

# Rights: health rights as human rights

## Introduction

Health rights are often seen as human rights – in international law, in (European) regional human rights law, and in national constitutions, including those of the EU's Member States. Rights are a potent theme in health law and biomedical ethics.<sup>1</sup> Recognition for fundamental human rights and the notion of respect for individual decision-making autonomy, privacy and human dignity have played an important part in the evolution of health law internationally and across individual Member States of the EU.<sup>2</sup> One important catalyst for the development of health rights as human rights in European contexts was, of course, the events of the middle of the twentieth century.<sup>3</sup> In particular, the atrocities perpetuated in Nazi Germany, and the response of the international community, led to the United Nations' Universal Declaration of Human Rights 1948,<sup>4</sup> the Council of Europe's European Convention of Human Rights and Fundamental Freedoms 1950 (ECHR)<sup>5</sup> and the later European Social Charter 1961.<sup>6</sup>

<sup>1</sup> See, for example: Mann, Gruskin, Grodin and Annas (eds), *Health and Human Rights: A Reader* (Routledge 1999); Mann, Gostin, Gruskin, Brennan, Lazzarini and Fineberg, 'Health and Human Rights' (1994) 1(1) *Health and Human Rights* 6; Wicks, *Human Rights and Health Care* (Hart 2007); Hendriks, 'The Right to Health' (1998) 5 *European Journal of Health Law* 389; McHale, 'Enforcing Health Care Rights in the English Courts' in Burchill, Harris and Owers (eds), *Economic, Social and Cultural Rights: Their Implementation in UK Law* (University of Nottingham Human Rights Centre 1999); Toebes, 'Right to Health and Health Care', *Encyclopaedia for Human Rights* (2009) vol 1, 365; Toebes, *The Right to Health as a Human Right in International Law* (Intersentia 1999).

<sup>2</sup> Beylveled and Brownsword, *Human Dignity in Bioethics and Biolaw* (OUP 2001).

<sup>3</sup> Fundamental rights in European countries of course went back much further as demonstrated, for example, by the age of the Enlightenment and post Revolutionary France.

<sup>4</sup> Universal Declaration of Human Rights 1948.

<sup>5</sup> European Convention of Human Rights and Fundamental Freedoms 1950.

<sup>6</sup> European Social Charter 1961. The European Social Charter was opened for signature originally in 1961, with a revised Charter being opened for signature in 1996. States must provide which provisions of the Charter that they accept (in contrast to Treaties which require them to enter a reservation). Article 20 of the ESC and Article A of the Revised ESC provide that states must accept a minimum of the provisions. States are also required to report upon their progress in implementation on a biannual basis in relation to the so-called "core provisions" and on a four

The EU is not, or not predominantly, a human rights organization.<sup>7</sup> But of course no international organization, least of all the EU, with its roots in post-conflict peacekeeping and economic development, could ever actively reject human rights.<sup>8</sup> According to its constitutive Treaties, the EU is founded upon ‘respect for dignity . . . and human rights.’<sup>9</sup> Acts of its institutions, bodies, offices and agencies, which have legal effect, are invalid if they breach human rights.<sup>10</sup> Indeed, should a Member State engage ‘in a serious and persistent breach’ of those values, there is (at least theoretical) provision for sanctions.<sup>11</sup> The principles of equality and non-discrimination are to be protected and respected.<sup>12</sup>

Standard accounts of the EU’s engagement with human rights over time tell a story of a gradual unfolding or recognition of human rights, initially led by the CJEU<sup>13</sup> and culminating in the incorporation of the EU’s Charter of Fundamental Rights (EU CFR) within its ‘constitutional’ texts at the Treaty of Lisbon<sup>14</sup> and the (eventual) accession of the EU to the ECHR.<sup>15</sup> Whether we agree with this story, and whether we judge it a ‘human rights success’ is not our central concern in this chapter. For our purposes, the focus is on the place of health rights as human rights in the EU’s contemporary legal order. The EU has recognized health as a human right in its policy documents, such as the European Commission’s White Paper, ‘Together for Health’.<sup>16</sup> But to what extent is this reflected in EU health law? This is not an easy question to answer because, as we shall see, EU human rights law both draws inspiration

year basis in relation to the rest. In addition to the traditional international law mechanisms of reporting, the ESC provides a complaints mechanism, whereby specific organisations, such as the European Trade Union Confederation may file a complaint which is heard by the European Committee of Social Rights. For more information, see: Council of Europe, ‘The European Social Charter’ (*Council of Europe*, 2014) See generally: Cullen, ‘The Collective Complaints System of the European Social Charter: Interpretative Methods of the European Committee of Social Rights’ (2009) 9(1) *Human Rights Law Review* (2009) 61.

<sup>7</sup> De Búrca, ‘The Road Not Taken: The EU as a Global Human Rights Actor’ (2011) 105(4) *American Journal of International Law* 649; Besson, ‘The EU and Human Rights: Towards a Post-National Human Rights Institution’ (2006) 6 *Human Rights Law Review* 323; Von Bogdandy, ‘The EU as a Human Rights Organisation: Human Rights and the Core of the EU’ (2000) 37 *Common Market Law Review* 1307; Alston (ed), *The EU and Human Rights* (OUP 1999).

<sup>8</sup> Douglas-Scott, ‘The European Union and Human Rights after the Treaty of Lisbon’ (2011) 11(4) *Human Rights Law Review* 645.

<sup>9</sup> Article 2 TEU. <sup>10</sup> Article 263 TFEU; Article 51 (1) EU CFR.

<sup>11</sup> Including suspension of voting rights in Council, see: Article 7 TEU.

<sup>12</sup> Article 2 TEU, Articles 8, 10, 18 TFEU, Chapter III, especially Articles 20, 21, 23, EU CFR.

<sup>13</sup> Contrast, e.g. *Stork*, C-1/58, EU:C:1959:4; with *Stauder*, C-29/69, EU:C:1969:57.

<sup>14</sup> See, for instance: Clapham, *Human Rights and the European Community, A Critical Overview* (Nomos 1991); Alston, above n 7; Lenaerts and Gutiérrez-Fons, ‘The Place of the Charter in the EU Constitutional Edifice’ in Peers, Hervey, Kenner and Ward (eds), *The EU Charter of Fundamental Rights: A Commentary* (Hart 2014).

<sup>15</sup> Article 6 (2) TEU. Opinion 2/13 on the Accession of the EU to the European Convention for the Protection of Human Rights and Fundamental Freedoms EU:C:2014:2454.

<sup>16</sup> Commission, ‘Together for Health: A Strategic Approach for the EU 2008-13’ (White Paper) COM (2007) 630 final.

from and interlocks with other human rights orders, and is in non-hierarchical relationships with those other legal systems.<sup>17</sup>

A brief note before we begin our analysis. Sometimes discussions of health and human rights draw on a distinction between ‘civil and political rights’ and ‘economic and social rights’. The former are seen as of higher legal value, and enforceable as a ‘freedom from’ state interference. The latter are regarded as aspirational ‘claims on’ the state for protection and assistance, involving expenditure of resources, and are characteristic of more affluent societies. Fundamental civil and political rights, such as the right to life, the right to privacy and bodily integrity, freedom of religion and the right to family life, are often brought to bear in litigation and legislation in health contexts. Relevant economic and social rights include the ‘right to health’ as well as associated rights, such as protection from poverty or access to essential medicines. A right to health was first explicitly stated in the Preamble of the Constitution of the World Health Organization in 1946.<sup>18</sup> Some international human rights provisions, such as the right to a standard of living adequate for health and well-being,<sup>19</sup> the need for recognition of the highest ascertainable standard of physical and mental health<sup>20</sup> and protection of health in the workplace,<sup>21</sup> directly address health rights. Certain other provisions contained in international statements of human rights, while they may not make a direct reference to health, may be seen as relevant in claims for rights to particular medical treatments, particularly at the beginning and end of life.<sup>22</sup>

<sup>17</sup> There is a significant literature on this question. See: e.g. Gragl, ‘Agreement on the Accession of the European Union to the European Convention on Human Rights’ in Peers et al., above n 14; Sarmiento, ‘Who’s Afraid of the Charter? The Court of Justice, National Courts and the New Framework of Fundamental Rights Protection in Europe’ (2013) 50 *Common Market Law Review* 1267; Canor, ‘My Brother’s Keeper? Horizontal *Solange*: An Ever Closer *Distrust* Among the Peoples of Europe’ (2013) 50 *Common Market Law Review* 38; Rosas, ‘The Charter and Universal Human Rights Instruments’ in Peers et al., above n 14; Itzcovich, ‘Legal Order, Legal Pluralism, Fundamental Principles: European and its Law in Three Concepts’ (2012) 18(3) *European Law Journal* 358; Klabbers, ‘Völkerrechtsfreundlich? International Law and the Union Legal Order’ in Koutrakos, (ed) *European Foreign Policy: Legal and Political Perspectives* (Edward Elgar 2011); Walker, ‘Beyond boundary disputes and basic grids: Mapping the global disorder of normative orders’ (2008) 6(3) & (4) *International Journal of Constitutional Law* 373; Krisch, ‘The open architecture of European human rights law’ (2008) 71(2) *Modern Law Review* 183; Eckes, ‘Does the European Court of Human Rights provide protection from the European Community? The Case of Bosphorus Airways’ (2007) 13(1) *European Public Law* 47; Douglas-Scott, ‘A Tale of Two Courts: Luxembourg, Strasbourg and the Growing European Human Rights *Acquis*’ (2006) 43 *Common Market Law Review* 629; Canor, ‘*Primus Inter Pares*: Who is the Ultimate Guardian of Fundamental Rights in Europe?’ (2000) 25 *European Law Review* 3.

<sup>18</sup> For an accessible overview of different approaches to the ‘right to health’, and an articulation of the author’s own ‘domain-based’ approach, see: e.g. Eleftheriadis, ‘A Right to Health Care’ (2012) 40 *Journal of Law, Medicine & Ethics* 268.

<sup>19</sup> Universal Declaration of Human Rights 1948, Article 25.

<sup>20</sup> International Covenant on Economic, Social and Cultural Rights, Article 12 (1).

<sup>21</sup> Universal Declaration of Human Rights 1948, Article 6.

<sup>22</sup> See: Universal Declaration of Human Rights 1948, Article 3; and International Covenant on Civil and Political Rights, Article 6. See, in the Council of Europe context: e.g. *Pretty*, no.

Many contemporary human rights scholars, including those working on health and human rights, reject the dichotomy between civil/political and economic/social rights.<sup>23</sup> They point out that civil and political rights have no practical force without the ability to enjoy them, and that rights have value in terms other than judicial enforcement. We are broadly sympathetic to this position, and so, in this chapter, we discuss health rights as encapsulating a cluster of rights, falling in both categories. What is of interest to us here is not whether health rights as human rights in the EU's legal order are a particular type of human right. Our agenda for this chapter, and the next, is to discover the extent to which, and the circumstances in which, EU health law recognizes health rights as human rights, and to draw out the implications.

