

# 6 *Fundamental rights and health care*

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## 1. Introduction

The Charter of Fundamental Rights of the European Union (EU Charter) has caused much debate and controversy since it was proclaimed in Nice in December 2000.<sup>1</sup> For health care lawyers, the potential impact of the EU Charter on law and policy in the EU Member States is particularly intriguing. While there is a long history of engagement with litigation concerning human rights and health care in many European jurisdictions, what is notable is the considerable diversity of approaches to fundamental human rights that relate to health. The EU has shown increasing involvement with health care law and health policy over the last fifteen years.<sup>2</sup> It is also increasingly concerned with human rights.<sup>3</sup> What is perhaps not yet so clear is how the two will relate to each other. In other words, how will enhanced engagement with human rights at the EU level impact upon health law? And will one consequence of the EU Charter be that a particularly 'EU' approach to human rights in health and health care develops?

<sup>1</sup> See T. Hervey and J. Kenner (eds.), *Economic and social rights under the EU Charter of Fundamental Rights: a legal perspective* (Oxford: Hart 2003); S. Peers and A. Ward, *The EU Charter of Fundamental Rights; politics, law and policy* (Oxford: Hart, 2004). The Treaty of Lisbon changes the position of the Charter from that of soft law to being legally enforceable.

<sup>2</sup> See, for example, T. Hervey and J. McHale, *Health law and the European Union* (Cambridge: Cambridge University Press, 2004); M. McKee, E. Mossialos and R. Baeten (eds.), *The impact of EU law on health care systems* (Brussels: PIE-Peter Lang, 2002). This chapter takes an expansive interpretation of the terms 'health care law' and 'health law', following the approach taken in Hervey and McHale.

<sup>3</sup> Most recently, with the establishment of the European Fundamental Rights Agency, which commenced its first work programme in 2008. See Council Decision 2008/203/EC implementing Regulation 168/2007/EC as regards the adoption of a multi-annual framework for the European Union Agency for Fundamental Rights for 2007–2012, OJ 2008 No. L63/14.

Section two of this chapter explores the relationship between human rights and the regulation of health and health care. It considers various human rights principles with relevance in health contexts, as developed at the international and Council of Europe level. By reference to selected examples, it explores some of the ways in which human rights have affected health and health care at the Member State level. Diverse national approaches to controversial ethical questions may give rise to particular challenges for the EU in attempting to construct health and health care law and policy in the light of human rights principles in the future.

The third section of the chapter focuses upon the impact of human rights principles upon the EU itself. That is, in the formulation of health law and health policy in the light of the EU Charter and the recent creation of the European Union Agency for Fundamental Rights. The chapter considers how such fundamental rights principles may be utilized in developing law and policy in this area in the future. It explores whether the EU Charter will really provide radical change or whether, ultimately, the EU Charter is likely to operate more at a rhetorical level, with limited practical effects.

## 2. Fundamental human rights and health care law

The discourse of human rights has pervaded the regulation of health care across jurisdictions.<sup>4</sup> This has been particularly the case following the Nuremberg trials and the development of the Universal Declaration of Human Rights. Human rights can be loosely divided into ‘negative’ and ‘positive’ rights. Negative rights are typically contained in traditional so-called civil and political statements of human rights. These rights statements have been in existence for considerable periods of time – in some cases, several hundred years, as in the case of the United States Bill of Rights. Such rights include

<sup>4</sup> See, for example, J. Mann *et al.* (eds.), *Health and human rights: a reader* (London: Routledge, 1999); E. Wicks, *Human rights and health care* (Oxford: Hart, 2006); A. Hendriks, ‘The right to health’, *European Journal of Health Law* 5 (1998), 389; J. McHale, ‘Enforcing health care rights in the English courts’, in R. Burchill, D. Harris and A. Owers (eds.), *Economic, social and cultural rights: their implementation in UK law* (Nottingham: University of Nottingham Human Rights Centre, 1999); B. Tobes, *The right to health as a human right in international law* (Antwerp: Intersentia Publishers, 1999).

the right to life and rights to privacy of home and family life. They do not usually involve expenditure of public resources. In contrast, positive rights are to be found in more modern, frequently termed 'socioeconomic', human rights statements. Examples include the right to health and right to education. Positive rights typically involve expenditure of public money and tend to be characteristic of more affluent societies.

Several international human rights documents refer to rights applicable in the context of health law and health policy. A right to health was first explicitly stated in the Preamble of the World Health Organization (WHO) Constitution in 1946. Some United Nations human rights documents directly address health, such as the right to a standard of living adequate for health and well-being,<sup>5</sup> or the need for recognition of the highest attainable standard of physical and mental health.<sup>6</sup> International rights declarations refer to health in the work-place.<sup>7</sup> Other provisions contained in international statements of human rights, while not referring directly to health, may be seen as relevant to claims for rights to particular treatments.<sup>8</sup> Right to life claims may be used in disputes concerning the law on abortion or end of life decision-making, while rights on non-discrimination and privacy may also apply to those with particular medical conditions and their right not to be required to disclose this. Rights declarations also commonly contain prohibitions on torture and inhuman and degrading treatment, seen as a fundamental non-derogable right,<sup>9</sup> and prohibitions on unjustified detention. These may apply in health contexts, for instance where restrictions or limitations are placed upon persons with HIV/AIDS.<sup>10</sup> They may

<sup>5</sup> Article 25, Universal Declaration of Human Rights, adopted 10 December 1948 under General Assembly Resolution 217 A (III), UN Doc. A/810, 71.

<sup>6</sup> Article 12(1), *International Covenant on Economic, Social and Cultural Rights*, New York, 19 December 1966, in force 3 January 1976, 993 UNTS 3; 6 ILM 360.

<sup>7</sup> Article 6, Universal Declaration of Human Rights, above n.5.

<sup>8</sup> See Article 3, Universal Declaration of Human Rights, above n.5; and Article 1, *International Covenant on Civil and Political Rights*, New York, 19 December 1966, in force 23 March 1976, 999 UNTS 171; 6 ILM 368.

<sup>9</sup> Article 5, Universal Declaration of Human Rights, above n.5.

<sup>10</sup> See, for example, *Enhorn v. Sweden* (2005) 41 EHRR 633.

also apply in a situation in which a severely incapacitated person is denied access to euthanasia.<sup>11</sup>

The perceived importance in Europe of recognizing human rights in the context of health care is illustrated by the Council of Europe's Convention on Human Rights and Biomedicine.<sup>12</sup> Article 1 of the Biomedicine Convention states that its purpose and object is to safeguard the dignity and identity of all human beings and respect their integrity and other fundamental rights and freedoms. The Convention refers to several rights that are central in health care settings, such as those concerning: consent to treatment;<sup>13</sup> private life and the right to information;<sup>14</sup> controls on genetics and the prohibition of discrimination;<sup>15</sup> research;<sup>16</sup> and the removal of organs and tissue from living donors for transplantation purposes.<sup>17</sup> The Council of Europe has also produced additional protocols on cloning,<sup>18</sup> transplantation<sup>19</sup> and biomedical research.<sup>20</sup> While the Convention and its related protocols are influential, a number of European countries, including Austria, Belgium, France, Germany,

<sup>11</sup> *Pretty v. UK* (2002) 35 EHRR 1.

<sup>12</sup> Council of Europe 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, Oviedo, 4 April 1997, in force 1 December 1999, ETS No. 164, <http://conventions.coe.int/treaty/en/treaties/html/164.htm>. See P. Zilgavis, 'The European Convention on Biomedicine: its past, present and future', in A. Garwood-Gowers, J. Tingle and T. Lewis (eds.), *Healthcare law: the impact of the Human Rights Act 1998* (London: Cavendish, 2001).

<sup>13</sup> Articles 5–9, Biomedicine Convention, above n.12.

<sup>14</sup> Article 12, Biomedicine Convention, above n.12.

<sup>15</sup> Articles 11–3, Biomedicine Convention, above n.12.

<sup>16</sup> Articles 15–8, Biomedicine Convention, above n.12.

<sup>17</sup> Articles 21–2, Biomedicine Convention, above n.12.

<sup>18</sup> Council of Europe 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, Paris, 12 January 1998, in force 1 March 2001, ETS No. 168, <http://conventions.coe.int/treaty/en/treaties/html/168.htm>.

<sup>19</sup> Council of Europe Additional Protocol to the Convention on Human Rights and Biomedicine, on Transplantation of Organs and Tissues of Human Origin, Strasbourg, 24 January 2002, in force 1 May 2006, ETS No. 186, <http://conventions.coe.int/treaty/en/treaties/html/186.htm>.

<sup>20</sup> Council of Europe Additional Protocol to the Convention on Human Rights and Biomedicine, on Biomedical Research, Strasbourg, 25 January 2005, in force 1 September 2007, ETS No. 195, <http://conventions.coe.int/treaty/en/treaties/html/195.htm>.

