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ABSTRACT

Name of University: The University of Manchester

Candidate Name: Sacha Rebecca Waxman

Degree Title: PhD in Bioethics and Medical Jurisprudence

Thesis Title: The Pre-Conception Welfare Principle: A Case Against Regulation

Submission Date:

This thesis focuses on the use of a child welfare principle in human assisted reproduction in the UK, as contained in section 13 (5) of the Human Fertilisation and Embryology Act 1990 (as amended). Given the principle is applied prior to conception, I argue that it should be distinguished from the familiarly known child welfare principle in child law and thus my focus is on the pre-conception welfare principle (PCWP). The aim of this thesis is to provide an argument for abolition of the PCWP from UK regulation.

This thesis aims to add to the debate and complement the existing body of legal and philosophical literature which has critically analysed the function of the PCWP from various perspectives. It does so by highlighting the importance of terminology throughout the work and focusing on the broader implications of the PCWP in practice. I argue that the implications of the PCWP go far beyond its position in the legislation and in order to substantiate that central argument, I separate the function of the PCWP assessment into distinct categories of harm based regulation. Before doing so, however, I critically analyse the development of the PCWP; I consider its function as a regulatory method and I challenge whether it has a defendable ethical position in the current framework. Overall, I argue against the PCWP and the harm threshold rationale underpinning it in practice.

In Part I, I first set out the background to this type of research and explain why this work is important for challenging unjustified state intervention on reproductive choice. Second, I set the scene by outlining the development of the welfare principle in child law; the legislative chronology of the PCWP and the function of Principles Based Regulation (PBR) in the current regulatory framework. This entails setting out a number of assumptions, arguments and debates surrounding the concepts of welfare and harm and how these have been framed in regulation; in addition to setting out a central theme of this thesis, which is an argument that the regulation of the PCWP does not meet requisite standards of consistent, transparent, objective, proportionate and contextually-sensitive regulation. These assumptions and
arguments are vital for understanding the basis on which this work challenges the suitability
of the PCWP in the current regulatory framework.

Part II of the thesis contains the papers and delivers the arguments against the PCWP in
sequence. The overall aim of Part II is to present the central argument of the thesis and
answer the research questions set out in the introduction. To accomplish this, the thesis first
explores how the borders of child welfare have been defined by child law and judge-made
law in wrongful life cases or cases involving the withdrawal or withholding of treatment from
sick children. This is followed by a chronological and comparative legislative assessment of
the development of the regulation of child welfare in the context of the PCWP. This
develops into the main argument of the thesis which demonstrates the application of PCWP
in practice departs from benchmark standards of better regulation. The thesis moves on to
provoke a fresh debate on the relationship between pre-conception child welfare and the
familial and genetic harm thresholds which are mandated by the PCWP assessment. The
concept of harm is explored in a philosophical sense and the arguments culminate in a
contention that no single philosophy underpins the PCWP, and that there is therefore no good
reason to retain a principle which is problematic in both a functional and substantive sense.

The thesis concludes with an overview of the progression of the main themes in this thesis, as
well as identifying some promising opportunities for future research which have arisen as a
result of this work.
DECLARATION AND COPYRIGHT STATEMENT

DECLARATION

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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If not for the unconditional support, trust and love from my parents, Maxwell and Jacqueline, I would never have achieved this.

This is all for you.
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THE AUTHOR

PhD in Medical Jurisprudence and Bioethics
The University of Manchester, School of Law
January 2014 – Present
“The Pre-Conception Welfare Principle: A Case Against Regulation”
Supervisors: Professor Rebecca Bennett and Dr. Sarah Devaney

Legal Practice Course
BPP Professional Education, Manchester
September 2005 - September 2006
Grade: Commendation

MA Healthcare Ethics and Law
The University of Manchester, School of Law
September 2004 - September 2005
Dissertation: ‘Eugenics in Disguise’
Grade: Merit

LL.B Law (Hons)
Manchester Metropolitan University, School of Law
September 2001 - September 2004
Dissertation: ‘From the Feminist perspective, discuss in relation to domestic violence the women who kill their abusers’.
Grade: Second Class Honours

AWARDS AND SUCCESSFUL FUNDING BIDS:

(£5,000) Lead Investigator

‘Postgraduate Bioethics: Binaries in Bioethics’ (2015) Institute of Medical Ethics
(£1,000) Lead Investigator

PEER-REVIEWED PUBLICATIONS

M. Brazier and S. Waxman. ‘Reforming the law regulating surrogacy: extending the family’ (2016) *Journal of Medical Law and Ethics* 4, 159-180.


**DESTINATION**

From 1st September 2017 I will be working as a Lecturer in Law at the University of Liverpool.
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Serious Crime Act 2003
Serious Crime Act 2015
Sex Offenders Act 1977
Sexual Offences Act 2003
Surrogacy Arrangements Act 1985
United Nations Convention on the Rights of Persons with Disabilities
United Nations Convention on the Rights of the Child
### LIST OF ABBREVIATIONS

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<th>Description</th>
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<tbody>
<tr>
<td>ACGT</td>
<td>Advisory Committee on Genetic Testing</td>
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<td>ARTs</td>
<td>Assisted Reproductive Technologies</td>
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<td>BRTF</td>
<td>Better Regulation Taskforce</td>
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<tr>
<td>Cafcass</td>
<td>Children and Family Court Advisory and Support Service</td>
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<td>CF</td>
<td>Cystic Fibrosis</td>
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<tr>
<td>CoP</td>
<td>Code of Practice (HFEA)</td>
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<tr>
<td>CRISPR</td>
<td>Clustered regularly interspaced short palindromic repeats</td>
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<tr>
<td>ECtHR</td>
<td>European Court of Human Rights</td>
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<tr>
<td>GOSH</td>
<td>Great Ormond Street Hospital</td>
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<td>HCSTC</td>
<td>House of Commons Science and Technology Committee</td>
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<td>HD</td>
<td>Huntington’s disease</td>
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<td>HFE Act 1990</td>
<td>Human Fertilisation and Embryology Act 1990</td>
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<td>HFE Act</td>
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<td>HFEA</td>
<td>Human Fertilisation and Embryology Authority</td>
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<td>HGC</td>
<td>Human Genetics Commission</td>
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<td>HGP</td>
<td>Human Genome Project</td>
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<td>IVF</td>
<td>In Vitro Fertilisation</td>
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<td>LAs</td>
<td>Local Authority’s</td>
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<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
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<td>PBR</td>
<td>Principles Based Regulation</td>
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<tr>
<td>PCWP</td>
<td>Pre-Conception Welfare Principle</td>
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<tr>
<td>PGD</td>
<td>Preimplantation Genetic Diagnosis</td>
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<tr>
<td>PND</td>
<td>Prenatal Diagnosis</td>
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<tr>
<td>RCPCH</td>
<td>Royal College of Paediatrics and Child Health</td>
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<td>SC Research</td>
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<td>UNCRC</td>
<td>United Nations Convention on the Rights of the Child</td>
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<td>UNCRPD</td>
<td>United Nations Convention on the Rights of Persons with Disabilities</td>
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No society, no religion, no culture, and no system of national law has been neutral about issues of human reproduction.¹

PART I

INTRODUCTION
1.0 INTRODUCTION

Sometimes it seems as though the dizzying pace of reform reflects little thought about the whole picture. More attention is paid to policy and ethical debate than law. There is insufficient rigorous analysis of what the limits of the law’s remit should be.

In the United Kingdom (UK), it is estimated that one in seven heterosexual couples may experience difficulty conceiving. That accounts for approximately 3.5 million people. It is an absolute certainty, therefore, that human assisted reproductive technologies (ARTs) will continue to affect many people’s lives to a great extent in years to come. The continuous advancement of human embryonic science, genetics and biotechnology is likely to be inevitable. The expanding capabilities of ARTs, genetic diagnostic techniques and modification technologies have the power to irrevocably change the human population as we know it. Whilst increasing attention is paid in legal and theoretical discourse to the uses of reproductive technologies, it often provides just a partial picture which is lacking in a legal analysis of the core question of the legitimacy of the state’s control over reproductive activity. This is important for two reasons. First, because of the issues surrounding who can access licensed fertility treatments and second, because how much individuals receiving treatment are allowed to be maximally autonomous is predetermined in UK law. In theory, such control affects private as much as state funded patients. Thus, despite the broad normalisation of ARTs in the last four decades, the law has significant impact. This has very important implications not just for those who are alive today, but also for the people of tomorrow embarking on their reproductive path.

1.1 THE IMPORTANCE OF TERMINOLOGY

The issues explored in this thesis relate to the centrality of one principle in the law regulating ARTs, familiarly known as the ‘welfare principle’. In the UK the concept of a child welfare principle has its origins in child law. When the welfare of a born child is in issue the welfare principle is a key dimension in the legislative regime authorising state intervention into private aspects of family life. However, from the outset, a crucial point must be elucidated upon. Throughout this work, terminology is utilised to distinguish and reframe a basic

---

2 Margaret Brazier and Emma Cave. Medicine Patients and the Law (6th edn Manchester University Press 2016) xxii.
contextual understanding of the ambit of the child welfare principle in the context of ARTs regulation. I refer to the principle in this context as the PCWP. Linguistically this achieves one central aim: to be a continual reminder that this version of it is entirely theoretical. The PCWP applies pre-emptively, as opposed to upon birth and throughout the child’s life. It requires clinics providing licensed fertility services to consider the welfare of future individuals before their conception. Thus, the PCWP, which is central to the normative framework regulating ARTs, is distinct from considerations of an existing child’s welfare in healthcare or child law. Crucially, it relates to a theoretical child, one that is yet to be conceived and often is yet to exist in embryo form. In order to engage with what the PCWP means, and understand what it demands, it is crucial to acknowledge that unique feature.

The title of this work: *The Pre-Conception Welfare Principle: The Case Against Regulation* is intended to reflect that this topic is a live issue. The aim is to direct discussion in a slightly different direction and provoke new debate concerning the broader function of the PCWP in practice. While state intervention might be thought necessary in order to prevent a maverick doctor embarking on contentious research or to prevent the secret use of his own sperm in patients’ treatment; and to protect the rights and interests of individuals involved, it can also be dangerous if legal intervention in individuals’ reproductive choices goes too far without question. The problem is that there is a tendency to become rather blinded by the law and resist asking questions about the functionality or fairness of law and public policy. Despite the PCWP occupying only section 13 (5) of the Human Fertilisation and Embryology Act (as amended) (the HFE Act), its practical effect is not so confined and its impact far outweighs its presence on paper. This aspect of regulation is often overlooked and the broader implications of the PCWP are the focus of this work. In that regard, this work provides an important quality check on the nature of state intervention via PCWP regulation. This is important since reproductive choices in the context of ARTs demand a balanced response from law and public policy. Unnecessary state intervention in the context of reproductive decision-making can have an unjustifiable and negative effect on individuals and society as a whole.