One claim which has been made in this respect relates to the standard accounts of human rights in EU law. This is the idea that fundamental health rights have become increasingly significant in the EU's legal order. The chapter investigates the extent to which this is true for health rights by tracking the place of health rights as human rights in EU health law across time. To do so, we consider the position before and after the year 2000, the date on which the EU CFR was promulgated.<sup>24</sup> The chapter then considers some of the implications of this story. The focus here is on whether, and if so, the extent to which, and in what contexts, fundamental human rights provide a basis for effectively changing and reforming health law or policy within the EU and its Member States. The question of whether human rights provide a platform for reforming *external* EU health law is considered in Part IV.

An important aspect of health rights as human rights is the question of human rights claims to health resources. In the EU context, typically such rights approaches have arisen in connection with the movement of patients across internal EU borders. We have already seen the ways in which free movement rights encapsulated in Treaty provisions have provided a platform for patients to seek treatment in other jurisdictions, and to claim reimbursement of the cost of such treatment from the social insurance/national health system of their home Member State.<sup>25</sup> Such claims themselves have led to the new 'Patients' Rights Directive', a document somewhat confusingly labelled, given that, in contrast to the domestic legislation of certain EU Member States, it does not provide a 'patients' rights manifesto', still less a Patients' Rights Act.<sup>26</sup> Instead,

2346/02, ECHR 2002-III. See: Clarke, 'Abortion: A Rights Issue?' in Lee and Morgan (eds), *Birthrights* (Routledge 1989); Harris, *The Value of Life: An Introduction to Medical Ethics* (Routledge 1985) ch 8; Lewis, *Assisted Dying and Legal Change* (OUP 2007); Huxtable, *Euthanasia, Ethics and Law from Conflict to Compromise* (Routledge 2007); Keown, *Euthanasia, Ethics and Public Policy: An Argument Against Legalisation* (CUP 2002); Mason and Laurie, *Mason & McCall Smith's Law and Medical Ethics* (9th edn, OUP 2013) chapters 16 and 17.

<sup>23</sup> Murphy, *Health and Human Rights* (Hart 2013); See also, by implication: Toebes, Hartlev, Hendriks and Hermann (eds), *Health and Human Rights in Europe* (Intersentia 2012); Selgelid and Pogge (eds), *Health Rights* (Ashgate 2010).

<sup>24</sup> [2000] OJ C83/2. <sup>25</sup> See further the cases discussed in chapter 4.

<sup>26</sup> Directive 2011/24/EU [2011] OJ L88/45. See further chapter 8.

the Directive clarifies the free movement case law, builds in further controls upon free movement from Member States, and seeks to perpetuate a health care standards agenda. Scott Greer and Tomislav Sokol read this law as an emergent model of social citizenship expressed as ‘rules for rights’ rather than a social rights model per se.<sup>27</sup> The question of whether EU health law protects mobile patients’ rights, in the sense of claims to resources, *as human rights*, is the subject of the following chapter.

## The development of health rights as human rights in EU law

### Judicial development: human rights as ‘general principles’ of EU health law

The CJEU recognized human rights as ‘general principles’ of EU law in the 1960s.<sup>28</sup> One of the most important sources of such general principles of EU law is the ECHR.<sup>29</sup> Its position in EU law was recognized in the EU’s founding Treaties in the early 1990s, and it is now found in Article 6 (3) TEU, which asserts that the ECHR’s fundamental rights are general principles of EU law.

The ECHR is a traditional civil and political statement of human rights.<sup>30</sup> It was drafted in the aftermath of the Second World War, and came into force in 1953. All the EU’s Member States are signatories to the ECHR and thus individual citizens of all EU Member States may enforce their rights before the European Court of Human Rights.<sup>31</sup> A considerable number of actions brought before the European Court of Human Rights relate to health. For instance, Article 1 ECHR, which safeguards the right to life, has been used in claims concerning the status of the foetus and abortion,<sup>32</sup> resource allocation<sup>33</sup> and the right to die.<sup>34</sup> Article 5 ECHR, which safeguards the position of liberty and security of the person, has been used extensively in mental health claims.<sup>35</sup> Article 8 ECHR, the right to privacy of home and family life, has been used in the context of health privacy and confidentiality of patient information, autonomy of treatment decisions, and reproductive rights.<sup>36</sup> Article 12 ECHR, the right

<sup>27</sup> See: Greer and Sokol, ‘Rules for Rights: European Law, Health Care and Social Citizenship’ (2014) 20(1) *European Law Journal* 66.

<sup>28</sup> *Stauder* EU:C:1969:57.

<sup>29</sup> *Nold*, C-4/73, EU:C:1974:51; *Rutili*, C-36/75, EU:C:1975:137; *Johnson v RUC*, C-222/84, EU:C:1986:206.

<sup>30</sup> See further: White and Overy, *The European Convention on Human Rights* (OUP 2010).

<sup>31</sup> There are important limitations on this entitlement, in particular the doctrine of exhaustion of domestic remedies.

<sup>32</sup> *H v Norway* App no 17004/90 (ECtHR, 19 May 1992); *Open Door and Dublin Well Woman v Ireland* (1992) Series A no 246; *Paton v UK* App no 8416/78 (ECtHR 13 May 1980); *A, B, C v Ireland*, no. 25579/05, ECHR 2010-I.

<sup>33</sup> *Osman v UK*, no. 23452/94, ECHR 1998-VIII. *Scialaqua v Italy* App no. 34151/96 (ECtHR, 1 July 1998).

<sup>34</sup> *Pretty v UK*, no. 2346/02, ECHR 2002-III.

<sup>35</sup> See: e.g. *Winterwerp v The Netherlands* (1992) Series A no 33; *Aerts v Belgium*, no. 25357/94, ECHR 1998-V.

<sup>36</sup> *Evans v UK*, no. 6339/05, ECHR 2007-I.

to marry and found a family, has featured in claims concerning reproductive rights.<sup>37</sup>

The various ECHR rights relevant to health contexts, as general principles of EU law, did not feature directly in a claim before the CJEU in a health context during this phase of the EU's human rights law development. The *SPUC v. Grogan* case<sup>38</sup> from the 1980s concerned abortion, but this was discussed in terms of free movement of services, and the CJEU was reluctant to engage with the human rights aspects of the litigation. Similarly, national courts applying EU law in circumstances concerning reproductive medical treatments, such as the UK's Court of Appeal in *R. v. Human Fertilisation and Embryology Authority ex parte Blood*,<sup>39</sup> did not refer directly to ECHR rights to life, privacy or family life.

In its general jurisprudence, the CJEU has also recognized some other regional and international human rights instruments.<sup>40</sup> Those which are of particular relevance in the health field include the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine,<sup>41</sup> 1997, a statement which, as its title suggests, is specifically targeted at biomedicine.<sup>42</sup> Article 1 of the Biomedicine Convention states that its purpose and object is safeguarding the dignity and identity of all human beings, and respecting their integrity and other fundamental rights and freedoms. The Convention refers to rights to consent,<sup>43</sup> private life and the right to information,<sup>44</sup> controls on genetics and prohibition on discrimination,<sup>45</sup> research<sup>46</sup> and removal of organs and tissue from living donors for transplantation purposes.<sup>47</sup> The Council of Europe has also

<sup>37</sup> *Dickson v UK*, no 44362/04, ECHR 2007-V.

<sup>38</sup> *Grogan*, C-159/90, EU:C:1991:378. See: De Búrca, 'Fundamental Human Rights and the Reach of EC Law' (1993) 13 *Oxford Journal of Legal Studies* 283; Rossa Phelan, 'Right to Life of the Unborn v Promotion of Trade in Services: the ECJ and the normative shaping of the EU' (1992) 55 *Modern Law Review* 670.

<sup>39</sup> [1997] 2 All ER 687. See: Hervey, 'Buy Baby: the European Union and the Regulation of Human Reproduction' (1998) 18 *Oxford Journal of Legal Studies* 207; Morgan and Lee, 'In the Name of the Father? *Ex parte Blood*: Dealing with Novelty and Anomaly' (1997) 60 *Modern Law Review* 840.

<sup>40</sup> *Defrenne v SABENA*, C-149/77, EU:C:1978:130, paragraph 26, in which the CJEU drew on the European Social Charter.

<sup>41</sup> Recognised by the CJEU in: Opinion in *Biotechnology Directive*, C-377/98, EU:C:2001:329, paragraph 210; although in *De Fruytier*, C-237/09, EU:C:2010:316, paragraph 27, the CJEU noted that the Convention on Human Rights and Biomedicine has been ratified by only a small number of Member States and not by the EU itself. As at January 2014, 17 Member States have ratified the Convention, 5 have signed but not ratified, and 6 have not even signed.

<sup>42</sup> Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to Biology and Medicine: Convention on Human Rights and Biomedicine 1997; and see also: Zilgavis, 'The European Convention on Biomedicine: Its Past, Present and Future' in Garwood-Gowers, Tingle and Lewis (eds), *Healthcare Law: The Impact of the Human Rights Act 1998*, (Routledge-Cavendish 2001).

<sup>43</sup> Biomedicine Convention, Articles 5-9.

<sup>44</sup> Biomedicine Convention, Article 12.

<sup>45</sup> Biomedicine Convention, Articles 11-13.

<sup>46</sup> Biomedicine Convention, Articles 15-18.

<sup>47</sup> Biomedicine, Articles 21-22.

produced additional protocols on cloning,<sup>48</sup> transplantation<sup>49</sup> and biomedical research.<sup>50</sup>

Again, the CJEU did not rely on these provisions in health litigation during this period of time. *Netherlands v. European Parliament and Council (Biotechnology Directive)*,<sup>51</sup> concerning the validity of Directive 98/44/EC on the legal protection of biotechnological inventions,<sup>52</sup> was one possible opportunity in which to do so. However, the CJEU's judgment considered only 'the fundamental right to human dignity and integrity'.<sup>53</sup> The Advocate General referred to the ECHR, and to the Biomedicine Convention once,<sup>54</sup> but did not rely significantly on this human rights instrument in his reasoning.

The Council of Europe's European Social Charter (ESC),<sup>55</sup> Article 11, covers the 'right to the protection of health', obliging states to 'take appropriate measures' to 'remove as far as possible the causes of ill-health', 'to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health', and 'to prevent as far as possible epidemic, endemic and other diseases as well as accidents'. The work of the European Committee of Social Rights, including under the complaints mechanism, has elaborated a 'jurisprudence' of social rights, in particular articulating the values (autonomy, dignity, equality and solidarity) which underpin the ESC. As Cullen has noted, the ways the Committee understands these values supports a generous interpretation of ESC rights, for instance, solidarity is seen as 'a value supporting inclusion and protection against vulnerability'.<sup>56</sup> Although, again, the ESC and the European Committee's work could form a resource for the

<sup>48</sup> Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to Biology and Medicine on the Prohibition of Cloning Human Beings 1998.