Ireland, Luxembourg, Malta, the Netherlands, Poland, Sweden and the United Kingdom, have not ratified – or, in some cases, even become signatories to – the Convention. Of more significance, therefore, are the Council of Europe’s general human rights instruments: the European Convention for the Protection of Human Rights and Fundamental Freedoms and the European Social Charter.<sup>21</sup>

### A. *The European Convention on Human Rights*

The Council of Europe’s 1950 Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) has been particularly influential in framing human rights discourse across Europe. All Member States of the EU are also members of the Council of Europe. The ECHR is a traditional statement of civil and political rights. Many Member States who are subject to the Convention have signed protocols enabling individual citizens to bring cases before the European Court of Human Rights. Over the years, a considerable number of actions brought before the European Court of Human Rights have concerned health and health care. For example, the right to life in Article 2 ECHR has been used in claims concerning the status of the fetus and abortion,<sup>22</sup> resource allocation in health care systems<sup>23</sup> and the ‘right to die’.<sup>24</sup> Article 5 ECHR on the right to liberty and security of the person has been used extensively in the context of mental health.<sup>25</sup> Article 8 on the right to privacy has been used in claims concerning reproductive rights<sup>26</sup> (and may also have relevance to people with learning disabilities or mental illness), as has Article 12 ECHR on the right to marry and found a family.<sup>27</sup>

<sup>21</sup> Council of Europe Convention for the Protection of Human Rights and Fundamental Freedoms, Rome, 4 November 1950, in force 3 September 1953, ETS No. 5, <http://conventions.coe.int/treaty/en/treaties/html/5.htm>; Council of Europe European Social Charter, Turin, 18 October 1961, in force 26 February 1965, ETS No. 35, <http://conventions.coe.int/treaty/en/treaties/html/35.htm>.

<sup>22</sup> *H v. Norway* (1992) 73 DR 155; *Open Door and Dublin Well Woman v. Ireland* (1992) 15 EHRR 244; *Paton v. UK* (1981) 3 EHRR 408.

<sup>23</sup> *Osman v. UK* (1998) 29 EHRR 245; *Scialaqua v. Italy* (1998) 26 EHRR 164.

<sup>24</sup> *Pretty v. UK*, above n.11.

<sup>25</sup> See, for example, *Winterwerp v. The Netherlands* (1992) 15 EHRR 437; *Aerts v. Belgium* (2000) 29 EHRR 50.

<sup>26</sup> *Evans v. UK* (2007) 43 EHRR 21. <sup>27</sup> *Dickson v. UK* (2006) 46 EHRR 419.

The jurisprudence of the European Court of Human Rights has had an impact on the development of health care rights across Europe. Nonetheless, the approach taken by the Court to certain controversial issues where there are wide differences in religious and ethical perspectives across states illustrates the difficulty in utilizing a human rights approach in developing health law and health policy across the EU. This is particularly notable, for example, in the context of reproductive rights. In some Member States, specific legal status is given to the embryo and fetus, which leads to consequent limitations on women's claims to reproductive rights. For example, in the Republic of Ireland, Article 40(3)(3) of the Irish Constitution provides that: '[t]he 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'. This provision is regarded as so fundamental in the Irish Republic that it led to Protocol 17 being annexed to the Treaty on European Union.<sup>28</sup> This states that: '[n]othing in the Treaty on European Union or in the Treaties establishing the European Communities or in the Treaties or Acts modifying or supplementing those Treaties, shall affect the application in Ireland of Article 40.3.3. of the Constitution of Ireland'.

Poland also has restrictive abortion laws. The Polish Family Planning (Protection of the Human Fetus and Conditions Permitting Pregnancy Termination) Act 1993 provides that abortion may be undertaken only where a woman's health is at serious risk, where the fetus is irreparably damaged or if the pregnancy was the result of rape or incest.<sup>29</sup> In contrast, other Member States have comparatively broad abortion legislation. In England and Wales for example, while abortion itself still remains a criminal offence,<sup>30</sup> the fetus is not recognized as having separate legal personality<sup>31</sup> and the current grounds for abortion contained in the Abortion Act 1967 apply

<sup>28</sup> Indeed, public distrust of the EU and its potential effect on this provision of the Irish Constitution may partially account for the 'no' vote in the Irish referendum on the Treaty of Lisbon, June 2008.

<sup>29</sup> The operation of this provision was recently challenged successfully at the ECtHR in *Tysiac v. Poland* (2007) 45 EHRR 42, and in September 2007 the ECtHR said that it would not review this judgement.

<sup>30</sup> Sections 58 and 59, Offences Against the Person Act 1861.

<sup>31</sup> *Paton v. BPAS* [1978] 2 All ER 987.

particularly where women seek an abortion in the first twenty-four weeks of pregnancy.<sup>32</sup>

Another example is that of the disparate approaches taken to the regulation of modern reproductive technology across Europe. In some Member States, there is statutory regulation of modern reproductive technologies. So, for example, in the United Kingdom, modern reproductive technology is regulated through the Human Fertilisation and Embryology Act 1990 and a regulatory authority established under that Act, the Human Fertilisation and Embryology Authority (HFEA). There are certain statutory prohibitions on some controversial technologies, such as reproductive cloning.<sup>33</sup> The HFEA also prohibits clinics undertaking certain techniques such as sex selection for social purposes.<sup>34</sup> Nonetheless, it remains the case that clinics providing modern reproductive services are given considerable discretion in selecting patients and the legislation allows the storage of gametes and embryos for research and treatment purposes. While there are some limitations on the conduct of embryo research (for example, research cannot be undertaken on the embryo fourteen days after creation) the embryo has no recognition as having legal personality.<sup>35</sup> Likewise, in Belgium, where the law was reformed in 2007 with the introduction of the Law on Medically Assisted Reproduction and the Disposition of Supernumerary Embryos and Gametes, there is a liberal scheme of regulation.<sup>36</sup> Considerable discretion is given to physicians and in vitro fertilization (IVF) centres in determining both which treatments should be provided and who should have access to those treatments. So, for example, although there is a ban on eugenic selection and sex-selection for nonmedical purposes, IVF centres appear to be free to decide where pre-implantation genetic diagnosis can be used.

A contrasting regulatory approach is that of Italy, a Member State notable in the past for its limited regulation of modern reproductive

<sup>32</sup> Abortion Act 1967, as amended by the Human Fertilisation and Embryology Act 1990.

<sup>33</sup> Human Reproductive Cloning Act 2001.

<sup>34</sup> Human Fertilisation and Embryology Authority, *Code of Practice*, 7th ed. (London: Human Fertilisation and Embryology Authority, 2007), para. 1.13.11.

<sup>35</sup> Section 3, Human Fertilisation and Embryology Act 1990.

<sup>36</sup> See G. Pennings, 'Belgian law on medically assisted reproduction and the disposition of supernumerary embryos and gametes', *European Journal of Health Law* 14 (2007), p. 251.

technology. The legal position in Italy changed radically in 2004 when the new law imposed a much more restrictive regime.<sup>37</sup> Embryos are now equated in their legal status with neonates. The Italian law prohibits embryo screening, freezing of pre-implanted embryos, sperm and egg donation, surrogacy and embryo research.

Given such disparities in the approaches, it is unsurprising that the Council of Europe institutions have afforded a wide margin of appreciation to states where the issues that come before it are acutely and ethically controversial in nature.<sup>38</sup> The margin of appreciation doctrine allows discretion to individual states to interpret Convention provisions, taking into account their particular national circumstances and traditions, such as cultural practices or religious or historic traditions. So, for example, in *Paton v. United Kingdom*,<sup>39</sup> a married man sought, unsuccessfully, to stop his wife from having an abortion. It was alleged that not preventing the abortion constituted an infringement of the right to life of the fetus. The European Court of Human Rights rejected this claim, emphasizing the relationship between woman and fetus. It was noted that, were Article 2 on the right to life to apply to the fetus, then this would have the consequence that abortions would be unavailable even in a situation in which further continuation with pregnancy constituted a risk to the woman's life. Subsequently, in *Vo v. France*,<sup>40</sup> the European Court of Human Rights recognized that there were widely divergent views across Europe as to the status of the fetus, whether it was a 'person' and when life began. The Court also noted that this issue was left unclear in the Council of Europe Convention on Human Rights and Biomedicine, and took the approach that: 'it is neither desirable, nor even possible as matters stand, to answer in the abstract the question whether the unborn child is a person for purposes of the Article of the

<sup>37</sup> See J. A. Robertson, 'Protecting embryos and burdening women: assisted reproduction in Italy', *Human Reproduction* 19 (2004), 1693; R. Fenton, 'Catholic law versus women's reproductive rights', *Medical Law Review* 14 (2005), 73.

