food, pharmaceuticals, and medical devices; and (4) the possible impact of the full harmonisation under the Product Liability Directive on the level of health protection.

In line with the overall orientation of this volume, an institution has a 'human face' if it adequately takes basic human interests into account. As mentioned in the *Introduction* to this volume, considerable EU legal discourse, including that on EU private law, focuses on the duality of social and economic human interests – the social human interests *versus* the economic human interests. This chapter agrees with Kostakopoulou,[11] Ferreira,[12] and Kukovec[13] that there is value in moving beyond this dichotomy. In light of global power dynamics and wealth inequalities, one person's social interest is another person's economic interest, and *vice versa*. Assuming shared notions of 'social interests' when critiquing the technocratic nature of EU integration is not without its consequences. It may be argued that it leads to a bias, for example where the 'social' interest behind the free movement claim is not portrayed adequately, but is, instead, politically obscured by its pre-classification as inherently 'economic'.[14]

This chapter, therefore, cautiously embraces the intellectual move towards a so-called 'humane-based approach' to EU law. It subscribes to the argument put forth by Kostakopoulou that a humanistic axiology

[11] See D Kostakopoulou's chapter: 'Towards a Humanistic Philosophy of the European Union', in this volume.

[12] See N Ferreira's chapter: 'The Human Face of the European Union: Are EU Law and Policy Humane Enough? An Introduction', in this volume.

[13] See D Kukovec, 'Taking Change Seriously: The Rhetoric of Justice and the Reproduction of the Status Quo' in D Kochenov, G de Búrca and A Williams (eds), *Europe's Justice Deficit?* (Hart, 2015) 319–337.

[14] See the critique of the *Laval* and *Viking* aftermath by Kukovec, ibid.

may focus our critical awareness away from the economic paradigm of the EU's institutional design and policy efforts. Instead of critiquing the 'justness' of EU private law by identifying a preference for an economic or social interest, the substantive outcome may be assessed vis-à-vis its impact on 'human flourishing' (taking account of available empirical evidence).[15] Returning to the matter at hand, we can identify nine interests core to 'human flourishing' that are relevant in the domain of substantive private law: (1) life, (2) physical and mental integrity, (3) health care, (4) private and family life, (5) freedom of thought, conscience and religion, (6) freedom of expression and information, (7) freedom of association, (8) equality and non-discrimination, and (9) education. This list is non-exhaustive.

A complete assessment of the extent to which EU private law respects and protects these nine interests would require writing an entire book. Not even a summarial, overview-like analysis of the level of protection of these nine interests in EU private law could be carried out within a chapter of this length.[16] Therefore, this chapter will first briefly discuss the European fundamental rights/human rights dimension of the abovementioned nine interests, and then it will focus on only one of them: health care. Before doing so, it is worth briefly explaining why a fundamental/human rights focus (notwithstanding its challenges) is relevant to 'going about assessing humaneness' in European private law and why health care is an appropriate choice for a case study.

A fundamental/human rights focus is relevant to 'going about assessing humaneness' in European private law for three reasons. Firstly, the 'inner dimension' of the universality of human rights (which incorporates both substantive aspects[17] and functional aspects)[18] is, arguably, a

[15] See Kostakopoulou's final chapter in this volume.

[16] Each of these nine interests could be, and some have been indeed, the subject of a thick book. See for example M Hunter-Hening (ed) *Law, Religious Freedom and Education in Europe* (Ashgate, 2012); R Schulze (ed) *Non-Discrimination in European Private Law* (Mohr, 2011); K Ziegler (ed) *Human Rights and Private Law. Privacy as Autonomy* (Hart Publishing, 2007).

[17] The 'substantive' aspects are as follows: human rights are inherent to all human beings; human rights must be protected against all encroachments; the basic values such as dignity, freedom and autonomy of an individual must be explicitly or implicitly protected. See: R Arnold, 'Reflections on the Universality of Human Rights' in R Arnold (ed), *The Universalism of Human Rights* (Springer, 2013) 2.

[18] The 'functional' aspects are as follows: necessary limitations must respect the principle of optimalisation of human rights; intervention by public power must be founded on law, be backed up by a legitimate reason, be necessary for the needs of the democratic society and

type of 'universalist humanism'.[19] From this view, normative human rights structures,[20] which profess the central value and dignity of each human being and the liberty and the equality of all human beings, are built on a 'humanist axiology'.[21] As Ferry and Renaut insist: some form of humanism is necessary for the preservation of human rights.[22] Secondly, there is an intellectual movement within legal thought towards human rights in private law prompted by the need to have a unified legal order.[23] Statements of fundamental rights and principles (stemming from national constitutions, European or international treaties) may be seen as serving as 'the bedrock values of an entire legal order'.[24] These values infuse both public and private law.[25] Thirdly, once European private law is perceived as a regulatory instrument of private relationships designed

be the sole adequate means of achieving such a legitimate reason (principle of proportionality); the core (the very nature, the essence) of human rights must not be affected; and efficient judicial protection is indispensable. See Arnold, ibid.

[19] See A Reis Monteiro, *Ethics of Human Rights* (Springer, 2014) 3–6.

[20] I.e. the UN Covenants and specific human rights instruments on the regional level with guarantee systems in America, in Africa, and – deemed as the most efficient and influential – in Europe with the European Convention of Human Rights (ECHR).

[21] This axiology is, according to Kostakopoulou (final chapter in this volume), that: 'structures and policies must contribute to creating, and bettering, the conditions for a more fulfilled and dignified living'.

[22] See the Foreword by Alexander Nehamas, in A Renaut, M B Debevoise, F Phillip, *The Era of the Individual: A Contribution to a History of Subjectivity* (Princeton University Press, 2014).

[23] A Barak, 'Constitutional Human Rights and Private Law', in D Friedmann and D Barak-Erez (eds), *Human Rights in Private Law* (Hart Publishing, 2001) 13, 21–22; J Smits, 'Private Law and Fundamental Rights: A Sceptical View', in T Barkhuysen and S Lindenbergh (eds), *Constitutionalization of Private Law* (Martinus Nijhoff, 2006) 9.

[24] H Collins, 'The Impact of Human Rights Law on Contract Law in Europe' (2011) 13 *University of Cambridge Legal Studies Research Paper* 1.