Throughout the work presented here I aim to develop the argument for abolition of the PCWP adding additional original arguments to those advanced in the literature.\(^4\) It is argued that the

law regulating the PCWP, when properly understood, is fundamentally flawed and indefensible. This is because the PCWP is built on intuition, grounded in abstract concepts and demands impossible considerations based on unsubstantiated hypotheses. In addition, the PCWP is lacking key benchmark standards of regulation that are expected in law and public policy, this is particularly so given it occupies such a powerful role within the framework. The purpose of this work is to highlight the legal, practical and theoretical complexities in regulating the PCWP and to reveal that the tensions in the current framework actually go far beyond normative issues of child welfare.

1.2 IDENTIFYING THE TWO KEY PROBLEMS

The fundamental problem with the PCWP is that it is used to justify state intervention in the context of ARTs. This is problematic because it is grounded in misconceived notions pertaining to the welfare of the born child. Attention in legal discourse to the concept of a child welfare principle in ARTs was normalised through an extrapolation of the existing welfare principle in child law. Judicial commentary in child law traces back to Lord MacDermott in the seminal decision of \textit{J v. C} \textsuperscript{5} in which he denotes child welfare as the paramount consideration defined by:

\begin{quote}
A process whereby, when all the relevant facts, relationships, claims and wishes of parents, risks, choices, and other circumstances are taken into account and weighed, the course to be followed will be that which is most in the interests of the child’s welfare. That is the paramount consideration because it rules upon or determines the course to be followed.\textsuperscript{6}
\end{quote}

Later incorporated into the Children Act 1989 (CA 1989) the widespread acceptance of the welfare principle provided Parliament with a tool to regulate prospective families in the context of ARTs when Parliament came to debate the Human Fertilisation and Embryology

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\textsuperscript{5} \textit{J v. C} [1970] AC 668.

\textsuperscript{6} Ibid, 710.
Bill and what was to become the PCWP. In developing the latter piece of legislation however, Parliament stepped into uncharted territory, regulating the application of a welfare principle in a pre-conception context. This link between the welfare principle in child law and the PCWP demonstrates the extension of the dominant tradition of social administration of families. State intervention created an additional supervisory framework of regulation in which state institutions and agencies regulate the formation of families by assessing the suitability of those prospective parents who require assistance to conceive. The most important factor then in play, which must be held paramount when the policy implications of the PCWP are considered, is the constraint on reproductive choice it imposes. Whether the intrusion was necessary and justifiable is one matter; whether it has anything to do with child welfare is another.

The other key problem with the PCWP involves the formation of a harm threshold assessment in the regulatory framework governing ARTs. It is provided by the sector’s regulator, the Human Fertilisation and Embryology Authority (the HFEA). Contained within the PCWP’s codified assessment of child welfare in the Code of Practice (the CoP), it pre-assesses potential familial harm and genetic harm as regards the pre-conceived and thus theoretical child. Under the ambit of the PCWP, the two pronged harm threshold assessment represents the core of state interference in ARTs. This thesis separates the two distinct strands of harm-based regulation – which isolate and assess familial harm and genetic harm – and demonstrates that each harm threshold is based on a nebulous concept of pre-conception harm. Both mandate a projected harm assessment at the clinical level in every case when couples or individuals seek access to ARTs. If the PCWP assessment is not satisfied then licenced fertility treatment should be refused. If the familial aspect of the harm assessment

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7 CoP 8th edn (2009) at 8.0. The CoP 8th edition was first published in 2009 and is in effect at the time of writing. It was revised and updated in April 2010, April 2011, October 2011, April 2012, October 2013, October 2014, April 2015, October 2015, July 2016 and May 2017. Each paper included in this work refers to the CoP 8th edn (2009) and the references relate to the particular version of the CoP which was in force at the time of writing and submission to the peer reviewed journal.

8 The exact terminology contained in section 13 (9) of the HFE Act 1990 (as amended) states: “Persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop (a) a serious physical or mental disability (b) a serious illness, or (c) any other serious medical condition.” This provision largely mirrors the content and terminology contained in the CoP 8th edn (2009) at 8.0 and 10.0, which detail the PCWP harm threshold assessment and embryo testing guidance respectively. For the purpose of continuity and given the overarching argument advanced in this thesis, I refer to the regulation of serious medical harm as contained in section 13 (9) as the ‘genetic harm threshold’.

9 CoP 8th edn (2009) details the factors to consider during the PCWP assessment process at 8.10. At 8.15 it documents the procedure for refusing treatment. The CoP states a centre should refuse treatment if it (a)
is passed then licensed fertility treatment can progress. If the genetic harm threshold assessment then establishes a risk of serious harm to a theoretical child, separate legislative and regulatory restrictions on embryo selection (based on the PCWP harm assessment) limit the scope of reproductive choice in the embryo selection process.\textsuperscript{10} The restrictions on reproductive choice, and the basis on which they are justified in the regime, are explored in full in the body of this thesis in \textbf{Part II}. The central argument arising out of this examination, which identifies the PCWP as the justifying component for state intervention, is a call for abolition of the principle.

There are several questions to be asked which allow me to construct this argument. These are:

1. How is the PCWP used in the regulation of ARTs?
2. What is the PCWP asking decision-makers to do in practice?
3. What is the harm threshold?
4. How is the PCWP used in practice to restrict reproductive choice?
5. On what basis is this state interference justified?
6. What does this mean regarding the PCWP as an appropriate regulatory method?

These questions are addressed separately and together within the published papers in \textbf{Part II} that comprise the main body of this work. To a certain extent, there is some overlap in the content of the papers, in terms of the development and function of the PCWP, and the explanatory detail as regards the statutory restrictions on embryo selection that are linked to it. But this overlap is inevitable given that the papers are self-contained pieces in which it was necessary to outline the state of play in regulation for the academic peer-reviewed journals to which they were sent. That being said, each paper in turn explores a different aspect of the overall regulatory approach to the PCWP and addresses a different core problem in the framework. A more detailed overview of the papers is provided below in [3.1].

\textsuperscript{10} Section 13 of the HFE Act 1990 stipulates the conditions of licences for treatment. Subsection (9) and (10) expressly relate to the use of embryo testing and embryo selection. In addition to the PCWP assessment contained in the CoP, there is additional guidance on embryo testing, embryo selection and sex selection. The legislative and regulatory provisions are discussed in depth in \textbf{Part II}.  

\underline{concludes that any child who may be born or any existing child of the family is likely to be at risk of significant harm or neglect, or (b) it cannot obtain enough information to conclude that there is no significant risk.}
1.3 THE NEED FOR FORETHOUGHT

Decisions about reproducing are profoundly meaningful to most individuals. How we exercise reproductive choice in the context of ARTs is unique in the sense that it is one of the most private aspects of procreative decision-making, which also involves a public dimension. It is now possible to make reproductive choices that were once merely matters of chance. For example, just under forty years ago there was only one way for humans to reproduce and yet today more than a quarter of a million babies have been born in the UK following in vitro fertilisation (IVF).\textsuperscript{11} In the last four decades the business of reproductive medicine has burgeoned. Scientific advances in reproductive medicine have taken what was once a private affair into a public domain. IVF is a relatively common prospect now.\textsuperscript{12} It does not attract the levels of controversy it once did\textsuperscript{13} even despite the ubiquitous debates on the moral status of a human embryo.\textsuperscript{14} More controversially, perhaps, are the diagnostic technologies that enable selection between embryos on the basis of genetic data. The human genome was successfully mapped in April 2003\textsuperscript{15} and thus our understanding of human genetics has stretched beyond the parameters previously envisaged. The Human Genome Project (the HGP) stated:

The HGP was one of the great feats of exploration in history, an inward voyage of discovery rather than an outward exploration of the planet or cosmos; an international research effort to sequence and map all of the genes – together known as the genome – of members of our species. Completed in April 2003, the HGP gave us the ability,
for the first time to read nature’s complete genetic blueprint for building a human being.\textsuperscript{16}

As ARTs have developed and the application of genetic testing has grown, so has the hype surrounding them. Recently in the UK a selection of exciting research projects have received regulatory approval which demonstrates the growing need for regulatory forethought. In 2015, the Health Research Authority approved the UK’s first clinical trial of womb transplants,\textsuperscript{17} making the once impossible very real and inspiring practical questions about who will regulate the treatment in the future; how it should be regulated; and whether it should be regulated at all.\textsuperscript{18} In early 2016 the HFEA became the first regulator in the world to approve clinical research on healthy embryos – for investigating possible causes of miscarriage - by using a genome editing procedure called CRISPR-cas9.\textsuperscript{19} The technique has raised hope for powerful gene therapies that add new genes and also delete or repair flawed genes. Toward the end of 2016, fresh debate emerged regarding embryo research taking place beyond the current fourteen-day statutory restriction after researchers found a way to chemically mimic the womb.\textsuperscript{20} In August 2017, in its first practical application to human health since the scientific community unveiled it, CRISPR-cas9 was used to repair diseased genes in embryos.\textsuperscript{21} Again, thanks to CRISPR-cas9 another research initiative is editing genes in pigs to make them into safe organ donor candidates for humans.\textsuperscript{22} While none of this research has created a child, the work signals the future potential in prevention of genetic disease, human genome editing and even potential organ supply. It represents the marvel of modern medicine in the context of ARTs. Importantly, if such techniques are

\textsuperscript{16}Ibid.

\textsuperscript{17}Womb Transplant UK. ‘Current Research Programme’ Available at http://wombtransplantuk.org/ Accessed 19.08.17.

\textsuperscript{18}Amel Alghrani. ‘Womb transplants: Now the impossible has become real’ (2014) BioNews 775.


\textsuperscript{20}Matthew Hill. ‘Is it time for embryo research rules to be changed?’ BBC News (17 January 2017) Available at http://www.bbc.co.uk/news/health-38635083 Accessed 19.08.17; Greg Ball. 'International genetics groups advocate germline CRISPR research’ (2017) BioNews 912; Section 3 of the HFE Act specifies the prohibitions in connection with the use of embryos and provides the 14-day rule.


optimised and mastered then very important questions will need to be addressed regarding regulation and the acceptability of the technologies, especially if the use is going to be contingent on PCWP considerations.