<sup>38</sup> See Y. Arai-Takahashi, *The margin of appreciation doctrine and the principle of proportionality* (New York: Intersentia Publishers, 2002).

<sup>39</sup> *Paton v. UK* (1980) 3 EHRR 408.

<sup>40</sup> *Vo v. France* (2005) 40 EHRR 12. See also K. O. Donovan, 'Taking a neutral stance on the legal protection of the fetus', *Medical Law Review* 14 (2006), 115. See confirmation that the embryo has no right to life under *Evans v. UK*, above n.26, p. 200.



Convention'. Instead, the Court afforded a margin of appreciation to the state on this issue.<sup>41</sup>

### B. *The European Social Charter*

The European Convention on Human Rights is largely a traditional civil/political statement of ('negative') rights. Nonetheless, there has been some engagement with socioeconomic ('positive') rights at the Council of Europe, notably through the 1961 European Social Charter (revised 1996).<sup>42</sup> Like the ECHR, the European Social Charter operates through international law, binding the states that are signatories to it, which include all the Member States of the EU. Article 11 of the European Social Charter refers to the right to the protection of health:

With a view to ensuring the effective exercise of the right to protection of health, the Contracting Parties undertake, either directly or in co-operation with public or private organizations, to take appropriate measures designed, *inter alia*:

1. to remove as far as possible the causes of ill-health;
2. to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health; and
3. to prevent as far as possible epidemic, endemic and other diseases as well as accidents.

The European Social Charter is overseen by the European Committee of Social Rights, which 'makes a legal assessment of the conformity of national situations with the European Social Charter ... and adopts conclusions in the framework of the reporting procedure'.<sup>43</sup> According

<sup>41</sup> There were dissenting judgements. Two judges took the approach that Article 2 was applicable but not violated. See also *Evans v. UK*, above n.26; *RH v. Norway* (1992) 73 DR 155; *Boso v. Italy* [2002] ECHR-VII.

<sup>42</sup> European Social Charter, above n.21; Council of Europe European Social Charter (revised), Strasbourg, 3 May 1996, in force 1 July 1999, <http://conventions.coe.int/Treaty/en/Treaties/Html/163.htm>. See T. Hervey, 'We don't see a connection: "the right to health" in the EU Charter and European Social Charter', in G. de Búrca and B. de Witte (eds.), *Social rights in Europe* (Oxford: Oxford University Press, 2005).

<sup>43</sup> Rules of the European Committee of Social Rights, March 2004. See R. Brillat, 'The supervisory machinery of the ESC: recent developments and their impact', in *ibid*.

to the Committee's Conclusions, under the European Social Charter states must provide evidence of compliance with six aspects of the right to health. These are, first, a health care system including public health arrangements providing for generally available 'medical and para-medical practitioners and adequate equipment consistent with meeting its main health problems ensuring a proper medical care for the whole population'. Second, it requires the provision of special measures safeguarding health and health care access for vulnerable groups. Third, public health protection measures, preventing air and water pollution, noise abatement, food control and environmental hygiene, must be provided. Fourth, there is a requirement to provide health education. Fifth, in order to prevent epidemics, measures providing vaccination, disinfection and control of epidemics are required. A sixth aspect, although, as noted by Hervey,<sup>44</sup> not explicitly stated as such, is that there shall be 'the bearing by collective bodies of all, or at least a part of, the cost of health services'.<sup>45</sup>

The Committee has in the past been critical of health care provision by several Member States of the EU. For example, in 2001, the Committee expressed concern that there were increased waiting list times in the United Kingdom and they stated that, in light of the data, they considered that 'the organization of health care in the United Kingdom is manifestly not adapted to ensure the right to health for everyone'.<sup>46</sup> Regarding the sixth aspect of Article 11 of the Revised European Social Charter, the efficacy of this provision, however, is limited in that considerable discretion is given to states to determine its ambit.<sup>47</sup> In addition, although collective complaints can be brought by specific international nongovernmental organizations

<sup>44</sup> Hervey, 'We don't see a connection', above n.42.

<sup>45</sup> Council of Europe, *Case Law on the European Social Charter* (Strasbourg: Council of Europe, 1982), Conclusions I, at 59.

<sup>46</sup> See Doc. c-15-2-en2, discussed in T. Hervey, 'The right to health in European Union law', in Hervey and Kenner (eds.), *Economic and social rights*, above n.1, p. 208. The Committee has also cited Greece as not properly fulfilling its obligations under Article 2(4) in granting compensatory measures to workers exposed to occupational health risks. See Council of Europe European Social Charter, Turin, 18 October, 1961, in force 26 February 1965, ETS No. 35, <http://conventions.coe.int/treaty/en/treaties/html/195.htm>, European Committee of Social Rights, General Introduction – Conclusions XVIII-2.

<sup>47</sup> Hervey, 'We don't see a connection', above n.42.

enjoying participatory status with the Council of Europe, in contrast to the ECHR, the European Social Charter does not have a mechanism enabling individuals to bring specific claims before the European Committee of Social Rights.<sup>48</sup>

### *C. Health, human rights and Member States*

In addition to the recognition given to human rights principles applicable in health care at the international and Council of Europe level, notable protection is given to human rights principles in general and, in certain cases, specifically to rights in the context of health care law at individual Member State level. All EU Member States have their own human rights legislation and, in many cases, this has been utilized in the context of health care. The United Kingdom, for example, has the Human Rights Act 1998, which has the effect of incorporating certain of the provisions of the ECHR into English law. Legislation and case-law must be interpreted in a manner that is compatible with the ECHR.<sup>49</sup> While the legislation does not enable the courts to strike down primary legislation, they may issue what is known as a 'declaration of incompatibility',<sup>50</sup> which places considerable pressure upon the United Kingdom Government to amend the law accordingly. However, in practice, the impact of human rights principles upon health care law in the United Kingdom since the Act came into force on 1 October 2001 has been somewhat muted. Mirroring the position at ECHR level, the national courts have afforded a wide margin of appreciation in ethically controversial cases.<sup>51</sup> The main exception is a willingness to intervene in mental health cases, where the European Commission and Court of Human Rights have a long history of judicial intervention.

Many EU Member States have enacted specific patients' rights legislation, although before the 1994 Amsterdam Declaration only Finland

<sup>48</sup> See further discussion in P. Alston, 'Assessing the strengths and weaknesses of the European Social Charter's advisory system', in de Búrca and de Witte (eds.), *Social rights in Europe*, above n.42.

<sup>49</sup> Sections 2 and 3, Human Rights Act 1998.

<sup>50</sup> Section 4, Human Rights Act 1998.

<sup>51</sup> For example, see in relation to assisted suicide, *R (on the application of Pretty) v. DPP* [2001] 1 All ER 1; *NHS Trust A v. M* [2001] Fam 348, on withdrawal of artificial nutrition/hydration from adults lacking mental capacity.

had its own specific patients' rights legislation as separate from more general health legislation. The Amsterdam Declaration, which followed the European Consultation on the Rights of Patients held in Amsterdam on 28–30 March 1994 (organized by the WHO Regional Office for Europe and hosted by the Government of the Netherlands), endorsed a document entitled 'The principles of the rights of patients in Europe: a common framework'.<sup>52</sup> Patients' rights legislation followed in a range of Member States.<sup>53</sup> The Danish Patients' Rights Act 1998, for instance, makes specific provision for the protection of the rights to dignity, integrity and autonomy.<sup>54</sup> In other European states, patients' rights continue to be included as part of general health legislation.<sup>55</sup> Rights to health are also found in the constitutions of several Member States.<sup>56</sup> It is perhaps interesting to note that in Germany, while the right to health is included in the constitutions of several *Bundesländer*, it is not part of the Federal Constitution. The closest provision here is the 'right to life and physical integrity'.<sup>57</sup>

At the international, European and national levels, there is considerable engagement with human rights in health and health care. But what is striking is that, while there is a commonality of

<sup>52</sup> Declaration of the World Health Organization's European Member States on the Promotion of Patients' Rights in Europe, European Consultation on the Rights of Patients, Amsterdam, 28–30 March 1994, Doc No. ICP/HLE 121, 28 June 1994, Annex, [www.who.int/genomics/public/eu\\_declaration1994.pdf](http://www.who.int/genomics/public/eu_declaration1994.pdf).

<sup>53</sup> For example, Belgium, Patients Rights Act 2002; Romania, Law of Patients Rights 2003; Lithuania, Law on Patients' Rights and Compensation of Damage to their Health 2005. For a discussion, see L. Fallsberg, 'Patients' rights in Europe', *European Journal of Health Law* 10 (2003), 5.

<sup>54</sup> L. Fallsberg, 'Patients' rights in the Nordic countries', *European Journal of Health Law* 7 (2000), 123.