[25] There is a growing amount of scholarship on the impact of fundamental rights on national and European private law, see, amongst others: O Cherednychenko, 'EU Fundamental Rights, EC Fundamental Freedoms and Private Law' (2006) 1 *European Review of Private Law* 23–61; A Colombi Ciacchi, 'The Constitutionalization of European Contract Law: Judicial Convergence and Social Justice' (2006) *European Review of Contract Law* 2; M. Kumm, 'Who is Afraid of the Total Constitution? Constitutional Rights as Principles and the Constitutionalization of Private Law' (2006) 7(4) *German Law Journal* 341–370; D Oliver and J Fedtke (eds), *Human Rights and the Private Sphere: A Comparative Study* (Routledge-Cavendish, 2007); C Mak, *Fundamental Rights in European Contract Law: A Comparison of the Impact of Fundamental Rights on Contractual Relationships in Germany, the Netherlands, Italy and England* (Kluwer Law International, 2008); G Brüggemeier, A Colombi Ciacchi and G Comandé (eds), *Fundamental Rights and Private Law in the European Union. Volume 1: A Comparative Overview* (Cambridge University Press, 2010).

to protect certain goals such as consumer protection or the internal market, and in doing so, shaping certain public law objectives (such as the provision of health care), then the relevance of human rights to European private law is 'brought to the fore'.[26]

The Introduction to this volume alludes to the inherent problem of isolation in rights discourse, i.e. the failure to consider individuals' contexts, communities and relationships.[27] As stated above, we understand the humane-based approach,[28] outlined in the *Introduction* to this volume, to be concomitant with the norms underlining a balanced rights-based approach. In this respect, it is hard to see how a humane-based approach (based on contested concepts of compassion, empathy, caring, etc.) is better equipped to avoid the isolation problem. Moreover, rights discourse has been subject to numerous more criticisms: it has been said to be profoundly indeterminate,[29] to distort the debate,[30] to be uncompromising,[31] and to be simplistic.[32] Arguably, these same dangers face a loosely defined humane-based approach to law and policy making.

Notwithstanding such criticisms, this chapter is premised on the assumption that the notion of humaneness and the question of human rights protection inevitably intertwine (or at least they cannot be clearly normatively distinguished), and are of value in assessing substantive policy outcomes (in the EU or otherwise). Yet, to be of real value, they require careful contextualisation between the individual and the community, between freedoms and limitations. For example, a more balanced non-isolated rights critique shows that the horizontal application of fundamental rights in national legal systems mostly serve to counterbalance excessive abuse of power (i.e. protect the weaker party) and

[26] See H Collins (note 24 above) 2–3.

[27] See N Ferreira's introductory chapter in this volume, whereby it is stated that an abstract human rights critique 'without sufficiently considering individuals' context, communities and relationships [. . .] contributes to the dangers of pitting opposing rights, and therefore, individuals and entities against each other'.

[28] This (areligious) ethical framework is informed by Western (feminist) ethics-of-care, Confucian philosophy and African customary law.

[29] See D Kennedy, 'Critical Labour Law Theory: A Comment' (1981) 4 *Industrial Relations Law Journal* 506.

[30] See L R Klass, 'Is There a Right to Die?' (1993) 23(1) *Hastings Centre Report Journal* 37.

[31] See M A Glendon, *Right Talk: The Impoverishment of Political Discourse* (Free Press, 1993) 44.

[32] Ibid, 15.

to uphold democratic values impacted by private law relationships (such as freedom of religion, freedom of speech, equality between men and women, etc.).[33]

In terms of justifying the case study of health care, the overarching norms alluded to in the *Introduction* of this volume, *jen* and *ubuntu*, possess another common thread beyond a shared humane-centred concern: they both recognise the normative co-dependency between individual well-being and communal well-being.[34] This co-dependency is pertinently clear in the dual function of health care.[35] A dual function which is, as we will see later, also reflected in the different dimensions of the fundamental/human right to health care at the European and international level (the libertarian dimension and the social solidarity dimension). On the one hand, there exists a need to provide for universal, permanent and adequate access to medical demands that increase the lifespan of individuals and that adds to their basic quality of life. On the other hand, health care is a consumable good that reflects the significance of individual control over one's own body and mind; in this sense, patients must be free to access health care structures that satisfy their personal preference. A given policy on the provision of health care that actualises this dual function as much as possible, is one striving to meet the normative demands of *jen* and *ubuntu*. The question that hereby arises is: what impact does EU private law have on the ability to meet these normative demands?

2 Fundamental rights dimension of nine interests core to 'human flourishing'

The nine interests mentioned above will resonate with readers who have some knowledge of human rights or constitutionally protected fundamental rights. One may ask whether and to what extent these interests are acknowledged as European fundamental rights. As touched on above, this question bears relevance also in the European private law context. Indeed, it is widely acknowledged that fundamental rights in general, and

[33] See A Colombi Ciacchi, 'The Constitutionalization of European Contract Law: Judicial Convergence and Contract Law' (2006) 2 *European Review of Contract Law* 177.

[34] See Ferreira's introductory chapter in this volume.

[35] See J Ruger, *Health and Social Justice* (Oxford University Press, 2009) 2–4. See also J McHale, 'Fundamental rights and health care' in E Mossialos et al (eds) *Health Systems Governance in Europe – The Role of European Union Law and Policy* (Cambridge University Press, 2010) 283–294.

European fundamental rights in particular, have both a vertical and a horizontal effect on private law and private relationships. Vertically, these rights create obligations for lawmakers, and horizontally, they create obligations for courts and – to a certain extent – for private parties directly.[36]

This chapter understands the concept of 'European fundamental rights' as embracing the following types of rights:

- human rights, i.e. the rights enshrined in the European Convention on Human Rights (ECHR) or other international treaties acknowledging human rights, and the rights otherwise acknowledged as human rights under international law;
- rights enshrined in the Charter of Fundamental Rights of the European Union (CFREU, hereinafter also 'the Charter');[37]
- rights resulting from the constitutional traditions common to the EU Member States; and
- rights otherwise generally acknowledged as fundamental in the EU legal order.

This body of European fundamental rights is thus much older than the Charter of Fundamental Rights of the European Union. In the 1960s–1970s, the European Court of Justice (CJEU) introduced and progressively developed the rule according to which the human rights enshrined in international conventions binding upon the Member States of the EU (then EC) and the fundamental rights resulting from the constitutional traditions common to the Member States are to be observed as general principles of Community law.[38] This rule became established

[36] See amongst others G Brüggemeier, A Colombi Ciacchi and G Comandé (eds) *Fundamental Rights and Private Law in the European Union* (note 9 above); D Leczykiewicz, 'Horizontal Effect of Fundamental Rights: In Search of Social Justice or Private Autonomy in EU Law?', in U Bernitz, X Groussot and F Schulyok (eds), *General Principles of EU Law and European Private Law* (Kluwer Law International, 2013); M Safjan, 'Reflections on the Horizontal Effect of Fundamental Rights in EU Law – Limits of Direct Influence of CJEU Decisions' in K Purnhagen and P Rott (eds), *Varieties of European Economic Law and Regulation. Liber Amicorum for Hans Micklitz* (Springer, 2014) 139 et seq.; A Colombi Ciacchi (note 8 above) 102 at 104 et seq., with further references.

