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The Immediate Futures of EU Health Law in the UK after Brexit

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Abstract

Over a year after the referendum on EU membership, even the broad parameters of the legal arrangements of Brexit remain frustratingly unclear. Details are woefully lacking. The EU insists that a withdrawal agreement must be settled before discussing any future EU/UK (trade) agreement(s). The withdrawal agreement will cover the position of R-EU nationals in the UK and vice versa and the UK's liabilities to the EU. Both have implications for health law. The UK intends to secure legal continuity and reform through statute and executive action. EU law is deeply entwined in UK health law, albeit often indirectly. No area of health law will remain entirely untouched by Brexit. This article considers the implications of the withdrawal agreement, and the EU (Withdrawal) Bill, on key aspects of UK health law, and argues that the health law community must be attentive to these unfolding processes. [146 words]

1. Introduction

Health – in particular the NHS – was a key issue in the EU referendum. Many people voted to leave the EU on the promise of an extra £350 million a week being paid into the NHS. That promise turned out to be unfounded in reality. Far from improving health, or enhancing the NHS, Brexit brings huge challenges for legislators and policymakers who seek to secure health care and population health in the UK outside of the EU. This is because EU law has affected health law and policy in the UK for decades – in many instances since the UK joined the EU in the 1970s.[1] It is deeply entwined in the delivery of health (both population health and health and social care) in the UK's devolved nations, and in health law and policy that applies across the whole of the UK.

This article explores how changes to UK health law, policy and practice, covered by EU law since before the UK joined, will be managed immediately post-Brexit.[2] Before we can consider that in any detail, we need to understand what UK health law will lose with EU membership. EU health law is 'transversal'.[3] Cutting across different areas of EU law, it is found in what may seem to be surprising places, especially to health lawyers and those in the health policy community.

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[1] For an overview, see, e.g., T. Hervey and J. McHale, *European Union Health Law: Themes and Implications* (Cambridge University Press, 2015).

[2] There are also important implications for EU health law without the UK: these will not be covered here.

[3] T. Hervey, 'EU Health Law' in C. Barnard and S. Peers, eds, 2nd ed, *EU Law* (Oxford: OUP, forthcoming 2017).

If one considers – as perhaps UK ministers or civil servants may have done –the standard headings of EU law, taken either from the EU Treaties[4] or indeed from a good textbook on EU law, or from the 'chapters' used to negotiate accession of a new EU Member State, or the list of topics of EU law in the EU's Official Journal,[5] one might well imagine that EU law has very little to do with health law. The EU is a body of constrained competences: constitutionally it only has the powers conferred upon it by the Member States as expressed in the EU Treaties. The EU Treaties expressly state that 'the definition of health policy' and 'the organisation and delivery of health services and health care' are a *national* competence.[6] Before the 1990s, when the EU legislature was granted formal competence to adopt health measures, it relied on implied competence, based on the objectives in Article 2 EEC, particularly the 'raising of the standard of living'. Explicit competence to adopt *public* health measures was given to the EU legislature by the Treaty of Maastricht. So the direct effects of EU health law on UK health law are limited to the public health field.[7] These are significant, covering a wide range of matters contributing to overall population health, in particular through the EU's environmental law, including air and water quality, and waste management; the EU's governance of health research; and its steering of behaviour through its public health programmes.[8]

But what is much more important is the *indirect* effects of EU law on UK health law. Much of the EU's health law is based on other competence provisions, in particular those on creating and sustaining the 'internal market'.[9] When the EU legislature adopts measures in other fields that affect health, it is obliged to 'take into account' 'requirements linked to … the protection of human health'.[10] These aspects of EU health legislation include a huge range of matters pertaining to the delivery of health and social care in the UK and for its population. Non-exhaustively, these include, for people: patient mobility; cross-border contracts for health services delivered electronically; protection of patient information and privacy; aspects of health insurance; recognition of medical professional qualifications; aspects of the migration entitlements of the health and social care workforce, such as entitlement to remain in the UK after retiring, to be accompanied by family members whatever their nationality, access to a range of social benefits including housing and education on the same basis as UK nationals; and aspects of the employment entitlements of the health and social care workforce, such as working hours, non-discrimination at work, maternity and paternity leave. They also include, again non-exhaustively, pertaining to products: transparency of pricing of pharmaceuticals within the health system; liability for

[4] The 'Treaty on the Functioning of the European Union' (TFEU) and the 'Treaty on European Union' (TEU), essentially the EU's 'constitution'.

[5] A formal source of EU law.

[6] Article 168 (7) TFEU.

[7] See further, J. Coggon, *What Makes Health Public?* (Cambridge University Press, 2012); L. Gostin, *Public Health Law: Power, Duties and Restraints* (University of California Press, 2008).

[8] For a brief overview, see S. Greer, T. Hervey, M. McKee, J. Mackenbach, 'Health Law and Policy of the European Union' *The Lancet* 27 March 2013 doi:10.1016/S0140-6736(12)62083-2. See further, M. Flear *Governing Public Health: EU Law, Regulation and Biopolitics* (Hart, 2015).

[9] Defined as 'an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties', Article 26 (2) TFEU.

[10] This 'mainstreaming' obligation is found in Articles 9 and 168 (1) Treaty on the Functioning of the EU (TFEU).

harm from defective pharmaceuticals, medical devices or medical equipment; safety of blood, human tissue and organs; marketing of pharmaceuticals, with special rules for 'orphan medicines'; clinical trials; animal research; and aspects of procurement of products and services within the NHS. A wide range of public health matters are also covered, especially food safety, and tobacco regulation.[11]

In addition to Treaty reform and EU legislation, EU health law has been developed through litigation. Such litigation relies on the 'supremacy' of EU law,[12] and the 'directly effective'[13] provisions of the TFEU, especially those on free movement of the factors of production, and on free and fair competition. The Court of Justice of the EU (CJEU) has found that EU law on free movement of goods, services, workers and freedom of establishment, as well as on anti-competitive agreements, and abuse of a dominant position, applies in health contexts. There is nothing special about health law that keeps it immune from the application of EU free movement and competition law. The way the rules are interpreted within EU law matters too: the CJEU often takes into account the special position of health, and a national health (insurance) service, when it interprets the relevant rules.[14] Further, both UK courts and the CJEU refer to 'the right to health' as a provision of EU law when balancing the different interests at issue in health litigation.[15]

Through its direct, but especially its indirect, effects, there is barely an area of UK health law that is untouched by EU health law. Therefore, the terms of the UK's withdrawal agreement with the EU, and what happens to EU law in the UK on Brexit day, will make a significant difference to UK health law. That is why the health law community should be attentive to the political processes as they unfold during the two year period beginning on 29 March 2017, when the UK invoked Article 50 TEU, indicating its intention to leave the EU.

Of course, it will also be critical for the health law community to be attentive to the effects on UK health law of EU/UK relationships further into the future. But as we know so little about what those relationships might be,[16] the focus in this article is on the immediate future.

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[11] For details on all of the above, see T. Hervey and J. McHale, *European Union Health Law: Themes and Implications* (Cambridge University Press, 2015), parts II-III.

[12] Validly adopted EU law must be applied in priority over all conflicting national law, whatever its date of enactment or normative status, see Case 6/64 *Costa v ENEL* [1964] ECR 585.

[13] 'Directly effective' provisions of EU law confer upon individuals rights which are enforceable in national courts, see Case 26/62 *Van Gend en Loos* [1963] ECR 1.

[14] See further, T. Hervey and J. McHale, *European Union Health Law: Themes and Implications* (Cambridge University Press, 2015), pp 73-85; 88-97; 98-126; 127-155; 184-210; 229-291; 536-538.

[15] Article 35 TFEU. See, e.g., Case C-333/14 *Scotch Whisky Association*; Case C-544/10 *Deutsches Weintor*; see also P. Roderick and A. Pollock, 'Brexit's Great Repeal Bill will axe the right to health' *BMJ Editorial*, 357 (2017). Available at: https://doi.org/10.1136/bmj.j2013 (accessed 13 July 2017).

[16] The political signals are changing all the time, which makes it virtually impossible to develop a sustained legal analysis of realistic outcomes further into the future. PM Theresa May's Lancaster House speech on 17 January 2017 (https://www.gov.uk/government/speeches/the-governments-negotiating-objectives-for-exiting-the-eu-pm-speech) included the now infamous line that 'no deal for Britain is better than a bad deal for Britain', suggesting what some have called a 'cliff-edge' or 'no deal' Brexit, where the UK leaves the EU without even negotiating a withdrawal agreement, still less a future EU/UK trade relationship. But the Government's

The next section of the article sets out the broad parameters of the negotiations and the withdrawal agreement, inasmuch as currently available information permits. The third section explains what we currently know about the UK government's plans for legal certainty and continuity. Throughout, the implications of different processes and outcomes for UK health law are analysed.