In order to look to the future and devise a model of regulation which is fit for purpose it is important to reflect on the past. The UK paved the way in both a medical and legislative sense following the birth of the world’s “first test-tube baby” at Oldham General Hospital in 1978. After Louise Brown was born protracted legislative development began and the Human Fertilisation and Embryology Act 1990 (HFE Act 1990) was eventually enacted. The post-IVF system of governance traces back to the Committee of Inquiry into Human Fertilisation and Embryology (the Warnock Committee). Chaired by Mary Warnock in 1982 it signalled the beginning of the regulation of the reproductive revolution. The report of the Warnock Committee (the Warnock Report) was published in 1984, providing the foundation for a liberal yet extensively regulated climate of reproductive medicine, and leading the way for the landmark HFE Act 1990. Margaret Brazier observed that following the implementation of a distinctively UK regulatory method, comparative “legislation has proliferated across the developed world, and beyond”. The PCWP was located at the core of the HFE Act 1990 contained in section 13 (5). It stipulated:

A woman shall not be provided with treatment services, unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth.

In 2004 the Government announced its intention to review the legislation in order to ensure that law was effective and fit for purpose, including holding a public consultation in 2005. The consultation document made clear that it sought views on “whether and how the law might be updated given the rise of new technologies, changes in societal attitudes, international developments and the need to ensure effective regulation”. The Human Fertilisation and Embryology Act 2008 (the HFE Act 2008) served to update the UK’s laws on the use and regulation of ARTs, retaining the PCWP subject to a minor amendment of the

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23 On July 25th 1978, Louise Joy Brown, the world’s first “test-tube baby” was born.
parenting provision that substituted the need “for a father” with “supportive parenting”. The end result of the reform is a consolidated piece of legislation, the Human Fertilisation and Embryology Act 1990 (as amended) (hereinafter the consolidated version will be referred to as the HFE Act). As in 1990, the legislative agenda is to make provisions:

[i]n connection with human embryos and any subsequent development of such embryos; to prohibit certain practices in connection with embryos and gametes; to establish a Human Fertilisation and Embryology Authority; to make provision about the persons who in certain circumstances are to be treated in law as the parents of a child; and to amend the Surrogacy Arrangements Act 1985.27

It should be acknowledged that the law in this area has a very difficult task. It must - in equal terms - be reactive and responsive to change, be able to manage scientific progress and also reflect on the ethical implications of the technologies at hand. ARTs are promising us reproductive options beyond the limitations of infertile individuals. When they are combined with the development of genetic technologies – which advance at increasingly rapid speed and are stimulated by the development of genetics – the prospects in reproductive biomedicine seem almost infinite. Given that the PCWP plays such a pivotal role in the regulation of these technologies this, then, is one obvious area of law, regulation and ethical debate that would benefit from a measured approach; balancing the interests of the parties involved and taking as its starting point a firm understanding of what is meant by pre-conception child welfare. Moreover, it is an area of regulation that should be approached modestly. This entails not presuming the need for regulation but rather finding good and justifiable reason to implement and enforce it. Even if good reason was found to regulate the PCWP, and even if we knew what the principle actually meant, that would not indicate the end of the inquiry. Even if we arrived at an agreeable definition for the PCWP and determined its constitution, the issue of who gets to decide what can and cannot happen during the treatment would still need to be determined in law.

Although this is a study of reproductive regulation, it is apparent that the ramifications of regulating the PCWP extend beyond the specific reproductive technologies focused on in this thesis. In this work the technologies focused on are IVF and pre-implantation genetic diagnosis (PGD), the latter is a technique that provides individuals with the opportunity to

27 HFE Act 1990, front page.
genetically test their embryos prior to selection and implantation. IVF and PGD were deliberately chosen for three simple reasons. First, every individual seeking access to IVF – whether publicly or privately funded – has to satisfy the PCWP assessment detailed in paper one at [4.0] and paper two at [5.0]. This process aims to identify whether there is a risk to child welfare of significant harm or neglect before treatment can be offered to individuals seeking assistance to conceive. Second, in order for PGD to be used the PCWP assessment of genetic harm mandates that a medical history is taken from the individuals seeking treatment in order to assess “that any child who may be born is likely to suffer from a serious medical condition”. The genetic harm threshold contained in section 13 (9) of the HFE Act similarly demands a level of ‘serious harm’ in order to warrant the testing. Thus, the regulation of PGD inextricably links to the overarching PCWP assessment of genetic harm. Third, if PGD is used successfully and a diagnosis is obtained, the same regulatory mandate of serious harm contained in section 13 (9) of the HFE Act substantiates the restriction on preferential embryo selection in certain circumstances outlined in paper two at [5.5] and paper three at [6.4]. It is clear, then, that the PCWP intrudes in reproductive choice at every major juncture of receiving IVF and PGD. Therefore, the effect of the PCWP goes far beyond the theoretical. Within the current regulatory framework its impact on reproductive choice is significant and unrivalled. In practice, its impact even extends beyond its practical application to IVF and PGD; it intertwines with all aspects of ARTs and embryology, human enhancement and scientific innovation, in a social, ethical, political and regulatory sense. The relationship in regulation between the PCWP and the familial and genetic harm thresholds, and its connection to section 13 (9) of the HFE Act, is explored in the body of this work and particularly in sections [4.3.5] [5.5] and [6.4]. Importantly, the PCWP and its connection to PGD has a social dimension, it is relational and the interrelatedness of its use and effect demands the full exploration contained in this thesis in Part II.

1.4 A BRIEF NOTE ON PREIMPLANTATION GENETIC DIAGNOSIS

PGD was first successfully performed in 1990 by Robert Winston and Alan Handyside at London’s Hammersmith hospital for a case involving Duchenne muscular dystrophy sexing – in short – ‘sex selection’ which is commonly referred to as ‘x-linked’ given the gene causing

28 CoP 8th edn (2009) 8.10 (b) (iii). The aspect of regulation is discussed in particular depth in paper II at [5.0].
the disorder is located on the X chromosome.30 Since then it has developed significantly from experimental testing and has become a major field of diagnostic embryo testing on a global scale. Built from the platform of in vitro fertilisation (IVF) PGD was “the first bridge between the effort to ‘assist’ human reproduction and the ability to intervene in human heredity, thus extending the helping of medical science into the innermost workings of early human life”.31 It enables individuals to genetically test their embryos ex vivo prior to selection and implantation. While genetic selection in the UK is currently limited to selection against genetic disease,32 theoretically PGD could be used in the future to select for Mendelian33 traits (such as freckles) or other non-medical traits (such as eye colour or hair colour).34 It can be used to test for a range of genetic conditions, including but not limited to autosomal dominant diseases such as Huntington’s disease (HD);35 single gene disorders including cystic fibrosis (CF), spinal myotonic dystrophy and sickle-cell disease;36 sex-linked conditions such as Duchenne muscular dystrophy or Turner’s syndrome; chromosomal abnormalities such as Down’s syndrome; and genetic mutations such as BRCA 1 and 2.37 It

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30 X-linked recessive inheritance describes a genetic characteristic or condition in which one gene on the X chromosome will cause the condition in males. This is because females have two X chromosomes and males have one X and one Y chromosome. It means that if a male has a genetic disorder on his X chromosome he will develop the genetic condition. A female who has the characteristic will be a carrier. As males transmit the Y chromosome to their sons it means the sons will not inherit the condition from their father. If the mother is a carrier then statistically each daughter has a 50% chance of inheriting the condition and being a carrier, and each son has a 50% chance of inheriting the condition.


32 Section 13 (9) and (10) of the HFE Act specify the permissible and prohibited uses of embryo testing and embryo selection. The connection of the PCWP to the statutory restriction set out in 13 (9) are examined in detail in Part II.

33 Mendelian inheritance originates from the work of Gregor Mendel which became the core of genetic study and theories of heredity in the early 1900’s. In humans, Mendelian inheritance explains how a child receives dominant forms of phenotypic traits or characteristics from either parent. See: Peter Bowler. The Mendelian Revolution: The Emergence of Hereditation Concepts In Modern Science and Society (The Johns Hopkins University Press 1989).


35 HD is a late onset neurodegenerative genetic disorder and typically becomes noticeable in mid-late adult life.

36 Sickle cell anaemia is a genetic blood disorder in which red blood cells develop abnormally, leading to clogged sections of blood vessels and sickle cell crisis. There are many different types of gene mutations that cause cystic fibrosis and this is discussed in detail in [5.5]. People with CF have a reduced lung function given a build up of mucus in the lungs which can cause chronic infection.

37 BRCA 1 and 2 are genes that produce tumour suppressor proteins and increase the risk of breast and ovarian cancers; also see: Tara Clancy. ‘A clinical perspective on ethical arguments around prenatal diagnosis and preimplantation genetic diagnosis for later onset inherited cancer predispositions’ (2010) Familial Cancer 9:1, 9-14.
can also be used to tissue match compatibility of an embryo with an existing sick sibling, creating what are generally referred to as “saviour siblings”.  

Although the actual establishment of a genetic diagnosis is said to be difficult, the basic technique of PGD is described as being relatively simple. PGD follows on from successful IVF treatment. In brief, once an embryo has grown for between two to three days and its cells have divided an embryologist removes one or two of the blastomeres from it. The biopsied material is then amplified and analysed to detect the presence of a genetic condition, abnormality or mutation. Some clinics allow the embryo to grow for between five to six days when multiple cells have developed and therefore more cells can be removed possibly increasing the accuracy of testing without compromising the embryo’s viability. The success rates are similar to those for IVF without PGD. In 2014, 461 women received 578 cycles of PGD. This resulted in 148 live births which is a birth rate of 25.6%.  

The important feature of PGD which distinguishes it from other available treatments for infertility problems is that in PGD patients are usually not biologically infertile. This distinguishes it from IVF. Some individuals undergo IVF and are unaware of a genetic condition until several failed attempts occur; others know of the presence or risk of a heritable genetic condition and thus deliberately wish to prevent the birth of a child with that condition. On its face, PGD has important implications for reproductive choice. PGD makes it possible – technically – to select against disability, for disability, for non-medical traits and for gender. Thus, if reproductive autonomy is interpreted liberally it should mean that individuals receiving treatment are empowered to make a choice, whatever the potential outcome. But not all choices are legally permitted on embryo selection. This work will show how the PCWP is used to justify the restrictions on embryo selection and in paper one between [4.0] and [4.4] I challenge the application of the PCWP in this way given the lack of

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40 Amplification means making multiple identical replicates of a DNA sequence in order to conduct clinical testing.

