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## **The Human Fertilisation and Embryology Act 2008**

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The UK Human Fertilisation and Embryology Act 2008<sup>1</sup> was a landmark in national scientific decision-making, covering emotive issues such as the creation of human admixed embryos and 'saviour siblings'. The process of debate and policymaking leading to its passage has remained controversial after the fact, as have its myriad provisions and their impact in practice.

This special issue of *New Genetics and Society* on the Human Fertilisation and Embryology Act 2008 ("the 2008 Act")<sup>2</sup> arises out of a multidisciplinary workshop held at the Economic and Social Research Council's (ESRC) Genomics Policy and Research Forum (the Forum),<sup>3</sup> University of Edinburgh, in January 2011. The Forum's ongoing engagement with the 2008 Act began two years earlier, in March 2009, with a major "Retrospective" workshop in London.<sup>4</sup> The majority of the 2008 Act came into force in October 2009, and the Forum

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<sup>1</sup> [http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH\\_080211](http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_080211).

<sup>2</sup> In this editorial, we use the term "HFE Act" to refer to the legislative framework in a general sense, compared to the use of the terms "the 2008 Act" and "the 1990 Act" to refer to the relevant legislation specifically.

<sup>3</sup> The ESRC Genomics Policy and Research Forum (the Forum) is a novel initiative funded by the UK's Economic and Social Research Council (ESRC). The Forum is a knowledge exchange unit that aims to connect social science research on genomics and related areas of the life sciences with policymakers, business, the media and civil society. The Forum also has a capacity-building remit, strengthening UK and international research capacity in this field, and in particular building capacity for interdisciplinary research by enabling dialogue and networking between researchers in different disciplines. The Forum is part of the ESRC Genomics Network, a major ESRC investment spanning five UK universities, which researches ethical, legal and social aspects of genomics, biotechnology and the life sciences. See <http://www.genomicsnetwork.ac.uk/forum/>

<sup>4</sup> <http://www.genomicsnetwork.ac.uk/forum/publications/egneventreportsvideospresentations/title.8496.en.html>.

organised a second workshop that same month at the Genomics Network Annual Conference in Cardiff.<sup>5</sup> At both of these previous events it was evident that scholars across a wide range of different social science and humanities disciplines were researching the legislation. However, it appeared that there was little opportunity for these individuals to connect with one another across disciplinary boundaries, leaving scope for the development of cross-disciplinary dialogue. Consequently the Forum conceived its next event in the series explicitly as a capacity-building and networking event for academics working in this area.

The January 2011 workshop, from which this special issue arises, took place more than two years after the Human Fertilisation and Embryology Bill ("the HFE Bill") passed through Parliament to become legislation.<sup>6</sup> This meant that by the time the workshop took place, a number of researchers in the field had analysed the legislation's development, considered the legislation's provisions and the implications of them, and had contemplated future issues that may arise as a result of the new legislation. The workshop was attended by scholars from a range of different disciplines (sociology, law, media studies, bioethics, and political science, for example) and offered researchers who were working on the 2008 Act the chance to meet, network, share their findings, and begin discussions across disciplinary boundaries. Presentations at the event covered the full chronology of the 2008 Act, including the

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<sup>5</sup> <http://www.genomicsnetwork.ac.uk/media/Workshop%20Forum.pdf>.

<sup>6</sup> For a full programme and presentations from the event, see <http://www.genomicsnetwork.ac.uk/forum/events/pastevents/workshops/title,24118,en.html> For a detailed event report, see Knight and Smith (2011).

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polymaking process, the legislative provisions themselves, and the subsequent impact of the legislation. The co-authors/editors of this issue planned the workshop in their capacity as Genomics Forum Policy Research Fellow (Knight) and Bright Ideas Programme<sup>7</sup> Visiting Fellow (Smith).