2. The negotiations and the withdrawal agreement

2.1 The negotiations

Many of the parameters of the legal arrangements on Brexit remain unclear. Details are woefully lacking. But some certainties are emerging, in particular from the EU's negotiating position. The overall EU position was agreed (infamously in less than 15 minutes[17]) at a 'Special European Council' meeting of the heads of state of the 27 Member States in the rest of the EU (R-EU) on 29 April 2017,[18] following a proposal from the European Commission and a resolution of the European Parliament.[19] The European Commission then proposed somewhat more detailed 'negotiating directives',[20] which were adopted by the R-EU European Council on 22 May 2017. These authorise the European Commission to negotiate on behalf of the EU, consistent with Article 50 (2) TEU, which provides that negotiations must take place in accordance with the procedure in Article 218 (3) TFEU. The R-EU European Council will conclude the withdrawal agreement on behalf of the EU, acting by qualified majority, and with the consent of the European Parliament. In other words, no one government (other than the UK, of course) has the power to block the withdrawal agreement, but the European Parliament does have that power.

White Paper on Exiting the EU Cm 9417, February 2017 and May's letter triggering Article 50 TEU on 29 March 2017 suggest otherwise. The letter uses the phrase 'deep and special partnership' and explicitly states that a future EU/UK free trade agreement should be more ambitious than others. This is suggestive of 'deep and comprehensive free trade agreement', and 'association agreement', many of which are expressed in terms of partnerships between the EU and its geographical neighbours. See the *Financial Times* analysis: https://ig.ft.com/article-50-annotated/. However, the leaks from the Juncker/May dinner on 29 April 2017, reported in the Frankfurter Algemeine Zeitung (http://www.faz.net/aktuell/brexit/juncker-bei-may-das-desastroese-brexit-dinner-14993605.html. Translation available here: https://www.arcofprosperity.org/the-brexit-dinner/) suggest quite the opposite. Jean-Claude Juncker, the President of the European Commission, is reported to have left the meeting 'ten times more sceptical than he was before'. He apparently called Angela Merkel the morning after, saying that May is 'in a different galaxy'.

[17] I. Wishart, S. Bodoni and D. Simenas, 'European Leaders Back Brexit Negotiating Plan Before Talks' *Bloomberg* (2017) https://www.bloomberg.com/politics/articles/2017-04-28/eu-says-it-s-already-europe-1-britain-0-as-brexit-reality-dawns (accessed 13 July 2017).

[18] European Council, *Guidelines Following the EU's Notification under Article 50 TEU* Brussels, 29 April 2017 EUCO XT 20004/17.

[19] 5 April 2017.

[20] Recommendation for a Council Decision authorising the Commission to open negotiations on an agreement with the United Kingdom of Great Britain and Northern Ireland setting out the arrangements for its withdrawal from the European Union 3 May 2017 COM(2017) 218 final.

There is a question about whether the withdrawal agreement might be what is called a 'mixed agreement',[21] covering areas where the EU and Member States share competence. If the withdrawal agreement is a mixed agreement, then in order to come into effect, it must be ratified both by the EU institutions *and* by the Member States, in accordance with their individual constitutional requirements. In some Member States that gives veto power to national, or even regional, parliaments.[22] If this is required, it will be more difficult to conclude the withdrawal agreement. Probably the better view, however, is that the withdrawal agreement is covered only by the procedures set out in Article 50 TEU, whatever its content, because it is a *lex specialis*, and the EU is competent to agree it acting alone. Ultimately, the CJEU has jurisdiction over such a dispute, although private individuals, NGOs and so on do not have *locus standi* to bring a claim,[23] so it is difficult to see who might bring such litigation unless a particular Member State is thwarted politically. It is possible, for instance, if Spain is not satisfied with the arrangements concerning Gibraltar that it might challenge the validity of the withdrawal agreement.

In practice, negotiations did not commence until after the UK general election on 8 June 2017. In terms of the sequencing of negotiations, the EU insists that a withdrawal agreement must be settled before any future EU/UK trade agreement(s). Whatever the politics, and of course these may ultimately prevail, the legal position suggests that this is correct. The UK cannot negotiate a *future* relationship with the EU, or *vice versa*, until the UK has left the EU, because to do so would breach the 'duty of sincere cooperation' which binds all EU Member States.[24]

The EU's negotiating directives cover: citizens' rights, that is, the position of R-EU nationals in the UK and *vice versa*; the financial settlement; the island of Ireland, in particular arrangements for the land border between the Republic of Ireland and Northern Ireland; the situation for products placed on the EU market before the withdrawal date, including live litigation and administrative procedures on the withdrawal date; arrangements for material covered by the European Atomic Energy Community; and the governance of the withdrawal agreement, including disputes about the continued application of EU law, citizens rights; and the application and interpretation of the rest of the withdrawal agreement.

The EU's position is significantly more transparent than that of the UK. The European Commission issued its transparency policy on 22 May 2017.[25] The EU has undertaken to

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[21] See Case 22/70 *ERTA*; Cases 3, 4 & 6/76 *Kramer*; Opinion 1/76 on *Inland Waterways*; Opinion 2/92 on the *OECD*; Opinion 1/94 on the *WTO*; the *Open Skies* rulings; Opinion 2/15 on the *EU/Singapore FTA*; Article 3 TFEU; Article 207 TFEU.

[22] The Walloon parliament in Belgium came close to blocking the EU-Canada trade agreement 'CETA', see J. Brunsden, 'Belgium's Walloon Parliament blocks EU free trade deal' *Financial Times*, (2016) https://www.ft.com/content/df6841f4-113e-3b56-9559-61bcc6c3ed11 (accessed 13 July 2017).

[23] Article 218 (11) TFEU.

[24] Article 4 (3) TEU.

[25] See https://ec.europa.eu/commission/article-50-negotiations-united-kingdom/european-commissions-approach-transparency-article-50-negotiations-united-kingdom_en (accessed 13 July 2017). This complies with Regulation 1049/2001/EC OJ [2001] 145/43 on public access to EU documents.

operate under a 'maximum level of transparency' during the negotiating process. Where documents are shared between the R-EU Member States, the Commission, the European Parliament and the European Council, they will also be shared with the public. In this regard, the EU institutions may be learning from their experiences over negotiating the (ultimately unsuccessful) EU/USA Transatlantic Trade and Investment Partnership (TTIP). In those negotiations, the EU found it easier to respond to opposition by making its position open for public debate. There is also the very practical issue that documents leak in any event. In the UK, we may learn more about our own government's negotiating position from the EU's documents than from official UK sources. It will be important to track the negotiations as they unfold, not least because it is not clear who will represent the interests of health in those negotiations. We know that Jeremy Hunt, the Health Secretary from 2016-2017 and from 2017, does not have a seat at the Brexit 'top-table' in May's government.[26]

The EU has shared clear information about the key individuals in the EU's negotiating team, and their roles and remit.[27] On the UK side, by contrast, it is difficult to discern a clear overall strategy or position, other than that 'Brexit' (by which the UK government means *both* the withdrawal process/agreement *and* the future EU/UK agreement) should be bespoke,[28] and be 'a great success'.[29] There was also some lack of clarity about who the UK negotiators were to be, and how the UK's position is being coordinated, with some suggesting 'disarray'.[30] David Davis' Department for Exiting the EU is responsible for overseeing negotiations, and its Permanent Secretary, Oliver Robbins, and Director General, Sarah Healey, work closely with Davis. But there is also the Foreign Office, led by Boris Johnson, and indeed the Prime Minister herself, both of whom would normally be expected to play a leading role in negotiations of this type. Johnson was alone among UK ministers in insisting that the financial settlement should involve the EU paying the UK, and the UK has now conceded on this point by accepting that it has liabilities to the EU which it will meet. Other key ministers, such as Chancellor Philip Hammond, are said to favour 'softer' variants of Brexit.[31] And the reshuffle following the June 2017 election led to more prominence for pro-EU ministers.[32]

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[26] House of Commons Health Committee, *Brexit and health and social care – people and process* 25 April 2017 HC640.

[27] See https://ec.europa.eu/info/departments/taskforce-article-50-negotiations-united-kingdom_en#negotiationdocuments (accessed 15 May 2017).