41 Joyce Harper. Joy Delhanty and Alan Handyside (eds). Preimplantation Genetic Diagnosis (John Wiley & Sons Ltd 2001), 3-12; in clinical practice this method is referred to as a ‘trophectoderm biopsy’.

42 HFEA. ‘PGD: What are the chances of having a baby with PGD?’ Available at https://www.hfea.gov.uk/treatments/embryo-testing-and-treatments-for-disease/pre-implantation-genetic-diagnosis-pgd/ Accessed 24.08.17.
objectivity, transparency, consistency and contextual-sensitivity in the current regulatory framework. This thesis will demonstrate not only how the PCWP considerations underpin the restrictions discussed in paper two at [5.0] but also, it will show why the underpinning is inherently paradoxical in paper three at [6.0] and thus problematic in its application. What is clear at this stage is that the restrictions on embryo selection after PGD creates tensions in regulation, raises concern for public policy, and frustrates the exercise of reproductive choice based on nebulous PCWP considerations involving speculative and intangible harms.

1.5 THE HUMAN EMBRYO'S MORAL STATUS

Few issues have provoked perennial debate more than the question of the moral status of the human embryo. In the early stages of policy development the topic occupied the minds of the Warnock Committee members who were unable to reach a definitive conclusion, but went on to recommend a path of maximum social consensus.43 Given that this thesis examines the law and regulation of the PCWP as it applies to PGD and IVF, it is appropriate that I make clear my own moral position on the embryo’s status. I do not propose to dwell on the topic and it is not my intention to re-evaluate the intractable problem that has incited so much debate among theologians, ethicists and others in the literature.44 But given the PCWP demands that a non-existent child’s welfare be taken into account and that PGD provides for selection between embryos based on genetic data, the issue of moral status is relevant.

Critics worry that the development of ARTs will result in a lack of respect for the special status of an embryo, while many others reject the idea that it should be afforded any special status.45 Don Marquis asserts that the destruction of an embryo is prima facie wrong because it robs that being of its future.46 Some supporters of ARTs adopt a more lenient view that affords an embryo with unique status demanding special consideration.47 Michael Sandel

explains “there are three possible ways of conceiving the moral status of the embryo: as a thing, as a person, or as something in between”. By analogy with the development of the foetus, law and public policy in ARTs is largely based on the idea that an embryo gradually acquires value. The gradualist perspective does not recognise the human embryo as a person or a thing; its status lies somewhere in between.

I accept the use of PGD because I accord the human embryo limited moral status. For me, an embryo enjoys limited moral protection, which is partly dependent on the potential for its development into a person with a certain quality of life. Like John Harris, I dismiss the potentiality argument in full given that we should not treat a thing as something it has the potential to become but is not yet, so, we should not treat human beings as already dead simply because they are potential corpses. I respect the human embryo for what it could be, but I take no issue with the fact that embryos are created, used in research, tested on and destroyed by virtue of PGD, and all other ARTs. The problem with the current approach to regulating the PCWP is not so much where the line has been drawn regarding the status of an embryo, but with the lack of consideration given to how best to regulate ARTs and respect reproductive choice in the context of embryo use and selection.

Having now introduced the overarching purpose of this thesis and outlined the central research questions posed, I will now turn in the following sections to provide the background information which is important to this work. The following sections combined aim to set out the legislative and regulatory development of the PCWP and provide an overview of the range of debates that are commonplace in this field. The background information provides the reasoning for the positions I adopt and the arguments against regulation of the PCWP that I advance in this thesis in Part II.

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2.0 BACKGROUND

Now that I have introduced the broader theme of this thesis and set out the area of law and policy which is covered here, my purpose is to give a sense of the legal and policy landscape surrounding child welfare when the HFE Act 1990 and the PCWP was enacted. I suggest that is important to look at this aspect of child welfare regulation through a wide lens and I aim to illustrate how the traditional child welfare principle developed into the PCWP within the statutory regulation of fertility treatments beginning with the HFE Act 1990, before I go on to explore how it functions as a regulatory method and the impact it has on reproductive choice.

2.1 THE APPROACH IN CHILD LAW TO THE WELFARE PRINCIPLE

For a considerable length of time the welfare of the child principle has reigned as one of the most dominant principles in child law.\textsuperscript{50} No single piece of legislation covers child protection in England and Wales. In accordance with the inherent jurisdiction of the Court the “best interests of the child” is the prime concern.\textsuperscript{51} The best interests of the child is also the primary consideration in decisions taken affecting a child in accordance with the United Nations Convention on the Rights of the Child;\textsuperscript{52} a factor through which to safeguard and promote children’s health, development and welfare in Scotland;\textsuperscript{53} and the “paramount” consideration in English family proceedings.\textsuperscript{54}

Initially used to settle parental disputes of custody of children, the principle has evolved in child law and developed into the ‘welfare of the child principle’ which displaced the absolute paternal authority of fathers.\textsuperscript{55} In 1986 the Law Commission conducted a review of child law

\textsuperscript{50}The statutory ancestor of the principle was contained in the Guardianship of Infants Act 1925 section 1. This was later consolidated into section 1 of the Guardianship of Minors Act 1971 which read “the court… shall regard the welfare of the infant as the first and paramount consideration”.
\textsuperscript{52}Article 3 of the United Nations Convention on the Rights of the Child states “In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration”. The UNCRC is an international agreement setting out the civil, political, economic, social and cultural rights of every child, regardless of their race or abilities. The UK signed the convention in April 1990 and ratified it December 1991.
\textsuperscript{53}\textit{Children (Scotland) Act 1995 section 1 (1) (a)}.
\textsuperscript{54}\textit{Children Act 1989 section 1 (1) (b)}.
\textsuperscript{55}Ibid, section 2 (1) specifies joint parental responsibility for children in the event “the child’s father and mother were married at the time of his birth” or in accordance with section 2 (2) if the father and mother are unmarried at the time of birth then the mother shall have parental responsibility and the father shall have parental responsibility for the child if he has acquired it and has not ceased to have it in accordance with the provisions of the Children Act 1989.
relating to the upbringing of children and recommended the welfare principle as the foundation of the legislation. It stated:

[T]he welfare of each child in the family should continue to be the paramount consideration whenever their custody or upbringing is in question between private individuals. The welfare test itself is well able to encompass any special contribution which natural parents can make to the emotional needs of their child, in particular to his sense of identity and self-esteem, as well as the added commitment which knowledge of their parenthood may bring. We have already said that the indications are that the priority given to the welfare of the child needs to be strengthened rather than undermined.\(^{56}\)

The CA 1989 is the primary Act that legislates for children in England and Wales. It provides what is deemed to be the strongest form of a child welfare principle, with section 1(1) stating that when a court determines any question with respect to the upbringing of a child or the administration of a child’s property, the child’s welfare shall be the court’s paramount consideration. It mandates the court and any other party to proceedings to account for a list of statutory welfare factors when making inquiries to safeguard an existing child.\(^{57}\) These factors include the age, sex and background,\(^{58}\) the physical, emotional and educational needs of the child,\(^{59}\) any harm the child has suffered or is at risk of suffering\(^{60}\) and the parental capability of those who will be meeting the child’s needs.\(^{61}\) In this way, child welfare is understood in a broad sense and it “trumps and outweighs all other considerations; no other interests or values may affect the decision; children’s interests are the only ones that count”\(^{62}\).

In *Re B* Butler Sloss LJ described the paramountcy principle as the “bedrock of the Act”,\(^{63}\)

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57 Children Act 1989 section 1 (3).
58 Ibid, section 1 (3) (d).
59 Ibid, section 1 (3) (b).
60 Ibid, section 1 (3) (c).
61 Ibid, section 1 (3) (f). A central tenet of the legislation was that children are best looked after within the family and where ascertainable the wishes and feelings of the child should be considered, including considering the child’s welfare in the future until adulthood. Parental responsibility emphasises the responsibilities of the parent as opposed to their rights as a parent. On the subject of parental responsibility and decision-making regarding medical treatment see: *Re B (A Minor) (Wardship: Sterilisation)* [1998] AC 199.
essentially enjoying free reign in private law proceedings. The paramountcy of child welfare similarly plays a key role in public law proceedings that question the removal of children in order to protect them from inadequate parenting. Interestingly, the CA 1989 also established a harm threshold which must be met, based on actual or anticipated significant harm to the child, before children can be taken into care. In the context of healthcare law, judicial appraisals of child welfare also regularly endorse the paramountcy principle as the threshold test. In the recent and highly publicised case of Great Ormond Street Hospital v Yates and Gard, Lady Hale declared that the child welfare “provision reflects but is stronger than Article 3.1 of the United Nations Convention on the Rights of the Child”. There can be little doubt, therefore, as regards the importance of the child welfare principle in child law.

The paramountcy of child welfare for born children also features in the current law relating to surrogacy. Surrogacy provides an interesting example of both the paramountcy principle applying when the child is born and the application of PCWP in certain but not all surrogacy cases. The first UK statute to address surrogacy, the Surrogacy Arrangements Act 1985 (the SA Act 1985) defined the key terms involved in surrogacy arrangements, made contracts unenforceable and banned payments, but did not include a child welfare principle in any form. When the HFE Act 1990 was enacted the PCWP automatically applied to full gestational domestic surrogacy arrangements and donor insemination if carried out in the UK in a licensed clinic, just as it applied in the context of many other ARTs. However, those who travel abroad or enter into ‘do-it-yourself’ surrogacy arrangements escape the engagement of the PCWP assessment.

Once a child is born the commissioning parents will in most cases require a parental order. Such permits them to re-register the birth and record themselves as the legal parents of the child. Both the HFE Act 1990 and the HFE Act 2008 sought to clarify matters of legal

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64 Private and public law concerning children are distinct and the role of the courts is separate when dealing with disputes between parents over contact or residence and state intervention to remove a child from the family home and take a child into care.

65 Section 31 (2) and (9) of the Children Act 1989 defines harm as the impairment of health or development, including emotional development of a child.


67 The Surrogacy Arrangements Act 1985 section 1 (2) defines a surrogate mother and a surrogacy arrangement is defined in section 1 (3). Section 2 of the legislation sets out the restrictions on negotiating surrogacy arrangements on a commercial basis. In addition, section 36 of the HFE 1990 inserted section 1A into the Surrogacy Arrangements Act 1985 which made contracts unenforceable.