[37] As amended by the Treaty of Lisbon. See the consolidated version of March 2010: http://europa.eu/eu-law/decision-making/treaties/pdf/consolidated_versions_of_the_treaty_on_european_union_2012/consolidated_versions_of_the_treaty_on_european_union_2012_en.pdf.

[38] See Case C-29/69, *Stauder*, [1969] ECR 1–419: '... the fundamental human rights enshrined in the general principles of Community law and protected by the Court'; ECJ Case C-4/73, *Nold v European Commission*, [1974] ECR 372: '... fundamental rights

jurisprudence of the ECJ. It was then codified in the Maastricht Treaty and maintained in all successive treaties.[39]

Therefore, the above body of European fundamental rights must be respected by: (1) the EU institutions, agencies and bodies when making, interpreting, and applying primary or secondary EU law in the field of public or private law; and (2) the Member States when they are 'implementing EU law' (see specifically Article 51 of the CFREU). In light of CJEU case law, Cherednychenko succinctly (and correctly) states that 'implementing EU law' must be understood in a wide sense subsuming 'all national public acts within the scope of EU law'.[40] This has meant that national public authorities are bound by European fundamental rights not only in the process of transposing EU law, but also when they derogate from EU legal provisions.[41]

Six of the above-mentioned nine interests find explicit recognition both as human rights in the ECHR and as EU fundamental rights in the Charter: the right to life (Art. 2 ECHR and Art. 2 CFREU), the right to private and family life (Art. 8 ECHR and Art. 7 CFREU), freedom of thought, conscience and religion (Art. 9 ECHR and Art. 10 CFREU),

form an integral part of the general principles of law, the observance of which [the Court] ensures. In safeguarding these rights, the Court is bound to draw inspiration from constitutional tradition common to the Member States. [. . .] Similarly, international Treaties for the protection of human rights on which the Member States have collaborated or of which they are signatories, can supply guidelines which should be followed within the framework of community law'.

[39] With the introduction of Art F (now. Article 6 TEU). For general reading on human rights/fundamental rights in the EU see: S De Vries, U Bernitz and S Weatherill, *The Protection of Fundamental Rights in the EU After Lisbon* (Hart Publishing, 2013); P Alston, J Heenan and M Bustelo (eds), *The EU and Human Rights* (Oxford University Press, 1999); A Williams, *EU Human Rights Policies: A Study in Irony* (Oxford University Press, 2004); O De Schutter and I Butler, 'Binding the EU to International Human Rights Law (2008) 27 *Yearbook of European Law* 277.

[40] O Cherednychenko (note 5 above) 173. This viewpoint was confirmed in a recent CJEU decision, see: Case C-617/10 *Åklagaren v. Hans Åkerberg Fransson* [2013] ECR I-0000.

[41] See for example: Case C-60/00 *Carpenter v Home Secretary* [2002] ECR I-6279; Case C-109/01 *Home Secretary v Akrich* [2003] ECR I-9607; Case C-441/02 *Commission v Germany* [2006] ECR I-3449; Case C-145/09 *Land BadenWürtemberg v Tsakouridis* [2010] ECR I-11979; Case C-34/09 *Ruiz Zambrano v ONEM* [2011] ECR I-1177. Less controversially, the CJEU has also held that the protection of fundamental/human rights *in itself* constitutes a legitimate interest which will justify a restriction on EU law, see: Case C-36/02 *Omega Spielhallen* [2004] ECR I-9609; Case C-112/00 *Schmidberger v Austria* [2003] ECR I-5659; Case C-208/09 *Sayn-Wittgenstein* [2010] ECR I-13693.

freedom of expression and information (Art. 10 ECHR and Art. 11 CFREU), freedom of association (Art. 11 ECHR and Art. 12 CFREU), and non-discrimination (Art. 14 ECHR and Art. 21 CFREU).

The remaining three interests (physical and mental integrity, health and education) are not expressly mentioned in the ECHR, whilst the Charter explicitly codifies them as EU fundamental rights. The first Title of the Charter ('Dignity') enshrines the right to physical and mental integrity (Art. 3 CFREU)[42] among the most fundamental of all rights, placing it immediately after the right to human dignity and the right to life. The right to education (Art. 14 CFREU)[43] can be found in the second Title of the Charter ('Freedoms'). Again a different section of the Charter, Title III ('Solidarity'), enshrines the right to health care (Art. 35 CFREU).[44]

3 Two different fundamental rights relating to health care interests

Without physical and mental integrity, one cannot be a healthy human being. If the interest in one's health is logically connected to the interest in one's physical and mental integrity, why has the Charter codified these two interests so far from each other – the right to physical and mental integrity under the heading 'Dignity' and the right to health care under the heading 'Solidarity'? Why do the right

[42] Which reads: '1. Everyone has the right to respect for his or her physical and mental integrity; 2. In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law, the prohibition of eugenic practices, in particular those aiming at the selection of persons, the prohibition on making the human body and its parts as such a source of financial gain, the prohibition of the reproductive cloning of human beings'.

[43] Which reads: 'Everyone has the right to education and to have access to vocational and continuing training. 2. This right includes the possibility to receive free compulsory education. 3. The freedom to found educational establishments with due respect for democratic principles and the right of parents to ensure the education and teaching of their children in conformity with their religious, philosophical and pedagogical convictions shall be respected, in accordance with the national laws governing the exercise of such freedom and right'.

[44] Which reads: 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities'.

to physical and mental integrity on the one hand, and the right to health care on the other, appear as two remarkably different rights in the system of European fundamental rights?

A first answer to this question can be found in the case law of the European Court of Human Rights (ECtHR). According to this Court's established jurisprudence, the protection of private life under Article 8 ECHR encompasses a person's physical and psychological integrity.[45] Measures affecting the physical or psychological integrity have to reach a certain degree of severity to qualify as an interference with the right to private life under Article 8 ECHR.[46] Nonetheless, even minor interferences with a person's physical integrity (for example a gynaecological examination[47]) may fall within the scope of Article 8 ECHR if they are against the person's will.[48]

As shaped by the ECtHR's case law, the right to physical or psychological integrity is a liberty right, which corresponds to the *negative* obligations not to cause bodily or mental injuries to others, and not to administer medical treatment without the patient's consent. The content of this right is substantially different from the social right to health, which entails the *positive* obligations of providing adequate health care.[49] This explains why the Charter codified the liberty right to physical or psychological integrity in Article 3, and the social right to health care in Article 35.

The qualification of the basic interest in health care as a human right[50] is controverted, at least outside Europe.[51] At the international level, health care finds recognition in the framework of the socio-economic

[45] ECtHR *Y.F. v Turkey* (application no. 24209/94) 22 July 2003; ECtHR *Bensaid v UK* (application no. 44599/98) 6 February 2001, 6 May 2001 final, para 47.