[28] 'Theresa May: We want a red, white and blue Brexit' *BBC News* (2016) http://www.bbc.co.uk/news/av/38223990/theresa-may-we-want-a-red-white-and-blue-brexit (accessed 13 July 2017).

[29] 'Das desaströse Brexit-Dinner', *Frankfurther Allgemeine* (2017) http://www.faz.net/aktuell/brexit/juncker-bei-may-das-desastroese-brexit-dinner-14993605.html (accessed 13 July 2017).

[30] 'A tale of two negotiating teams', *Financial Times* (2017) https://www.ft.com/content/ca522044-0b0d-11e7-97d1-5e720a26771b (accessed 13 July 2017).

[31] 'Philip Hammond to prioritise economic prosperity in Brexit talks' *The Guardian* (2017) https://www.theguardian.com/politics/2017/jun/16/philip-hammond-brexit-talks-brussels-uk-eu (accessed 13 July 2017).

[32] 'David Davis stripped of his hardline anti-EU minister in department clear-out days before Brexit talks start' (2017) http://www.telegraph.co.uk/news/2017/06/13/david-davis-stripped-hardline-brexit-minister-department-clear/ (accessed 13 July 2017).

Obviously the amount of the settlement will affect the UK government's budget, and, unless revenues are raised from elsewhere, spending on other matters, including the NHS, will inevitably be affected. The UK has now accepted that its financial liabilities to the EU will outlast its membership.[33] Ministers such as Liam Fox have made statements about negotiations pertaining to citizens rights.[34] Fox's position that students should not be included in migration figures[35] affects recruitment to health and research positions, in particular, the UK's ability to attract 'the brightest and best'.

The UK's diplomatic lead is Sir Tim Barrow, the UK's ambassador to the EU, following the unexpected and controversial resignation of Sir Ivor Rogers on 3 January 2017, urging civil servants to continue to challenge 'ill-founded arguments and muddled thinking' and warning that 'serious multilateral negotiating experience is in short supply in Whitehall, and that is not the case in the Commission or in the Council'.[36] But, no matter how experienced, how the civil service will negotiate when there is a lack of ministerial consistency is fundamentally unclear. The worry that an uncoordinated UK negotiating team will mean that important matters, such as health, will be lost in discussions, was noted by the House of Commons Health Committee in its Brexit report:

> 'Be sure that health has a place at the table when ministers of trade and finance negotiate trade agreements. My dear ministers of health, if you are not at the table, you are on the menu.'[37]

2.2 The withdrawal agreement

Every aspect of the withdrawal agreement affects UK health law, either directly or indirectly. Failure to agree a withdrawal agreement at all will have the most detrimental effects: these involve a 'no-deal' or 'crash out' Brexit, in which all EU/UK relations fall back on WTO law, or other international cooperative mechanisms if they exist, on Brexit day.

The most significant, and politically salient, aspect of the withdrawal agreement for the UK NHS and social care is that on citizens' rights. Both the EU and the UK[38] agree in principle

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[33] Department for Exiting the European Union, 'EU Exit Negotiations July 2017: Written Statement - HLWS43' House of Lords 2017.

[34] 'Liam Fox: EU nationals in UK one of 'main cards' in Brexit negotiations', *The Guardian* (2016) https://www.theguardian.com/politics/2016/oct/04/liam-fox-refuses-to-guarantee-right-of-eu-citizens-to-remain-in-uk (accessed 13 July 2017).

[35] 'Fox attacks inclusion of students in UK immigration statistics', *Financial Times* (2017) https://www.ft.com/content/20f64b6e-09a6-11e7-97d1-5e720a26771b?mhq5j=e2 (accessed 13 July 2017).

[36] 'Sir Ivan Rogers' resignation letter in full', *The Telegraph* (2017) http://www.telegraph.co.uk/news/2017/01/03/sir-ivan-rogers-resignation-britains-eu-ambassador-letter/ (accessed 13 July 2017). Rogers' second in command left in November 2016 to a role in the Welsh government.

[37] House of Commons Health Committee, *Brexit and health and social care – people and process* 25 April 2017 HC640, para 9, citing Dr Margaret Chan, Director-General of the World Health Organization, Keynote address to the Regional Committee for the Western Pacific, Sixty-fourth session Manila, Philippines, 21 October 2013.

that it is a matter of the highest priority to secure the position of R-EU nationals in the UK and *vice versa*. For health law, there are three aspects of citizens' rights that matter most: the position of the R-EU nationals who work in health and social care in the UK; the arrangements for temporarily migrant patients; and the position of UK nationals who are resident in R-EU, many of whom are retired people. The details of the agreement on each of these will have a direct effect on the law surrounding patients' access to care, and professional licensure, recognition or accreditation, and consequently a profound indirect effect on the NHS and social care in the UK.

Some 140,000 R-EU nationals currently work in the NHS and social care across the UK.[39] Looking at doctors alone, one tenth are graduates of non-UK European Economic Area countries. London, Scotland, and the south East of England are particularly reliant on R-EU nationals in their health and social care workforce. In Northern Ireland, many health professionals effectively work across the border with the Republic of Ireland throughout their working lives.[40] The withdrawal agreement's settlement on the island of Ireland will need careful oversight, to ensure that the many shared health facilities and activities that underpin the peace process are not lost. NHS England's 2017 scheme, piloted in Lincolnshire, which seeks to plug the staffing gap by recruiting 500 GPs from overseas once it is rolled out, is reported to have recruited GPs from Poland, Lithuania, Croatia, Greece and Spain.[41] Eight percent of doctors in Wales are from R-EU, where reliance on R-EU workforce has increased in recent years.[42] Applications from R-EU nationals to University nursing courses reduced by 24% in July 2017.[43] Research and teaching hospitals, especially those in London, are particularly reliant on R-EU nationals when recruiting the very best clinical/research staff: the UK is currently regarded as a top place globally to build such a career.[44]

These R-EU citizens currently enjoy a suite of rights that are readily enforceable, and relatively administratively simple to secure. The entitlements endowed by EU law on migrant workers, and their families (irrespective of nationality), as defined by EU law, are extensive. Although they stop short of full UK citizens rights, they reach far beyond residence entitlements, or the rights associated with 'normal' immigration. They include the

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[38] UK Government, *Policy Paper: Safeguarding the Position of EU citizens in the UK and UK nationals in the EU* https://www.gov.uk/government/publications/safeguarding-the-position-of-eu-citizens-in-the-uk-and-uk-nationals-in-the-eu (accessed 13 July 2017).

[39] House of Commons Health Committee, Oral Evidence: *Brexit and health and social care*, HC 640 (2016-17), House of Commons 2017.

[40] House of Commons Health Committee, Oral Evidence: *Brexit and health and social care*, HC 640 (2016-17), House of Commons 2017.

[41] 'NHS to recruit hundreds of GPs from Poland, Lithuania and Greece', *The Telegraph* (2017) http://www.telegraph.co.uk/news/2017/01/11/nhs-recruit-hundreds-gps-poland-lithuania-greece/.

[42] 'Brexit: NHS "may struggle" without more non-UK staff', *BBC News* (2017) http://www.bbc.co.uk/news/uk-wales-politics-38981129 (accessed 13 July 2017).

[43] 'University applicants for nursing courses remain down by 23% at final deadline', *Nursing Times* (2017) https://www.nursingtimes.net/news/education/nursing-course-applicants-remain-down-by-23-at-final-deadline/7019446.article (accessed 13 July 2017).

[44] House of Commons Health Committee, Oral Evidence: *Brexit and health and social care*, HC 640 (2016-17), House of Commons 2017.

right not to be discriminated against on grounds of nationality in accessing a huge range of employment and social rights: access to employment; mutual recognition of qualifications from other EU countries (subject to linguistic competency tests); access to housing, education and other welfare benefits; right to access accrued pensions and healthcare on retirement in another EU country; right to access healthcare on a temporary basis in another EU country (which is often relied up by women giving birth in their original home country); and the right to vote in local and European parliamentary elections.