<sup>55</sup> For example, Bulgarian Health Care Reform and Health Care Act 2004. See, further, S. Aleksandrova, 'The Bulgarian health care reform and Health Care Act 2004', *Medicine and Law* 26 (2007), 1.

<sup>56</sup> See, for example, Article 23 of the Belgian Constitution; Article 31 of the Constitution of the Czech Republic; Article 28 of the Estonian Constitution; Chapter 2, Section 19(3) of the Finnish Constitution; Article 70D of the Hungarian Constitution; Article 32 of the Italian Constitution; Article 111 of the Lithuanian Constitution; Article 11(5) of the Luxembourg Constitution; Article 22(1) of the Netherlands Constitution; Article 64(1) of the Portuguese Constitution; Article 40 of the Slovak Constitution; Article 43 of the Spanish Constitution.

<sup>57</sup> Article 2 (Personal Freedoms) of the German Constitution.

approaches across many jurisdictions in *general* rights statements, the interpretation and *specific* regulatory responses to such rights can be considerably different. This is particularly notable in the ethical controversies around the boundaries of life and death, such as abortion and euthanasia. However, it can also be observed in different responses to respect for principles of autonomy in matters which, on their face, would appear to attract less controversy, such as consent to treatment. Such diversity may result in regulatory challenges as the EU develops its health law and policy in light of increasing engagement with human rights.

### 3. Human rights, health law and the EU

The international and Council of Europe statements, along with the developments at national level outlined so far, provide the backdrop to the current position of the EU. The EU has itself affirmed recognition of principles of fundamental rights. The European Court of Justice has long recognized fundamental rights as part of EU law.<sup>58</sup> It has confirmed that those rights included in the ECHR are part of EU law and has further noted that the ECHR is of special significance when formulating fundamental rights in EU law.<sup>59</sup> When implementing EU law<sup>60</sup> or in derogating from Treaty obligations,<sup>61</sup> Member States must respect fundamental rights as general principles of EU law. However, historically, the EU has followed a ‘negative’ approach to the protection of fundamental rights. De Schutter comments that these have operated as limitations on EU institutions or the authority of Member States in the application of EU law.<sup>62</sup> They do not, in general, provide ‘positive’ entitlements against national authorities, which remain the main bodies that might infringe an individual’s human rights in health care settings or elsewhere. Moreover, the European Court of Justice has ruled that

<sup>58</sup> Case 11/70, *International Handelsgesellschaft mbH v. Einfuhr* [1970] ECR 1125.

<sup>59</sup> Case 36/75, *Rutili* [1975] ECR 1219; Case 44/79, *Hauer* [1979] ECR 321; Case C-274/99, *Connolly v. Commission* [2001] ECR I-1611; Opinion 2/94 on Accession by the Community to the ECHR [1996] ECR-I-1759, para. 33.

<sup>60</sup> Case 5/88, *Wachauf* [1989] ECR 2609.

<sup>61</sup> Case C-260/89, *ERT* [1991] ECR-I-2925.

<sup>62</sup> O. De Schutter, ‘Fundamental rights and the transformation of governance in the European Union’, Reflexive Governance in the Public Interest Programme Working Paper REFGOV-FR-13 (2007).

the EU institutions do not enjoy general powers to enact human rights rules or to conclude international human rights conventions.<sup>63</sup>

The Treaty on European Union states that the EU rests on principles of 'liberty, democracy, respect for human rights and fundamental freedoms and the rule of law'.<sup>64</sup> The European Court of Justice has the power to ensure that these principles are respected by the European institutions.<sup>65</sup> The Treaty on European Union also provides in Article 6(2) that:

The Union shall respect fundamental rights as these are guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional traditions common to Member States, as general principles of Community law.

In addition, the Council has power under Article 7 TEU to take actions in relation to actual or threatened breaches of principles, which are set out in Article 6(1) TEU. There is also specific provision in Article 13 of the EC Treaty for the Council to act against 'discrimination based on sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation'.

A major development in the EU's human rights agenda is undoubtedly the adoption of the 2000 EU Charter of Fundamental Rights. This section of the chapter focuses upon the EU Charter in the light of the Lisbon Treaty.<sup>66</sup> Although ratification of the Lisbon Treaty has been stalled by the Irish 'no' referendum vote on 12 June 2008, the EU Charter remains a validly adopted measure of EU 'soft law'. The EU Charter draws upon the Treaty of the European Union, the EC Treaty, the ECHR, the European Social Charter and also the case-law of the European Court of Justice and the European Court of Human Rights. The EU Charter thus has considerable symbolic significance. As Kenner has stated: '[p]ut simply, the objective is to make the process of

<sup>63</sup> Accession of the European Commission to the European Convention for the Protection of Fundamental Freedoms. Opinion 2/94, above n.59, paras. 27 and 34.

<sup>64</sup> Article 6(1) TEU. <sup>65</sup> Article 46 TEU.

<sup>66</sup> Charter of Fundamental Rights of the European Union, Nice, 7 December 2000, not yet in force; an adapted version was proclaimed in Strasbourg on 12 December 2007.

European integration more open and legitimate by furnishing it with a layer of rights embodying values with which intrinsically most people can readily identify'.<sup>67</sup> So, although currently a matter of 'soft' law, as Hervey comments, the provisions may still be relevant. For instance, Article 51(1) of the EU Charter, which is addressed to the 'institutions and bodies of the Union', considered alongside Article 6(2) TEU, 'suggests a positive obligation on the institutions to take full account of the EU Charter when performing their legislative tasks'.<sup>68</sup> It also raises the question as to whether the EU Charter may become the basis of judicial review of actions by EU institutions. In addition, as she notes, there is the prospect that courts may consider the related jurisprudence of the European Committee of Social Rights.

Recent developments now suggest that, in the future, the EU Charter may play a much more visible role in health law and health policy issues in the EU.<sup>69</sup> The Treaty of Lisbon will, if it comes into force, change the EU Charter's legal status.<sup>70</sup> A new Article 6(1) will be inserted into the Treaty of the European Union, which provides that the Charter will have the same 'legal value' as the Treaties. The new Article 6(1) also explicitly states that it does not extend the competences of the Union. The impact of this provision is that the Charter provisions will become 'general principles' of EU law. This means that both EU and Member States, when implementing EU law, will need to comply with the EU Charter. The Charter does not itself expand the competence of the EU; rather, principles of EU law can be utilized in areas where there is already competence. Thus, individual EU citizens will be able to challenge decisions made by EU institutions or by Member States in relation to an issue within EU competence. However, if an issue arises outside the scope of EU law, then a human rights challenge would, as before, have to be brought before national courts, or, if possible, the European Court of Human Rights. In addition, the European Commission will have the power to challenge Member States if it takes the view that the Charter is being violated.

<sup>67</sup> J. Kenner, 'Economic and social rights in the EU legal order: the mirage of indivisibility in economic and social rights in the EU legal order', in Hervey and Kenner (eds.), *Economic and social rights*, above n.1.

<sup>68</sup> T. Hervey, 'We don't see a connection', above n.42.

<sup>69</sup> See, for instance, Hervey and McHale, *Health law*, above n.2.

<sup>70</sup> Treaty of Lisbon, Conference of the Representatives of the Governments of the Member States, C16 14/07, Brussels, 3 December 2007.

Reference is also made in the Treaty to the relationship with the ECHR. The new Article 6 of the Treaty of the European Union as inserted by the Treaty of Lisbon now also states in an important development that:

2. The Union shall accede to the European Convention for the Protection of Fundamental Rights and Freedoms. Such accession shall not affect the Union's competences as defined in the Treaties.
3. Fundamental rights, as guaranteed by the European Convention for the Protection of Fundamental Rights and Fundamental Freedoms and as they result from the constitutional traditions common to the Member States, shall constitute general principles of the Union's law.

This is to be subject to the arrangements set out in the Protocol Relating to Article 6(2) of the Treaty on European Union, which includes that there will be specific provisions in relation to preserving Union law, and for participation of the Union in the control bodies of the European Convention. In addition, mechanisms are to be established to ensure that proceedings regarding non-Member States and individuals are correctly dealt with by Member States and/or the Union where appropriate. Here the focus is on the EU Charter, but the relationship with the Council of Europe institutions will undoubtedly prove to be important and it remains to be seen how the new mechanisms will be developed and will operate.

It is possible that the change to the legal status of the EU Charter may result in more litigation constructed in the form of fundamental rights language.<sup>71</sup> There may also be attempts by individuals to use the EU Charter when bringing litigation at the national level, for example, in respect of seeking access to health care (explored further below).<sup>72</sup> The prospect of such expanded use of the EU Charter led to concerns being expressed during the drafting of the Lisbon Treaty by the United Kingdom and Poland. Polish concerns were that certain provisions of the Charter on moral and family issues would conflict with Polish law. In particular, concerns were expressed regarding same sex marriages. While a new Polish Government

<sup>71</sup> See, further, Hervey and McHale, *Health law*, above n.2, p. 407.