<sup>49</sup> Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin 2002. The Council of Europe has adopted a Convention against Trafficking in Human Organs, 9 July 2014; see: Council of Europe, 'Towards a Council of Europe convention to combat trafficking in organs, tissues and cells of human origin' (*Committee on Social Affairs, health and Sustainable Development*, Council of Europe, 20 December 2012); Council of Europe, 'Committee of Experts on Trafficking in Human Organs, Tissues and Cells (PC-TO)' (*European Committee on Crime Problems (CDPC)*, Council of Europe).

<sup>50</sup> Additional Protocol to the Convention on Human Rights and Biomedicine, on Biomedical Research 2005.

<sup>51</sup> *Biotechnology Directive*, C-377/98 EU:C:2001:523.

<sup>52</sup> Directive 98/44/EC [1998] OJ L213/13.

<sup>53</sup> *Biotechnology Directive* EU:C:2001:523, paragraphs 6 and 70.

<sup>54</sup> Opinion in *Biotechnology Directive* EU:C:2001:329, paragraph 210, referring to the principle of free and informed consent.

<sup>55</sup> First recognised by the CJEU in: *Defrenne* EU:C:1978:130.

<sup>56</sup> Cullen, 'The Collective Complaints System of the European Social Charter: Interpretative Methods of the European Committee of Social Rights' (2009) 9(1) *Human Rights Law Review* 61, 92.

CJEU, in practice connections between EU law and the ESC are notable in their absence during this period.<sup>57</sup>

Another important source of human rights as ‘general principles’ of EU law is the constitutional traditions of the Member States.<sup>58</sup> The Member States protect ECHR rights, including those relied upon in health contexts, in their constitutions. The concept of human dignity from the German constitution has been particularly influential on the CJEU.<sup>59</sup> Although the CJEU has stated that the concept of human dignity has an independent meaning in EU law,<sup>60</sup> the ways in which national and EU human rights orders interlock<sup>61</sup> is underlined by Article 52 (4) EU CFR, which provides that rights from the common constitutional traditions of the Member States are to be interpreted ‘in harmony with those traditions.’<sup>62</sup> A majority (18/28) of Member States’ constitutions explicitly recognize a ‘right to health’.<sup>63</sup>

Although the Member States share health rights as human rights at the level of general legal or constitutional provisions, when it comes to the specifics of how these rights are understood and implemented, there are significant differences. Abortion, and the status of the human embryo, is the canonical example;<sup>64</sup> but others include details on free and informed consent to medical treatment,

<sup>57</sup> Hervey, ‘We Don’t See a Connection: The ‘Right to Health’ in the EU Charter and European Social Charter’ in De Búrca and De Witte (eds), *Social Rights in Europe* (OUP 2005) 305.

<sup>58</sup> Article 6 (3) TEU. <sup>59</sup> See: Dupré, ‘Article 1 – Human Dignity’ in Peers et al., above n 14. <sup>60</sup> *Omega*, C-36/02, EU:C:2004:614.

<sup>61</sup> See, for instance: Lenaerts, ‘Interlocking Legal Orders in the EU and Comparative Law’ (2003) 52 *International and Comparative Law Quarterly* 873.

<sup>62</sup> For further discussion, see Peers and Prechal, ‘Article 52 – Scope and Interpretation of Rights and Principles’ in Peers et al., above n 14.

<sup>63</sup> Article 23 of the Belgian Constitution; Chapter 2, Article 52 of the Bulgarian Constitution; Article 59 of the Croatian Constitution; Article 4 Czech Charter of Fundamental Rights and Freedoms; Article 28 of the Estonian Constitution; section 19 (3) of the Finnish Constitution; Article 70 D of the Hungarian Constitution; Article 32 of the Italian Constitution; Article 111 of the Latvian Constitution; Article 53 of the Lithuanian Constitution, Article 11(5) of the Luxembourg Constitution; Article 22 (1) of the Netherlands Constitution; Article 68 of the Polish Constitution; Article 64 (1) of the Portuguese Constitution; Article 34 of the Romanian Constitution; Article 40 of the Spanish Constitution; Article 51 of the Slovenian Constitution; Article 43 of the Spanish Constitution. According to the former UN Special Rapporteur on the Right to Health, Paul Hunt, over 100 national constitutional provisions now include the right to health, the right to health care, or health-related rights such as a right to a healthy environment. Hunt, ‘The human right to the highest attainable standard of health: new opportunities and challenges’ (2006) 100(7) *Transactions of the Royal Society of Tropical Medicine and Hygiene* 603, 603 cited Toebes et al., above n 23, 91.

<sup>64</sup> Ireland, Malta, and Poland are outliers in this respect, and their position is enshrined in the Protocol No. 35 on Article 40.3.3 of the Constitution of Ireland annexed to the TFEU and the Protocol No. 7 on Abortion in Malta, annexed to the Treaty of Accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia [2003] OJ L236/17. Other Member States, including Lithuania and Spain, have recently considered or implemented more restrictive abortion laws. As the CJEU observed in *Brüstle*, C-34/10, EU:C:2011:669, paragraph 30, the definition of embryo is ‘marked by [the Member States’] multiple traditions and value systems’.



or participation in clinical trials; details on the arrangements for donation of blood, organs and other human tissue; how human rights apply in the context of biotechnological and nanotechnological research; and on how privacy rights are reconciled with other interests in the context of the handling of health data. As we will see, EU law allows for reasonably significant variations in this regard.<sup>65</sup>

### Treaty amendments: health rights in the EU Charter of Fundamental Rights

The formal place of human rights in the EU's legal order changed with the incorporation of the EU's Charter of Fundamental Rights and Freedoms 2000 (EU CFR) into the Treaties in December 2009.<sup>66</sup> Assessments of the significance of the EU CFR vary. Certainly the promulgation of the instrument in 2000, as a measure of soft law, was a low-key affair. The CJEU did not cite the EU CFR until 2006, but continued its practice of referring to the ECHR.<sup>67</sup> Since then, however, references to the EU CFR have increased, and, since the Treaty of Lisbon, its provisions now have the 'same legal value' as Treaty provisions.<sup>68</sup>

The EU CFR brings together a long list of human rights, drawing inspiration from international and regional human rights instruments, EU legislation and the jurisprudence of the CJEU. Its provisions are organized into six substantive 'Chapters', of which those on dignity, freedoms, equality, and solidarity are of most relevance to health rights. The EU CFR distinguishes between 'rights',

<sup>65</sup> Although, where the internal market and free movement law are engaged, not as much discretion to the Member States as the ECtHR's 'margin of appreciation'. The margin of appreciation doctrine allows discretion to individual States Parties to interpret Convention provisions taking into account their particular national circumstances and traditions, such as cultural practices or religious or historic traditions. See generally: Arai-Takahashi, *The Margin of Appreciation Doctrine and the Principle of Proportionality* (Intersentia 2002). The ECtHR has been prepared to afford a wide margin of appreciation to States Parties where the issues which come before it are acutely ethically controversial in nature. Examples include abortion (see: *Paton v UK* App no 8416/78 (ECtHR 13 May 1980); *Vo v France* ECHR [2004] 2 FCR 577; *A, B, C v Ireland*, no. 25579/05, ECHR 2010-I; end of life decision-making (see: *Pretty v UK*, no. 2346/02, ECHR 2002-III) and reproductive rights (see: *Evans v UK*, no. 6339/05, ECHR 2007-I. See: O'Donovan, 'Taking a Neutral Stance on the Legal Protection of the Fetus' (2006) 14 *Medical Law Review* 115; Hewson, 'Dancing on the Head of a Pin: Foetal Life and the European Convention' (2005) 13 *Feminist Legal Studies* 363; Mason, 'What's in a Name? The Vagaries of *Vo v France*' (2005) 17(5) *Child and Family Law Quarterly* 97; Plomer, 'A Foetal Right to Life? The Case of *Vo v France*' (2005) 5(2) *Human Rights Law Review* 311; Krishnan, 'What's the consensus: The Grand Chamber's decision on abortion in *A, B and C v Ireland*' (2011) 2 *European Human Rights Review* 200; McGuinness, '*A, B and C* leads to D for delegation!' (2011) 19(3) *Medical Law Review* 476; Freeman, 'Denying Death its Dominion: thoughts on the Dianne Pretty case' (2002) 10 *Medical Law Review* 245; Tur, 'Legislative Techniques and human rights; the sad case of assisted suicide' (2003) *Criminal Law Review* 3.

<sup>66</sup> Commission, 'Declaration concerning the Charter of Fundamental Rights of the EU' (European Union 2010) 337.

<sup>67</sup> Douglas-Scott, 'The European Union and Human Rights after Lisbon' (2011) 11(4) *Human Rights Law Review* 645.

<sup>68</sup> Article 6 (1) TEU.

'freedoms' and 'principles', although does not explicitly identify which provisions fall in which category.<sup>69</sup> While 'rights' and 'freedoms' are (potentially) individually enforceable, 'principles' are 'judicially cognisable only in the interpretation of legislative and executive acts of the EU, and national acts which implement EU law.'<sup>70</sup>

Since 2009, health rights (whether 'rights' or 'principles') have been expressed in the EU's 'constitutional' legal texts. However, as we have seen, this development may not be as significant in practice as it appears, given that most relevant rights had already been recognized as general principles of EU law, as noted above. In some ways, the EU CFR could be read as seeking to *restrict*, rather than encourage, the CJEU-led development of human rights in EU law. For instance, the Treaties explicitly state that the EU CFR 'does not extend the field of application of Union law beyond the powers of the Union, or establish and new power or task for the Union, or modify powers or tasks as defined by the Treaties'.<sup>71</sup> The CJEU's case law establishes that human rights as general principles of EU law apply where Member States derogate from EU law; the Charter provides explicitly that it applies to the Member States 'only when they are implementing Union law'.<sup>72</sup> However, the CJEU has stated more recently that the EU CFR applies 'in all situations governed by EU law'.<sup>73</sup>

On the other hand, it is at least arguable that the incorporation of the EU CFR in the EU's Treaties has enhanced the role and significance of human rights in EU law.<sup>74</sup> In the context of health rights, looking at the jurisprudence of the CJEU, for instance, we see an increased willingness to consider human rights implications in EU litigation. For instance, the EU CFR's 'right to health care'<sup>75</sup> was cited by the CJEU only once before 2009 (and that only in an AG Opinion),<sup>76</sup> but has been cited five times since then.<sup>77</sup>

<sup>69</sup> According to the EU CFR's 'Explanations' (non-binding explanatory text adopted at the same time as the EU CFR itself), an Article of the EU CFR may contain elements of a right and a principle, see: Explanations to Article 52(2) EU CFR.

<sup>70</sup> Article 52 (5) EU CFR. On the difference, see: Peers and Prechal, 'Article 52 – Scope and Interpretation of Rights and Principles' in Peers et al., above n 14, and the literature cited therein.

<sup>71</sup> Article 52 (2) EU CFR; and Commission, 'Declaration concerning the Charter of Fundamental Rights of the EU' (European Union 2010) 337.

<sup>72</sup> Article 51 (1) EU CFR.