[46] *Bensaid v UK*, ibid, para 46.

[47] This was the case in *Y.F. v Turkey* (note 45 above).

[48] ECtHR *Storck v Germany* (application no. 61603/00) 6 June 2005, para 143. Confer http://echr-online.info/physical-integrity/.

[49] For critiques arguing that the distinction between positive and negative human rights obligations should be abandoned, see: G de Becco, *Non-judicial Mechanisms for the Implementation of Human Rights in European States* (Bruylant, 2010) 24; O De Schutter, *Fonction de juger et droits fondamentaux. Transformation du contróle juridictionnel dans les orders juridiques américain et européens* (Bruylant, 1999) 141–143.

[50] On health as a human right see among others B Toebes, 'Health, Human Rights and Social Justice in Europe' in I Lintel, A Buyse and L McGoingle (eds.), *Defending Human Rights: Tools for Social Justice* (Intersentia, 2013) 109–125.

[51] Some neo-liberal American thinkers refuse to acknowledge a human right to health care. See GE Vidal, 'Healthcare is Not a Human Right', The Libertarian Standard, http://libertarianstandard.com/articles/gabriel-e-vidal/healthcare-is-not-a-human-right/.

rights, or human rights of second generation.[52] It is explicitly enshrined in Article 12 of the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR),[53] and implicitly embraced by the human right to an adequate standard of living under Article 25(1) of the 1948 Universal Declaration of Human Rights (UDHR).[54]

One may therefore conclude that at both the international and the EU level, the fundamental right to health presents two dimensions: a libertarian one, corresponding to the obligation not to interfere with someone's physical and psychological integrity, and a dimension of social solidarity, corresponding to the obligation to ensure a high level of human health protection.

4 Is European private Law humane enough from the viewpoint of health protection?

4.1 Preliminary remarks

Article 35 CFREU states: 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities'.

One question that arises is whether European private law adequately respects the social solidarity dimension of the fundamental right to health care. Considering that some conceptualisation of humanism is

[52] The first known mention of different generations of human rights goes back to K Vasak, 'A 30-Year Struggle', *The UNESCO Courier* (November 1977) 29; confer also K Vasak (ed), *The International Dimensions of Human Rights* (Greenwood Press, 1982). For extensive discussion on, and examples of human rights of first, second and third generations, see C Tomuschat, *Human Rights Between Idealism and Realism* (Oxford University Press, 2003) 24 et seq. Sometimes the three generations of rights are delineated by a colour scheme as 'blue', 'red' and 'green' rights: J Galtung, *Human Rights in Another Key* (Oxford: Polity, 1994) 151 et seq. For a brilliant critique from a 'colour blind' viewpoint U Baxi, *The Future of Human Rights* (Oxford University Press, 2002) 70.

[53] This Article acknowledges 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health', and obliges the States Parties to take the steps necessary to achieve the full realisation of this right, including 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness'.

[54] 'Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services [. . .]'.

a requisite component of the inner dimension[55] of universal fundamental/human rights, this line of inquiry may go some way to assessing whether European private law is 'humane' enough from the viewpoint of health protection. The answer to this question can be split into four parts. The first part (see Section 4.2) addresses the relevant CJEU judgments on cross-border health care and the Patient Rights Directive. The second part (see Section 4.3) deals with the consumer law Directives applicable also to health-related contractual relationships. The third part (see Section 4.4) considers the EU legislation on safety standards for products, food, pharmaceuticals, and medical devices. The fourth part (see Section 4.5) discusses the possible impact of the full harmonisation under the Product Liability Directive on the level of health protection.

4.2 The CJEU case law on cross-border healthcare and the Patient Rights Directive

Some scholars perceive EU law in general, and EU free movement law in particular, as a threat to national health care standards. For example, according to Hervey, the institutional structures that support law and policy-making at EU level are often unsupportive of, or even unaware of, health care concerns.[56] Such claims seem, however, to be based more on the general assumption that EU free movement law might weaken the national welfare systems, than on a specific analysis of how each relevant EU law instrument affects the level of human health protection.

[55] As alluded to in Section 1 above, a loose baseline 'humanist perspective' (see Kostakopoulou's chapter in this volume, where certain core elements may be discerned from the various schools of humanism) is a perspective, at least as we understand it, normatively at the heart of the established substantive and functional aspects of universal human rights. Kostakopoulou discerns core elements of humanism as '(i) the significance given to the Latin term humanus (human) which is, in turn, derived from the noun 'homo' which means human being, ii) the belief that the social realities and institutional structures that house and bind human beings must be fit for human living and iii) that there is an explicit, or implicit, expectation that some form of 'anthropoplassy' is both possible and desirable'. Compare this perspective on humanism with the perspective on human rights alluded to by Reis Monteiro (note 19 above).

[56] T Hervey, 'The Impacts of European Union Law on the Health Care Sector: Institutional Overview' (2010) 16 *Eurohealth* 5. The author stresses the 'clash of logic' between internal market law and the solidarity model of the national healthcare systems, organised through the exclusion of those outside the nation state concerned. See also T Hervey and L Trubek, 'Freedom to Provide Healthcare Services in the EU: An Opportunity for "Hybrid Governance"' (2007) 13 *Columbia Journal of European Law* 623.

In the cases *Kohll*,[57] *Geraets-Smits and Peerbooms*,[58] *Muller-Fauré and Van Riet*,[59] *Inzian*,[60] *Watts*,[61] and *Elchinov*,[62] patients unsatisfied with the health care provided in their country of residence (an EU Member State) sought better, or earlier, medical treatment in another Member State and claimed the reimbursement of such treatment in their country of residence. In all the above-mentioned cases, the CJEU supported this patient mobility.[63] Given the broad definition of European private law set out in the introduction of this chapter, these cases cannot be understood as strictly public law matters. The public law relationship between the individual and the state of affiliation (concerning the entitlement to reimbursement of expenses from the public purse) happened to arise out of an *a priori* private law relationship (the existence of a cross-border agreement between a patient and a private health care provider). From this perspective, these cross-border health care cases evidence Böhm's concept of the private law society – public power was constrained by the supremacy of private law arrangements. The public power to limit reimbursement in such cases was subject to the rationale of EU rules[64] and the CJEU's interpretation of these rules. Now a question arises: how does this CJEU jurisprudence affect the level of health protection offered to EU citizens? To help us answer this

[57] C-158/96 *Kohll* [1998] ECR I-1931.

[58] C-157/99 *Gereats-Smits and Peerbooms* [2001] ECR I-5473.

[59] C-385/99 *Müller-Fauré and Van Riet* [2003] ECR I-4509. For a comment of this judgment see G Davies 'Health and Efficiency: Community Law and National Health Systems in the Light of Müller-Fauré' (2004) 67 *Modern Law Review* 94.