68 Parental order provisions are contained in section 54 of the HFE Act 2008.
parentage and the transfer of parental responsibility from the surrogate – who is treated as the legal mother in UK law - to the commissioning parents, the complexities of which are explored more fully in paper four at [7.2]. But importantly, twenty years after the HFE Act 1990 the Human Fertilisation and Embryology (Parental Orders) Regulations 2010 (the 2010 Regulations) mandated that the welfare of the child became the paramount consideration after surrogacy in every application for a parental order. The 2010 Regulations also introduced a welfare checklist of factors, taken from section 1 the Adoption and Children Act 2002 (the ACA 2002), which the court must take into account on every application made by the commissioning parents. It follows then, in domestic surrogacy arrangements where the surrogate is treated in a licensed clinic, the law demands that consideration of child welfare takes place prior to conception and ex post facto. The only difference being that the PCWP demands that child welfare is taken account of, whereas the 2010 Regulations dictate the paramountcy standard. Although the individuals involved in a full surrogacy arrangement in the UK, or other licensed treatment are subject to the PCWP, the 2010 Regulations only take effect after a child is born and on application for a parental order. Therefore, the legal framework surrounding child welfare considerations, in a pre-conception and ex post facto context, demonstrate a unique feature of child welfare regulation which is not seen elsewhere in law and policy. Thus on its face, as regards child welfare the law regulating surrogacy in the UK is convoluted and confusing. Kirsty Horsey and Sally Sheldon have described the law in general governing surrogacy as “confused, incoherent, and poorly adapted to the specific realities of the practice of surrogacy”. In terms of reform of the law which is discussed in paper four at [7.5], many argue that rather than assess the suitability of the arrangements and the transfer of parental status post birth, courts should be asked to grant parental status prior to conception. This it might be hoped would rule out post birth disputes about the child, disputes that may well negatively impact a child’s welfare. The problem is that if the arrangement is made abroad it is unlikely that the parties will seek pre-conception court approval.

However, it is important to clarify that surrogacy arrangements are different to many other ARTs which invoke the PCWP considerations. Surrogacy raises few medical issues, unlike

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PGD and other ARTs, and the practical questions which emerge often pivot around legal parentage, the supply of commercial surrogacy, the facilitation of payments and honouring agreements given that such are legally unenforceable in UK law. The Warnock Committee declared it would be degrading for a child to be “bought for money”,71 alluding to the idea that the exchange of money itself might harm the welfare of children born. However, I argue that the risk of harm to a child’s welfare after surrogacy arises out of the inadequacy of UK law relating to surrogacy arrangements. The difficulties which emerge regarding legal parentage often but not always involve foreign surrogacy arrangements and the confusing mix of UK and foreign laws. Foreign surrogacy arrangements present a different set of problems in relation to child welfare considerations. Decisions about the implications of the arrangements are not made by clinicians but by judges in the aftermath of the birth and this can create practical difficulties after a child is born and before a parental order is made. The fact that children born abroad are “effectively legal orphans’ and stateless” when an application for a parental order is made is increasingly problematic as more couples are entering in to over-seas arrangements.72 Mrs Justice Thesis recently described the “legal ticking time bomb” that has arisen in the absence of an improved international legal framework with court sanctioned parental orders being sought in every case involving ‘stateless’ children.73

This means that the risk of possible harm to a child’s welfare after surrogacy is more practical in nature than other ARTs notwithstanding the inclusion of the paramountcy principle in the 2010 Regulations. Thus, the unique pre-conception and post birth welfare considerations after surrogacy is a good example of where the current regulatory framework governing traditional conceptions of family forms and of child welfare is also not fit for purpose.

State intervention of this kind does have significant implications for those involved in surrogacy arrangements, which must also be met in terms of justification, proportionality and  

72 See the case of Re Z (2015) EWFC 90. The commissioning parents were a British couple who entered into a surrogacy agreement in India. Despite applying for a parental order 3 months after the birth of the twin girls, they waited over 12 months for a British passport; The data on surrogacy arrangements is limited but the Children and Family Court Advisory and Support Service (Cafcass) parental order statistics documented 107 international surrogacy applications were logged in 2015 between January and August, in comparison to 76 UK cases of surrogacy recorded in the same time period; Prosser and Gamble, op. cit Modern Surrogacy, n.70 at 263.
reasonability. While many would accept that some degree of state intervention is warranted in this particular setting, the circumstances in which child welfare is considered in surrogacy cases and which arrangements fall into a category when a PCWP assessment is required, as well as the *ex post facto* assessment, reveals the tensions in the current framework. While the pitfalls in the regulatory approach to surrogacy in the UK are explored in depth here in paper four at [7.0], it is clear that the *ex post facto* scrutiny applied to arrangements shows further strands of regulatory inconsistency and incoherence which links to a central argument advanced in this thesis against the current PCWP framework. This is particularly relevant given the paramountcy principle enforced by the 2010 Regulations can often acquire a different role when parental orders are being applied for. For example, judicial reference to child welfare considerations has avoided adverse consequences arising from a breach of the law on expenses; incompatible laws on parenthood; failure to comply with the statutory six month time limit when applying for a parental order; or failure to take formal measures to grant parental status to one or both of the intended parents. Again, this makes the law confusing. Thus, the problems with UK surrogacy regulation in terms of incoherence and inconsistency, links to the overarching theme of regulatory disconnection which is explored throughout this thesis in regards to the PCWP and PGD regulation.

The ACA 2002 – which is closely aligned to the UK law on surrogacy - also largely mirrors the CA 1989 paramountcy provision. Some commentators suggest adoption is largely associated with child protection which is dominated now by the welfare principle. Section 1 declares “the paramount consideration of the Court or adoption agency must be the child’s welfare, throughout his life”. The ACA 2002 also provides factors to be considered in adoption proceedings irrespective of the child’s age, all of which echo those contained in the

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78 *JP v LP* [2014] EWHC 595 (Fam).
80 Adoption and Children Act 2002 section 1 (2); Also note that the Human Fertilisation and Embryology (Parental Orders) Regulations 2010 inserted section 1 of the ACA 2002 into section 54 of the HFE Act 2008. Consequently, the welfare of the child is the paramount consideration in the 2010 Regulations.
CA 1989. Significant regard is given to the effect on the child that removal and placement from one family to another can have and thus a prediction of lifetime aggregate welfare is necessitated in adoption proceedings.

Overall, this tells us that the assessment of the born child’s best interests is responsive to context in child law. The CA 1989 and the ACA 2002 set out what the courts and Local Authorities (LAs) should do in order to protect the welfare of children. LAs have a duty to investigate if there is reasonable cause to suspect that a child is suffering, or is likely to suffer significant harm. Harm is defined as ill-treatment, including sexual abuse and non-physical forms of ill-treatment, or the impairment of health (physical or mental) or impairment of development, including physical, intellectual, emotional, social and behavioural. The ACA 2002 also amended the CA 1989 by expanding the definition of harm to include a child witnessing domestic violence. The Children Act 2004 (CA 2004) placed additional statutory duties on LAs and their partners – such as the police, youth offending teams and social services – to cooperate regarding the permanent promotion of the welfare of children. Inevitably, this demands a multi-agency approach regarding the coordination of welfare assessments, potential adoption placements, the organisation of assessments of support services for children in need; in addition to assessing the birth parents, foster parents and adopters. Therefore, the overarching message in child law is clear: a welfare assessment dictates thorough evaluation and methodical analyses across multiple disciplines. This task is completed by investigating and responding to the actual risks presented in the family environment in which a child is living or will live in; it is, in effect, a method of regulating the conduct of parenthood in order to reduce risks to children.

Despite being “the most widely accepted principle within child law” it has not avoided academic criticism in relation to its place in the CA 1989. Some commentators have claimed

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81 Adoption and Children Act 2002 section 1 (4) - (6).
82 Ibid, section 30 -34 and section 52.
83 Section 17 of the Children Act 1989 sets out the provisions of services for children in need and section 47 details LA’s duty to investigate.
84 Ibid, section 31 for care and supervision.
85 Adoption and Children Act 2002 section 120.
86 Children Act 2004 section 11.
87 In accordance with the Children Act 1989 section 31(2) a court may only make a care order or supervision order if it is satisfied that the child concerned is suffering, or is likely to suffer, significant harm; and that the harm, or likelihood of harm, is attributable to either the care given to the child, or likely to be given to him if the order were not made, not being what it would be reasonable to expect a parent to give to him; or the child’s being beyond parental control.
88 Reece, op. cit consensus, n.62 at 269.
it is “used as the basis for controlling women”; 89 others suggest it was a rhetorical or political device in the Thatcher era when the rhetoric surrounding family, poverty and parental responsibility was translated into policy. 90 Helen Reece suggested that the consensus of acceptance “exist[ed] across the mainstream political parties, as a result of which the paramountcy principle passed through the legislative process with no dissent”. 91 Interestingly, she argued that the heavily loaded political principle “must be abandoned and replaced with a framework which recognises that the child is merely one participant in a process in which the interest of all the participants”. 92 She criticised the inevitable prejudices, the lack of protection of parents’ interests - mainly focusing on gay parents - and challenged the practicality of the principle in terms of interpretation, objectivity and evidence. Andrew Bainham observes that “[t]he notion of the ‘good enough’ parent can become obscured where the courts in essence…move straight to the welfare or disposal stage” in proceedings. 94 Jonathan Herring, although critical of the principle, observes the difficulty in abandoning the principle in child law given that deregulation would afford no protection to children. He states that the “conception of the welfare principle adopted by the courts is often too narrowly individualist and focuses on a self-centred approach to welfare” 95 and suggested “it should be reconceptualised by emphasising that recognition of the interests of others, and particularly the relationship between the child and the parents, is part of a child’s welfare”. 96

Even if one takes issue with the application of the paramountcy principle in child law, it is rarely disputed that a born child’s welfare should be prioritised as a consideration. On a practical level though, given the widespread acceptance of it 97 and especially its success in practice, its insertion into the law regulating aspects of parenthood is supported in the context of child protection. Nevertheless, while this might be true, the impact of the provision is

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93 Reece, op. cit Consensus, n.62.
94 Bainham, op. cit, n.79 at 157.
96 Ibid, 101.
97 Bainham, op. cit, n.79.
striking. In placing child welfare as the paramount consideration, parenthood as a concept and all the responsibilities it entails – including genetic parenthood, gestational parenthood and psycho-social parenthood - provide a source of material for judges determining a welfare appraisal. Baroness Hale (as she was then) declared in the case of *Re G (Children)*, that while the fact of parenthood is an important and significant factor in a welfare test, it does not necessarily equate to the importance of a parent to a child’s welfare. Three years later, the Supreme Court in *Re B (A Child)* reaffirmed the central message of *Re G* and indicated its central message was “to give the final quietus to the notion that parental rights have any part to play in the assessment of where the best interests of a child lay”. Thus, the importance of parenthood is deemed a contributor to a child welfare appraisal; it is a factor to be considered in the assessment alongside other common welfare factors. Importantly, it is not indicative of parental rights which are capable of overriding the paramountcy principle.