<sup>73</sup> *Fransson*, C-617/10, EU:C:2013:280, paragraph 19. See also: Opinion in *Ruiz Zambrano*, C-34/09, EU:C:2010:560. See discussion in Ward, 'Article 51 – Field of Application' in Peers et al., above n 14.

<sup>74</sup> Peers et al., 'Editors' Preface' in Peers et al., above n 14; Cartabia, 'Europe and Rights: Taking Dialogue Seriously' (2009) 5(1) *European Constitutional Review* 5; Peers and Ward (eds), *The EU Charter of Fundamental Rights: Politics, Law and Policy* (Hart 2004); Hervey and Kenner (eds), *Economic and Social Rights under the EU Charter of Fundamental Rights* (Hart 2003).

<sup>75</sup> Article 35 EU CFR.

<sup>76</sup> Opinion in *Stamatelaki*, C-444/05, EU:C:2007:24.

<sup>77</sup> *Deutsches Weintor*, C-544/10, EU:C:2012:526; *Susisalo*, C-84/11, EU:C:2012:374; *Pérez and Gómez*, C-570/07 and C-571/07, EU:C:2010:300; Opinion in *Josemans*, C-137/09,

Furthermore, it is also at least arguable that, with the incorporation of the EU CFR into EU Treaty law, the *possibilities* for health claims being articulated as human rights claims in EU law have increased. Articulating a claim within a human rights frame may have implications for both legal reasoning and for legal outcomes, such as determining the standard of proof required to interfere with free movement rules. The CJEU has long recognized that the protection of human rights objectively justifies restrictions on free movement.<sup>78</sup> For instance, what if a cross-border patient in a situation such as that in the *Peerbooms* case were in a *life-threatening* coma?<sup>79</sup> Would the burden of proof on a Member State refusing to authorize cross-border treatment be greater in such a circumstance than if the right to life were not engaged? Equally, could a Member State more easily justify refusal to authorize cross-border treatment that could be interpreted as infringing the right to life, such as euthanasia<sup>80</sup> or abortion?<sup>81</sup> Only future litigation would determine the answers to these questions, but the power of human rights-based reasoning in European legal traditions suggests that it is at least conceivable that human rights reasoning could make a difference.

Moreover, some relevant rights were given increased prominence in the EU CFR. The best example is Article 1 EU CFR, on human dignity. Although this human right was recognized in pre-2009 litigation,<sup>82</sup> as well as legislation,<sup>83</sup> its explicit articulation, and its place (the first provision of the EU CFR), suggest an increased importance. That said, the CJEU has delivered rulings referring to or explicitly relying upon Article 1 EU CFR only a few times, in cases involving asylum.<sup>84</sup> However, particularly in combination with other provisions, such as the right to life,<sup>85</sup> human dignity has significant potential in the EU's regulation of novel health technologies in particular.<sup>86</sup>

### Institutional developments: the European Fundamental Rights Agency

The argument that health rights as human rights have become increasingly significant in EU law is lent strength by considering institutional developments

EU:C:2010:433. Another case, Order in *Rossius and Collard*, C-267/10 and C-268/10, EU:C:2011:332, was found inadmissible for lack of jurisdiction.

<sup>78</sup> *ERT*, C-260/89, EU:C:1991:254; *Schmidberger*, C-112/00, EU:C:2003:333.

<sup>79</sup> See Wicks, 'Article 2 – Right to Life' in Peers et al., above n 14, 26.

<sup>80</sup> See: Michalowski, 'Health Care Law' in Peers and Ward, above n 74, 295-6.

<sup>81</sup> See: Wicks, above n 79, 27.

<sup>82</sup> *P v S and Cornwall CC*, C-13/94, EU:C:1996:170; *Biotechnology Directive* EU:C:2001:523.

<sup>83</sup> For discussion of examples, which range from children's audiovisual service to reception conditions for asylum seekers, see: Dupré, above n 59.

<sup>84</sup> Judgment in *NS v Secretary of State for the Home Department*, C-411/10, EU:C:2011:865.

<sup>85</sup> Wicks, above n 79.

<sup>86</sup> See: Millns, 'Reproducing inequalities: assisted conception and the challenge of legal pluralism' (2002) 24 *Journal of Social Welfare and Family Law* 19; Flear et al., 'A European Law of New Health Technologies' in Flear et al. (eds), *European Law and New Health Technologies* (OUP 2013).

beyond the role of the CJEU. In 2007, the EU established a Fundamental Rights Agency (FRA),<sup>87</sup> replacing an earlier institution, with a narrower remit.<sup>88</sup> The EU's FRA has an advisory role, gathering and disseminating information and good human rights practice to the EU institutions and the Member States and (through its Fundamental Rights Platform) promoting dialogue within civil society to raise human rights awareness.

The FRA works through a 'Multiannual Framework', which is agreed by the EU legislature. The first such Framework ran from 2007 to 2012.<sup>89</sup> Its basic focus, at first glance, is on traditional 'civil and political rights', particularly in areas such as access to justice and exercise of democratic rights. Much of the FRA's early work, therefore, cannot be said to be increasing the ways in which EU law or policy treats health rights as human rights. However, several of the Framework's thematic priorities were relevant to health rights, in particular when combined with principles of non-discrimination. The relevant thematic priorities are tackling racism and xenophobia, discrimination based on a range of forbidden grounds, rights of the child and protection of children, asylum and respect for private life and personal data protection. A good illustrative example is its first Annual Report published after the EU CFR was incorporated into the Treaties.<sup>90</sup> Health does not feature generally, but it is mentioned in the context of an examination of discrimination safeguards, particularly in terms of the social and economic position of members of the Roma community in the EU<sup>91</sup> and tensions between religious belief and health provision.<sup>92</sup>

The current Multiannual Framework runs from 2013 to 2017.<sup>93</sup> Its thematic priorities are very similar to those of the previous Framework, although 'Roma integration' features as a specific priority in this Framework. In 2011, the FRA reported a serious data deficiency in terms of the human rights position of the Roma, including in terms of social and economic rights such as health.<sup>94</sup> The FRA set about rectifying that information gap, commissioning research and making recommendations of good practice. Research from surveys, reviews of official information and qualitative data through participatory action research reveals that Roma are systematically worse off than other Europeans, in a range of areas including health and life expectancy.<sup>95</sup> The headline figures of its key

<sup>87</sup> Regulation 168/2007/EC [2007] OJ L53/1.

<sup>88</sup> The European Monitoring Centre on Racism and Xenophobia.

<sup>89</sup> Decision 2008/203/EC [2007] OJ L63/14.

<sup>90</sup> European Union Agency for Fundamental Rights (FRA), 'Annual Report. Fundamental Rights: challenges and achievements in 2010' (FRA 2011).

<sup>91</sup> FRA, 'Annual Report. Fundamental Rights: challenges and achievements in 2010' (FRA 2011) 15, 21–22.

<sup>92</sup> FRA, above n 90. <sup>93</sup> Decision 252/2013/EU [2013] OJ L79/1.

<sup>94</sup> The FRA began its work on Roma as the European Monitoring Centre on Racism and Xenophobia (EUMC). Its first report concerned health. EUMC, 'Breaking the Barriers – Romani Women and Access to Public Health Care' (EUMC 2003).

<sup>95</sup> FRA, 'Multi-Annual Programme' (FRA, 2013) and Commission, 'National Roma Integration Strategies: a first step in the implementation of the EU Framework' (Communication) COM

report are shocking: one out of three Roma respondents aged 35 to 54 report health problems limiting their daily activities; on average, about 20 per cent of Roma respondents are not covered by medical insurance or do not know if they are covered.<sup>96</sup> Drawing on the work of the FRA, the European Commission called upon Member States to improve integration of Roma in four areas, one of which is health.<sup>97</sup> A working group is developing indicators and measuring progress towards these goals.<sup>98</sup>

The FRA also uses a more legal approach in instances where its reports highlight deficiencies in implementing relevant EU law, or untapped potential legal avenues for enforcing human rights, often coupled with the principle of non-discrimination.<sup>99</sup> Directive 2000/43 on race equality, for instance, applies to 'social protection, including . . . healthcare'.<sup>100</sup> A report on the Directive highlights the judicial, administrative and alternative dispute mechanisms available to enforce it.<sup>101</sup> The FRA has also worked on the health rights of people with disabilities.<sup>102</sup> In addition, a major FRA report in 2013 considered questions of 'intersectionality' in health inequalities.<sup>103</sup> It found that unequal and unfair treatment in access to health and quality of health care persists across the EU, with particularly ill-served groups being those who experience discrimination on more than one 'forbidden ground' (for instance, a Muslim, older, woman with a disability). The report cites examples of discrimination at the intersection of sex, ethnicity and disability in violations of human rights provisions on informed consent to treatment, coupled with rights to human reproduction, such as sterilization of Roma women and women with disabilities.

The FRA has highlighted the limitations of the law and legal processes in remedying such human rights infringements in health contexts. Barriers include tolerance of or failure to recognize unlawful discrimination,<sup>104</sup> difficulties in

(2012) 226 final; FRA, 'Collecting secondary data and mapping official data sources' (FRA, ongoing) FRA, 'Multi-Annual Programme' (FRA, 2013).

<sup>96</sup> FRA, 'The Situation of Roma in 11 Member States' (FRA 2012) 12 and 21.

<sup>97</sup> Commission, 'An EU Framework for National Roma Integration Strategies up to 2020' (Communication) COM (2011) 173 final.

<sup>98</sup> FRA, 'Assisting Member States to measure the progress of Roma integration' (FRA, ongoing).

<sup>99</sup> Article 21 EU CFR.

<sup>100</sup> Directive 2000/43/EC [2000] OJ L180/22. The CJEU has not heard a claim involving a health context based on the Directive. In *Kamberaj*, C-571/10, EU:C:2012:233, involving housing benefit rules, the CJEU found that the Directive does not cover nationality discrimination. But there is no reason why it should not cover race discrimination in health contexts.

<sup>101</sup> FRA, 'The Race Equality Directive: application and challenges' (FRA 2011).

<sup>102</sup> FRA, 'Involuntary placement and involuntary treatment of persons with mental health problems' (FRA 2012); FRA, 'Choice and control: the right to independent living' (FRA 2012); FRA, 'Legal capacity of persons with intellectual disabilities and persons with mental health problems' (FRA 2013).

<sup>103</sup> FRA, 'Inequalities in multiple discrimination in access to and quality of healthcare' (FRA 2013) For more information about 'intersectionality' in EU law, see: Schiek and Lawson (eds), *European Union Non-Discrimination Law and Intersectionality: Investigating the Triangle of Racial, Gender and Disability Discrimination* (Ashgate 2011).