At the time the workshop took place, the participants and organisers noted that although the literature existing at that time included a range of individual articles addressing specific areas of the 2008 Act, there was no collection (either as a journal special issue, or an edited book) that considered the legislation as a whole. This special issue of *New Genetics and Society* fills that gap. The five papers that follow in this special edition are written by scholars from law and political science. They engage with the full range of substantive issues covered by the HFE Bill and the 2008 Act, including animal-human hybrid embryos, abortion, the welfare and parenthood provisions, the creation of 'saviour siblings', and the issue of pro-disability selection. The papers in this special edition cover the full chronology of the 2008 Act, ranging from the public and parliamentary debates through to implementation. Importantly, they consider the HFE Act not only as a concluded piece of legislation, but as a process, by bringing together analyses of the key legislative changes and the political process that brought them about. The collection includes three of the four papers presented at the workshop (Childs et al.; McCandless; Smith) along with two further research papers (Porter and Smith; Gillott) to ensure full coverage of the above topics. The fourth paper presented at

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<sup>7</sup> <http://www.genomicsnetwork.ac.uk/forum/people/brightideasfellowshipsandresidencies/>.

the workshop has been published elsewhere (Williams and Gajevic 2012), and will, we hope, be read in conjunction with this collection.

### **The legislative reform process**

The detailed process of review and reform of the HFE Act 1990 ("the 1990 Act") began in January 2004, when the Parliamentary Under-Secretary for Public Health announced that the UK Government had decided to review the 1990 Act by way of public consultation, and that the review would be conducted by the Department of Health (Department of Health 2005).

The reform of the 1990 Act was intended to preserve the original regulatory framework overseeing assisted reproductive technologies (ARTs) and embryo research in the UK. By 2004, it had become evident that the legislative scheme was unable to keep pace with the scientific, technological and social advances since its introduction in 1990. Some of these problems were highlighted in the 2005 report of the House of Commons Science and Technology Committee (HCSTC), *Human Reproductive Technologies and the Law*. Other commentators have also highlighted the numerous problems with, and challenges to, the statutory framework that had occurred over the years (Fox 2009). The 2008 Act sought to address these problems, rather than introduce a different system of regulatory control: '[n]owhere was a blank piece of paper offered for reform, in a way that allowed for a thorough and fundamental rethinking of the kind of regulation which might best suit this area' (McCandless and Sheldon 2010, 180).

When the Department of Health launched its consultation process in 2005, it made clear that the review process was not intended to consider fundamental or underlying aspects of the legislation (House of Commons Science and Technology Committee 2005, 136). As noted by the HCSTC, the focus of the legislative reform process sought to avoid revisiting some of the more controversial issues underlying ARTs, observing: 'nevertheless we see dangers in conducting a review in which around 20% of the population feel that their view that the embryo is entitled to full human rights at conception is ignored' (House of Commons Science and Technology Committee 2005, 136). The Department of Health sought submissions from the public on the range of issues dealt with by the 1990 legislation.

The Department of Health published its report in December 2006, which included a proposal to merge the Human Fertilisation and Embryology Authority (HFEA) with the Human Tissue Authority (HTA) to form the Regulatory Authority for Tissue and Embryos (RATE). This proposal was later abandoned. The Department of Health then produced a draft bill in May 2007. Following this, a motion was passed in both Houses of Parliament to appoint a Joint Committee to scrutinise the proposals for legislation. The draft bill was then considered by the Joint Committee on the Human Tissue and Embryos (Draft) Bill ("the Joint Committee"). The Joint Committee also published a report addressing the proposed changes to the legislation (Joint Committee on the Human Tissue and Embryos (Draft) Bill 2007). The Committee's report was met by a formal Government response (UK Government 2007). In addition to this significant legislative review process, the House of Commons Science and

Technology Committee also considered the issues relating to the regulation of hybrid and chimera embryos and published its report in 2007 (HCSTC 2007).

The proposals for reforming the law reached Parliament in 2007, in the form of the HFE Bill. Debate on the Bill commenced in the House of Lords in November of that year and progressed to the House of Commons in May 2008. Some of the Bill's provisions were subject to considerable scrutiny, following which a number of further changes were made. The debate focused on a number of issues that were considered to be of particular concern, including the 'welfare clause'; creation of 'saviour siblings'; human-animal hybrid embryos; and abortion. All four of these issues are considered in detail within this special edition (McCandless; Smith; Gillott; Childs et al.).

The reform of the 1990 Act thus involved a high degree of public debate and consultation, a process that is not as extensively undertaken in other areas of law reform. Baroness Williams of Crosby noted that the 'Bill is a remarkable counter-example of how to involve people in the deepest discussion on a matter of such complexity and importance' (HL Deb, 19 November 2007, 696, col. 685).