The details of the withdrawal agreement will have critical implications for the position of those R-EU nationals who already work in the UK in health and social care, and for those who arrive between now and the date on which the UK leaves the EU (29 March 2019, unless the UK and EU agree to extend the negotiating period under Article 50 TEU). Will the status of R-EU nationals be assimilated to that of other lawful immigrants to the UK, covered by a special set of UK immigration rules, as the UK government's negotiating position[45] envisages? Or will they continue to be distinguished from 'ordinary' immigration law, a kind of *lex specialis* based on the UK's (future) status as a former EU Member State? To whom will entitlements apply: everyone lawfully resident in the UK on the date of Brexit, or a different date, with transitional arrangements; or to not-yet resident family members of those who are lawfully resident in the UK on whatever date is chosen? Will entitlements apply only up to a cut off date, or will they reach into the future, for instance, in terms of access to higher education for children of R-EU nationals in the UK, or portability of pensions across the EU in the future? There is speculation that the Government's 'Explanatory Notes' to the EU (Withdrawal) Bill 2017 (discussed further below) signal an intention to remove rights from EU nationals in the UK should no withdrawal agreement be negotiated.[46] The Bill, if adopted, would give power to the UK government to remove rights arising from reciprocal arrangements, without Parliamentary oversight. Such rights include all rights of R-EU citizens resident in the UK; they also include rights under the EHIC scheme. There is also the crucial question of enforcement of rights, discussed below.

The implications of the financial settlement aspect of the withdrawal agreement will have an indirect effect on the NHS in terms of the UK's liabilities and hence the available resources for public spending. The precise permutations of these depend of course primarily on other government policy, particularly taxation policy. But in the absence of a change of direction from the austerity politics of the current government, a call on the public purse in the form of the settlement means less available taxation for the NHS.

In the withdrawal agreement, the intention is to clarify the situation for products placed on the EU market before the withdrawal date. To be effective, clarification must include how live litigation and administrative procedures on the withdrawal date will be resolved. A bewildering array of products are bought by UK-based health or social care providers from EU suppliers on a daily basis: ranging from simple tongue depressors to positron emission tomography (PET) scanners. These products, and their components, are currently governed

[45] UK Government, *Policy Paper: Safeguarding the Position of EU citizens in the UK and UK nationals in the EU* https://www.gov.uk/government/publications/safeguarding-the-position-of-eu-citizens-in-the-uk-and-uk-nationals-in-the-eu (accessed 13 July 2017).

[46] Department for Exiting the EU, *European Union (Withdrawal) Bill: Explanatory Notes* 13 July 2017, available https://www.publications.parliament.uk/pa/bills/cbill/2017-2019/0005/en/18005en.pdf, at p 10.

by EU law that secures their safety and protects consumers/patients. Pharmaceuticals enjoy marketing authorisations that permit their sale anywhere in the EU,[47] and supply chains typically involve several EU countries.[48] The UK currently purchases all of its plasma used for anyone born after 1996 from Austria.[49] The safety of blood,[50] human organs,[51] and tissue[52] is guaranteed by EU law and regulatory processes. The aim of this aspect of the withdrawal agreement is to secure continuity regarding these 'non-tariff barriers' to trade in products between the EU and the UK. It is consistent with the UK government's intentions for legal certainty as outlined in its White Paper on Legislating for the EU's withdrawal from the EU and European Union (Withdrawal) Bill 2017 (discussed further below).[53]

The withdrawal agreement may also include arrangements facilitating the transfer from the UK of EU agencies and facilities to R-EU countries. The most important of these for health is the European Medicines Agency. The EU has indicated that it will decide on its future location by October 2017.[54] There are clear negative implications for the UK of the EMA's relocation. Indeed, the UK government seems to have been in denial about the matter until relatively recently.[55] The larger market of the EU, for which marketing authorisations are granted by the EMA is likely to mean that pharmaceuticals reach the UK market later than at present. The relocation of 700 regulatory specialist jobs means that the pharmaceutical industry may move at least some of its operations to the new home of the EMA, for ease of interaction with the regulator.[56] The UK will lose its seat (through the EU) in the ICH.[57]

There are also some very specific elements of the relocation which may be settled in the withdrawal agreement. One is the question of liability for the building rental, reportedly running to €400m.[58] A second is the position of the EMA's staff, and their families, where the issues raised above apply. Furthermore, the relocation of the EMA may well affect the

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[47] Directive 2001/83/EC [2001] OJ L311/67, Article 6 (1), as amended.

[48] P. Kanavos, W. Schrurer and S. Vogler, 'The pharmaceutical distribution chain in the European Union: structure and impact on pharmaceutical prices', European Commission (2011), pp. 1-120.

[49] EU Commission, 'An EU-wide overview of market of blood, blood components and plasma derivative focusing on their availability for patients' (2015) *Creative Ceutical Report*, 61 http://ec.europa.eu/health//sites/health/files/blood_tissues_organs/docs/20150408_cc_report_en.pdf (accessed 22 May 2017).

[50] Directive 2002/98/EC [2003] OJ L33/30.

[51] Directive 2010/53/EU [2010] OJ L243/68.

[52] Directive 2004/23/EC [2004] OJ L102/48.

[53] Department for Exiting the EU, *White Paper on Legislating for the UK's withdrawal from the EU*, March 2017, Cm 9446; European Union (Withdrawal Bill) 2017 (HC Bill 5, 2017).

[54] 'EU sets out criteria for relocating EU agencies' *EU Observer* (2017) https://euobserver.com/uk-referendum/138008 (accessed 13 July 2017).

[55] 'London battles to keep hold of two main EU agencies', *Financial Times* (2017) https://www.ft.com/content/72ead180-229a-11e7-8691-d5f7e0cd0a16 (accessed 13 July 2017).

[56] 'Brexit's Potential Health Benefits', *Financial Times* (2017) https://www.ft.com/content/4560f016-3a2b-11e7-ac89-b01cc67cfeec (accessed 13 July 2017).

[57] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use www.ich.org. See further M. Flear in this issue.

[58] 'EU agency faces €400m London rent bill after post-Brexit move', *Financial Times* (2017) https://www.ft.com/content/4ad548c6-2b58-11e7-9ec8-168383da43b7?mhq5j=e2 (accessed 13 July 2017).

timing of the entry into force of the new Clinical Trials Regulation.[59] This is due to take place once the new portal and database has been created, and adequately tested and audited.[60] This process was supposed to be completed by October 2018. But the European Medicines Agency has now confirmed that this will not be until 'some time in 2019', citing 'technical difficulties with the development of the IT systems'.[61]

Computed Tomography (CT), Magnetic Resonance Imaging (MRI) and PET scanning, some cancer treatments (such as radionuclide therapy), biochemical analysis, sterilisation of medical equipment, and other diagnostic and therapeutic technologies rely on nuclear medicine.[62] The radioisotopes used in these procedures in the UK are manufactured in research reactors based in other countries in the EU (Netherlands, Belgium, Poland, France, Germany, Czech Republic). The main supplier is the Belgian-based company IRE.[63] All of these materials are covered by the European Atomic Energy Community (Euratom), which governs the peaceful use of nuclear energy within the EU, relying on the EU institutions to do so. It is our membership of Euratom that allows UK hospitals and clinics to import radioisotopes. The withdrawal agreement will need to cover Euratom also. If this matter cannot be resolved in the withdrawal agreement, the basis on which all radioisotopes are currently lawfully imported into the UK will be removed. At the very least, it would take some time for the UK to negotiate a new agreement through the International Atomic Energy Agency.[64] In the meantime, presumably, imports would cease.

Finally, the terms of agreement on the governance of the withdrawal agreement, will affect all the matters discussed above. Where people or companies have disputes with the UK

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[59] Clinical Trials Regulation 536/2014/EU OJ [2014] 158/1.

[60] Article 96: repeals Clinical Trials Directive from date in Article 99 (2); Article 99 (2): Regulation applies from 6 months after notice referred to in Article 82 (3); Article 82 (3): EMA collaborates with Member States and Commission to draw up functional specification for EU portal and database and a timeframe. EMA informs Commission when full functionality reached. The Commission, when satisfied, publishes notice to that effect in the Official Journal.

[61] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000629.jsp&mid=WC0b01ac05808768df (accessed 19 July 2017).

[62] World Nuclear Association, *Radioisotopes in Medicine*, (2017) http://www.world-nuclear.org/information-library/non-power-nuclear-applications/radioisotopes-research/radioisotopes-in-medicine.aspx (accessed 13 July 2017).

[63] http://www.ire.eu/ (accessed 13 July 2017). See also 'EU Officials Warn UK over radioactive isotopes', *Financial Times* https://www.ft.com/content/f146cd86-6714-11e7-8526-7b38dcaef614?emailId=596cf33b5961130004f15d33&segmentId=488e9a50-190e-700c-cc1c-6a339da99cab (accessed 17 July 2017).