<sup>104</sup> FRA, 'The Race Equality Directive', above n 101.

evidencing discrimination, and in choice of comparator, and lack of understanding of intersectionality by lawyers and judges alike. The consequence is that disputes are often pursued through non-human rights legal frameworks, such as medical negligence, or alternative dispute mechanisms such as Ombudsmen.<sup>105</sup> So, on balance, although the FRA's work on the Roma communities of Europe is probably its most significant practical contribution to health and human rights,<sup>106</sup> the mechanisms used here are not the traditional mechanisms of human rights law.<sup>107</sup> Again, therefore, the conclusion is that the claim that health rights as human rights are increasingly significant in EU law may have some merit, but needs some nuance.

### The implications of increased significance of health rights as human rights in EU law

To the extent that fundamental health rights, as human rights, have become more significant in the EU's legal order, what are the implications? Have health rights made a difference – to national or EU level health policies? In what contexts? What opportunities arise from the recognition by EU law of health rights as human rights? In 2004, we concluded that many health rights were already protected within EU law, as general principles of law, and so little change was expected, even if the EU CFR were to become binding EU law,<sup>108</sup> as has now taken place. Writing in 2003, of the 'right to health', Hervey concluded that, were the right to health to become articulated more strongly in EU law, *in some contexts* change could be anticipated. In the context of internal market litigation, there might be changes in terms of how claims were articulated and decisions made, but the *outcomes* of any relevant decisions would remain unaltered. The area of most promise, in terms of promoting the health status of some of the most vulnerable human beings within the EU, was that of human migration.<sup>109</sup>

The remainder of this chapter considers the current position, some ten years later. We consider first the scope for health rights as human rights to affect the

<sup>105</sup> FRA, 'Inequalities in multiple discrimination in access to and quality of healthcare' (FRA 2013).

<sup>106</sup> Although it is too soon to assess its effects.

<sup>107</sup> For a discussion of the FRA's potential, and its contribution to 'an administrative law of fundamental rights protection and promotion', see: Von Bogdandy and Von Bernstoff, 'The EU Fundamental Rights Agency within the European and International Human Rights Architecture: The Legal Framework and Some Unsettled Issues in a new field of Administrative Law' (2009) 46 *Common Market Law Review* 1035; Toggenburg, 'The role of the new EU Fundamental Rights Agency: debating the "sex of angels" or improving Europe's human rights performance?' (2008) 33 *European Law Review* 385. For a critique of the FRA's use of comparative statistics as a technique of government, see: Sokhi-Bulley, 'Governing (Through) Rights: Statistics as Technologies of Governmentality' (2011) 20 *Social and Legal Studies* 139.

<sup>108</sup> Hervey and McHale, *Health Law and the European Union* (CUP 2004) 406-7.

<sup>109</sup> Hervey, 'The right to health in EU law' in Hervey and Kenner (eds), above n 74.

validity of EU legislation and administrative acts, and how EU law is interpreted. Either or both of these processes can have the effect of making a difference to EU health law or policy. We also consider the national context, examining ways in which health rights as human rights affect the interpretation of national implementing legislation. Coupled with the doctrine of supremacy of EU law, such interpretations often, *de facto*, amount to testing the consistency of national legislation with EU law. Second, we consider an important example of how health rights as human rights may extend individual entitlements, particularly in claims against state bodies. This is the possibility of health rights being coupled with equality and non-discrimination, in interpreting EU law, national implementing law or both. Third, we consider the relevance of human rights in the context of internal market law, where Member States seek to justify restrictions on free movement on the basis that they breach a health right of some sort. Finally, we consider some more nebulous or indirect effects of health rights as human rights in EU health law.

### The validity and interpretation of EU legislation or administrative decisions and national implementing acts

Acts of the EU institutions which breach fundamental human rights are invalid. The CJEU has jurisdiction to hear judicial review claims on this (and other) ground(s),<sup>110</sup> brought by the ‘privileged’ applicants of the EU institutions and Member State governments, and by individuals in certain restricted circumstances.<sup>111</sup> In principle, therefore, health rights could act as a constraint on the EU’s law and policymaking powers. In practice, however, such constraining effects have been very limited.

As noted above, the CJEU mentioned human dignity<sup>112</sup> in its judicial review of Directive 98/44/EC on the legal protection of biotechnological inventions.<sup>113</sup> But none of the EU’s other legislation concerning development of new health technologies, or involving the use of human material in clinical research, has been challenged on grounds of breaching fundamental rights. The Advanced Therapy Medicinal Products Regulation,<sup>114</sup> for instance, establishes a special

<sup>110</sup> Article 263 TFEU.

<sup>111</sup> The main context in which an individual may bring a claim is where an act of an EU institution is addressed to that individual. The restricted *locus standi* of individuals in EU law has been controversial in some health contexts, such as the CJEU’s ruling in *Olivieri v Commission*, T-326/99, EU:T:2003:351, that Dr Nancy Olivieri did not have *locus* to review the decision of the European Medicines Agency to authorise deferiprone, a drug whose clinical trials she originally directed. Dr Olivieri left the deferiprone trials when she became concerned about the safety of the drug. See further: Abraham and Davis, ‘Science, Law and the Medical-Industrial Complex in EU Pharmaceutical Regulation: The Deferiprone Controversy’ in Flear et al., above n 86.

<sup>112</sup> *Biotechnology Directive* EU:C:2001:523, paragraphs 70–77.

<sup>113</sup> Directive 98/44/EC [1998] OJ L213/13.

<sup>114</sup> Regulation 1394/2007/EC [2007] OJ L324/121.

marketing authorization system for novel products based on genes, cells and tissues, at the boundaries between pharmaceuticals and medical devices, and using human material. Although the Regulation itself declares compliance with human rights instruments,<sup>115</sup> it is at least arguable that even developing these products at all, let alone authorizing their marketing, breaches fundamental human rights such as dignity or the right to life, as expressed through the idea that the human body is not a commodity. But no litigation was brought challenging the validity of the provisions of the Regulation. Nor has there been litigation challenging EU administrative acts, for instance, the decision to fund, or not to fund, certain types of research – even though such a decision might be claimed to breach human dignity, the right to life, or, conversely, freedom of scientific research.<sup>116</sup>

On reflection, however, this is not such a surprise. The European Court of Human Rights is ambivalent about the application of the ‘right to life’ in the context of novel health technologies,<sup>117</sup> and there is every reason to expect similar caution from the CJEU. Perhaps this is in part because of the presence of competing rights (to life, to dignity) of those patients who might benefit from future therapies, and because a public interest justification applies in the context of developing novel health technologies. The EU CFR explicitly prohibits ‘the reproductive cloning of human beings’,<sup>118</sup> but is silent on the question of so-called ‘therapeutic cloning’,<sup>119</sup> perhaps implying that such uses of human material do not infringe human rights according to EU law.

<sup>115</sup> Regulation 1394/2007/EC, Recital 8: ‘This Regulation respects the fundamental rights and observes the principles reflected in the Charter of Fundamental Rights of the European Union and also takes into account the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.’

<sup>116</sup> Article 13, EU CFR. See: Sayers, ‘Article 13 – Freedom of the Arts and Sciences’ in Peers et al., above n 14, 394.

<sup>117</sup> Gevers and O’Connell, ‘Fixed Points in a Changing Age? The Council of Europe, Human Rights and the Regulation of New Health Technologies’ in Flear et al., above n 86; Hervey and McHale, above n 108, 400-402; Nys, ‘Comparative health law and the harmonisation of patients’ rights in Europe’ (2001) 8(4) *European Journal of Health Law* 317; Millns, ‘Consolidating Bio-rights in Europe’ in Francioni (ed), *Biotechnologies and International Human Rights* (Hart 2007); Brownsword, ‘Human Dignity, Ethical Pluralism and the Regulation of Modern Biotechnologies’ in Murphy (ed), *New Technologies and Human Rights* (OUP 2009); Mason and Laurie, above n 22.

<sup>118</sup> Article 3 (2) (d) EU CFR.

<sup>119</sup> Defined by the UK Human Genetics Advisory Commission (HGAC) as: “medical and scientific applications of cloning technology which do not result in the production of genetically identical fetuses or babies. These techniques may be undertaken to advance fundamental research and therefore not all such applications will lead to immediate therapeutic utility”, UK HGAC, ‘Cloning Issues in Reproduction Science and Medicine (Consultation Document)’ (HGAC 1998) Annex B. See further: Hervey and McHale, above n 108, 271-273; UK HGAC and UK Human Fertilisation and Embryology Authority (HFEA), ‘Cloning Issues in Reproduction, Science and Medicine’ (HGAC and HFEA 1998) 19-23.



Health rights as human rights have, however, played a stronger role in the interpretation of EU law. The CJEU was asked to interpret the Biotechnology Directive in the 2011 *Brüstle* case,<sup>120</sup> in the context of German patents for ‘neural crest cells’ (a type of cell that can develop into many types of cells and tissues), derived from a blastocyst (the entity which has developed around five days after fertilization of an ovum), and the process of deriving these cells. These cells offer the promise of treatment of diseases such as Parkinson’s disease. The national referring court asked whether the patent was excluded from patentability, in so far as it concerns cells obtained from embryonic stem cells. To answer that question, the CJEU was required to interpret Article 6 (2) (c) of the Biotechnology Directive, which provides that ‘uses of human embryos for industrial or commercial purposes’ shall be unpatentable. In essence, this involved an interpretation of the term ‘human embryo’, in this context.

The CJEU’s judgment, and in particular the Opinion of its Advocate General, AG Bot, strongly articulate human rights as the rationale underpinning the decision. AG Bot goes so far as to say that the EU is ‘not only a market to be regulated’, but also ‘has values [in particular that of human dignity] to be expressed’.<sup>121</sup> The CJEU’s interpretation of the Directive begins from ‘fundamental rights and the dignity of the person’,<sup>122</sup> and it is on this basis that the CJEU concludes that

The context and aim of the Directive . . . show that the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected. It follows that the concept of ‘human embryo’ within the meaning of Article 6(2) (c) of the Directive must be understood in a wide sense.<sup>123</sup>

Hence, according to the CJEU in *Brüstle*, ‘human embryo’ includes any fertilized human ovum; a non-fertilized human ovum into which a mature human cell nucleus has been transplanted (‘therapeutic cloning’); and a non-fertilized human ovum whose division and further development has been stimulated by parthenogenesis (a form of reproduction where embryos grow without fertilization, which has been achieved in human embryos since around 2004). The ruling means that these entities, and processes, are not patentable in the EU – although the CJEU left to the national court the final determination of whether the specific products and processes at issue in the *Brüstle* case fell within this definition.<sup>124</sup> In this context, therefore, the human rights engaged meant that the concept of ‘human embryo’ was given a wide interpretation, hence

<sup>120</sup> *Brüstle*, C-34/10, EU:C:2011:669. <sup>121</sup> Opinion in *Brüstle*, paragraph 46.

<sup>122</sup> *Brüstle*, paragraph 32. <sup>123</sup> *Brüstle*, paragraph 34.