<sup>72</sup> See, further, *ibid.*, p. 408.



took office in November 2007, it indicated that, although it did not share this objection, the opt-out would remain because the governing party needed the support of opposition parties to carry the vote on the Lisbon Treaty.<sup>73</sup> The United Kingdom expressed concerns as to the impact of a legally-binding Charter of Fundamental Rights and Freedoms on British labour law. These two Member States have negotiated a Protocol that provides that the Charter will not extend to enabling the European Court of Justice to find that United Kingdom or Polish law is inconsistent with fundamental rights. Article 1(2) of the Protocol goes on to provide that: ‘nothing in Title IV of the Charter creates justiciable rights applicable to Poland or the UK except in so far that Poland or the United Kingdom has provided for such rights in its national law’.<sup>74</sup>

The most fundamental ‘opt out’ from Lisbon was the Irish ‘no’ vote in its referendum on the Lisbon Treaty. Among the various issues of concern to the Irish population, it seems that the idea that the Lisbon Treaty would challenge current Irish constitutional law on abortion was part of the rationale for this vote.

### *A. The impact of the Charter on health law*

How then will the EU Charter apply to health law and health policy? The EU Charter’s seven titles are: dignity, freedoms, equality, solidarity, citizens’ rights, justice and general provisions involving interpretation and application. The EU Charter differs from documents such as the ECHR in that the rights are very much phrased in absolute terms. Nonetheless, those rights that are included in the EU Charter are likely to be qualified in practice when they are interpreted and applied.<sup>75</sup> In addition, the EU Charter’s Preamble distinguishes between ‘rights, freedoms and principles’. Some of the EU Charter’s articles are certainly written in a manner that indicates that they may be regarded as aspirational (‘principles’) rather than necessarily effectively justiciable (‘rights’ or ‘freedoms’).<sup>76</sup>

<sup>73</sup> BBC, ‘No EU rights charter for Poland’, *BBC News*, 23 November 2007, <http://news.bbc.co.uk/1/hi/world/europe/7109528.stm>.

<sup>74</sup> Protocol No. 7, Treaty of Lisbon.

<sup>75</sup> See, for example, Article 52(1), EU Charter, discussed above and below.

<sup>76</sup> See Lord Goldsmith, ‘A charter of rights, freedoms and principles’, *Common Market Law Review* 38 (2001), 1201.

Several EU Charter provisions are relevant to health law. Chapter I is headed 'Dignity'. Article 1 refers to the fundamental principle of human dignity. There is considerable debate as to what precisely constitutes respect for human dignity.<sup>77</sup> Within this title, as in many international statements of human rights, Article 2 makes explicit reference to the right to life. This, as noted above, is of relevance to the position of the fetus and in end-of-life decision-making. It is also possible that Article 2, combined with Article 35 (discussed below) on the right to health care, may be used in a situation in which access to health care has been denied on the basis that resources are limited. This argument has been utilized in the context of the ECHR.<sup>78</sup> However, more recent cases suggest that its utility in resource allocation challenges may be limited due to the fact that Article 2 ECHR 'must be interpreted in a way which does not impose an impossible or disproportionate burden on the authorities'.<sup>79</sup>

In addition, Article 3 refers to the integrity of the person. The drafting of this provision echoes that of the Council of Europe Convention on Human Rights and Biomedicine. Reference to the integrity of the person is also to be found in the constitutions of a number of EU Member States.<sup>80</sup> Article 3 states that:

2. In the fields of medicine and biology the following must be respected;
  - (a) The free and informed consent of the person concerned according to the procedures laid down by law;
  - (b) The prohibition of eugenic practices, in particular those aiming at the selection of persons;
  - (c) The prohibition on making the human body and its parts as such a source of financial gain;
  - (d) The prohibition of the reproductive cloning of human beings.

<sup>77</sup> See, for example, the discussion in. D. Beylvelde and R. Brownsword, *Human dignity in bioethics and biolaw* (Oxford: Oxford University Press, 2001); H. Biggs, *Euthanasia, death with dignity and the law* (Oxford: Hart, 2001).

<sup>78</sup> *Scialacqua v. Italy* (1998) 26 EHRR 164.

<sup>79</sup> *Osman v. UK*, above n.23.

<sup>80</sup> Article 2, Basic Law of the Federal Republic of Germany: '[e]veryone has the right to life and to physical integrity'; Article 15, Constitution of the Kingdom of Spain: '[e]veryone has a right to life and physical and moral integrity'; Article 25, Constitution of the Portuguese Republic: '[t]he moral and physical integrity of the person is inviolable'.

The provision on informed consent leaves a considerable degree of discretion to Member States and thus implicitly recognizes the prospect for a wide range of different approaches as to what informed consent means and who can give that consent. The prohibition on eugenic practices and selection of persons may prove controversial and lead to challenges if Member States sanction sex selection using modern reproductive technology. The prohibition on making the human body and its parts a source of financial gain also draws upon Article 21 of the Council of Europe Convention on Human Rights and Biomedicine. This principle is already recognized in the EU's Blood Safety Directive<sup>81</sup> and Tissue and Cells Directive.<sup>82</sup> So, for example, the Blood Safety Directive states in Article 20 that: 'Member States shall take the necessary measures to encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are in so far as possible provided from such donations'. The same principle is also now to be found in the Commission's Communication on organ transplantation.<sup>83</sup> This provision could potentially be used in the future as a means of challenges to any proposed legislation facilitating patenting of human genetic material.<sup>84</sup>

Article 4 of the Charter concerns the prohibition on the infliction of torture and inhuman and degrading treatment or punishment. This is a fundamental and universally-recognized civil and political right. Its use in the health care context is a little more problematic. It could be coupled with other rights to challenge provisions that undermine decision-making autonomy. It could perhaps be utilized to claim that failure to make available health care resources resulting in denial of treatment constitutes inhuman or degrading treatment, although in

<sup>81</sup> European Parliament and Council Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, OJ 2003 No. L33/30.

<sup>82</sup> European Parliament and Council Directive 2004/23/EC setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, OJ 2004 No. L102/48.

<sup>83</sup> European Commission, 'Organ donation and transplantation: policy actions at EU level', COM (2007) 275 final, 30 May 2007, para. 3.3; and see also World Health Organization Resolution WHA 42.5 condemning the sale and purchase of organs of human origin.

<sup>84</sup> See Hervey and McHale, *Health law*, above n.2, p. 408.

practice this may be difficult to establish, as the experience of the ECHR illustrates.<sup>85</sup> Article 7 in Chapter II, entitled ‘Freedoms’, covers the right to private life. This provision has been interpreted in the ECHR context as not only being applicable to the privacy of personal information but, in addition, as conferring respect for individual decision-making autonomy and requiring consent to any medical activity that involves an assault on the physical or psychological integrity of a person. Thus, ‘a compulsory medical intervention [without the consent of the person being treated or examined], even if it is of minor importance, constitutes an interference with this right’.<sup>86</sup> Article 7 could, for example, be used in the context of a challenge to national implementation of the Clinical Trials Directive, which concerns the regulation of clinical trials concerning medicinal products in relation to adults lacking mental capacity, on the basis that the Member State had insufficiently protected the rights of the trial subject.<sup>87</sup> It could perhaps be used in a challenge to the faulty implementation of EU environmental law, on the basis that failure to properly assess environmental health risks can constitute a breach of the right to private life.<sup>88</sup>

Also under the title of ‘Freedoms’, Article 8 provides specific protection for personal data. This is relevant in protection of personal health records. The EU has already addressed the need for safeguards of the privacy of personal data through the Data Protection Directive, which

<sup>85</sup> See, for example, an unsuccessful attempt to utilize Article 3 of the ECHR in relation to resource allocation in the UK context in the Court of Appeal in *R v. North West Lancashire HA ex parte A* [2000] 1 WLR 977.

<sup>86</sup> *Y F v. Turkey* (2004) 39 EHRR 34. See also *X v. Austria* (1980) 18 DR 154, p. 155; and *Acmanne and Others v. Belgium* (1984) 40 DR 251, p. 254.

<sup>87</sup> European Parliament and Council Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, OJ 2001 No. L121/34; and Hervey and McHale, *Health law*, above n.2, p. 408.