[64] F. Livens, J. Matthews, T. Abram, 'Euratom and Leaving the EU' (2017) http://blog.policy.manchester.ac.uk/posts/2017/02/euratom-and-leaving-the-european-union/ (accessed 13 July 2017). David Davis announced in January 2017 that if no agreement could be reached on a relationship with Euratom, the UK would seek an 'alternative agreement' with the International Atomic Energy Agency, see http://www.nucnet.org/all-the-news/2017/02/02/uk-could-seek-alternative-agreement-to-euratom-with-iaea-after-bexit (accessed 13 July 2017). Reports in July 2017 that the UK might not leave Euratom https://www.ft.com/content/0f57f69d-305d-3f9f-834f-90e43e3f2633?mhq5j=e1 (accessed 19 July) were quashed by the UK government's position paper on the matter https://www.gov.uk/government/publications/nuclear-materials-and-safeguards-issues-position-paper (accessed 19 July 2017).

government about the continued application of EU law, or the application or interpretation of citizens' rights as agreed in the withdrawal agreement, or whether products are lawfully being marketed in the UK after Brexit day, the agreement itself will determine how those disputes are to be resolved. The UK's negotiating position on this is that 'the Court of Justice of the EU will not have jurisdiction in the UK'.[65] The EU's negotiating position is that this part of the negotiation must 'bear in mind the EU's interest in effectively protecting its autonomy and its legal order, including the role of the CJEU'.[66] The special and autonomous nature of EU law, according to its CJEU and accepted by courts in every Member State, including the UK, marks out its distinction from ordinary international law.[67] It is this inherent nature of EU law that leads to its direct effect (that is to say, enforceability at the suit of individuals, whether legal or natural persons) and its supremacy (that is to say, its application in priority over contradictory national law, whatever the date or type of that national law).

These aspects of EU law have been relied upon by patients, to secure cross-border medical services; by health professionals, to secure entitlement to practice; by providers of a range of health products or services, seeking to sell their products or services in the UK; and by public health campaigners, seeking to ensure that population health measures of EU law are interpreted in ways which, for instance, protect the 'right to health'.[68]

Yet these are also the aspects of EU law which the 'take back control' facet of the UK government's position most seeks to remove from application within the UK. It seems difficult to reconcile these positions. The EU would seem to be suggesting that it will accept nothing less than oversight by a court (ideally the CJEU, but potentially a bespoke court). The UK position appears more consistent with the kinds of arbitration arrangements more common to resolve international trade disputes. It may be possible for the UK to accept the EU's position here, for instance, if there is a clear date by which the application of the governance arrangements under the withdrawal agreement will cease to apply (i.e, a date on which the UK can be said to have 'taken back control'). If that is agreed, however, it is likely to be a date far into the future, given the nature of the rights of R-EU citizens in the UK and *vice versa*, including, for instance, access to pensions on the basis of national insurance contributions made while the UK was a member of the EU.

To summarise, although of course not all legal texts are yet available, we have some information about the upcoming negotiations and the likely details of the withdrawal agreement, not least because of the EU's position on transparency. Health lawyers can, and should, therefore continue to ensure that health remains as much in view as it was during the referendum campaign, as the negotiations progress; scrutinise proposals for their likely

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[65] UK Government, *Policy Paper: Safeguarding the Position of EU citizens in the UK and UK nationals in the EU* https://www.gov.uk/government/publications/safeguarding-the-position-of-eu-citizens-in-the-uk-and-uk-nationals-in-the-eu (accessed 13 July 2017), pp. 4, 17; see European Union (Withdrawal) Bill, clause 6.

[66] COM(2017) 218, para 39.

[67] Case 26/62 *Van Gend en Loos* [1963] ECR 1.

[68] For full details of such litigation, which amounts to literally hundreds of cases before the CJEU, and more before national courts, see T. Hervey and J. McHale, *European Union Health Law: Themes and Implications* (Cambridge University Press, 2015).

effects on the NHS, and on population health; and seek to secure the best possible outcomes for health in the withdrawal agreement.

3. The European Union (Withdrawal) Act (formerly known as the 'Great Repeal Bill')

The UK government intends to secure legal continuity in the aftermath of Brexit day through statutory means: a European Union (Withdrawal) Act (the Withdrawal Act/Bill).[69] It will take some time to disentangle UK law from EU law: indeed it may take a long time, perhaps as much as '40 years in, 40 years out'. The government first indicated through its White Paper on *Legislating from the UK's Withdrawal from the EU*[70] how it envisages avoiding legal vacuums that would otherwise appear on the day EU law ceases to apply in the UK. The approach adopted in the Withdrawal Bill gives the UK the time it needs to make changes to the law, while securing legal certainty for people and businesses in the UK in the meantime.

Although the text for the Withdrawal Bill is available at the time of writing, it is yet to complete its passage through the Commons and Lords. Given the political situation, and especially the May government's narrow Commons majority, much of the analysis that follows is necessarily speculative. The June 2017 general election resulted in a narrowing of the May government's majority, and this may make it more difficult for the Bill to be adopted without amendments. There will be more clarity as the Bill is debated by Parliament, and scrutinized by external stakeholders.

The Withdrawal Bill provides that, on Brexit day, the European Communities Act 1972 will be repealed.[71] The European Communities Act is the provision by which the UK constitutionally complies with its EU membership obligations. On Brexit day, to secure continuity, EU law which is 'directly applicable'[72] will become a formal source of UK law.[73] Treaty provisions – including the EU Charter of Fundamental Rights[74] – will no longer be a formal source of UK law after Brexit day. All EU Regulations[75] and any directly effective Treaty provisions[76] will be converted into UK law. In effect, there will be a new formal source of UK law. We might call it 'EU derived law', or 'domesticated EU law'.[77] The

[69] At the time of writing, the UK government had published the Withdrawal Bill, but it had not been adopted.

[70] Department for Exiting the EU, *White Paper on Legislating for the UK's withdrawal from the EU*, March 2017, Cm 9446.

[71] European Union (Withdrawal) Bill 2017, clause 1.

[72] That is to say, Treaty provisions (including the EU Charter of Fundamental Rights), and EU Regulations.

[73] European Union (Withdrawal) Bill 2017, clause 3.

[74] European Union (Withdrawal) Bill 2017, clause 5 (4). See also White Paper, Para 2.23.

[75] European Union (Withdrawal) Bill 2017, clause 3 (2) (a). See also White Paper, Para 2.4.

[76] European Union (Withdrawal) Bill 2017, clause 3, clause 4. See also White Paper, Para 2.11.

[77] Department for Exiting the European Union, 'European Union (Withdrawal) Bill Explanatory Notes' (2017), p. 8, call it 'converted legislation'.

incorporation of EU law into domestic law covers all EU law that 'has effect in domestic law' and is 'operative immediately before' Brexit day.[78]

So provisions of health law such as the Advanced Therapy Medicinal Products Regulation 1394/2007; the Data Protection Regulation 2016/679; Regulation 883/2004, which includes the provisions on the European Health Insurance Card (EHIC), which allow UK nationals to access medical treatments when in other EU countries; and a host of others, which are currently part of UK law because of the European Communities Act 1972, will become part of UK law via the provisions of the Withdrawal Act on Brexit day. However, provisions such as Regulation 536/2014 on clinical trials, which have yet to enter into effect although they have been agreed by the EU legislature, are not covered by the terms of the Withdrawal Bill as it currently stands.

Where aspects of UK health law derive from EU law that is not directly applicable, it is *already* incorporated into UK law. This is particularly the case for Directives, which typically become part of UK law either through legislation, or through statutory instruments, using the enabling power in the European Communities Act.[79] Where implementation of Directives has been carried out through primary legislation, that legislation will continue to be part of UK law. So, for instance, the UK complies with its obligations in the Human Tissue and Cells Directive through the Human Tissue Act 2004, the Human Tissue (Scotland) Act 2004, and the Human Fertilisation and Embryology Act 1990. Those Acts will remain part of UK law after the European Communities Act is no longer in force. But, where incorporation of EU law into UK law has been carried out by secondary legislation, without the European Communities Act, it would 'fall away', as its enabling legislation would no longer be in force. To avoid this unintended effect, the Withdrawal Act will also preserve those laws as a source of UK law.[80] For instance, some 65 provisions of national law and soft law, including the NHS (Cross-Border Healthcare) Regulations 2013[81] and the Cross Border Healthcare and Patient Mobility – Guidance for the NHS,[82] implement the 'Patients' Rights Directive' 2011/24 in England and Wales, Scotland and Northern Ireland. Under the Withdrawal Act, they will continue in force, as 'EU-derived domestic legislation'.[83]

The Withdrawal Bill groups all of these new sources of UK law (EU-derived law/domesticated EU law and 'EU-derived domestic legislation') under the category 'retained EU law'.[84]

In order to prevent ossification, the Withdrawal Bill also envisages that this 'retained EU law' will be amended, 'at the appropriate time'.[85] Some of this amending of existing law will

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[78] European Union (Withdrawal) Bill 2017, clauses 2 (1) and 3 (1).