<sup>124</sup> *Brüstle*, paragraph 38. See: Harmon, Laurie and Courtney, ‘Dignity, plurality and patentability: the unfinished story of *Brüstle v Greenpeace*’ (2013) 38(1) *European Law Review* 92; Varju and Sandor, ‘Patenting Stem Cells in Europe: The Challenge of Multiplicity in EU Law’ (2012) 49(3) *Common Market Law Review* 1007; Bonadio, ‘Biotech Patents and Morality after *Brüstle*’ (2012) 34(7) *European Intellectual Property Review* 433.

excluding patentability of a range of possible novel health technologies on the basis of the imperative of protecting human dignity.

By contrast, however, in *International Stem Cell*,<sup>125</sup> the wide definition of *Brüstle* was not embraced. *International Stem Cell* concerned the patentability of a ‘parthenote’ – an oocyte which can, once activated chemically and/or electrically, develop into a blastocyst (over about 5 days) but can never develop to term, because it lacks paternal DNA. Admittedly, the CJEU in *International Stem Cell* restates the *Brüstle* principle that ‘human embryo’ in Article 6 (2) (c) of the Directive must be interpreted broadly.<sup>126</sup> But, following its Advocate General, the CJEU reasoned that ‘human embryo’ in that context ‘must . . . have the inherent capacity of developing into a human being’.<sup>127</sup> In *Brüstle*, that was the case. Here, it is not, and hence the cases must be distinguished. The question of capability of the particular invention concerned to develop into a human being was left ultimately for the national court.

It has been claimed that the ruling in *Brüstle* will encourage certain types of research or certain types of industry behaviour. The *International Stem Cell* case certainly suggests that the patent concerned was for a process deliberately designed to avoid the creation of an entity that could, in theory, develop into a human being. The EU CFR’s protection of ‘freedom of the arts and sciences’<sup>128</sup> is unlikely to change future CJEU rulings on the subject, as it must be exercised consistently with Article 1 EU CFR on human dignity. It has been suggested that *Brüstle* is likely to encourage research using adult, rather than embryonic, stem cells. Greater investment in non-European companies developing these new technologies, and greater use of trade secrecy, are both expected,<sup>129</sup> although little concrete evidence of widespread changes of behaviour has yet been reported.

The CJEU adopts a similar wide interpretation of provisions, where human rights are engaged, in the context of the EU’s Data Protection Directive.<sup>130</sup> In *Lindqvist*,<sup>131</sup> the CJEU was asked to interpret the term ‘personal data . . . concerning health’.<sup>132</sup> This category of data is given special treatment within

<sup>125</sup> *International Stem Cell* C-364/13 EU:C:2014:2451.

<sup>126</sup> *International Stem Cell* EU:C:2014:2451, paragraph 24.

<sup>127</sup> *International Stem Cell* EU:C:2014:2451, paragraph 27.

<sup>128</sup> Article 13, EU CFR; and see: Sayers, above n 116, 380, 393-4.

<sup>129</sup> See: Bache et al., ‘The Defining Features of the European Union’s Approach to Regulating New Health Technologies’ in Flear et al., above n 86, 14, and the sources cited therein.

<sup>130</sup> Directive 95/46/EC [1995] OJ L281/31. This Directive is currently being revised, see: Commission, ‘Safeguarding Privacy in a Connected World A European Data Protection Framework for the 21st Century’ COM (2012) 09 final; Commission, ‘Proposal for a Directive of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and the free movement of such data’ COM (2012) 10 final; Commission, ‘Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)’ COM (2012) 11 final.

<sup>131</sup> *Lindqvist*, C-101/01, EU:C:2003:596. <sup>132</sup> Directive 95/46/EC, Article 8 (1).

the Directive. The rationale for the Directive is to enable the transmission of data between Member States. Hence, the general approach of the Directive is to harmonize information privacy. Without such harmonization, Member States with higher levels of privacy protection could prevent data sharing across borders within the EU, and thus impede the creation of the internal market in data, and data-based services. So the main thrust of the Directive is to allow legitimate and lawful processing of data, including personal data. The Directive covers two types of personal data. Ordinary personal data may be legitimately processed only if the person concerned has unambiguously given consent.<sup>133</sup> But for special categories of data the presumption is reversed. The processing of this type of data (which includes data concerning health),<sup>134</sup> is prohibited under the Directive, unless one of a list of exceptions applies.<sup>135</sup> A broad interpretation of ‘data concerning health’ thus extends the scope of the exceptional category within the Directive. This is the approach taken by the CJEU in *Lindqvist*. Although the underlying rationale of the Directive is market creation, the CJEU expresses its purposes as multiple, and states that a key purpose of the Directive is human rights protection. Hence, ‘in light of the purpose of the Directive’, the term ‘data concerning health’ must be interpreted widely – it includes ‘information concerning all aspects, both physical and mental, of the health of an individual’.<sup>136</sup>

A third illustration of the way in which the CJEU interprets health rights is found in cases which also demonstrate an important feature of human rights litigation – how to reconcile competing rights. In *Deutsches Weintor*,<sup>137</sup> the CJEU considered the interpretation of a Regulation on nutritional claims on food labelling.<sup>138</sup> The Regulation provides that ‘beverages containing more than 1.2 per cent by volume of alcohol shall not bear health claims’.<sup>139</sup> The CJEU held that the phrase ‘easily digestible’ constitutes such a claim. The CJEU then turned to the question of whether the prohibition of such a product description nonetheless breaches Articles 15 (1) and 16 EU CFR, on freedom to

<sup>133</sup> Directive 95/46/EC, Article 7 (a). For a discussion of ‘unambiguous consent’ in this context, see: Kranenborg, ‘Article 8 – Protection of Personal Data’ in Peers et al., above n 14, 250–251. Consent may be implied in other circumstances, such as where it is necessary to protect the vital interests of the individual concerned, or on public interest grounds, see: Directive 95/46/EC, Articles 7 (b) (c) (d) (e). The proposed new Regulation strengthens the conditions for consent.

<sup>134</sup> The ECtHR has confirmed that health data have a special relationship with the right to privacy and family life, see: *I v Finland* App no 20511/03 (ECtHR, 17 July 2008), paragraph 38. For discussion of the Data Protection Directive in health research, see: Beylveeld, Townend, Rouillé-Mirza and Wright, *Implementation of the Data Protection Directive in Relation to Medical Research in Europe* (Ashgate 2004).

<sup>135</sup> These include where explicit consent has been given, where necessary to meet the vital interests of the individual or a third party and the individual is incapable of consenting, see: Directive 95/46/EC, Article 8 (2) (a)–(e). A specific exemption applies where data processing is required in a health care context: Directive 95/46/EC, Article 8 (3).

<sup>136</sup> *Lindqvist* EU:C:2003:596, paragraph 50. <sup>137</sup> *Deutsches Weintor* EU:C:2012:526.

<sup>138</sup> Regulation 1924/2006/EC [2007] OJ L12/3. <sup>139</sup> Regulation 1924/2006/EC, Article 4 (3).

pursue an occupation and to conduct a business. It found that ‘the prohibition does not in any way affect the actual substance’ of those freedoms.<sup>140</sup> In its reasoning, the CJEU balanced the freedom to conduct a business with Article 35 EU CFR, second sentence, which provides that ‘a high level of human health protection shall be ensured in the definition and implementation of all the Union’s policies and activities.’<sup>141</sup> The CJEU’s rationale in so doing was that health protection is among the principal aims of the Regulation.<sup>142</sup> Assessment of the validity of the Regulation must reconcile such competing fundamental rights, striking a ‘fair balance’ between them.<sup>143</sup> The EU’s legislature was entitled to prohibit such health claims, in order to ensure a high level of health protection for consumers.<sup>144</sup> A similar balancing approach between freedom of thought, conscience and religion, and health rights, is found in the ECtHR’s ruling in *Pichon and Sajous v. France*,<sup>145</sup> upholding national policy requiring pharmacists to supply contraceptives, because of the need to protect health policy, as well as the rights and freedoms of others.

The effect of human rights law, as a tool for interpretation of these areas of EU health law, is to articulate a particular version of the EU’s internal market. The underlying context and aims of the relevant legislation is to create and sustain the market for health products, data or services, or products that might have an effect on health. But this market is heavily regulated, and not only for reasons of patient safety. It is also regulated in order to protect an ethic of human dignity, expressed through human rights. Human rights claims must be balanced with market objectives, as well as with other human rights claims. The significance of human rights as health rights in this context is an underlying process of legitimization – the EU’s claim to rule over human health is bolstered by its protection of human rights.<sup>146</sup>

However, the effects of human rights in this respect are limited. For instance, it is highly unlikely that the CJEU would interpret the Patients’ Rights Directive by reference to the right to life and the right to health care so as to find an individual entitlement to access life-saving treatment for a particular patient.<sup>147</sup> Another example of the limitation of health rights as human rights in EU law is that the CJEU’s case law has done little, if anything, to disrupt the Data Protection Directive’s position over one of the major concerns of the health policy community: the use of ‘big data’ in health contexts, particularly clinical and epidemiological research and public health monitoring. This is an

<sup>140</sup> *Deutsches Weintor*, paragraph 58.      <sup>141</sup> *Deutsches Weintor*, paragraph 45.

<sup>142</sup> *Deutsches Weintor*, paragraph 45, referring to Regulation 1924/2006/EC [2007] OJ L12/3, Recitals 1 and 18.

<sup>143</sup> *Deutsches Weintor*, paragraphs 44–47.      <sup>144</sup> *Deutsches Weintor*, paragraph 52.

<sup>145</sup> *Pichon and Sajous v France*, no. 49853/99, ECHR 2001-X.

<sup>146</sup> See: further, Bache et al., above n 129, 30–41.

<sup>147</sup> See: Wicks, above n 79, 28, Di Federico, ‘Access to Healthcare in the Post-Lisbon Era and the Genuine Enjoyment of EU Citizens’ Rights’ in Rossi and Casolari (eds), *The EU After Lisbon: Amending or Coping with the Existing Treaties* (Springer 2014); and see further chapter 8.

area where there are significant differences between national approaches, and moves to a greater use of electronic record keeping in health contexts mean that the traditional protections for human rights through health data management between patient and health care provider are under challenge.<sup>148</sup> The consent provisions of the Directive have come under particular criticism from the research community. If taken literally, they would seem to impede research using health data collected from young children, or adults who are mentally incompetent to give consent. Moreover, much of the data held in banks of health information, such as cancer registries, could contravene the Directive, as it was information that had been transferred and used without explicit consent being given, and where none of the exceptions in the Directive appeared to apply.<sup>149</sup> It may be that making such health data anonymous, as the Directive implies is to be effected wherever possible, is sufficient to protect privacy and data protection rights, although it is not clear how anonymization or ‘depersonalization’ is defined in the Directive.<sup>150</sup>

The CJEU is yet to rule on this question, but some national courts have done so, interpreting their implementing legislation. In the *Source Informatics* case,<sup>151</sup> the English Court of Appeal held that collection by a private company of data about the prescribing habits of general practitioners collected from pharmacists did not contravene the Directive. Indeed, the Court held that the fact that the data was anonymized *protected* the patients’ privacy, rather than undermining it.<sup>152</sup> In the context of that ruling, then, health rights as human rights have made little difference in terms of disrupting the legislative settlement, either through challenge to the validity of legislation, or its interpretation. We might therefore expect a similar approach by national courts to the interpretation of implementing legislation in a range of areas where human rights might be engaged. These include implementation of the Patients’ Rights Directive where the right to found a family might be impeded; of the Clinical Trial Directive, regarding consent of mentally incapacitated adults; or of freedom of expression where EU law places restrictions on advertising, for instance, of alcohol or tobacco.<sup>153</sup>

### Health rights plus non-discrimination/equality

Where health rights have the potential to make the most difference to interpretation of EU legislation is where they are combined with the principles

<sup>148</sup> See: Kranenborg, above n 133, 254. <sup>149</sup> See: Hervey and McHale, above n 108, 179-80.