### **The key legislative changes**

As a result of the reform process, a number of key amendments were made to the 1990 Act. An overview of these changes is outlined below. The reforms are grouped within four 'broad categories' that have been identified by Fox (2009). The first group concerns the 'impact of



fertility treatment on the family', and most notably includes the amendments relating to the 'welfare clause' and the parenthood provisions (Fox 2009, 337). As outlined by McCandless in this edition, the statutory requirement to consider the prospective child's welfare has been amended so that there is no longer a need to consider the child's 'need for a father', but instead the child's need for 'supportive parenting'. Moreover, as noted by Fox (and also discussed by McCandless in this edition), the changes to the parenthood provisions 'expand the range of those who will legally count as parents'; a change that represents a 'shift towards gender neutrality' (Fox 2009, 337). These latter changes were enacted in an attempt to recognise the changing nature of familial relationships within modern society, and to reflect other legal advancements concerning the recognition of same-sex relationships. In addition to these major changes, there were also a number of further changes that fall within this first 'broad category'. Thus the 2008 Act amended the statutory storage periods for gametes and embryos; this included the introduction of a one-year 'cooling off' period to enable ART centres to lawfully store embryos in circumstances where an individual seeks to withdraw his or her consent to the use of embryos that were created from that person's gametes. This specific amendment was intended to address issues such as those raised by the case of *Evans v UK* (Application no. 6339/05).

The second 'broad category' of changes to the 1990 Act, as outlined by Fox, concerns the reform of the HFEA's data collection policies and how information is held on the HFEA's register (Fox 2009, 338). The provisions implemented by way of the 2008 Act confer 'certain new rights to information' and confirm previous reforms that had removed donor anonymity

(Fox 2009, 338). This aspect of the reformed legislation has been considered elsewhere by Jones (2009).

The third group of legislative changes concerns the issue of reproductive choice, and more specifically the use of reproductive technologies to select certain characteristics in future offspring (Fox 2009, 339). Fox observes that these changes seem to endorse the policy of the HFEA that was in place prior to the legislative reform process (2009, 339). For example, the 2008 Act imposes a prohibition on the use of ARTs for social sex-selection, a prohibition that was previously found within the HFEA's Code of Practice. The HFE Act also now directly permits the use of embryo selection techniques in cases where parents seek to create a child as a source of tissue for an existing sick child. Furthermore, the 2008 Act has also introduced a prohibition that prevents the utilisation of ARTs to screen *in favour* of disability. Smith, and Porter and Smith, examine these latter two issues further in this special issue.

The final 'broad category' of reform concerns the statutory provisions addressing embryo research. There were three major changes implemented within this final category as a result of the 2008 Act (Fox 2009). First, the 2008 Act consolidated and expanded 'the list of permissible purposes for which research licences may be granted under the 1990 Act and the 2001 Human Fertilisation and Embryology (Research Purposes) Regulations (the latter are repealed)' (Fox 2009, 340). Second, the Act also redefines the meaning of 'embryo' 'to omit any reference to its mode of creation'; a change that was implemented in response to legal challenges mounted against cloning techniques, which argued that such techniques fell

outside the prohibition on reproductive cloning contained within the original 1990 Act (Fox 2009, 340). Third, and most significantly, the 2008 Act was a bold move in the sphere of embryo research, as it permitted the granting of research licences for the creation of hybrid embryos, which are a mix of human and animal tissue. As acknowledged by Fox, proposals to change the law to allow the creation of such embryos was an extremely contentious issue, and one that was initially opposed by the government (Fox 2009, 340). The issue concerning the move to allow licensing of hybrid embryo research is considered extensively in this special edition by Gillott.

### **Overview of the special issue**

The HFE Act covers a wide range of issues relating to assisted reproduction and embryology. The papers in this special issue cover a similarly wide range of issues relevant to the legislation, looking back at the consultation process and parliamentary debates, and forward to the Act's implications in unforeseen situations.