[79] Section 2 (2).

[80] European Union (Withdrawal) Bill 2017, clause 2. See also White Paper, Para 2.5.

[81] The National Health Service (Cross-Border Healthcare) Regulations 2013.

[82] Welsh Government, *Cross Border Healthcare and Patient Mobility - Guidance for the NHS*, 14 August 2015 http://gov.wales/docs/dhss/publications/150727cross-border-guidanceen.pdf.

[83] European Union (Withdrawal) Bill 2017, clause 2.

[84] European Union (Withdrawal) Bill 2017, clause 6 (7).

[85] White Paper, para 1.24, see also p 1 'at a time that we choose'.

be done by legislation. The White Paper explicitly mentions a customs bill and an immigration bill. The latter (misleadingly) is suggested to be 'so nothing will change for any EU citizen, whether already resident in the UK or moving from the EU, without Parliament's approval'.[86] From the point of view of R-EU citizens who feel that they 'belong' in the UK precisely because they are EU citizens and the UK is a member of the EU, or indeed UK citizens resident in EU-27 countries, everything will change,[87] whatever the Parliamentary intent is. As noted above, this is likely to have significant ramifications for health and social care staffing, as well as recruitment to health research posts in the UK.[88] The details of the immigration bill, when it eventually emerges, will be something to which health lawyers should pay close and careful attention.

Controversially, under the Withdrawal Act such amendments will also be effected by secondary legislation, through what are known as 'Henry VIII clauses'.[89] This power may be used to 'prevent, remedy or mitigate any failure of retained EU law to operate effectively, or any other deficiency in retained EU law, arising from the withdrawal of the United Kingdom from the EU'.[90] Executive action 'under this section may make *any* provision that could be made by an Act of Parliament'.[91] A 'deficiency' is defined by reference to the view of a relevant Minister.[92] 'Deficiencies' are essentially of two types: inoperability of retained EU law; and 'any other deficiency'. There is a non-exhaustive list of 'deficiencies in retained EU law'.[93] Both types have implications for health law.

We noted one such example of a potential 'deficiency' above, concerning reciprocal rights for citizens, in the event of a 'no-deal' or 'crash out' Brexit. Clause 9 of the Withdrawal Bill explicitly gives the government power to 'make such provision as the Minister considers appropriate for the purposes of implementing the withdrawal agreement if the Minister considers that such provision should be in force on or before exit day'.[94] 'Minister' in this context is defined[95] by reference to the Ministers of the Crown Act 1975, which refers to the UK government (and not to ministers in the devolved nations/regions). If this power is as sweeping as it appears, every aspect of health law outlined above, as pertaining to the

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[86] White Paper, Para 1.21.

[87] T. Hervey, S. McCloskey, 'All of life is changed: The impact of Brexit on UK nationals living in other EU Member States', *EU Law Analysis*, 7 July 2017. http://eulawanalysis.blogspot.co.uk/2017/07/all-of-life-is-changed-impact-of-brexit.html (accessed 13 July 2017).

[88] House of Commons Health Committee, 6th Report, *Brexit and health and social care – people and process*, paras 28-69, HC640 28 April 2017 https://www.publications.parliament.uk/pa/cm201617/cmselect/cmhealth/640/64002.htm.

[89] M. Elliott and R. Thomas, *Public Law* (2nd edn, Oxford University Press 2014), pp. 136-138. Henry VIII clauses authorise Ministers to make secondary legislation amending or even repealing Acts of Parliament. Power usually reserved for the legislature is therefore conferred on the executive and thus lacks the checks and balances that holds legislative creations to account.

[90] European Union (Withdrawal) Bill 2017, clause 7 (1).

[91] European Union (Withdrawal) Bill 2017, clause 7 (4), italics added.

[92] European Union (Withdrawal) Bill 2017, clause 7 (2).

[93] European Union (Withdrawal) Bill 2017, clause 7 (2).

[94] See also White Paper, Para 1.18. The Withdrawal Bill explicitly excludes the power to implement the withdrawal agreement from the enabling power in clause 7, which applies after Brexit day, European Union (Withdrawal) Bill 2017, clause 7 (6) (d).

[95] European Union (Withdrawal) Bill 2017, clause 14 (1).

withdrawal agreement, could potentially be altered by executive action taken at Whitehall. So – for instance – a change to the rights of R-EU nationals to access healthcare in the UK, negotiated as part of the withdrawal, or arising in the event of a 'no-deal' Brexit, would according to the Bill be something that the Westminster government had power to implement through delegated legislation, without involving the devolved nations/regions, even though access to healthcare is a devolved power.

A second potential 'deficiency in retained EU law' is to provide for functions of EU entities (such as, for instance, the European Medicines Agency) to be carried out instead by a UK public authority – either already-existing (such as the Medicines and Healthcare Products Regulatory Agency[96]), or newly-established under the powers given in the Withdrawal Bill.[97] Such functions may include adopting laws, or providing funding. Alternatively, functions of EU entities may be 'replaced, abolished, or otherwise modified'.[98] The reference to 'abolished' presumably intends to indicate the so -called 'red tape' of EU regulation that features so strongly in Leavers' narratives. Formally speaking, the Withdrawal Bill gives power to UK ministers to remove all marketing authorisation rules from pharmaceuticals sold in the UK, or all food safety law, or all environmental protections, if these are deemed 'deficiencies' in retained EU law. A 'deficiency' is not defined in the Bill, although the Explanatory Notes[99] state that 'the law is not deficient merely because a minister considers that EU law was flawed prior to exit'.

A third example of a future 'deficiency in retained EU law' is where EU law currently requires and facilitates information-sharing with EU institutions. In health law contexts, this includes sharing information on fitness to practice of health professionals within the Internal Market Information System,[100] sharing pharmacoviligence information as part of the 'Community code' on pharmaceuticals regulation,[101] or sharing data on cancer outcomes,[102] or emerging on communicable disease threats,[103] within the EU's public health policies. The eventual details here will depend on the withdrawal agreement, and whether some information-sharing continues. The Withdrawal Act will give power to the UK government to remove the information-giving obligation from the UK statute book.[104] If the UK leaves the EU with 'no deal', in other words, if the negotiations over the withdrawal agreement fail, the Act would give executive power to remove regulatory oversight in a host of areas pertaining to health, without parliamentary or other stakeholder oversight. The

[96] The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK. It is an executive agency, sponsored by the Department of Health. See: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about.
[97] European Union (Withdrawal) Bill 2017, clause 7 (5).
[98] European Union (Withdrawal) Bill 2017, clause 7 (5).
[99] Department for Exiting the European Union, 'European Union (Withdrawal) Bill Explanatory Notes' (2017), p. 29.
[100] Regulation (EU) No 1024/2012 [2013] OJ L354/132.
[101] Directive 2010/84/EU [2010] OJ L348/74.
[102] See, originally, Resolution of the Council and the Representatives of the Governments of the Member States, meeting within the Council, of 7 July 1986, on a programme of action of the European Communities against cancer [1986] OJ C184/19.
[103] Regulation 851/2004/EC [2004] OJ L142/1.
[104] European Union (Withdrawal) Bill 2017, clause 7. See also White Paper, Case study 3: information sharing with EU institutions, p 21.

implications for health law would be particularly stark if the UK government pursues an agenda of 'cutting red tape' to secure a low regulation economy, as some government information has suggested may be on the table.[105] This will certainly be an area where oversight by health lawyers will be crucial.

Fourth, the Bill permits use of executive powers where necessary for the UK to continue to comply with its international obligations.[106] The UK currently complies with a host of international obligation relevant to health law through its membership of the EU. Import of radioisotopes for use in cancer treatment is one example; food safety law under the UN's Codex Alimentarius another. Compliance with standards set by the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use on 'good clinical practice' in clinical trials for pharmaceuticals is a third.[107]

Even with the text of the Bill, it is difficult to say how sweeping the uses of this executive power will be in practice. There are 'sunset clauses', limiting its use in matters pertaining to the withdrawal agreement to Brexit day itself,[108] and otherwise to two years from Brexit day.[109] There is a list of exclusions, for instance protecting the Human Rights Act from amendment using these powers.[110]

Otherwise, however, potential for extensive powers and broad ministerial discretion remains.[111] Then the question arises as to what means exist to hold this power to account. The price of Henry VIII powers' convenience is the possibility of court challenges. Specifically, reviewability of executive action and secondary legislation adopted under these clauses take the form of judicial review. This empowers the Administrative Court to quash, prohibit, or compel certain exercises of power on the grounds of illegality, unreasonableness, or procedural impropriety.[112] There is a world of difference between a provision of 'retained EU law' that is 'deficient' for practical reasons of lack of operability, or non-compliance with international obligations, once the UK is outside the EU; and a provision of such law that is deemed 'deficient' because it is not an optimal regulatory approach. It may perhaps be possible to argue successfully that uses of the Bill's Henry VIII clauses in the latter instance are illegal or unreasonable. However, judicial review is inadequate for two primary reasons: first, its relative inaccessibility; and second, the exclusion of any parliamentary involvement.