<sup>150</sup> Directive 95/46/EC, Article 6 (1) (e). See: Hervey and McHale, above n 108, 172-4.

<sup>151</sup> *Source Informatics* [2001] QB 424 (CA).

<sup>152</sup> For critical discussion, see: e.g. Beylveland and Histed, ‘Anonymisation is not Exoneration’ (1999) 4 *Medical Law International* 69.

<sup>153</sup> Neither the CJEU nor the ECtHR have yet decided a case concerning access to reproductive technologies, see: e.g. Choudry, ‘Article 9 – Right to Marry and Right to Found a Family’ in Peers et al., above n 14, 271-2, 284. On freedom of expression and tobacco advertising, see: Opinion in *Tobacco Advertising*, C-376/98, EU:C:2000:324. See also: Hervey and McHale, above n 108, 408-9.

of non-discrimination<sup>154</sup> or equality.<sup>155</sup> These principles are a potent ‘bridge’ between the social and the civil rights components of the EU CFR.<sup>156</sup> For instance, as Claire Kilpatrick suggests, were access to cross-border health care to be denied because of morbid obesity, Article 21 EU CFR on non-discrimination on grounds of disability would be engaged.<sup>157</sup> Equally, as EU law plays an increasingly important role in health, as well as social, care, the rights of the elderly in the EU CFR apply.<sup>158</sup>

The link between social rights and enforceable entitlements is particularly important where some of the most vulnerable people in the EU are concerned: asylum seekers, unaccompanied migrant children, members of the Roma community, people with physical or mental disabilities, elderly people.<sup>159</sup> While there is yet to be a decision of the CJEU involving the ‘right to health care’ in this regard, the *Kamberaj* case,<sup>160</sup> concerning housing benefit, applies by analogy.

Servet Kamberaj, an Albanian national, was a lawful long-term resident in Italy. He was refused housing benefit, because the fund for ‘third country’ (non-EU) nationals ran out of resources. A separate fund covered housing benefit for EU nationals. Kamberaj claimed that this breached the ‘Long-term residents Directive’,<sup>161</sup> Article 11 of which provides that long-term residents are to be treated equally with nationals, as regards social assistance and social protection (as defined nationally). Member States may, however, limit equal treatment in social assistance and social protection to ‘core benefits’.<sup>162</sup> The CJEU was asked to interpret the Directive, in particular whether housing benefit was ‘social assistance or social protection’, and whether it was a ‘core benefit’.

Referring explicitly to Articles 12 and 34 EU CFR, the CJEU held that

when determining the social security, social assistance and social protection measures defined by their national law and subject to the principle of equal treatment enshrined in Article 11(1)(d) of Directive 2003/109, the Member States must comply with the rights and observe the principles provided for under the Charter, including those laid down in Article 34 thereof. Under Article 34(3) of the Charter, in order to combat social exclusion and poverty, the Union (and thus the Member States when they are implementing European Union law) ‘recognises and respects the right to social and housing assistance so as to ensure a decent existence for all those who lack sufficient resources, in accordance with the rules laid down by European Union law and national laws and practices’.<sup>163</sup>

<sup>154</sup> EU CFR, Article 21.

<sup>155</sup> EU CFR, Article 20. The legal distinction between the two provisions appears to be that Article 21 enumerates several ‘suspect grounds’, whereas Article 20 is a residual provision, covering other types of distinction, see: Bell, ‘Article 20 – Equality before the Law’ in Peers et al., above n 14.

<sup>156</sup> See: Kilpatrick, ‘Article 21 – Non-Discrimination’ in Peers et al., above n 14, 586.

<sup>157</sup> See: Kilpatrick, above n 156, 581.

<sup>158</sup> See: O’Cinneide, ‘Article 25 – The Rights of the Elderly’ in Peers et al., above n 14, 694.

<sup>159</sup> See: Hervey, ‘The Right to Health in EU Law’, in Hervey and Kenner, above n 74, 217–222.

<sup>160</sup> *Kamberaj* EU:C:2012:233. <sup>161</sup> Directive 2003/109/EC [2003] OJ L16/44.

<sup>162</sup> Directive 2003/109/EC, Article 11 (4). <sup>163</sup> *Kamberaj* EU:C:2012:233, paragraph 80.

Technically, the question of application of the Directive to housing benefit is a matter for the national court. But the CJEU gives a ‘very strong steer’<sup>164</sup> to the national court, stressing the basic nature of housing benefit, as well as the ‘right to ensure a decent existence for all those who lack sufficient resources’.<sup>165</sup>

Although yet to be tested, the reasoning in *Kamberaj* should apply also to core health care benefits, especially as the Long-term Residents Directive itself refers to ‘assistance in case of illness, pregnancy’ in recital 13. By extension, and more significantly, it applies also in the context of EU asylum law. The qualification Directive 2011/95/EU<sup>166</sup> requires Member States to grant access to health care to refugees or those with ‘subsidiary protection’, on the same basis as nationals.<sup>167</sup> The reception conditions Directive 2013/33/EU<sup>168</sup> provides that applicants for asylum must be given ‘an adequate standard of living for applicants, which guarantees their subsistence and protects their physical and mental health’, although this may be means tested.<sup>169</sup> When implementing the Directive, Member States must take into account the needs of vulnerable applicants, including ‘persons with serious illnesses’, ‘persons with mental disorders’, disabled people, elderly people and pregnant women. And Directive 2008/115/EC on common standards and procedures for returning illegally staying third-country nationals (the returns Directive)<sup>170</sup> gives safeguards pending return of third country nationals, including ‘emergency health care and essential treatment of illness’.<sup>171</sup> These provisions apply even to some of the categories of third country nationals which Member States may exclude from the Directive,<sup>172</sup> such as those who have been apprehended by the border authorities because of an irregular crossing of an external EU border, and who do not subsequently obtain an authorization to stay in that Member State.<sup>173</sup>

The potential for health rights as human rights to make a difference in this context is significant. The ECtHR has stressed that the particularly vulnerable position of asylum seekers requires special attention to their material needs, including health protection.<sup>174</sup> The public health conditions in detention

<sup>164</sup> White, ‘Article 34 – Social Security and Social Assistance’ in Peers et al., above n 14, 940. The CJEU states that housing benefit ‘cannot be considered . . . as not being part of core benefits’: *Kamberaj* EU:C:2012:233, paragraph 92.

<sup>165</sup> *Kamberaj*, paragraph 92. <sup>166</sup> Directive 2011/95/EU [2011] L337/9.

<sup>167</sup> Directive 2011/95/EU, Article 30 (1). Article 30 (2) makes special mention of ‘beneficiaries of international protection who have special needs, such as pregnant women, disabled people, persons who have undergone torture, rape or other serious forms of psychological, physical or sexual violence or minors who have been victims of any form of abuse, neglect, exploitation, torture, cruel, inhuman and degrading treatment or who have suffered from armed conflict’, who are entitled to adequate healthcare, including treatment of mental disorders when needed.

<sup>168</sup> Directive 2013/33/EU [2013] OJ L180/96. <sup>169</sup> Directive 2013/33/EU, Article 17 (2).

<sup>170</sup> Directive 2008/115/EC [2008] OJ L348/98. <sup>171</sup> Directive 2008/115/EC, Article 14 (1) (b).

<sup>172</sup> Directive 2008/115/EC, Articles 4 (4) and 2 (2) (a).

<sup>173</sup> Directive 2008/115/EC, Article 2 (2) (a).

<sup>174</sup> *MSS v Belgium and Greece* App no 30696/09 (ECtHR, 2011), paragraphs 250–251, 263. See: Den Heijer, ‘Article 18 – Right to Asylum’ in Peers et al., above n 14, 522–3.

centres are a matter of concern for human rights groups.<sup>175</sup> They highlight, in particular, the position of children,<sup>176</sup> with significant breaches of their right to health, in contravention of the UN Convention on the Rights of the Child. The FRA has also identified uneven protection for the right to health care for irregular migrants in the EU, both ‘undetected’ and ‘non-removed’ people. In its view, ‘EU Member States should disconnect healthcare from immigration control policies’.<sup>177</sup> As noted above, the FRA’s work concerning inequalities and multiple discrimination in health care<sup>178</sup> is based on Articles 21 and 35 EU CFR.<sup>179</sup>

### Justifying restrictions on free movement

According to Article 51 (1) EU CFR, the provisions of the EU CFR apply to Member States ‘only when they are implementing EU law’. However, as noted above, the CJEU has held that human rights (as general principles of EU law) apply where Member States act ‘within the scope of application of EU law’.<sup>180</sup> The case law on this topic is complex, and demonstrates the ways in which EU law, ECHR law and national constitutional law interact in non-hierarchical relationships.<sup>181</sup> Whether the EU CFR applies when Member States derogate from free movement rules (by justifying restrictions on freedom of movement within the internal market, on the basis of an objective public interest which is the protection of a human right) is not yet definitively settled by the CJEU.<sup>182</sup> For our purposes, however, the focus is on the implications of health rights as human rights in the context of internal market law. Two important questions arise. The first is the implication of interpreting an objective public interest (an *exception* to internal market law) as a human right. The second is the

<sup>175</sup> Médecins Sans Frontières, ‘Not Criminals’ (Médecins Sans Frontières 2009); FRA, ‘Coping with a fundamental rights emergency: the situation of persons crossing the Greek land border in an irregular manner’ (FRA 2011).

<sup>176</sup> Human Rights Watch, ‘Left to Survive: Systematic Failure to Protect Unaccompanied Migrant Children in Greece’ (Human Rights Watch 2008); Hammarberg (Commissioner for Human Rights of the Council of Europe), ‘Human Rights of Asylum Seekers and Refugees’ (CommDH(2009)31, Council of Europe 2009); FRA, ‘Separated asylum-seeking children in EU Member States: a comparative report’ (FRA 2011). See: Lamont, ‘Article 24 – The Rights of the Child’ in Peers et al., above n 14.

<sup>177</sup> FRA, ‘Migrants in an irregular situation: access to health care in 10 EU Member States’ (FRA 2011) 10.

<sup>178</sup> FRA, ‘Inequalities and multiple discrimination in healthcare’ (FRA 2012).

<sup>179</sup> For further discussion, see: Hervey and McHale, ‘Article 35 – The Right to Health Care’ in Peers et al., above n 14, 958-9, 961-4.