Childs et al.'s paper analyses the parliamentary votes and debates relating to amendments that were proposed concerning the legal time limit, the grounds, and the requirements for abortion in the UK, following introduction of the HFE Bill in November 2007. Specifically, Childs et al. focus on the role of women parliamentarians in the debates, showing that 'women's presence matters' in Parliament in supporting women's current abortion rights. Abortion was covered by the HFE Act 1990, and consequently by the statute as amended in 2008. The recent HFE Bill did not contain any clauses that addressed abortion directly; however,

abortion amendments were proposed, though none were ultimately successful. (All were more restrictive than the present position.) Consequently, abortion is absent from the amending statute (the 2008 Act). Amongst many important points relating to women's political representation, Childs et al.'s paper shows that which is *not* in the legislation as passed is just as important as what *is*, in terms of political and public controversy and debate. Methodologically, a full analysis of the significance of the 2008 Act therefore requires attention to evidence beyond the legislation itself, including the parliamentary debates.

In her paper, McCandless examines the parliamentary debates surrounding two specific issues that have been the subject of reform under the 2008 Act: the 'welfare clause' and the parenthood provisions. In particular, she asks why, out of eighty hours of parliamentary debate, eight of those hours were spent debating the welfare clause whilst only one was spent debating the parenthood provisions. The welfare clause is a standard licence condition imposed upon all licensed ART clinics and it requires staff to consider the welfare of any prospective child that may result from the provision of ART services. Under the 1990 Act, the welfare clause imposed a requirement to consider the prospective child's 'need for a father'. As outlined above, as a result of the reform process, the words 'need for a father' were removed from the welfare clause and the 2008 Act instead requires consideration of the child's need for 'supportive parenting'. McCandless argues the point that, in practical terms, the welfare clause deserved far less devotion by parliamentarians during debate, compared to the parenthood provisions. She considers some of the criticisms that have been levelled against the welfare clause and argues that this change in wording is unlikely to have any real

practical impact. In contrast to this position, McCandless highlights the importance of the legal parenthood provisions and argues that although the changes to the parenthood provisions are intended to better reflect changing social norms concerning parenting and modern family structures, there is an underlying tone within the legislation that points towards the 'traditional' family form. Her paper also addresses some of the inconsistencies in the reformed law, which, in some contexts, prioritises bio-genetic links in attributing parenthood but ignores such links in other cases. Significantly, McCandless' contribution to this special edition highlights how the failure to engage in sufficient debate concerning the parenthood provisions neglects a fundamental issue: the question of what makes someone a parent, and why.

The issue of creating 'saviour siblings' was also a matter that gained considerable attention during parliamentary debate about the HFE Bill. In his paper, Smith considers the significance of the decision to address the creation of 'saviour siblings' on the face of the legislative framework. Under the reformed legislation, a number of conditions are now imposed in circumstances where a family seeks access to ART services to purposely select an embryo on the basis of its tissue type, so that they may potentially create a child as a source of tissue for an existing sick child. Smith considers some of the difficulties that have been faced when attempting to regulate this particular issue, which was not contemplated prior to the enactment of the original statutory framework. His paper traces how regulatory policy in this field has developed and he highlights how the imposition of a number of restrictions on the face of the legislation concerning the creation of 'saviour siblings' seems to be contrary to

HFEA regulatory policy in other areas. Thus Smith demonstrates that the HFEA has frequently prioritised the notion of reproductive liberty, but argues that the restrictions imposed under the 2008 Act concerning the creation of 'saviour siblings' undermine this concept. Importantly, Smith considers whether the statutory restrictions concerning the creation of 'saviour siblings' can be justified alongside an approach that seeks to prioritise the welfare of the child to be born (which in this context is the 'saviour' child). He concludes that the underlying factors guiding such restrictions appear to be focused on other normative concepts.

In the fourth paper in this special edition, Porter and Smith consider an issue that gained very little attention during the consultation and reform process, despite its inclusion in the 2008 Act. Section 14(4) of the 2008 Act introduces a prohibition to prevent the utilisation of ARTs to select *in favour* of 'serious' disabilities. The authors outline how this statutory ground is (or at least, was) aimed primarily at preventing the selection of deaf children. They note that whilst the issue of selecting in favour of deafness in the context of reproductive decision-making is ethically controversial, the real issue of significance in the context of the 2008 Act was that the automatic classification of deafness as a serious disability problematised deafness as a disability. Thus, during the reform process, a presumption was made by the legislature to imply that deafness should be classified as a *serious disability*. What is original about Porter and Smith's paper is that instead of seeking to address whether the selection of deaf children is ethically acceptable, they aim to demonstrate how the presumption to classify deafness as a serious disability is problematic because of the fact that it ignores the view that

many Deaf people do not identify as being disabled. This is a point of view that was significantly neglected during the consultation and reform process. The authors highlight how there may be a need to engage with the issue again in the future, should the statutory provision be subject to challenge or require further amendment.