Having discussed the welfare principle in child law in general, and conceptually distinguishing it from the PCWP, I now turn to examine the more particular issue of the PCWP itself. In the following section, I illustrate the legislative development of the PCWP and demonstrate the underlying reasons for its inclusion in the law regulating ARTs.

### 2.2 THE WARNOCK STRATEGY

The state responded to the birth of Louise Brown in 1978 by pursuing the arduous task of creating a legislative and regulatory framework governing ARTs in the UK. The Warnock Committee was established in 1982 to make recommendations for a system of regulation and governance by addressing fundamental questions about reproductive technologies and related research. As such, it was informed by a combination of theological, philosophical and bioethical perspectives. It should be acknowledged that when the Warnock Committee conducted its inquiry, IVF had not long developed from an experimental practice into an established technology. Embryonic biopsy was discussed in the inquiry as a “possible future

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99 *Re G (Residence: Same Sex Partner)* [2006] UKHL 43, at 33-35. This case is explored further in [7.2].
100 Ibid.
101 Ibid, at 31-32.
development” which would allow for the detection of genetic abnormalities, but similarly the development of human genetics was in its infancy during the 1980’s. The Warnock Report confirmed its approach by stating “we took the pragmatic view that we could react only to what we knew, and what we could realistically foresee”. Given that PGD was not anticipated to become the successor of IVF in human genomics, the Warnock Report did not address it. Instead, the Warnock Committee set out to resolve the tensions between ideology and reproductive technology it knew about; and address how axiomatic moral principles – such as the sanctity of human life and the nature of the family - might assist in the debates. In that sense, the strategy engaged with concerns surrounding possible familial harm rather than medical or genetic harm. As Chair of the Committee, Mary Warnock’s task was to encourage logic and blend morality and reason in the inquiry into ARTs regulation.

Jose Miola described the Warnock Report as “the defining report of its decade”. Crucially, however, its recommendations were sociological rather than philosophical. They adopted a “steady and general point of view” of the moral reasoning by outlining a set of principles on which legislation should rest. The Warnock Report declared that:

People generally want some principles or other to govern the development and use of new techniques. There must be some barriers that are not crossed, some limits fixed, beyond which people must not be allowed to go…The very existence of morality depends on it. A society without which had no inhibiting limits, especially in the areas with which we have been concerned…of setting up families, and the valuing of human life, would be a society without scruples, and this nobody wants.

Rather than formulating a robust regulatory method that resolved moral differences according to philosophical principles, ‘principalism’ was a key feature of the Warnock strategy. The Report indicated that:

In recognising that there should be limits, people are bearing witness to the existence of a moral ideal of society. But in our pluralistic society it is not to be expected that any one set of principles can be enunciated to be completely accepted by everyone. This is not to say the enunciating of principles is arbitrary, or that there is no shared

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104 Warnock Report, op. cit, n.24 at 70.
105 Ibid, 5.
107 Warnock Report, op. cit, n.24 at 1.
108 Ibid, 2.
morality whatever. The law itself, binding on everyone in society, whatever their beliefs, is the embodiment of a common moral position. It sets a broad framework for what is morally acceptable.\textsuperscript{109}

The effect of principalism as the infrastructure of the regulatory framework was flexibility; it avoided providing a definitive answer on what was morally right or wrong. In retrospect Warnock stated that providing that answer was an “impossible” task, which did not fit with her objective to “try and assemble a coherent policy”.\textsuperscript{110} Michael Mulkay described the ‘Warnock position’ – which encouraged scientific innovation but subjected it to strict regulation - as the outcome of an attempt to identify social consensus amongst fundamentally opposing views on reproductive biomedicine.\textsuperscript{111} In a 2010 interview Warnock clarified the basis of the approach and stated:

We had to distinguish between what we were looking at and the pure science fiction, the images from Brave New World and Frankenstein which were sort of present in everybody. At that time we didn’t know anything about Dolly the sheep. But we did realise that there were ways in which one could split an embryo to make it into two embryos and that they would therefore share the same DNA. That produced a lot of exclaiming and throwing up of hands among the sillier members of the committee. I think, though, that all the shock and horror was dissipated when we came to talk about the actual possibilities, about why anyone would want to do such a thing.\textsuperscript{112}

Three important points can be taken from the Warnock strategy. First, the Report did not explicitly document the need for a PCWP in regulation. Instead, it focused on the patriarchal nuclear family and upholding family values.\textsuperscript{113} The Committee made clear its belief “that as a general rule it is better for children to be born into a two-parent family, with both father and mother, although we recognise that it is impossible to predict with any certainty how lasting a relationship will be”.\textsuperscript{114} Exactly why the traditional family is superior goes unexplained in the

\textsuperscript{109} Ibid, 2-3.


\textsuperscript{113} Warnock Report, op. cit, n.24 at 1.

\textsuperscript{114} Ibid, 11.
Report, but nevertheless it promotes a hierarchy of social values by approving a certain kind of family, over another. As regards the nuclear family form, the Committee also decried surrogacy and rejected its acceptability in reference to procreation outside the confines of a loving partnership as “an attack on the value of the marital relationship”.\textsuperscript{115} It implied women could be tempted to contract out their pregnancy for financial profit which was seen as inconsistent with human dignity.\textsuperscript{116} While it declared the child’s interests as “the first and paramount consideration”, \textsuperscript{117} it recommended that the statute provided “all surrogacy arrangements are illegal contracts and therefore unenforceable in the courts”.\textsuperscript{118} The second important point to note regarding the Warnock Report concerns the lack of critical analysis of the ethics involved. The moral ‘principles or other’ that the Committee set out to address were not divulged anywhere in the Report, neither were any roots of morality ever explored. John Harris argued that “the crucial questions are fudged, or rather never addressed”.\textsuperscript{119} Third, and by far the most practical and legally straightforward point, the Report indicated:

We believe that new laws will be necessary to cope with the new techniques for alleviating infertility and their consequences, and to deal with the developments in the field of embryology. But we foresee real dangers in the law intervening too fast and too extensively in areas where there is no clear public consensus.\textsuperscript{120}

The prediction of the need for new laws demonstrates that the Warnock Committee acknowledged the Report’s own weaknesses. It is for these reasons combined – and given the influence of the status of the embryo – that the need for a PCWP emerged in the Parliamentary debates that followed. The sociological approach to eligibility for treatment and Warnock’s pro-family ideology framed the basic formation of the PCWP. This strategy created the platform on which it was built. It easily linked to other well-established sub-disciplines such as existing child law and policy, social history and bio-politics of the technological developments.\textsuperscript{121} Moreover, in the absence of philosophical study that was vital for an understanding of how harm is measured as regards a pre-conceived child, the

\textsuperscript{115} Ibid, 44.
\textsuperscript{116} Ibid, 45.
\textsuperscript{117} Ibid, 43.
\textsuperscript{118} Ibid, at 47.
\textsuperscript{119} Harris, op. cit Value of Life n.49 at 130.
\textsuperscript{120} Warnock Report, op. cit, n.24 at 7.
government had no reason not to include a watered down pre-conception version of the paramountcy principle it enacted in the CA 1989. It is perhaps the case that the obvious lacking in conceptual clarity was deliberately overlooked given that the PCWP ensured the passing of the legislation.\textsuperscript{122}

What is clear when we reflect on the Warnock strategy is that a better philosophical analysis of the issues was required. This would have decreased the likelihood of a PCWP being included in the legislation which fails to demonstrate a defendable position, whether morally, legally or otherwise. The failure of the Warnock Committee to determine, or even appreciate, the metaphysical facts about the nature of IVF and person-affecting reproductive technologies (such as PGD) meant the basic foundation of the PCWP was confused. It lacked thorough philosophical analysis and was simply presumed to be practically important for the broader regulatory framework. Julian Savulescu recently addressed the issue of thorough philosophical analysis in connection with progress of bioethics and medical ethics as a whole. He argued that both bioethics and medical ethics together have, in many ways, failed as fields because of the need for better philosophical analysis in areas of research such as organ transplantation, gender selection, enhancement, disability and other related topics which necessitate the interaction of law, regulation and ethics.\textsuperscript{123} If Savulescu is correct, it means the relevance and irrelevance of philosophical concepts are at risk of being completely missed or misunderstood because they have not been properly considered. Thus by analogy, as a consequence of the Warnock strategy, from the outset the PCWP was not conceptually clear, nor did it have sufficient granularity to answer any questions concerning the real basis of its inclusion. The lasting impact is as Thérèse Callus points out, when she asserts:

> More than 20 years on from the publication of the Warnock Report...one concern of policy makers may be said to be the same: that regulation of assisted conception techniques and the use of \textit{in vitro} embryos be acceptable to the general public.\textsuperscript{124}

As will be shown in \textbf{Part II}, this systematic legislative and regulatory failure to explore robust ethical foundations, and thus defendable ethics, is prevalent in the PCWP and PGD

\textsuperscript{122} The legislative development of the PCWP is dealt with in depth in \textbf{Part II} at \textit{[4.3]} onwards.

\textsuperscript{123} Julian Savulescu. ‘Bioethics: Why Philosophy is Essential for Progress’ (2015) \textit{Journal of Medical Ethics} 41, 28-33.

framework. In paper three at [6.0] I argue that there is little conceptual clarity underpinning the PCWP and state interference flowing from it is an unjustified intrusion on reproductive choice. As a whole, this thesis argues that the law regulating the PCWP remains significantly inconsistent in its form and conceptual foundations.

However, before I engage with the ethical issues at stake which are central to the PCWP, a few words about the current hybrid model of regulation are in order.