[60] C-56/01 *Inzian* [2003] ECR I-12403.

[61] C-327/04 *Watts* [2006] ECR I-4325, para 75. For a comment of this judgment see G Davies 'The effect of Mrs Watts' trip to France on the National Health Service' (2007) *King's Law Journal* 158.

[62] C-173/09 *Elchinov* [2010] ECR I-08889.

[63] See W Sauter, 'Harmonisation in healthcare: the EU patient rights' Directive' (2011) *TILEC Discussion Paper* No. 2011–030, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1859251, 4.

[64] These rules are EU Treaty provisions, namely Article 56 TFEU on the freedom to provide services, and also secondary EU legislation aimed to facilitate the free movement of workers and self-employed persons, along with family members who accompany them, namely Regulation 1408/71, which was adopted to further the free movement of these persons within the Union by coordinating aspects of national social security systems. This regulation was superseded in 2004 by Regulation 883/2004 (coming into effect in 2010), which expanded the coverage of these rules to cover all persons lawfully resident in a Member State of affiliation.

question, we will reflect on particular studies carried out by Davies,[65] Kaczorowska,[66] and de Witte.[67]

First and foremost, we may say that in the aforementioned CJEU jurisprudence, the health care needs *specific* to the individual played a key role. The Court ruled that any restriction on the patient's contractual freedom to receive a medical service, such as the conditions on prior authorisation for reimbursement, must take into account the medical needs of the *individual* concerned.

In *Watts* and *Elchinov*, the Court used the fundamental freedoms and the relevant secondary legislation to compensate for the inadequacies/failures of national health systems and entitle the patient to seek the required treatment abroad.[68] Davies[69] addressed the clash between the patient-centred, needs-based approach of the CJEU,[70] and the logic of the national healthcare systems, in particular the one underlying the UK National Health Service (NHS). He rightfully pointed out that the *Watts* decision only affects the national healthcare systems insofar as they are unable to provide treatment without undue delay. If the national systems offered operations within a time corresponding to patients' medical needs, such decisions of the CJEU would have no effect.[71] In the *Watts* case, the UK government argued that the effect of the CJEU's patient-centred, needs-based approach to provision of health care would be to undermine the national authorities' capacity to manage the system via the use of waiting lists.[72] Davies commented sharply: 'Was the UK government really arguing for its right to act against the medical interests of patients waiting for treatment? It was, but it lost the point, and it can do so no longer'.[73] The demand for 'undue delay' and 'effective treatment' have granted the individual a right to adequate care whenever a

[65] G Davies (note 59 above) 94; id (note 61 above) 158.

[66] A Kaczorowska, 'A Review of the Creation by the European Court of Justice of the Right to Effective and Speedy Medical Treatment and its Outcomes' (2006) 12 *European Law Journal* 345.

[67] F de Witte, *EU law and the question of justice* (PhD thesis, London School of Economics, 2012), available at: http://etheses.lse.ac.uk/452/. Forthcoming in published format as: F de Witte, *Justice in the EU – The Emergence of Transnational Solidarity* (Oxford University Press 2015).

[68] Ibid, 746.

[69] G Davies (note 59 above) 94; id (note 61 above) 158.

[70] G Davies (note 61 above) 160.

[71] G Davies (note 61 above) 166.

[72] C-327/04 *Watts* [2006] ECR I-4325, para 75. For a comment of this judgment see G Davies (note 54 above) 158.

[73] G Davies (note 61 above) 161.

treatment option can be construed to fall within the 'basket of health care' in the state of affiliation but *cannot* be provided in its territory.

Kaczorowska convincingly demonstrated that the Court, by creating a new right to effective and speedy medical treatment, has to a certain extent attained the main objective of Article 35 of the CFREU. It is regrettable that this Article was not explicitly relied on by the Court. Nonetheless, this new right to effective and speedy medical treatment tangibly protects the EU citizens, who will neither have to wait indefinitely to obtain medical treatment, nor have to accept substandard treatment in their Member State of insurance.[74]

It is also worth noting that the unmet need of health care in the state of affiliation arises only in exceptional circumstances. A number of sources suggest that this unmet need, particularly related to the costs or the availability of specific medical treatment, is limited within the EU.[75] Furthermore, there is evidence that this line of case law has managed to partially *help* Member States meet their *positive* obligation (i.e. provide for basic health care). Empirical research shows that Member States have used the same rationale behind the *Watts* and *Elchinov* decisions to compensate for the lack of financial and technological resources required to treat rare diseases,[76] or to balance

[74] A Kaczorowska (note 66 above) 345.

[75] See S Allen and C Masseria, 'Research Note: Unmet need as an indicator of access to health care in Europe', European Commission, Directorate-General 'Employment, Social Affairs and Equal Opportunities', Unit E1 – Social and Demographic Analysis (December 2009); See Table 8.1, Commission Impact Assessment for the Directive on Cross-Border Healthcare, SEC (2008) 2163, 68. Note that more recent research found, somewhat expectedly, that the global financial crisis has increased the unmet need of health care in certain 'crisis' EU Member States (namely in Greece, Italy, and Latvia). However, 'this increase has often been less severe for those groups that previously reported higher-than-average enforced unmet need' in said countries. Also, the prevalence of enforced unmet health care has remained 'relatively low' in other 'crisis' Member States – 2% in Ireland and Portugal, 1% in Spain and 0.5% in Slovenia. See: European Commission Research note 7/2013, 'The impact of the financial crisis on unmet needs for healthcare' (November 2013).

[76] See De Witte (note 67 above) 95: 'Malta and Luxemburg, for example, simply outsource treatment of such patients to other systems, which frees up resources for other treatments. Likewise, it allows less rich Member States to offer treatment options that are (for the moment) unavailable at home'. See also Opinion of AG Villalón in *Elchinov* [2010], para. 72: 'a system such as the Bulgarian system, which seeks to offer a very advanced list of treatment that is paid for by the fund, benefits from the knowledge and technology of other Member States which have the technical resources to which Bulgaria aspires. If a Member State wishes to be at the cutting edge of medical treatment (which naturally takes time), European Union law allows its citizens to receive in another Member State

negative externalities between the supply and demand of health care at the border regions.[77]

As for the decisions in *Kohll* and *Muller-Fauré* concerning the receipt of medical services as an expression of patient *choice*, national governments brought forward two general arguments premised upon their positive obligation to protect immobile citizens. One argument is based on the infrastructural stability of the health care system of affiliation, while the other relates to the financial stability of the said system.