Finally, Gillott's paper focuses on the regulation of animal-human hybrid embryo research under the 2008 Act. The paper explores the interaction of 'state and social actors', especially research scientists, in the decision-making process that led ultimately to the 2008 legislation. Gillott draws on a series of interviews with key players in the hybrid embryo debates, an interview study remarkable for its star-studded participant list as well as the frank on-the-record comments. Yet what his paper interrogates is precisely the question of how 'key players' in such processes of governance are identified – whose voices shall be considered important in making decisions about controversial science? Gillott shows how 'a "representative scientists' view" was constructed, namely that hybrid embryo research should be controlled by a competent authority to reflect the ethical seriousness of the undertaking, but allowed in principle on account of its importance to developing cures for human diseases'. The corollary to this was that 'those who did not see the need for specific governance arrangements for embryo research, and specifically those who saw no need to be concerned about research using hybrid embryos, were [...] excluded'. As Gillott argues, the UK's scientific governance framework is now structured to engage with diverse stakeholders and views but this has 'contributed to regulatory complexity' that ultimately, he contends, holds the UK back from the cutting edge of research.

## **Cross-cutting themes and issues**

The political science papers in this collection clearly show the value of a qualitative, discourse-based approach to research in this area (eg, Childs et al.; Gillott). Such an analysis gives attention to discursive power in the public and parliamentary debates leading to the passage of the legislation. Who speaks in these debates? What factors enable them to do so? Are there limits on what they can say? What power do their utterances have? Childs and co-authors examine the significance of women MPs' and peers' voices in the UK Parliament. For example, while Gillott examines the science governance mechanisms that enabled certain scientists' voices to be heard by politicians, while effectively silencing others, both Childs et al. and Gillott also indicate how certain arguments became 'unsayable' in the 2008 debates. Childs et al. note, for instance, the partially successful attempts to close down discussion of abortion in Parliament, while Gillott points out that the construction of a pro-hybrid embryo 'representative scientists' view' silenced the concerns of dissenting scientists.

In relation to abortion and embryo research respectively, Childs et al.'s and Gillott's papers both point out the sidelining of pro-life arguments in 2008 compared to 1990, reminding readers that the 2008 Act, and the political process which produced it, must be understood in the historical context of the 1990 legislation that preceded it. (As editors, we intend that the present collection should be read in conjunction with work on the 1990 Act [eg, Mulkay 1997; Franklin 1993; Jackson 2001; Jackson 2002]). Previous literature, in particular on the parenthood provisions under the Act, highlights the very significant changes in social



attitudes and practices in relation to family, sexuality and reproduction between the passage of the 1990 and 2008 Acts (eg, Gamble 2009; Horsey & Sheldon 2012: 68-71). Jones (2011) notes that an 'equality agenda' underpinned the 2008 legislation, with a view to 'render[ing] it fit for the twenty-first century' (208). Similarly, we highlight here the continuing significant social and other legal changes that have taken place even between the passage of the 2008 Act and the publication of this special issue in 2013. In particular, we would highlight at the time of writing, the progress of the Marriage (Same Sex Couples) Bill 2012-13 through Parliament, which is likely to render some of the 2008 Act's provisions (particularly surrounding the concept of parenthood) in need of reform. Previous commentators have noted that although the Government sought to produce 'future proof' legislation in the HFE Act 2008 (Horsey & Sheldon 2012: 88), the legislation was already out of step with science, society and other areas of law at the time it was passed – for example, in distinguishing between marriage, civil partnership and non-formalised couple relationships (McCandless & Sheldon 2010: 190). Although the 2008 Act had limited potential in being an amending statute (Horsey & Sheldon 2012: 88; McCandless & Sheldon 2010), we follow others in pointing out that the legislation will inevitably require further reform sooner rather than later, as various papers in this collection confirm.