2.3 A HYBRID MODEL OF REGULATION

While the HFE Act 1990 provided the PCWP in section 13 (5), it did not provide any legislative direction to the HFEA regarding how the PCWP should be regulated or interpreted in practice. Some commentators challenge the very composition of the HFEA and others state it attains a “wider sphere of influence with every year that passes”. Notwithstanding commentary which describes its executive function as “narrow” or its role to “reassure the public that regulation was in place”, as the sector’s regulator that oversees fertility treatment and research in the UK, it is tasked with regulating the PCWP. Via its Code of Practice (CoP) the HFEA provides clinics offering treatment with the PCWP assessment – which is examined in depth in paper two at [5.0] - detailing the considerations to be taken into account for a determination of welfare. The CoP also provides guidance on the application of PGD which is read parallel to the provisions on embryo testing, also contained in the HFE Act at section 13 (9). The HFE Act 2008 introduced a significant change in that express provisions were introduced which imposed limitations on embryo testing and selection. Embryo testing is permitted only where there is a significant risk of serious


130 The HFEA is a statutory body and independent regulator of ARTs in the UK. It came into effect on 1 August 1991.

131 Schedule 2 1ZA.
physical or mental disability, a serious illness or any other serious medical condition.\textsuperscript{132} Embryo selection prohibits preferential selection of embryos which have been detected as affected by a genetic condition or abnormality.\textsuperscript{133} Embryo testing, permissible uses of PGD and restrictions on embryo selection are all justified under the remit of the PCWP and its harm threshold. The regulation of PGD does not, therefore, operate in a vacuum and the PCWP considerations are located at the crux of the wider regulatory framework. This dual system creates a hybrid model of regulation, formed from the critical convergence of the statutory provisions and the CoP guidance. As regards the PCWP and PGD regulation, the elements of the hybrid model must be read side by side in order to understand the full scope and impact of the regime.

Given that the Warnock strategy set out to provide a principled approach to regulation, the question then emerges as to whether there is an overall synthesis of moral principles identifiable in the regulatory framework governing the PCWP and PGD regulation? Or as Aurora Plomer suggests, is it unrealistic to think such different moral perspectives can be magically dissolved and reconciled in law?\textsuperscript{134} Plomer provides a critique of UK regulation as regards Stem Cell Research (SC Research) and her analysis of a principled resolution of ethics and law applies equally to the subject of this thesis. She asserts that the main difficulty faced by the regulator in the UK has been to identify a set of ethical principles which would justify a legal bright line for what is legally permissible and what is prohibited.\textsuperscript{135} Although she is not a promoter of an ethical hands-off approach in regulation, Plomer describes the HFE Act 1990 as, “a pragmatic, political and legal compromise”\textsuperscript{136} and suggests that it is to confuse law and morality to think that the Act should represent a collaboration of high moral principles.\textsuperscript{137} Influenced by the work of socialist philosopher Jürgen Habermas,\textsuperscript{138} Plomer rightly observes that the legitimacy of regulation is dependent on the procedures which underpin the law-making process, including political structures. She argues:

\textsuperscript{132} Ibid, Schedule 2 1ZA(2).
\textsuperscript{133} HFE Act section 13 (9) – (10).
\textsuperscript{135} Ibid, 135.
\textsuperscript{136} Ibid, 133.
\textsuperscript{137} Ibid, 161.
Legal discourse must not be confused with moral discourse. Legal discourse may remain open to ‘pragmatic, ethical and moral reasons’ but it would be misleading to conceive of legal discourse as a ‘subset of moral argumentation’.\textsuperscript{139} Interestingly though, Plomer encourages the adoption of moral principles in regulation in order to avoid judicial creativity that Ronald Dworkin argued can be limited via systematic constitutional checks.\textsuperscript{140} She concludes:

The authority of the law in a democratic society does not ultimately lie in law’s ability to capture a uniquely correct moral perspective, but the fact that it is the outcome of a due process of public debate which participants recognise as fair.\textsuperscript{141}

If Dworkin and Habermas are correct and the law is an interpretive concept,\textsuperscript{142} in that legal discourse is not confused with moral discourse, then a legitimate approach to regulating a version of a PCWP would be a consistent, transparent, objective and accountable regulatory method. The point here is that the law and regulation of the PCWP should be conceptually clear and based on defendable ethical foundation. More importantly, if a consensus on issues of morality is unachievable, then at the very least we should seek consistency and transparency in regulation, both of which I argue are lacking in the current PCWP framework. Hale J, as she was then, remarked in general terms “the law cannot impose a dictatorship however benevolent, which insists that it knows how best people should conduct their private and family lives.”\textsuperscript{143}

The advantage of the hybrid ‘principled’ model over one that relies on conventional rule-based definitions, objectivity and rationality is that it allows for interpretive flexibility. It also accounts for the partiality and plurality of how we go onto define moral values, about what is right or wrong in ARTs according to the HFEA criteria assessing the PCWP. But the approach still does not account for the legitimacy of state intervention and why ARTs are viewed as controversial or particularly sensitive areas of reproductive biotechnology, which requires regulatory micromanagement.

\textsuperscript{139} Plomer, op. cit, n.134 at 161.
\textsuperscript{141} Plomer, op. cit, n.134 at 161.
\textsuperscript{143} Justice Hale. \textit{From the Test Tube to the Coffin: Choice and Regulation in Private Life} (London: Stevens Sweet and Maxwell 1996) 125.
This introduces the concept of framing in regulation which, I argue in this thesis, is central to the function of the PCWP and its harm threshold. I also argue that the legal framing of surrogacy debates has given rise to a different set of practical problems in [7.0]. Framing in public policy is said to occur because of an over-reliance on key events that occur in history, like the birth of Louise Brown or Dolly the Sheep, and thus inspires the need for regulation.\footnote{Sheila Jasanoff. \textit{Designs on Nature: Science and Democracy in Europe and the United States} (Princeton: Princeton University Press 2005) 42.} Sheila Jasanoff conducted a twenty-five year comparative analysis of the politics and governance of biotechnology and life sciences across Britain, the United States of America, Germany and the European Union, which directly addressed policy agendas by examining the way in which western states sought to govern innovation in biotechnology and genetics. Jasanoff identifies the concept of framing in public policy which is the idea that debates are framed in a subtle but powerful way in order to ensure legislative decision-making goes according to plan.\footnote{Also see the work of John Evans. ‘Religion, Conceptions of Nature, and Assisted Reproductive Technology Policy’ In B. Andrew Lustig. Baruch A. Brody and Gerald P. McKenny (eds). \textit{Altering Nature: Volume II: Religion, Biotechnology and Public Policy} (Vol 98: Springer 2008) 97. He discusses the role of legislatures regarding ARTs policies and considers the work of Jasanoff on legal framing.} She explains that framing is more reliant on stereotypes than rigorous analysis and states that this can shape a response to technological change. She argues that political culture influences democratic policies and this helps account not only for divergent policy but also for the perceived legitimacy of state intervention.

But what does that mean for the PCWP? If obscure or reactive framing of policy issues is a means of accounting for the need of the PCWP, then this lends support to the earlier suggestion in that a political agenda was met as regards the regulation of parenthood in a pre-conception context.\footnote{Reece, op cit \textit{consensus}, n.62; Pilcher and Wagg, op. cit, n.121.} By framing a generic need for a PCWP the state inadvertently imposes control on procreative freedoms. If followed, this logic extends to the regulation of PGD given such issues as “designer babies”, human cloning or stem cell research have developed a hype of inquiry, negative imagery and brave new world debate.\footnote{Hazel Biggs. ‘Designer babies: where should we draw the line?’ (2004) \textit{Journal of Medical Ethics} 30:5. Available at http://dx.doi.org/10.1136/jme.2003.004465 Accessed 24.09.17; Phillip Ball. ‘Designer babies: an ethical horror waiting to happen’ \textit{The Guardian} (8 January 2017); Aldous Huxley. \textit{Brave New World} (Vintage Classics 2007).} The term “designer baby” is just as symbolic now as the “test-tube baby” once was. From a regulatory perspective, the imposition of the PCWP alleviates some of those concerns. It offers a solution to the complex issues surrounding reproductive biotechnology and genomic knowledge. It provides a generalised state response to issues about what might be on the
horizon. The vague concepts of welfare and harm are framed together in order to create a sense of legitimacy as regards state intervention in reproductive choice. Despite its intensely contested meaning it does not have a strong negative or stigmatising connotation. On its surface, it has the resemblance of a principle with benevolent intentions because it has been framed in that way.

However, the problem is that both its meaning and the way in which the PCWP is interpreted are deeply paradoxical. On the one hand, on a theoretical level, given the ambivalence generated by its meaning and application, it appears to be a flexible provision. On the other hand, on a practical level, it is one of the most concerning aspects of state intervention in the context of ARTs. Taking the time to look beyond the generalisation that the PCWP is ‘a good thing’ reveals some important misconceptions and tensions in the current framework. This is particularly so when the PCWP is applied to IVF and PGD, as it reveals the approach is incompatible with reproductive choice and is more geared toward reaching a position in which the state decides who is eligible to receive assistance to have children, and what type of children they can have.

### 2.4 UNDERSTANDING PRINCIPLES BASED REGULATION

Before Part II of this thesis begins, in order to clarify the overarching argument, an introductory note on the formation of Principles Based Regulation (PBR) is warranted. Section 6(2) (b) of the HFE Act 2008 amended section 8 of the HFE Act 1990 and inserted an additional responsibility of the HFEA. It acquired an additional regulatory function which was to maintain a statement of the general principles which it considers should be followed:

(i) in the carrying-on of activities governed by this Act, and

(ii) in the carrying-out of its functions in relation to such activities.

It was at this pivotal juncture, post the Warnock strategy of principalism discussed in [2.2], that the regulation of ARTs encountered the formal introduction of PBR.\(^{148}\) The effect of this was the inclusion of thirteen principles contained in the CoP, which purport to “inform every part of the Code” and are said to reflect the key priorities taken directly from the HFE Act.\(^{149}\)


\(^{149}\) CoP, 8\(^{th}\) edn 2009 (version 1.0) regulatory principles.
Although five of the thirteen principles link to the ‘Welfare of the Child’, only the fourth principle explicitly states the connection.\textsuperscript{150} Principle four mirrors the statutory PCWP to “take account of the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth”.\textsuperscript{151}

This model of PBR provides a broad set of principles of conduct - as set out by the HFEA within the CoP - which are principles-based. It is a regulatory model which has expectations of flexibility while maintaining a risk-based approach to devising public-policy. Julia Black observed that prior to the financial crisis PBR, in contrast to strict rules-based regulation, “[e]voked images of outcome orientated, flexible regulators harbouring ethical standards in largely responsible corporations”.\textsuperscript{152} The logic stems from the former Financial Services Authority,\textsuperscript{153} suggesting that PBR fostered an innovative and flexible style of responsive regulation. But given that “the advocacy of PBR is not confined to financial regulation”\textsuperscript{154} it was adopted in multiple sectors and regulatory regimes, including ARTs. In a search to identify benchmarks for good regulation the UK’s Better Regulation Task Force\textsuperscript{155} (BRTF) published a set of principles of better regulation in 2003 which were subsequently adopted by government.\textsuperscript{156} The principles of what good regulation should be were included in the Legislative and Regulatory Reform Act 2006 (LRR Act 2006) as: proportionate; accountable; consistent; transparent and targeted.\textsuperscript{157} Section 21 of the LRR Act 2006 states:

Principles

(1) Any person exercising a regulatory function to which this section applies must have regard to the principles in subsection (2) in the exercise of that function.