<sup>88</sup> See *Fadeyeva v. Russia* (2007) 45 EHRR 10, in which, in spite of the wide margin of discretion available to states under Article 8 ECHR, the ECtHR found violation of Article 8 ECHR (right to private life) in a situation where threats to health arose from a steel plant. The Court found that, although the ‘situation around the plant called for a special treatment of those living within the zone, the State did not offer the applicant any effective solution to help her move away from the dangerous area. Furthermore, although the polluting plant in issue operated in breach of domestic environmental standards, there is no indication that the State designed or applied effective measures which would take into account the interests of the local population,

provides controls regarding the processing of personal data.<sup>89</sup> The EU Charter reinforces the EU's commitment to informational privacy.<sup>90</sup> Article 9, the right to marry and found a family, is a right whose ECHR equivalent, Article 12 of the ECHR, as was noted above, has been used in reproductive rights claims. Article 10, which safeguards freedom of thought, conscience and religion, may be utilized by those who believe that the law should take into account principles of individual faith and belief when formulating health law and health policy. The right to freedom of expression and information contained in Article 11 may be pertinent both in relation to public health measures that limit advertising and also potentially to those health care professionals who wish to blow the whistle on poor standards of clinical practice.

Chapter III of the EU Charter concerns 'Equality'. Article 20 states that all people are equal before the law. Article 21 includes the prohibition of discrimination on grounds of sex, race, colour, ethnic or social origin, genetic features, language, religion or belief. Article 24 concerns the rights of the child and provides that children should have the ability to freely express their views and that these should be taken into account in accordance with their age and maturity. Provision is made for the rights of the elderly in Article 25, which include their right to lead a life of dignity and independence, and Article 26 calls for the integration of persons with disabilities into the life of the community on several levels (e.g., political, social). While these three groups containing vulnerable persons are subject to special protection, there is no specific provision safeguarding the rights of those adults who lack mental capacity. Here, the EU Charter stands in contrast to, for example, the EU's approach to the regulation of clinical research, where in the regulation of trials concerning medicinal products, the Clinical Trials Directive contains special controls on research involving both children and adults lacking mental capacity.<sup>91</sup>

affected by the pollution, and which would be capable of reducing the industrial pollution to acceptable levels.'

<sup>89</sup> See Chapter 13 in this volume.

<sup>90</sup> European Parliament and Council Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ 1995 No. L281/31. See, further, Hervey and McHale, *Health law*, above n.2, Chapter 5.

<sup>91</sup> Directive 2001/20/EC, above n.87. See A. Baeyens, 'Implementation of the Clinical Trials Directive: pitfalls and benefits', *European Journal of Health*

One notable aspect of the EU Charter contained in Chapter IV, ‘Solidarity’, is that specific provision is made for a right to health care in Article 35, a provision that is in turn based on Article 11 of the European Social Charter, discussed above. Article 35 provides that:

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

As Hervey notes, there are two elements to this Article.<sup>92</sup> The first is that there is an expression of individual entitlement to health care. The second is that of the repetition of the mainstreaming provision in Article 152 EC. She suggests that ‘[t]his element of the Charter may be seen as a kind of ‘super-mainstreaming’ expression of the values that should underpin EU law and policy’.<sup>93</sup> Article 35 may be (although has not so far been) used in free movement claims in the context of an individual who travels to another Member State to receive treatment and then claims reimbursement of the cost of that treatment. Such free movement claims have already been the subject of considerable jurisprudence over many years before the European Court of Justice.<sup>94</sup> The impact of these cases in arguably constructing a ‘right to health care’, through the application of ‘economic’ free movement principles rather than human rights principles in situations where individuals were subject to undue delay in their home Member States, has led to concerns at the national level as to their impact on resource allocation and to proposed new policy developments at the EU level. In July 2008, the Commission proposed

*Law 8* (2001), 293; and Hervey and McHale, *Health law*, above n.2, pp. 248–59.

<sup>92</sup> Opinion 2/94, above n.59, para. 33.

<sup>93</sup> Hervey, ‘The right to health’, above n.46, p. 202.

<sup>94</sup> See Case C-158/96, *Kohll v. Union des Caisses de Maladie* [1998] ECR-I-1935; Case C-157/99, *Geraet Smits and Peerbooms* [2001] ECR I-05473; Case C-368/98, *Vanbraekel* [2001] ECR-I-5363; Case C-385/99, *Muller Faure* [2003] ECR I-4509; Case C-56/01, *Inizan* [2003] ECR I-12403; Case C-372/04, *Watts* [2006] ECR I-4325; *R. (Watts) v. Bedford Primary Care Trust and Another* [2006] QB 667.

a directive on the application of patients' rights in cross-border health care.<sup>95</sup> This is in keeping with the Court's jurisprudence, in that it constructs patients' 'rights' largely as internal market entitlements.<sup>96</sup> In its explanatory memorandum, the Commission states that the proposal 'respects the fundamental rights and observes the principles recognized in particular by the [EU Charter]'.<sup>97</sup> However, this is expressed simply in terms of the need to implement it with 'due respect for ... the principle of non-discrimination'. Will Article 35 make a practical difference in terms of litigation in the future? Hervey has argued that, while:

[A] 'right to health' might make a difference in terms of the discourse available to judicial bodies to resolve what are effectively matters of resource allocation ... [but] in the final analysis would be unlikely to make a difference in the substantive outcome of any litigation.<sup>98</sup>

Interestingly, however, recent reference was made to the Charter in the opinion of the Advocate General in *Aikaterini Stamatelaki v. NPDD Organismos Asfaliseos Eleftheron Epangelmaton*.<sup>99</sup> Here, the Advocate General commented that:

[A]lthough the case-law takes as the main point of reference the fundamental freedoms established in the Treaty, there is another aspect which is becoming more and more important in the Community sphere, namely the right of citizens to health care, proclaimed in Article 35 of the Charter of Fundamental Rights of the European Union since "being a fundamental asset health cannot be considered solely in terms of social expenditure and latent economic difficulties. This right is perceived as a personal entitlement unconnected to a person's relationship with social security and the Court of Justice cannot overlook that aspect."<sup>100</sup>

<sup>95</sup> European Commission, 'Proposal for a European Parliament and Council Directive on the application of patients' rights in cross-border healthcare', COM (2008) 414 final, 2 July 2008. See also European Commission, 'Consultation Regarding Community action on Health Services', SEC (2006) 1195/4, 26 September 2006.

<sup>96</sup> This is reflected, *inter alia*, in the legal basis of the proposed Directive, Article 95 EC, concerning the creation of the internal market.

<sup>97</sup> European Commission, 'Proposal for a European Parliament and Council Directive', above n.95, p. 12.

<sup>98</sup> Hervey, 'The right to health', above n.46, p. 210.

<sup>99</sup> AG Opinion, Case C-444/05, *Stamatelaki* [2007] ECR I-3185.

<sup>100</sup> *Ibid.*, para. 40.

It remains to be seen to what extent such statements will be reflected in a reframing of jurisprudence in this area. They certainly do not seem to be significant in terms of the Commission's agenda here.

A further problem is that respecting a right to health care combined with other aspects of EU law may sit uneasily with respect for fundamental rights at the national level. So, for example, respect for the free movement principles in the EU Treaty may undermine individual Member States' approaches to issues such as abortion and regulation of reproduction because individuals are able to travel to other jurisdictions to receive services not allowed in their home Member State.<sup>101</sup>

While the provisions in the EU Charter are, on the surface, phrased very much in absolute terms, some limitations are set out in its final chapter. Article 52(1) provides that:

Any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others.

This is a very broad statement and also illustrates a further problem with human rights-based analysis – namely, how can a conflict between one person's rights and the rights and interests of others be effectively resolved? Put bluntly, are some rights more 'valuable' and thus of greater weight in any balancing calculation than others? As Hervey has commented, recognizing the right to health care of one individual is likely to have the effect of diverting resources from another person. She suggests that if an Article 35 right to health care becomes the subject of litigation, the claim of one individual seeking treatment may be denied on the basis that the rights of other persons to health care are respected in such a situation and the decision

<sup>101</sup> See, further, *R v. Human Fertilisation and Embryology Authority, ex parte Blood* [1997] 2 All ER 687; T. Hervey, 'Buy baby: the European Union and regulation of human reproduction', *Oxford Journal of Legal Studies* 18 (1998), 207; R. Lee and D. Morgan, 'In the name of the father? Ex parte Blood: dealing with novelty and anomaly', *Modern Law Review* 60 (1997), 840; Case C-159/90, *Grogan* [1991] ECR I-04685; and see also Hervey and McHale, *Health law*, above n.2, pp. 144–58.



to deny treatment was not disproportionate.<sup>102</sup> In addition, claims to human rights may prove problematic in public health – a matter clearly within the competence of the EU under Article 152 EC – where calculations are made that it is necessary to limit individual human rights in the interest of the community as a whole – for example, to contain the spread of disease.