<sup>180</sup> See: *ERT* EU:C:1991:254; *Familiapress*, C-368/95, EU:C:1997:325; *Schmidberger* EU:C:2003:333. Moreover, the CJEU has stated more recently that the EU CFR applies ‘in all situations governed by EU law’, see: *Fransson* EU:C:2013:280, paragraph 19.

<sup>181</sup> *Melloni*, C-399/11, EU:C:2013:107; *Fransson* EU:C:2013:280 and see above n 17.

<sup>182</sup> Ward, ‘Article 51 – Field of Application’ in Peers et al., above n 14, 1427. Advocate General Sharpston takes the view that it does, see: Opinion in *Pfleger*, C-390/12, EU:C:2013:747, paragraphs 45-46.



question of who gets to decide on the detailed contours of the interpretation of a particular human rights measure. Whether this is a matter for ECHR law, national constitutional law, or EU law, is essentially unresolved, although (put simplistically) from the point of view of the CJEU, it is the latter.<sup>183</sup>

The CJEU has been consistently criticized by the human rights community for placing human rights as technically subordinate to market freedoms in EU law (free movement is the rule; human rights protection is the exception).<sup>184</sup> However, the practical implications are probably less significant than would appear. Although the ways in which litigation may be carried out, and the reasoning of national courts, may be affected, the *outcomes* of relevant rulings are rarely, if ever, affected by human rights reasoning. For instance, in cases involving human reproduction, although free movement of services was engaged, national constitutional protections of human rights were ultimately safeguarded.<sup>185</sup> Human rights may provide analytical tools, but much more rarely will provide clear cut solutions.

The latter question (who gets to decide, and according to what standard) is potentially more significant. This question is illustrated by a case concerning human dignity, although not in a health context. It concerns the banning of laser ‘killing games’ by a German public authority. The provider of the games, Omega Spielhallen, challenged this decision as breaching EU law on free movement of services. In holding that the prohibition was justified on public policy grounds, and was a proportionate response, the CJEU referred to the concept of human dignity *as corresponding with the level of protection of human dignity found in the German constitution*.<sup>186</sup> The CJEU therefore implied that, although it retained the authority to decide on a question of interpretation of EU law, the standard according to which it would decide is the national standard. This approach is also reflected in Article 52 (4) EU CFR, which provides that where fundamental rights in the EU CFR come from constitutional traditions common to the

<sup>183</sup> Contrast, for example, the positions of the German, Polish, Czech national constitutional courts. The position of the ECtHR in *Bosphorus Airways v Ireland*, no. 45036/98, ECHR 2005-VI suggests that the ECtHR will review the CJEU’s interpretation of human rights provisions only if there is a manifest breach of the ECHR. See further: Peers and Prechal, ‘Article 52 – Scope and Interpretation of Rights and Principles’ in Peers et al., above n 14, 1469; Canor, (2013) above n 17; Krisch, above n 17; Eckes, above n 17; Douglas-Scott, above n 8; Canor, (2000) above n 17. See also Opinion on the Accession of the EU to the European Convention for the Protection of Human Rights and Fundamental Freedoms EU:C:2014:2454.

<sup>184</sup> See, seminally: Coppel and O’Neill, ‘The European Court of Justice: Taking Rights Seriously?’ (1992) 29 *Common Market Law Review* 669, and the robust two-part rebuttal in Weiler and Lockhart, ‘“Taking Rights Seriously” Seriously: The European Court and its Fundamental Rights Jurisprudence Part I’ (1995) 32(1) *Common Market Law Review* 51, and Weiler and Lockhart, ‘“Taking Rights Seriously” Seriously: The European Court and its Fundamental Rights Jurisprudence Part II’ (1995) 32(2) *Common Market Law Review* 579.

<sup>185</sup> See: e.g. *Grogan*, EU:C:1991:378; *Blood* [1997] 2 All ER 687; *AG v X* [1992] CMLR 227; and see: Hervey and McHale, above n 108, 144–55.

<sup>186</sup> *Omega* EU:C:2004:614, paragraph 30.

Member States, these rights ‘should be interpreted in harmony with those traditions’.<sup>187</sup>

If adopted more broadly, the approach of the CJEU in *Omega* would have significant consequences. Any restriction on free movement could be readily justified by reference to a national constitutional tradition, encapsulated in a human rights provision (and reflected in the EU CFR). Multiple examples in the health field spring to mind. As noted above, health rights can be derived from traditional civil and political rights, such as rights to life, to family life, and to privacy. However, the precise contours of entitlements, and general approaches to these human rights, differ considerably between the Member States, because of the potential fluidity of interpretation of human rights provisions. So, for example, the right to life, recognized universally, is subject to significant disparity in interpretation across EU Member States. Notable here is the scope for disagreement as to when life itself actually begins.<sup>188</sup> Equally, the right to found a family is interpreted very differently in different national contexts. So is the right to health care. The implication would be that health rights as human rights in EU law would prevent the application of internal market law from disrupting national interpretations of health entitlements.<sup>189</sup>

However, there are reasons to suggest that *Omega* may be an exceptional case. The German Constitution is undoubtedly the source of inspiration for Article 1 EU CFR, and has been highly influential in the Opinions of several Advocates General, when developing the concept of human dignity as a ‘general principle’ of EU law, as well as when interpreting Article 1.<sup>190</sup> By contrast, other provisions of the EU CFR, where a variety of different national understandings of the meaning of the human rights provision exist, may be interpreted by the CJEU by reference to an EU law, rather than national, standard. For instance, the CJEU has adopted an EU approach to interpretation of Article 35 EU CFR, in determining whether national laws regulating pharmacies are consistent with internal market law on freedom of establishment.<sup>191</sup>

<sup>187</sup> The EU CFR Explanations note that this should not be a ‘lowest common denominator approach’.

<sup>188</sup> So for example, in the Republic of Ireland where constitutional protection is given to the position of the foetus, Article 40.3.3 of the Constitution provides that “The State acknowledges the right to life of the unborn, and with due regard to the equal right to life of the mother, guarantees in its laws to respect, and as far as practicable by its laws to defend and vindicate that right”. Similar constitutional protections for the position of the foetus apply in Poland and Malta. The ECtHR has recognized an emerging European consensus on the provision of lawful abortion in *A, B, C v Ireland* App no 255579/05 (ECtHR, 16 December 2010), but it gave Ireland a very wide margin of discretion. See: Wicks, ‘*A, B, C v Ireland: Abortion Law under the European Convention on Human Rights*’ (2011) 11 *Human Rights Law Review* 556. Similarly, the CJEU in *Brüstle* EU:C:2011:669, paragraph 30, acknowledged that ‘the definition of a human embryo is a very sensitive issues in many Member States, marked by their multiple traditions and value systems’.

<sup>189</sup> For further discussion, see chapter 8.

<sup>190</sup> Dupré, above n 59, 11-12; Jones, ‘Common Constitutional Traditions’: Can the Meaning of Dignity under German Law Guide the European Court of Justice? [2004] *Public Law* 167.

<sup>191</sup> *Susisalo* EU:C:2012:374; *Pérez and Gómez* EU:C:2010:300.

### More nebulous or indirect effects

Finally, we consider some of the more indirect effects of health rights as human rights in EU law.

As we have seen in the above, human rights considerations have affected the terms of EU legislation in several areas relevant to human health. In particular, the non-commodification of the human body, as a specific expression of Articles 1 and 3 EU CFR features in a range of EU legislation on human blood, organs, tissues and cells. Similarly, Article 2 EU CFR has influenced EU administrative decisions concerning the funding of different types of health research. Shazia Choudry suggests that the right to marry and found a family may have effects on EU law and policy in health contexts, as the EU's competence in this field expands.<sup>192</sup>

However, although there may be agreement at the level of a general statement of a human right among the EU's Member States, there is often little agreement about its practical meaning in concrete circumstances. One of the most practical challenges arises where human rights conflict. One individual's human right may come in conflict with that of another individual. Or individual rights may come into conflict with rights of a broader group of persons. The ways in which these conflicts are managed differ significantly between EU Member States. The ECHR system manages these differences through the doctrine of margin of appreciation. And, in practice, EU law does little to change this. Now that EU law increasingly recognizes health rights as human rights, we might expect an increased reference to the *rhetoric* of rights, in both legislation and litigation, but no difference in terms of substantive outcomes of litigation, or the content of legislation.

### Conclusions

While the rhetoric or language of health rights as human rights has increased significantly since the foundation of the EU, and exponentially since 2000, the strong version of the claim that the EU now protects health rights as human rights cannot be supported. On the other hand, neither can it be claimed that the EU ignores or is blind to the idea of health rights as human rights. It remains true to say that the EU's legal order *recognizes* health rights as human rights in ways that it did not do before. Health rights as rhetoric underpin Europeanization processes, such as those pursued by the FRA, but it is rare that this happens through legal processes such as litigation.

It may well be that the *potential* for legal entitlements to health protection, or even particular types of medical treatment, being articulated as human rights within the EU has increased. But the practical implications, in terms of the legal position of patients, health professionals and the obligations owed to them by

<sup>192</sup> Choudry, 'Article 9 – Right to Marry and Right to Found a Family' in Peers et al., above n 153, 271-3.

Member States, are negligible, if not non-existent – at least in litigation and in the context of the EU’s ‘internal’ health law.<sup>193</sup> In the final analysis, the EU’s increasing recognition of health rights as human rights has not made much of a difference. No EU legislation, or administrative acts, in the health context have been set aside by the CJEU for breaching human rights. The specificities of human rights protection in health contexts remain determined at national level, in accordance with the ECHR’s margin of appreciation. EU law does not disrupt this position. In this respect, our overall conclusions in this chapter support those of human rights scholars or activists who are sceptical about the EU’s tangible commitment to human rights.<sup>194</sup>

Nonetheless, health rights as human rights have played an important role in the context of interpretation of EU law, and national law implementing EU obligations. Here, the CJEU has articulated a particular version of the EU’s internal market law – one in which human rights are protected. While this articulation may lend legitimacy to the EU’s regulation of health contexts through its internal market law, again, in practice, it does little to alter the entitlements of individuals, or the significant variations between national approaches in many key areas of health law. Rather, the CJEU’s position effectively leaves EU or national legislation unchallenged. The one possible exception to this general conclusion concerns an area of potential development, rather than representing the current legal position. This is where health rights as human rights apply alongside the principle of non-discrimination/equality. Here, especially as applied to people such as asylum seekers, or migrant children, health rights as human rights in EU law may require Member States to extend the entitlements of their health care systems to some of the most vulnerable individuals within the EU.

<sup>193</sup> The EU’s ‘external’ health law is discussed in Part IV of the book.

<sup>194</sup> See: e.g. Williams, *The Irony of Human Rights in the European Union* (OUP 2004). Human Rights organisations such as Amnesty International regularly call upon the EU to do more to protect, respect and fulfil human rights, see the reports available here: Multiple Authors (*Amnesty International*, 2009).