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[105] See, for instance, PM Theresa May's Lancaster House speech on 17 January 2017 (https://www.gov.uk/government/speeches/the-governments-negotiating-objectives-for-exiting-the-eu-pm-speech).

[106] European Union (Withdrawal) Bill 2017, clause 9.

[107] See M. Flear, 'Ensuring post-Brexit UK is a 'Maker' rather than a 'Taker' of Global Norms and Standards: the case of the International Council on Harmonisation' https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2992551 and in this issue.

[108] European Union (Withdrawal) Bill 2017, clause 9.

[109] European Union (Withdrawal) Bill 2017, clause 7 (7).

[110] European Union (Withdrawal) Bill 2017, clause 7 (6) (f).

[111] M. Elliott, '1,000 Words / The EU (Withdrawal) Bill' https://publiclawforeveryone.com/2017/07/14/1000-words-the-eu-withdrawal-bill/ (accessed 18 July 2017).

[112] *Council of Civil Service Unions v Minister for the Civil Service* [1985] AC 374, p. 410.

The Administrative Court is overloaded with applications.[113] To mitigate this, stringent criteria are imposed; applicants must comply with *locus standi* rules, bring their case within a reasonable time, and ultimately be subject to a highly discretionary determination of whether or not their case is arguable. In conjunction with limited legal aid,[114] bringing a case for judicial review is highly challenging. If the Bill's extensive Henry VIII powers result in increased litigation,[115] an even higher threshold may be inescapable. The alternative is greater delays and, as justice 'delayed is justice denied,'[116] neither outcome would ensure effective reviewability. The bottom line is that using the courts is not going to be an appropriate means to secure protection for health in the run up to and immediate aftermath of Brexit.

Further, even where a case is brought, judicial review of Henry VIII powers bypasses Parliament completely.[117] Any legislation or acts adopted are determined solely by the executive and they are only subject to judicial scrutiny and common law rules.[118] The only saving grace is that recent case law has demonstrated a suspicion towards delegated legislation that undermines primary legislation. As this represents a contradiction of the principle of parliamentary sovereignty, Lord Neuberger has advocated a particularly scrupulous approach.[119]

The Withdrawal Bill has been widely criticised for its potential effects on parliamentary control and scrutiny.[120] These effects have particular ramifications in the context of health law – for two reasons. First, the nature of health law is such that democratic processes are indicated. Even where health law is notionally 'technical', the 'technical' choices made have significant normative implications, including for individuals' lives, their dignity, and perhaps even their identities.

Second, much of health law is a devolved power in the UK. Giving power to Whitehall to alter 'retained EU law' potentially changes the constitutional arrangements for health within the UK. The White Paper notes that changes to devolved law would be better made by

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[113] M. Elliott and R. Thomas, *Public Law* (2nd edn, Oxford University Press 2014), p. 550.
[114] T. Hickman, 'Public Law's Disgrace' https://ukconstitutionallaw.org/2017/02/09/tom-hickman-public-laws-disgrace/ (accessed 17 July 2017).
[115] See Lord Neuberger's evidence to the House of Lords Constitution Committee, 'Uncorrected Oral Evidence: With The President And Deputy President Of The Supreme Court' (2017), p. 1.
[116] M. Elliott and R. Thomas, *Public Law* (2nd edn, Oxford University Press 2014), p. 550.
[117] D. A. Green, 'More problems than solutions in Brexit repeal bill' *Financial Times* (2017) http://blogs.ft.com/david-allen-green/2017/07/13/more-problems-than-solutions-in-brexit-repeal-bill/ (accessed 17 July 2017).
[118] M. Elliott and R. Thomas, *Public Law* (2nd edn, Oxford University Press 2014), p. 445.
[119] *R (Public Law Project) v Lord Chancellor* [2016] UKSC 39, para. 25-26.
[120] See, e.g., S. Peers, 'The White Paper on the Great Repeal Bill: Invasion of the Parliamentary Control Snatchers' http://eulawanalysis.blogspot.co.uk/2017/03/the-white-paper-on-great-repeal-bill.html; David Allen Green https://www.ft.com/content/7dbf749d-f9b4-38b5-b6ed-0d7463698a2d; Mark Elliott https://publiclawforeveryone.com/2016/10/02/theresa-mays-great-repeal-bill-some-preliminary-thoughts/; George Peretz QC https://www.monckton.com/the-great-repeal-bill-a-giant-henry-viii-clause/; Joelle Grogan http://blogs.lse.ac.uk/brexit/2016/11/30/rights-for-the-chop-how-a-henry-viii-clause-in-the-great-repeal-bill-will-undermine-democracy/; Another Europe, http://www.anothereurope.org/revealed-the-great-tory-power-grab/ (accessed 13 July 2017).

devolved institutions.[121] But it is light on detail as to what counts as a change to devolved law, in particular where the change emanates from a future EU/UK agreement (which by definition will be negotiated by the Westminster government). The Withdrawal Bill's Schedule Two purports to set out the powers of devolved nations/regions[122] to amend 'retained EU law'. Like the rest of the 'small print' at the 'back end of the bill,' there are 'alarming' details hidden within it.[123] In particular, Dunt highlights paragraph 3 (2) of Schedule Two[124] which states that devolved assemblies cannot make any changes 'inconsistent' with those made by Westminster. This creates the possibility that the UK could apply reduced standards to areas previously governed by EU law and the devolved nations/regions would be unable to retain the higher threshold. The Scots' approach to alcohol taxation[125] might be a case in point, if 'retained EU law' includes the approach to interpreting exemptions in Treaty provisions on free movement, alongside the EU legislation that organises the EU market in agricultural products (in this case alcoholic beverages). It could also make it impossible for the devolved nations/regions to continue to offer access to health care to R-EU nationals, even though access to health care is a devolved power. It will be important for health lawyers in the devolved nations/regions to argue for the maximum retention of devolved powers. The devolved nations/regions effectively have the power to veto an agreement to the effect that a UK-level approach is needed,[126] because, without their assent, executive instruments made under the Bill can effectively be annulled, so long as the devolved nations/regions deploy the procedure in Schedule 7.

Under the Withdrawal Act, the UK courts will be permitted to continue to look to the ways in which the CJEU interprets EU law where they are interpreting or applying 'retained EU law'.[127] UK courts may refer to CJEU decisions taken after Brexit day if they consider it appropriate to do so.[128] The question of appropriateness will of course depend on how UK courts interpret that text in the context of their understanding of the Parliamentary aims embodied in the Act. If their focus is on consistency, the aim may be understood as to ensure that UK courts continue to interpret 'retained EU law' consistently with the EU provisions on which it was originally based. It would therefore be appropriate to consider CJEU judgments issued *after* Brexit day. This is because when the CJEU interprets a text, it is 'discovering' what the text has always meant, not changing the text, or 'making the law'. If, on the other hand, the UK courts focus on 'taking back control', the aim of the Act may be understood as to ensure that UK courts depart from the future directions of EU law, as expressed in CJEU judgments after Brexit day.

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[121] White Paper, Para 1.15.

[122] Known as the 'devolved authorities' in the Bill, see clauses 10 and 14.

[123] I. Dunt, 'Small Print Of Repeal Bill Creates Unprecedented New Powers For Brexit Ministers' http://www.politics.co.uk/blogs/2017/07/13/small-print-of-repeal-bill-creates-unprecedented-new-powers (accessed 17 July 2017). See also D. A. Green who writes of the 'particular challenge' of the fit with the devolved regimes, see https://www.ft.com/content/96f9d7f6-4e8d-3b4e-b1e7-388ad04a4ac2 (accessed 17 July 2017).

[124] European Union (Withdrawal) Bill 2017, schedule 2 para. 3 (2).

[125] See *The Scotch Whisky Association and ors v The Lord Advocate* [2016] CSIH 77.

[126] European Union (Withdrawal) Bill 2017, clause 11 (1)(b); 11 (2)(b); 11 (3)(b); Schedule 3, clauses 1, 2, 3; Schedule 7, clause 2 (14). Explanatory Notes, para 36.