Article 52(3) states that, where rights included in the EU Charter correspond to those contained in the ECHR, then the meaning and the scope of those rights is treated as the same. This highlights the importance of the ECHR jurisprudence and, in addition, illustrates the limitations of the EU Charter. As noted above, the ECHR has its limitations – in particular, that states are afforded a clear margin of appreciation. It is further stated that the provisions of the EU Charter do not prevent EU law from providing more extensive protection to fundamental rights than that provided by the ECHR. Furthermore, Article 53 provides that the EU Charter is not to be interpreted as restricting human rights provisions that are contained in EU law, international law or international agreements to which the Member States are parties. These provisions thus position the EU Charter as a basic level of protection, while recognizing that human rights protection may be enhanced by the EU. Moreover, they reflect a strong statement that subsidiarity remains very much in force. Article 51(2) states explicitly that the EU Charter ‘does not establish any new power or task for the Community or the Union, or modify powers and tasks as defined by the Treaties’.

Currently, reference is certainly being made to the EU Charter in health policy documents produced by the European Union, such as those on organ transplantation. There is certainly the prospect that the use of the EU Charter may facilitate dialogue across the EU as to what is meant by certain fundamental principles, such as what constitutes ‘informed consent’. However, whether the EU Charter will itself make a considerable difference over the long term in relation to the development of health law and health policy in the EU is uncertain. Human rights concepts can be exceedingly fluid, and those set out in the EU Charter are no exception. Take, for example, the concept of respect for human dignity in Article 1 of the EU Charter. This concept is notoriously uncertain and capable of different interpretations. It has been the subject of

<sup>102</sup> See Hervey, ‘The right to health’, above n.46.

considerable jurisprudence in some jurisdictions, such as France, and yet is not included at all as a legal principle within other jurisdictions.<sup>103</sup> Or take a principle far more generally accepted across the international community, that of the right to life. Nys has commented:

There undoubtedly are certain vexed themes in medical law – such as abortion and euthanasia – where the ideas of the various Member States (but also within states) are so far apart due to religious, philosophical, ethical and other reasons that a common European regulation would be simply unthinkable.<sup>104</sup>

As noted above in the discussion of the ECHR on controversial issues such as abortion, there can be radical differences at the national level as to what constitute fundamental human rights and how such rights shall be protected. States that respect the principle of the sanctity of life may reach very different conclusions as to whether to sanction assisted death – as illustrated by the comparison between Belgium<sup>105</sup> and the Netherlands, where assisted dying is legally sanctioned,<sup>106</sup> and the United Kingdom, where it is a criminal offence.<sup>107</sup>

How might other challenges using the EU Charter operate? As noted previously, a proposed directive concerning stem cell research using fetal material could be subject to challenge under Article 1 (the need to respect human dignity), Article 2 (the right to life) and Article 3 (integrity of the person).<sup>108</sup> Nonetheless, the uncertainty regarding the interpretation of such provisions, along with the considerable discretion given to Member States in relation to issues such as the

<sup>103</sup> Beyleveld and Brownsword, *Human dignity*, above n.77; Biggs, *Euthanasia*, above n.77.

<sup>104</sup> H. Nys, 'Comparative health law and the harmonization of patients' rights in Europe', *European Journal of Health Law* 8 (2001), 317–331, at 317, 325.

<sup>105</sup> Belgium, Euthanasia Act 2002. See also M. Adams and H. Nys, 'Comparative reflections on the Belgium Euthanasia Act 2002', *Medical Law Review* 11 (2003), 353.

<sup>106</sup> Termination of Life on Request and Assisted Review Procedure Act 2001. See also H. Nys, 'Physician involvement in a patient's death: a continental European perspective', *Medical Law Review* 7 (1999), 208; J. de Haan, 'The new Dutch law on euthanasia', *Medical Law Review* 10 (2002), 57.

<sup>107</sup> Section 2, Suicide Act 1961; *R (on the application of Pretty) v. DPP*, above n.51.

<sup>108</sup> Hervey and McHale, *Health law*, above n.2, p. 407.

status or legal position of the fetus suggests that, in practice, such a challenge would be at best problematic and probably unsuccessful. There is the prospect that the EU Charter could have an impact at the national level through Article 51, which provides that the provisions within the Charter are applicable to Member States when implementing EU law.

The EU's continuing engagement with mental health may prove a more fertile area for engagement with human rights, given the extensive EHCR jurisprudence on this issue in the past.<sup>109</sup> The prospect of evolving European standards in the area of mental health is something that is effectively realizable. Here, there is the prospect that the EU may work with and build upon the work of the World Health Organization in the area of mental health.<sup>110</sup> Moreover, many of the issues that arise in mental health, as noted above in the context of the ECHR jurisprudence, relate to more traditional civil and political rights, such as privacy, 'negative' rights that may be less likely to prove controversial in that they usually will not explicitly involve resource allocation questions, nor usually will they involve particularly contentious ethical issues.

### *B. Health rights and the EU Agency for Fundamental Rights*

In addition to the developments mentioned above, in 2007 the EU also established the European Union Agency for Fundamental Rights.<sup>111</sup> This replaces an earlier organization, the European Monitoring Centre for Racism and Xenophobia. The Agency has three roles. First,

<sup>109</sup> See, for example, European Commission, 'Promoting the mental health of the population: towards a strategy on mental health for the European Union', Green Paper, COM (2005) 484 final, 14 October 2005; European Commission, 'Together for health: a strategic approach for the EU 2008–2013', White Paper, COM (2007) 630 final, 23 October 2007. At the meeting of the EPSCO Council on 6 December 2007, Commissioner Markos Kypriano explained to Member States that he intended to organize a High Level Conference on Mental Health. See also Hervey and McHale, *Health law*, above n.2, pp. 435–6; B. Kelly, 'The emerging mental health strategy of the European Union. A multi-level work in progress', *Health Policy* 85(1) (2008) 60–70.

<sup>110</sup> See, for example, World Health Organization, 'Framework on human rights mental health and legislation', [www.who.int/mental\\_health/policy/fact\\_sheet\\_mnh\\_hr\\_leg\\_2105.pdf](http://www.who.int/mental_health/policy/fact_sheet_mnh_hr_leg_2105.pdf).

<sup>111</sup> Council Regulation 168/2007/EC establishing a European Union Agency for Fundamental Rights, OJ 2007 No. L53/1.

it has the task of collating information and data regarding the effects of fundamental rights action taken by the EU and of good practice regarding the promotion of these rights. Second, it provides advice to the EU and its Member States. As part of this role, it undertakes scientific research and preparatory studies, and also formulates and publishes conclusions on specific thematic topics. Third, the Agency promotes dialogue within civil society, to raise awareness of fundamental human rights. This is effected through a cooperative network (a 'Fundamental Rights Platform'), which facilitates exchange of information between the Agency and key stakeholders.

However, the role of the Agency does not extend to systematic, permanent monitoring of human rights in the Member States for the purposes of Article 7 TEU.<sup>112</sup> It is not empowered to examine individual complaints brought by individuals. Neither is the Agency concerned with the legality of EU legislative acts within Article 230 EC. Rather, the Agency will have the task of cooperating with other bodies, such as governments of Member States, national human rights organizations and also other Community and Union agencies. These powers of the Agency suggest that it will fundamentally operate in an expert role, as opposed to that of a traditional supervisory body in international human rights law.

The Agency operates through nine thematic areas, which are determined through a five-year multi-annual framework. The current framework was adopted on 28 February 2008 by the Justice and Home Affairs Council of the European Union.<sup>113</sup> There is no explicit reference to the right to health – or indeed to any social or economic rights – although three areas may be relevant to health. These are: first, discrimination based on sex, race or ethnic origin, religion or belief, disability, age or sexual orientation and against persons belonging to minorities and any combination of these grounds; second, the rights of the child; and, third, the information society and, in particular, respect for private life and protection of personal data.<sup>114</sup> It is intended that the framework will be implemented in a

<sup>112</sup> The Council has stated that it may seek the assistance of the Agency as an independent person during a possible procedure under Article 7 TEU, but will not use the Agency for systematic monitoring for this purpose.

<sup>113</sup> Council Decision 2008/203/EC, above n.3.

<sup>114</sup> Two further thematic areas may also have some relevance to health, even if not as directly. These relate to the 'compensation of victims', which may

manner complementary to the work of other EU bodies, the Council of Europe and also international organizations operating in the area of human rights.