The infrastructural argument assumes that increased patient mobility will result in a waste of resources and cutbacks in cost-intensive treatments, leaving 'immobile' patients in the state of affiliation worse off.[78] This is a legitimate concern, but in order to be a justified exception to free movement rules, it must be objectively and empirically demonstrated. Indeed, this may be difficult, but a fair assessment can be based on the number of mobile patients. The Commission recently estimated that 1% of the total Gross Domestic Product of the EU is spent on cross-border health care (most of which is spent on emergency care and not planned care),[79] as the number of cross-border patients remains extremely low. In context, approximately EUR 9.7 billion of a total EUR 12,149 billion is spent on such health care.[80]

treatment which the former State wishes to make available domestically, although not at present in a position to do so'.

[77] Commission Impact Assessment for the Directive on Cross-border Healthcare, SEC (2008) 2163, p. 42: 'Belgium has had larger patient flows for planned care than most other Member States, in particular with Dutch patients being treated in Flanders through contracts between Dutch health insurers and Belgian providers. In this case study, the researchers consider that as well as being convenient for patients, this is more efficient for both the Dutch insurers (providing care that is faster and cheaper, as well as being perceived as technologically advanced and of high quality) and the Belgian providers (helping to overcome overcapacity in the acute hospital sector by treating patients from abroad)'.

[78] See F de Witte (note 67 above) 97–98.

[79] See European Commission, 'Memo on Q&A: Patients' Rights in Cross-border Healthcare' (2013), available at: http://europa.eu/rapid/press-release_MEMO-13-918_en.htm. See also Commission Impact Assessment (note 77 above) 9.

[80] In a national context, between 2001 and 2006, the United Kingdom spent approximately GBP 2 billion on cross-border health care, while during that same period it spent an estimated GBP 4 billion on overpaid benefits due to official mistakes. See E Van Ginneken and R Busse, 'Cross-Border Health Care Data', in M. Wissmaer, W. Palm *et al.* (eds), *Cross-Border Health Care in the EU: Mapping and Analyzing Practices and Policies, Observatory Studies Series* (2008) 310; and see annual rates regarding *Estimates of Fraud and Error Levels in the Benefit System in Great Britain*, National Statistics by the Department of Work and Pensions, UK government publications. See www.gov.uk/government/publications.

The second argument regarding financial stability assumes that patient mobility will destabilise access to adequate treatment for all citizens by producing financial asymmetries. Firstly, this argument is conceptually flawed. The Court has reiterated on numerous occasions that in the case of patients who *choose* treatment abroad, the Member State of affiliation is only required to reimburse costs up to the same amount it would have, had the treatment taken place in its territory. Any costs above this threshold are borne by the patient. Thus, as the patient contributes to the funding of the collective insurance scheme and becomes a beneficiary of that scheme at no extra cost, there can be no logical reasoning to assume that the financial stability of the health care system is suddenly under threat. Secondly, there is no empirical evidence as of yet that the financial stability of national distributive choices has been negatively affected. National actors argue that financial instability may be difficult to prove until it is too late; they fear a drop may become a flood. Nonetheless, as it stands, there exists empirical evidence to the contrary – the number of cross-border patients is extremely low and moderate estimates suggest that patient mobility is financially advantageous for the Member States.[81] This goes some way to explaining the difficulty in identifying the adverse effects repeatedly warned by such national actors. Indeed, a drop *may* become a flood in the future, but without signs of becoming even a stream, such arguments appear nothing more than hyped speculation.

Essentially, EU private law, vis-à-vis the fundamental freedoms, has protected the right to receive adequate health care free from unjustifiable restrictions, without so far disrupting (evidence actually shows it is marginally aiding) the positive obligation to ensure a universally accessible health system. This means that it cannot be said that either the libertarian or social solidarity dimension of the fundamental right to health care have been undermined. Note that the Court has also refrained from imposing any positive obligations upon the Member States. National policymakers retain the regulatory autonomy to decide whether or not to reimburse particular costs for treatment or under what conditions reimbursement is possible.[82] Yet, if they decide to offer reimbursement for certain treatment *within* the state of affiliation, they

[81] See Commission Impact Assessment (note 77 above) 34, 55.

[82] Aside from the Muller-Faure decision on this, see Case C-444/05, *Stamatelaki* [2007] ECR I-3185, para 26 and 38.

cannot deny reimbursement should that treatment be provided outside the state of affiliation.[83]

The same arguments that defend the Court's jurisprudence on cross-border healthcare also defend the Patient Rights Directive,[84] which to a large extent codifies this jurisprudence.[85] This Directive is, however, less intrusive in the functioning of the national healthcare systems than the CJEU rulings preceding it.[86] According to Hatzopoulous and Hervey, the CJEU's 'revolution is over' as the baton has been picked up by the political institutions at the EU and Member State level.[87] Agreement is had here with Cohen, that time (and the manner in which Member States actually implement the Directive) will tell how much judicial restraint we may expect to see from the CJEU in the coming years.[88]

In terms of any added benefit of the Directive, there are a number of advantages for the patient[89] (at least in theory, again, much hinges on its actual implementation by Member States). Firstly, it requires the establishment of national contact points providing patients with relevant information to help 'make an informed choice, including on treatment options, on the availability, quality, and safety of the healthcare' provided in the Member state of treatment, as well as 'clear information on prices [. . .] and insurance cover'.[90] The Directive, however, does not make any stipulation for this information to be legally provided in various EU languages. This means patients who cannot speak the official language of the Member State of treatment may find this information inaccessible. Secondly, patients must be made aware of the legal route via EU Regulation

[83] Case C-8/02 *Leichtle* [2004] ECR I-2641, para. 48.
[84] Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.
[85] The Commission's primary justification for proposing the Patient Rights Directive was the Member States' failure to properly implement the Court's case law on cross-border healthcare. See W Sauter (note 63 above) 4. For a discussion on the main components of the Patient Rights Directive – prior authorisation, reimbursement, patient rights and cooperation – in light of the CJEU's case law, see also G Cohen, *Patients with Passports: Medical Tourism, Law and Ethics* (Oxford University Press, 2014) 186–198.
[86] This is demonstrated by V Hatzopoulos and T Hervey, 'Coming into line: The EU's court softens on cross-border healthcare' (2012) *Health Economics Policy and Law* 1.
[87] Ibid, 5. [88] See Cohen (note 85 above) 198.
[89] See M Peeters, 'Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-border Healthcare' (2012) 19 *European Journal of Health Law* 29, 51; see also P Quinn and P de Hert, 'The European Patients' Rights Directive: A Clarification and Codification of Individual Rights Relating to Cross Border Healthcare and Novel Initiatives Aimed at Improve Pan-European Healthcare Cooperation' (2012) 12(1) *Medical Law International* 1, 37.
[90] Directive 2011/24/EU, Article 4(2)(b).