[127] European Union (Withdrawal) Bill 2017, clause 6. See also White Paper, Paras 2.9-2.11.

[128] European Union (Withdrawal) Bill 2017, clause 6 (2).

There is, of course, a significant difference between an enabling clause (UK courts *may* consider rulings of the CJEU) and the current position which is that UK courts *are obliged to* follow the authoritative interpretations of the CJEU of provisions of EU law, or provisions of UK law which implement the UK's EU obligations.[129] That obligation continues as a matter of UK law under the Withdrawal Bill, which envisages that 'retained case law' will include decisions of the CJEU up to Brexit day.[130] This embodies the UK's negotiating position vis a vis the CJEU. But whether that is the definitive position in UK law post-Brexit will in practice depend on what happens in the negotiations in terms of the position of the CJEU in the withdrawal agreement, and indeed potentially in any eventual future EU/UK agreement or agreements. What the White Paper envisages is that the Withdrawal Bill 'will not require the domestic courts to consider the CJEU's jurisprudence',[131] noting 'in that way, the Bill allows the UK to take control of its own laws',[132] although this may turn out not to be feasible if the withdrawal agreement (or any future EU/UK agreements) mandate(s) something different.

The obligation to continue to refer to the CJEU's interpretations includes those that refer to the rights underlying the EU's Charter of Fundamental Rights.[133] So – for instance – the UK courts will continue to be required to refer to EU CFR-compliant interpretations of 'retained EU law', such as was the case, for instance, in the High Court's ruling in *British American Tobacco*,[134] which referred explicitly to Article 35 EUCFR on the 'right to health' in interpreting EU tobacco regulations. The nature of the constitutional obligation on UK courts will change, though: the status of pre-Brexit day CJEU case law ('retained case law') is such that the Supreme Court may depart from it in circumstances where the Supreme Court would depart from its own previous rulings, and the Scottish High Court of Justiciary may do so when sitting as an appeal court or hearing a Lord Advocate's reference.[135]

Throughout the White Paper and the Withdrawal Bill, and consistent with the narrative of 'taking back control', the doctrine of UK parliamentary sovereignty, with all that implies for the behaviour of the UK courts, is reasserted. EU law will (obviously) no longer be a supreme source of UK law.[136] The *Factortame* ruling[137] will be overturned by the Withdrawal Act. Changing this balance of power between Parliament and the UK courts is an aspect of Brexit that may have significant implications for UK health law that have yet to be fully thought

[129] European Communities Act 1972, section 2 (4).

[130] European Union (Withdrawal) Bill 2017, clause 6 (7). See also White Paper, Para 2.14.

[131] White Paper, Para 2.13.

[132] White Paper, Para 2.13.

[133] White Paper, Para 2.25.

[134] [2016] EWHC 1169 (Admin) 19 May 2016, para 438.

[135] European Union (Withdrawal) Bill 2017, clause 6 (4) and (5). See also White Paper, Para 2.16.

[136] White Paper, Paras 2.18 and 2.19.

[137] [1991] 1 AC 603.

through. Any instances where UK courts have relied on EU law-compliant interpretations of UK health law would be vulnerable to change.[138]

4. Conclusions: risks and opportunities in the immediate future, and longer term agendas

Overall, there is no doubt that Brexit is bad for health. But different forms of Brexit have different implications.[139] As the UK leaves the EU, those who are concerned about health, the NHS, and the law that governs it, have a role to play to secure the 'least worst' outcome for health possible. In the immediate future, that means scrutiny of the withdrawal agreement, and the terms of the Withdrawal Bill, as well as future primary and secondary legislation that is brought forward in Parliament.

There may even be some small opportunities. At a time of significant constitutional change, great uncertainty, and openness, matters that seemed impossible to even put onto governmental agendas may suddenly become more feasible. There will be more or less legal space or constraint, depending on the terms of the withdrawal agreement and of any future EU/UK (trade) agreement(s). But any aspect of EU law that does not work terribly effectively in health contexts could be revisited. Some health professionals would like to revisit the application of the EU's working time rules.[140] The negative effects of EU public procurement law on NHS contracting behaviour could be mitigated. The UK could review its decision that UK-sourced plasma is unfit for those under the age of 21, and cease to rely on Austrian imports. Despite the lessons from the Poly Implant Prothese breast implant affair, the EU has failed to bring together its rules on marketing pharmaceuticals with those on more complex medical devices.[141] The UK could offer better patient protection here. Some of the ways in which EU pharmaceuticals law operates have not kept up with technological developments, and may be unnecessarily risk averse. There is scope for bringing together marketing authorisation decisions based on safety and efficacy, with those based on comparative clinical and cost effectiveness (health technology assessment).[142] Leaving the EU means that the UK can, if it wishes, adopt new rules for air or water quality, waste

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[138] Some examples include: the interpretation of the Human Fertilisation and Embryology Act in the *Diane Blood* ruling [1997] 2 All ER 687; the interpretation of product liability law in *A v National Blood Authority* [2001] 3 All ER 289; of the application of competition law to health services in *BetterCare* [2002] CAT 7, or in *Genzyme* [2004] CAT 4 and *Napp Pharmaceutical Holdings* [2002] CAT 1; of data protection law in *Source Informatics* [2001] QB 424; or of alcohol regulation in *The Scotch Whisky Association and ors v The Lord Advocate* [2013] CSOH 70; [2014] CSIH 38; [2016] CSIH 77.

[139] See N. Fahy, M. Galsworthy, S. Greer, T. Hervey, H. Jarman, M. McKee, D. Stuckler, 'How will Brexit affect health and health services in the UK? Evaluating three possible scenarios against the WHO health system building blocks' *The Lancet forthcoming* 2017.

[140] Directive 2003/88/EC [2003] OJ L299/9.

[141] European Parliament, 'Resolution of 14th June 2012 on defective silicone gel breast implants made by French company PIP (2012/2621(RSP)' (European Parliament 2012). Council also requested the Commission to take action see: Conclusions of the Council of the European Union on innovation in the medical device sector' [2011] OJ C202/7; see Regulation (EU) No 2017/745 [2017] OJ L117/3.

[142] 'Brexit's Potential Health Benefits' *Financial Times* (2017) https://www.ft.com/content/4560f016-3a2b-11e7-ac89-b01cc67cfeec (accessed 13 July 2017).

disposal, marketing food, alcohol and tobacco within the UK. All of this type of law can have significant effects on public health, particularly of children. Depending on the future EU/UK (trade) agreement(s), trade rules could exist and could be interpreted in ways that are similarly supportive of health to those of EU law. But there are dangers too. Outside of the EU, particularly if the UK adopts a 'low taxation, low regulation' approach to its economy, the current legal protections for consumers, patients and the population will (eventually) no longer be in place.

For PM May's government, Brexit must be seen to be 'a great success'.[143] Because health, and the NHS, was important in the referendum, the health community have at this moment a significant piece of political capital and resource for governmental time and attention. The human rights lawyer June Osborn has observed, 'Rights talk buys ten minutes of their attention. I use it like a magic wand'.[144] A crucial factor in the EU referendum was the pervasive belief that leaving the EU would mean more money for the NHS. The 'Brexit bus', upon which this lie[145] was emblazoned, along with the official NHS logo, became an iconic image of the campaign. Health lawyers and those in the health policy community can use the lie about the NHS on the Brexit bus as their own 'magic wand'. Deployed judiciously, it will attract attention from those who are making decisions for the UK's post-Brexit future, which can be used to argue for as healthy a Brexit as feasible.

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[143] 'Das desaströse Brexit-Dinner' *Frankfurther Allgemeine* (2017) http://www.faz.net/aktuell/brexit/juncker-bei-may-das-desastroese-brexit-dinner-14993605.html (accessed 13 July 2017).

[144] J. Osborn, Harvard Law School and François-Xavier Bagnoud Center for Health and Human Rights Workshop, *Economic and Social Rights and the Right to Health*, September 1993, www.law.harvard.edu/programs/HRP/Publications/economic1.html http://hrp.law.harvard.edu/wp-content/uploads/2013/08/EconomicandSocialRightsandtheRighttoHealth.pdf, p. 8.

[145] 'Brexit: Vote Leave camp abandon £350m-a-week NHS vow in Change Britain plans', *The Independent* (2016) http://www.independent.co.uk/news/uk/home-news/brexit-nhs-350m-a-week-eu-change-britain-gisela-stuart-referendum-bus-a7236706.html (accessed 13 July 2017).