Thus far, the work of the Agency of relevance to health rights has been focused in the area of non-discrimination. Health was added as a ‘thematic area’ of investigation for the first time in the 2007 Annual Report, following evidence from the country reports of the interconnected nature of discrimination against minorities in health and other fields of social life.<sup>115</sup> In particular, work on the most vulnerable in European society – for instance, illegally resident third-country nationals, rejected asylum seekers and members of Roma communities, especially Romani women – has highlighted inequalities (in the form of indirect discrimination) in their access to basic health care, a core component of the right to health care.<sup>116</sup> The work of the Agency builds on earlier work by the European Commission<sup>117</sup> and the European Monitoring Centre on Racism and Xenophobia, which recommends action at the national and local levels, such as establishing a legal duty on public authorities to promote equality; adopting special measures to ensure equality in practice, where cultural attitudes may impede full participation of women in health care decision-making; and a ‘multisectoral’ approach of inclusion in health, education and housing.<sup>118</sup> A consultative meeting in July 2008 set the Agency’s future strategy on Roma communities.

apply to occupational health in respect of claims stemming from injuries in the work-place; and to ‘asylum and immigration’ where the rights (including in regard to health care) of illegal immigrants and asylum seekers is often a source of debate/controversy in the Member States. This is particularly the case where such individuals have not sought asylum via the correct channels and are held in detention pending a decision.

<sup>115</sup> European Union Agency for Fundamental Rights (FRA), ‘Annual Report 2007’, [http://fra.europa.eu/fra/material/pub/ar08/ar-activity\\_En.pdf](http://fra.europa.eu/fra/material/pub/ar08/ar-activity_En.pdf).

<sup>116</sup> See FRA, ‘Annual report 2008’, [http://fra.europa.eu/fra/material/pub/ar08/ar08-memo\\_en.pdf](http://fra.europa.eu/fra/material/pub/ar08/ar08-memo_en.pdf).

<sup>117</sup> See P. Mladovsky, ‘To what extent are Roma disadvantaged in terms of health and access to health care? What policies have been introduced to foster health and social inclusion?’, Research Note for the European Commission, DG Employment and Social Affairs (2007), [http://ec.europa.eu/employment\\_social/spsi/docs/social\\_situation/rn\\_roma\\_health.pdf](http://ec.europa.eu/employment_social/spsi/docs/social_situation/rn_roma_health.pdf).

<sup>118</sup> Council of Europe, *Breaking the barriers – Romani women and access to public health care* (Luxembourg: European Monitoring Centre on Racism and Xenophobia, 2003).

The Agency's 2008 Annual Report<sup>119</sup> highlighted patchy implementation of the EU's anti-discrimination legislation. It also highlighted examples of good practice in tackling racism and discrimination in various areas of public service provision, including health care. Indeed, the 2008 Annual Report included a separate chapter on health care specifically as a new thematic area. Health care is treated as an 'important area of social life', and the report bases its inclusion and analysis on Article 152 of the Treaties along with the 2006 Council of Health Ministers' adoption of common values vis-à-vis health systems towards minimizing health inequalities.<sup>120</sup> The Agency thus adopts a broad view of health, but focuses primarily on issues surrounding discrimination and exclusion, and barriers to access to health care, especially those faced by migrants and minorities. Without going into the Report's findings in detail, noting huge variation in reported ethnic discrimination in health between Member States (both self-reported and reported by health professionals as witnesses to colleagues' behaviour), it highlights formal complaints of discrimination in health care access or treatment in some ten countries: Austria, Bulgaria, the Czech Republic, Cyprus, Finland, Germany, Latvia, Lithuania, the Netherlands and Sweden. At the same time, it points to examples in many countries (including in some of those listed above) of proactive 'good practice' measures taken by national authorities to reduce such inequalities. For instance, strategic plans aimed at those disadvantaged in national health care systems in Bulgaria, Germany, Spain, Hungary, Italy, Ireland, Poland, Portugal, Finland and the United Kingdom were commended.<sup>121</sup> In conclusion, the Agency's specific opinion is that 'Member States and the EU should encourage culturally sensitive training of the health workforce. Staff development and training programmes in the health care system should include components related to Roma-specific needs in health status.'<sup>122</sup> While the Agency's opinions are, of course, not legally enforceable, they may add to the weight of evidence where Member States are failing to guarantee access to health care in a way that discriminates on grounds of race, which may feed into challenges at the

<sup>119</sup> FRA, 'Annual report 2008', above n.116.

<sup>120</sup> Council Conclusions on common values and principles in European Union health systems, OJ 2006 No. C146/1.

<sup>121</sup> FRA, 'Annual report 2008', above n.116, pp. 91–4.

<sup>122</sup> FRA, 'Annual report 2008', above n.116, p. 118.

national level. The Report specifically highlights lack of awareness of potential avenues of legal redress as one of the reasons for low levels of complaints.<sup>123</sup> Awareness raising activities, carried out by national and international human rights NGOs, may lead to litigation based on non-discrimination entitlements, which may change the legal landscape over time. Moreover, the addition of a separate section on health care to the report, assuming that it remains a key thematic area for the future, has the potential to highlight divergences between Member States in the application of Council of Europe provisions concerning health rights, but also the intermeshing between human rights and health care in the EU in general.

#### 4. Conclusions

The EU is becoming increasingly engaged with both health care and with fundamental human rights. It seems likely that, in the future, respect for human rights will be further embedded into the EU with a movement towards rights that are enforceable, rather than operating as 'soft law'. But, while the discourse of fundamental human rights may be used at a general level, in practice it seems unlikely that this will have a radical impact on health law and policy. Respect for fundamental human rights in health care contexts is given practical effect through national laws, policies and practices. The ECHR and the Council of Europe's Social Charter also have had some impact on the development of health law and policy. The EU's Charter of Fundamental Rights and the Fundamental Rights Agency provide mechanisms for enhancing the respect given to fundamental rights in health law and policy in the EU. The Fundamental Rights Agency may play a role, but it is too soon to truly ascertain what its impact might be. In practice, use of the EU Charter, whether in developing health policy or in litigation, is likely to prove problematic for at least four reasons. First, the fluidity or breadth of certain concepts, such as dignity, or positive rights, such as the right to health care, makes them particularly difficult to enforce. Second, the differing religious, cultural and ethical perspectives regarding certain fundamental rights questions make it difficult to develop a truly distinctive EU dimension to fundamental human rights, which would

<sup>123</sup> FRA, 'Annual report 2008', above n.116, p. 107.

require the EU to resolve a wide range of differing religious and cultural approaches across Member States. Respect for equality and diversity of cultural and religious viewpoints does not sit easily with a single 'EU' approach to fundamental human rights in health care. This is notably illustrated by Poland's recent opt-out protocol to the Lisbon Treaty. Third, the EU Charter shares with other human rights instruments an ambiguity about situations where human rights conflict, and does not make it clear how to prioritize one 'fundamental' right against another. Fourth, the scope of the Charter, in itself, is constrained by the competence of the EU. In addition, the enforceability of rights is likely to operate against EU institutions rather than more generally against national authorities, which are the main providers of health care. Furthermore, it is questionable whether the European Court of Justice will utilize the EU Charter as a mechanism for developing a distinctive rights jurisprudence. As Freedman has argued:

The record of the Court of Justice shows that it does not see rights as weapons used to "trump" legislation in the way in which the US Supreme Court does. In fact it has only extremely rarely struck down any provision of EU law for violation of human rights. Instead the Charter is likely to "function as a source of values and norms ... to influence the interpretation of EU legislative and other measures and to feed into policy-making and into EU activities more generally".<sup>124</sup>

It is as yet uncertain whether a discernable EU-specific dimension to fundamental human rights in the context of health care will effectively evolve or whether that is at all possible in practice. Indeed, and relating to the impact of the Charter on domestic policy more generally, a question here is how Articles 51–3 – which appear to be reaffirmations of subsidiarity and the status quo regarding no interference with national laws, constitutions and practices – will be interpreted in practice, for a strong emphasis given to specific rights that are to be ensured and administered by the Member States, such as in respect of social security and health care, would be meaningless if no tangible impact on the Member States were envisaged.

<sup>124</sup> See S. Freedman, 'Transformation or dilution: fundamental rights in the EU social space', *European Law Journal* 12 (2006), 41–60, at 41, 57.



Thus, while fundamental human rights may raise awareness and may provide a means of framing debate, it is questionable whether the assertion of fundamental rights claims in the future will necessarily provide definitive 'solutions' in many areas of health and health care law and policy in the EU. Nonetheless, that does not mean that fundamental rights should be seen as redundant. Indeed, the conflicts between them, and the different perspectives that rights analysis brings, may be invaluable in structuring policy formulation. The provisions of the EU Charter, elaborated through the work of the EU Agency for Fundamental Rights, may place EU institutions and Member States in a better position to develop law and policy in the future. As has been suggested by Freedman, the EU Charter can in the long term, perhaps, be seen as valuable in terms of the use of new forms of governance in the context of health care, such as mainstreaming and the open method of coordination.<sup>125</sup> As the recent work of the Fundamental Rights Agency suggests, the principle of non-discrimination may also provide a rich source of legal claims in health fields that has as yet been underexploited.

<sup>125</sup> *Ibid.*, 41.