Some of the papers in this collection also demonstrate that for many of the substantive provisions implemented by the 2008 Act, little thought was given to their practical implications (see esp. McCandless). Furthermore, there was also a failure to consider the underlying normative reasoning that had previously guided the development of regulatory

policy in the field, in order to consider how this may overlap with some of the 2008 Act's substantive principles (Smith). It is also possible that some of the provisions implemented within the statutory framework as a result of the 2008 Act may potentially form the subject of legal challenge on human rights grounds (Porter and Smith).

Finally, previous literature has highlighted silences and missed opportunities in the legislation – for example in relation to gay male parenthood (McCandless & Sheldon 2010) and surrogacy arrangements (Horsey & Sheldon 2012). Similarly, this special issue highlights the provisions that received little attention in parliamentary or public debate, not to mention topics that are not directly addressed by the legislation, which may be just as significant (if not more so) as those that are more prominent (see esp. McCandless; Childs et al.; Porter and Smith). This collection also highlights how, in many respects, the reform process surrounding the 2008 Act failed to engage sufficiently with issues that required more detailed and adequate consideration (Porter and Smith; McCandless). In many instances, it was not necessarily the force of what was included in the substantive provisions of the 2008 Act that has proven problematic, but instead what was lacking or missing from the process that led to the passing of those provisions (Porter and Smith; McCandless). For example, in the context of selecting in favour of disability, Porter and Smith's paper demonstrates that there was a complete failure to consider how the automatic classification of deafness as a *serious* disability may impact upon the Deaf community and others who have lost the ability to hear. Whether such silences are considered missed opportunities, or successful avoidance of scope creep, may well depend on one's political views.

## **Postscript**

There are two matters of importance that we should highlight in relation to the 2008 Act, now that it has been fully implemented. First, the research landscape concerning hybrid embryos has altered significantly to that which was contemplated during the reform process. Thus, in October 2010, the HFEA responded to a request under the Freedom of Information Act 2000, with details of how many licences had been granted for research on human admixed embryos, noting that at that time, only three licences had been granted for this purpose (HFEA 2010). This response also highlighted the fact that the licences had since lapsed and that for one of the licences, an application had been made to have the licence revoked. Despite the fact that the impetus for legislative change was aimed at addressing the demand for licences to undertake research on hybrid embryos – a driving force that was backed by a ‘significant lobbying and media campaign by the research establishment’ (Fox 2009, 340) – the desire to undertake hybrid embryo research has since declined. However, it should also be noted that the ‘human embryo research’ section of the HFEA’s website contains a list of ‘approved research’, which, at the time of writing, confirms that a licence is held by the Centre for Stem Cell Biology & Developmental Genetics, at the University of Newcastle Upon Tyne’s Institute of Genetics.

Finally, the regulatory context for assisted reproduction and embryology in the UK has been uncertain and potentially fluid for nearly a decade, due to proposals by successive Governments for major reform of public bodies. As a result, scholarly contributions to this

field are inevitably specific to some extent to the date at which they were written, in this regard and others. The papers for this collection, and this editorial, were finalised at different points between mid-2011 and early 2013. As noted, the former Labour Government originally proposed merging the HFEA and HTA into a new Regulatory Authority for Tissue and Embryos (RATE) in 2004. The Joint Committee on the Draft Human Tissue and Embryos Bill considered this proposal, and ultimately convinced the Government to abandon the idea in 2007. However, following the general election of May 2010, the new Coalition Government again announced plans to abolish the HFEA and transfer its functions to other regulators, as part of wider reform of public bodies (dubbed the 'Bonfire of the Quangos'). Callus has recently argued that there may be a justificatory need to do away with the current 'regulatory architecture' in the UK concerning ARTs, noting that some of the HFEA's 'functions could now be absorbed by a general healthcare regulator' (2011, 111). This view is reflected by the fact that in the second half of 2012, the Department of Health consulted on the proposal to abolish the HFEA and HTA, and divide their functions between the Care Quality Commission and Human Research Authority. However, as a result of the consultation, the Government announced that it would not pursue this option further at this stage. At the time of writing, a further independent review, reporting to ministers in April 2013, is considering the feasibility of an HFEA-HTA merger. However, even if the review deems a merger feasible, it would seem impossible to predict if and when such a merger would take place, let alone its likely impact.

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