1408/71, i.e. the E112 form, if and when they make inquiries to the national contact points about planned care abroad.[91] The Regulation route may be more beneficial in many circumstances, for example, when up-front payment by the patient for the treatment is not required.[92] Thirdly, the Member State of affiliation must abide by data privacy,[93] set out a risk appropriate system of professional liability insurance[94] and ensure that for individuals who seek treatment in another Member State, if 'medical follow-up [care] proves necessary, the same medical follow-up is available as would have been if that healthcare had been provided on its territory'.[95]

4.3 The consumer law directives applicable to health-related contracts

Patients can be seen as a particular category of consumers. The Unfair Terms Directive[96] and the Consumer Sales Directive[97] apply also to contracts for the purchase of health-related products or services concluded between a consumer and a business (physician, hospital, pharmacy, health insurer, etc. as private actors). These Directives have considerably raised the standard of protection of consumers in all Member States. This also implies that, thanks to EU law, patients in healthcare related private contracts now enjoy a higher standard of protection compared with the years previous to the enactment of the EU Directives in the field of consumer contract law. The targeted full

[91] Ibid, Article 5(b).

[92] As Palm and Glinos state: 'patients using the well-defined procedures of Article 22 of Regulation 1408/71/EEC are better ensured that eventually their health care costs will be covered; they do not need to advance payment, as they can benefit from the third party payer system in place in the country of treatment; they have better guarantees that the level of coverage will match more closely the tariff charged by the treating provider and, in some cases, they can be covered for services that are not even included in the benefit basket of their country of affiliation' See W Palm and I A Glinos, 'Enabling Patient Mobility in the EU: Between Free Movement and Coordination', in: E Mossialos et al (eds) *Health Systems Governance in Europe – The Role of European Union Law and Policy* (Cambridge University Press 2010) 516.

[93] Directive 2011/24/EU, Article 4(2)(b).

[94] Ibid, Article 4(2)(d).

[95] Ibid, Article 5(c).

[96] Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts, OJ *L 095, 21/04/1993 p. 29.*

[97] Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees, OJ *L 171, 07/07/1999 p. 12.*

harmonisation approach introduced by the Consumer Rights Directive[98] does not extend to contracts related to healthcare and social services (including long-term care): these contracts remain outside of the scope of the Directive,[99] even in cases in which the healthcare provider is a private actor.[100]

4.4 The EU legislation on safety standards for products, food, pharmaceuticals, and medical devices

The standards of protection of consumers and patients have been enhanced by a large body of EU secondary law concerning the quality and safety standards that products have to comply with in order to be lawfully traded on the EU market. These EU law measures, albeit primarily concerning public law, bear a relevance also for private law because they contribute to the regulation of contractual relationships, including health-related contracts. As explained in the Introduction above, this chapter shares Cherednychenko's understanding of 'European private law' as comprising all legal rules regulating relationships between private parties regardless of the nature of the law, public or private, in which they have been included in national legal systems.[101] The Directives and Regulations on product safety,[102] food safety,[103] pharmaceuticals,[104] and medical devices[105] form a part of EU private law insofar as they contribute to determine the content, effects and limits of validity of contracts for these products and services in the EU. These EU law instruments have introduced and increasingly improved a sophisticated system of controls,

[98] Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council, OJ L 304, 22/11/2011 p. 64.

[99] See Article 3(3) (a) and (b) of the Consumer Rights Directive.

[100] Article 3(b) of the Consumer Rights Directive excludes from the scope of application of the Directive 'all contracts for healthcare as defined in point (a) of Article 3 of Directive 2011/24/EU, whether or not they are provided via healthcare facilities'.

[101] See O Cherednychenko (note 5 above).

[102] For an overview see http://ec.europa.eu/consumers/consumers_safety/product_safety_legislation/index_en.htm.

[103] For an overview see http://ec.europa.eu/food/food/foodlaw/index_en.htm.

[104] For an overview see http://ec.europa.eu/health/documents/eudralex/vol-1/index_en.htm#reg.

[105] For an overview see http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/index_en.htm.

which has certainly enhanced the level of health protection throughout the EU. For example, the numerous Directives and Regulations on pharmaceuticals (Directive 65/65 EEC,[106] Directive 75/318 EEC,[107] Directive 75/319 EEC,[108] Directive 93/41 EEC,[109] Regulation 141/2000,[110] Directive 2001/20 EC,[111] Directive 2001/83 EC,[112] Regulation 726/2004,[113] Directive 2005/28 EC,[114] Regulation 1901/2006,[115] Regulation

[106] Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products, OJ *022, 09/02/1965 p. 369.*

[107] Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products, OJ *L 147, 09/06/1975 p. 1.*

[108] Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products, OJ *L 147, 9/06/1975 p. 13.*

[109] Council Directive 93/41/EEC of 14 June 1993 repealing Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology, OJ *L 214, 24/08/1993 p. 40.*

[110] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (Consolidated version: 07/08/2009).

[111] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, OJ L 121, 1/5/2001 p. 34. On 16 April 2014, this Directive was repealed by the Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

[112] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28/11/2001 p. 67. This Directive was amended several times. See the consolidated version of 16/11/2012 at http://ec.europa.eu/health/documents/eudralex/vol-1/index_en.htm.

[113] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Consolidated version: 05/06/2013).

[114] Directive 2005/28/EC of 8 April 2005 of the European Parliament and of the Council laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products, OJ L 91, 9/4/2005 p. 13.

[115] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (consolidated version: 26/01/2007)

1394/2007,[116] Directive 2009/35/EC,[117] Directive 2009/41/EC[118]) have helped prevent mass health damages related to the use of pharmaceuticals. In fact, the first Pharmaceuticals Directive (65/65 EEC)[119] was enacted as a reaction to the Thalidomide scandal occurred in the early 1960s, before EU pharmaceuticals law came into existence.[120]

One may argue that the longer the history of EU legislative intervention, the higher the number of Directives and Regulations in a certain sector, and the tighter the system of controls, the smaller the risks for public health in this sector. It is noteworthy, here, that the defective breast implant scandal of 2010[121] occurred in a sector where EU regulation was and is still scarce, and the system of controls was underdeveloped.[122]

[116] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Consolidated version: 02/07/2012).

[117] Directive 2009/35/EC of the European Parliament and of the Council of 23 April 2009 on the colouring matters which may be added to medicinal products (recast), OJ L 109, 30/4/2009 p. 10.

[118] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast), OJ L 125, 21/5/2009 p. 75.

[119] See note 48 above.

[120] See A Saint-Raymond and A J Humphreys, 'Human Medicinals Products in the European Union: Regulations, Directives and Structures' in J P Griffin, J Posner, G R Barker (eds), *The Textbook of Pharmaceutical Medicine* (Wiley-Blackwell, 2013).

[121] Also known as PIP scandal, since Poly Implant Prothèse (PIP) was the name of the French company that used industrial-grade silicone for the production of breast implants instead of the mandated medical-grade silicone. On this case see S Singh, 'Private Regulation in the Medical Devices Sector: Muddling through Administrative Constitutionalism to Improve the Quality and Safety of Medical Devices on the European Market', in A Colombi Ciacchi, M Heldeweg, B van der Meulen and R Neerhof (eds), *Law and Governance: Beyond the Public–Private Law Divide* (Eleven International Publishing, 2013), 185 et seq. For a recent analysis of the liability law aspects of this scandal, see C Glinski and P Rott, 'Die Haftung der Zertifizierungsstelle im Produktsicherheitsrecht' (2015) *Zeitschrift für Europäisches Privatrecht (ZeuP)* 192 et seq., with further references. From a UK perspective see House of Commons, Science and Technology Committee, *Regulation of Medical Implants in the EU and UK*, Fifth Report of Session 2012/2013, 5 et seq.

[122] Only three Directives on medical devices exist: Directive 90/385/EEC, Directive 93/42/EEC, and Directive 98/79/EC. In reaction to the PIP scandal, the EU took immediate action to tighten controls on medical devices. See http://ec.europa.eu/growth/sectors/medical-devices/pip/index_en.htm; J Whalen, 'Medical Devices Face Tighter Rules in EU', *Wall Street Journal*, 22 October 2013, www.wsj.com/articles/SB10001424052702303672404579151781036297124.

4.5 *The Product Liability Directive*

The only EU private law instrument that could raise some doubt from the viewpoint of health protection and the humaneness of EU law and policy in this field is the Product Liability Directive.[123] Since this Directive is generally understood as a full harmonisation instrument, it precludes Member States from introducing higher product liability standards at the national level. But could it be argued that this has an adverse impact on health protection standards? We are not convinced that it has. Firstly, the standards of protection set by the Product Liability Directive are reasonably high. Secondly, the EU Regulations on product safety, pharmaceuticals, and medical devices mentioned in the previous section contain a large set of mandatory rules which secure a very high standard of health protection. These mandatory standards for healthcare related products and services arguably sufficiently counterbalance the risk of a lowering of the product liability standards in some Member States as a consequence of the full harmonisation under the Product Liability Directive. Thirdly, in the European Union, the health protection standards luckily do not depend primarily from the amounts of money that victims of torts or defective products can recover under tort liability from the private party responsible for the defect. If a health damage arising from a defective product sold by a private party cannot be compensated via tort liability, the economic burden of restoring the victim's health will fall back on the national health care system. The full harmonisation under the Product Liability Directive does not have any impact on the quality of the health care provided by the national health care systems. Therefore, the Product Liability Directive cannot constitute a danger for the humaneness of EU private law with regard to the fundamental right to health.

5 Conclusion

An institution has a 'human face' if it takes basic human interests seriously. This chapter has addressed the question of whether and how these interests find proper consideration in EU private law. We identified nine core interests for 'human flourishing' that are relevant in substantive

[123] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 7/8/1985 p. 29.

private law, and discussed their fundamental rights dimension. We then focused on one of these basic human interests protected as an EU fundamental right; namely, health care. We assessed the role played by this fundamental right in EU legislation and CJEU jurisprudence in the field of private law. In the light of this discussion, we would like to make four concluding remarks, which are as follows:

(1) The jurisprudence of the CJEU on cross-border healthcare and the Patient Rights Directive have created a new right to effective and speedy medical treatment. This right ensures that EU citizens will neither have to wait indefinitely to obtain medical treatment nor have to accept substandard treatment in their Member State of residence. The creation of this new right has, to a significant extent, attained the main objective of Article 35 of the Charter.[124] This new right does not appear to have any adverse effect on the good functioning of national health care systems. On the contrary, EU law seems to provide – also in the context of private, health care related contractual relations – a better protection of the individual right to receive adequate healthcare free from unjustifiable restrictions, without so far disrupting the positive obligation to ensure a universally accessible health system.[125] However, moving away from the core substantive outcomes of the above case law, certain issues arise. Firstly, the Court chose not to extrapolate the right to adequate and effective health care from Article 21 TFEU (as a citizenship based right) and Article 35 CFREU (as the right to access health care).[126] The complex and consistent couching of this right to health care in primary and secondary law facilitating the free movement of services and workers, respectively, means the Court has somewhat blurred its humane-focused achievement in health care. Secondly, if we are taking 'humaneness' in health care seriously, we cannot ignore the reality of the individual's treatment context. Evidence shows that cross-border health care is an unwanted option for many patients[127] – it is treatment away from their home, perhaps in a language they do not understand and with unfamiliar procedures.

[124] A Kaczorowska (note 66 above) 345. [125] A McCann (note 10 above).
[126] As alluded to by De Witte (note 67 above) 87.
[127] H Legido-Quigley, I A Glinos, R Baeten et al., 'Analysing Arrangements for Cross-Border Mobility of Patients in the European Union: A Proposal for a Framework' (2012) 108 *Health Policy* 27–36.

Nonetheless for those patients who are provided with an advantage,[128] it is a crucial tool for better quality care, more specialised care, or types of care otherwise unavailable.

(2) Patients can be seen as a particular category of consumers. The Unfair Terms Directive and the Consumer Sales Directive have considerably raised the standard of protection of these consumers in all Member States for what concerns contracts concluded between them and professional physicians, hospitals, pharmacies, health insurers, etc. The targeted full harmonisation approach introduced by the Consumer Rights Directive does not change anything in this field because the contracts related to healthcare and social services (including long-term care) remain outside of the scope of the Directive.

(3) The standards of protection of consumers and patients have been also enhanced by a large body of EU secondary law concerning the quality and safety standards that products have to comply with in order to be lawfully traded on the EU market. This body of law forms a part of EU private law insofar as it also regulates private relationships, in particular by contributing to determine the content, effects and limits of validity of contracts for healthcare related services in the EU. The increasingly tight controls provided by this body of EU law increasingly reduce the public health risks.

(4) The full harmonisation under the Product Liability Directive arguably does not have any substantial impact on the quality of the health care provided by the national health care systems.

From the above-mentioned four points, and from the arguments discussed in the previous sections of this chapter, the following overall conclusion can be drawn: for what concerns the substantive outcomes regarding health protection, European private law not only appears humane enough, but also enhances the protection offered by national law. This is notwithstanding legitimate critiques directed at the overall approach of the CJEU and other EU policy makers for failing to couch this rather 'humane' achievement in more explicit fundamental rights language.[129]

[128] I A Glinos, R Baeten, M Helble, et al. 2010. 'A Typology of Cross-Border Patient Mobility' (2010) 16(6) *Health and Place* 1145–1155.

[129] See for an example of such a critique: R O' Gorman, 'The ECHR, the EU and the Weakness of Social Rights Protection at the European Level' (2011) 12(10) *German Law Journal* 1833–1861.