\textsuperscript{150} Principles 1, 4, 6, 7 and 10 which are noted as linked to the PCWP within the current CoP guidance. Specific reference to the regulatory principles were withdrawn from the contents page in the most recent version of the CoP without any explanation in May 2017. At the time of submission the regulatory principles were then reintroduced on to the contents page and in the body of the CoP in October 2017, again without any explanation.

\textsuperscript{151} Ibid, regulatory principles for licensed centres in version 1.0 of the CoP 8th edn (2009).

\textsuperscript{152} Ibid, 3.


\textsuperscript{154} Black, op. cit, Rise and Fall n.148 at 3.

\textsuperscript{155} The BRTF was an independent advisory body set up in 1997 to advise the government on action to reduce unnecessary regulation. It closed in 2008 and was replaced by the Better Regulation Executive which now leads the regulatory reform agenda across government.


\textsuperscript{157} The Legislative and Regulatory Reform Act 2006 enacted the principles of good regulation, obliging regulatory bodies to have regard to the stated principles and a code of practice.
(2) Those principles are that –

a. Regulatory activities should be carried out in a way which is transparent, accountable, proportionate and consistent;

b. Regulatory activities should be targeted only at cases in which action is needed.

In the UK, PBR works parallel to the implementation of the Hampton Principles,\textsuperscript{158} under which all regulators have a statutory duty to implement the Hampton Principles according to Part 1 of the Regulatory Enforcement and Sanctions Act 2008. The intention of the legislation was to ensure compliance with principles of good regulation and that regulatory activities were carried out in the preferred way. The Hampton Review produced a report on “Reducing administrative burdens: effective inspection and enforcement” setting a vision for a risk-based approach to regulation and included a set of principles\textsuperscript{159} for regulatory inspection and enforcement, based around risk and proportionality, as well as streamlining regulatory systems.\textsuperscript{160} It recommended that “all regulatory activity should be on the basis of a clear comprehensive risk assessment…open to scrutiny…implemented uniformly and impartially”.\textsuperscript{161} But what is clear from an overarching analysis is that PBR operates on two levels: on paper and in practice. PBR on paper is contained in the CoP. The HFEA incorporated principles which set out the standard by which clinics must conduct themselves. This means the principles and the guidance contained in the CoP is an expression of the aims of the HFEA, couched in a generalised and purposive way while functioning under the consolidated HFE Act. PBR in practice, which operates at the clinic level, is more complicated and conflicted. This is because on the one hand it benefits from regulatory and interpretive flexibility, but on the other this can develop into practical hindrances for reasons argued in detail in paper one at [4.0].

An important argument central to this thesis is that PBR as an approach to ARTs regulation is open to criticism. On the one hand, while it might be considered a laudable approach to regulating some strands of ARTs in terms of functionality, given that it avoids a strict checklist style regulatory approach, on the other hand it produces tensions, uncertainty and

\textsuperscript{158} Reducing Administrative Burdens: Effective Inspection and Enforcement (March 2005): The Hampton Review, 1-147.
\textsuperscript{159} Ibid, 13.
\textsuperscript{160} Ibid, 55.
\textsuperscript{161} Ibid, 121.
ambivalence that this work seeks to chart in paper two at [5.0]. Take for an example the regulation of SC research. Given the scientific innovation it involves it is reasonable to accept that clinics are regulated but are given flexibility and responsibility to develop their own research methods while ensuring the adherence to the principle of “respect for the special status of the embryo”. In order for scientific and technological innovation to advance, a strict rules based regulatory method would create practical difficulties given rules are generally more rigid and less subjective. It could be argued, therefore, that the trajectory of potential investigations of novel techniques should not be precluded on the basis of ethical, social or other policy issues which demand a level of caution according to a circumscribed set of rules.

As regards the PCWP, whether it should fit into this model of regulation is questionable for three main reasons. First, assessing the probability of risk is inherently difficult insofar as the PCWP’s harm threshold assessment for familial harm and genetic harm are concerned. This is primarily because of the theoretical and speculative nature of the PCWP assessment. Although the nature of assessment appears permissive in that it is broad, general and abstract, it must be remembered that PBR is outcome focused and as such it encourages clinic staff to find a problem as they develop their own interpretation of the framework when they interview individuals seeking treatment. Second, by being outcome focused, the intentions of the HFEA are easy to identify given that the PCWP assessment criterion regulates an idealised family environment and the selection of embryo unaffected by a genetic condition. The problematic working relationship between PBR and the genetic harm threshold assessment is shown in the connection between the PCWP and the restriction on embryo selection following PGD. Crucially, the PBR model lacks the required transparency, consistency and proportionality expected in good regulation because there has never been a clear understanding of the concept of the PCWP, why a harm threshold has to be assessed or why a restriction on reproductive choice is justified because of it. It is difficult then to be certain how the PCWP translates into practice, how the theoretical or intangible harms it entails can be prejudged or whether the so-called risks of harm are met proportionately by state intervention. Julia Black has warned that a PBR regime can “effect quite significant

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162 Research on human embryos is allowed for certain purposes in the UK, outlined in the HFE Act 1990 and the subsequent Human Fertilisation and Embryology (Research Purposes) Regulations 2001. The HFE Act 2008 permitted the HFEA the power to grant licences (for research purposes only) to add limited amounts of animal cells to human ones to make hybrids such as true chimeras, true hybrids and transgenic human embryos.
163 CoP 8th edn (2009), principle 3.
164 HFE Act section 13 (9) and (10).
shifts in regulatory policy by promulgating a new interpretation of a Principle”.

As biotechnology progresses the way in which pre-conception welfare, familial harm and genetic harm is perceived and interpreted may change. It may evolve as our understanding of what is considered to be harmful or harmless expands. This could have significant consequences for individuals seeking assistance to conceive. The development of alternative therapeutic treatments could also alter our perception of how harmful it is to be born in a certain state of ill-health. While the nature of genetics and the expansion of diagnostic testing require regulatory flexibility, the individuals seeking treatment also require objectivity and transparency when they are being assessed as potentially suitable for treatment and their reproductive choices are being restricted by regulation. Third, and more practically straightforward, given that PBR is outcome focused, it could be argued the primary outcome is successfully achieved by assisting individuals to conceive and empowering their reproductive choice. In that regard, mandating an unduly burdensome pre-conception assessment offers no regulatory improvement on a conventional and inflexible rules-based system.

It could be argued that perhaps that PBR and a PCWP should be considered as mutually exclusive. The point being that it does not necessarily follow that regulatory flexibility in one area of ARTs necessitates its application across an entire framework. While the advances in SC research likely compelled Parliament to formalise a flexible regulatory stance; in contrast, a PCWP is dissimilar, in that it is not an evolving phenomenon thus demanding the same approach. Despite the apparent benevolent motive underlying the PCWP and the restrictions on embryo selection, the overriding question of when the use of PBR should become a public policy decision in its own right then emerges. This is particularly so given that the UK government previously revealed reluctance towards flexibly regulating embryo research because of the risk that it would lead to a lack of accountability and certainty.

Thus, the risk with PBR is easy to decipher: negative interpretation. Flexible and adaptive regulation demands the use of vague concepts and broad non-prescriptive principles such as the PCWP. But the problem is that new genetic knowledge and the development of PGD creates new societal choices about the appropriate extent of public policy on the use of the

166 Government Response to the Report from the Joint Committee on the Human Tissue and Embryos (Draft) Bill (2007) Cm 7209, 8.
knowledge and the interventions which make it possible to avoid harm.\textsuperscript{167} Sarah Devaney, a promoter of PBR, even observed that the introduction of PBR passed through Parliament without little question or explanation.\textsuperscript{168} She observes that:

Regulation developed without thorough consideration of all the ethical implications and moral pitfalls will therefore provide those who interpret it in the future with little guidance about the purpose behind the principles and decisions will primarily be based on their own value judgements.\textsuperscript{169}

It is hard to understand how the law can function and operate fairly, transparently and objectively without relying – explicitly or implicitly – on ethical principles of some sort to justify actions or restrictions in PBR. Despite the HFE Act 2008 reforms, I argue that the law on the PCWP has remained inconsistent and incomplete in its conceptual foundations.\textsuperscript{170} This lack of conceptual clarity presents a case for re-engaging with key philosophical principles – that were deliberately avoided by the Warnock Committee – and demands a much closer examination of the intertwined relationship between the PCWP, PBR and state intervention on reproductive choice throughout \textbf{Part II}.

Having discussed the development of the regulation of the PCWP in general, I now turn to examine the particular issue at the crux of state intervention: the concept of harm. In this part I introduce the basis of state intervention that is assumed to aim at protecting the welfare of future children born as a result of fertility treatment services. In the following section I turn to examine actual or foreseeable harm to the unconceived child in a philosophical sense, as a ground as well as a threshold for justifying state intervention in reproductive choice.

\textsuperscript{169} Ibid, 52.
2.5 UNDERSTANDING THE PRE-CONCEPTION WELFARE PRINCIPLE MEANS UNDERSTANDING HARM

Welfare: (1) The health, happiness, and fortunes of a person or group (2) Statutory procedure or social effort designed to promote basic physical and material well-being of people in need.\textsuperscript{171}

In any pluralistic society there are vast differences between the aggregate welfare of born individuals. Most differences are attributable to the choices we make for ourselves, for example, the choice to spend your time socialising at University rather than studying to become a lawyer. But a significant number of welfare affecting factors are not the result of choices we make in our lives. Some individuals, through no fault of their own, are born into ill-health. Similarly, the pre-conceived child is powerless to dictate which family she is born into and thus, how this may affect her aggregate welfare throughout her life. Importantly however, as our knowledge of the human genome has advanced in recent years, it has culminated in “the ability to use the knowledge of how genes function to intervene in significant ways in human life”.\textsuperscript{172} With the advent of IVF and PGD we can interfere with the natural order and prevent a child being born into a particular family or in a particular state of ill-health. Currently our ability to alter the genetic make-up of future children is limited to selection against – rather than for – an embryo affected by a genetic condition or abnormality given the restriction set out in section 13 (9) of the HFE Act. The dispute over whether or not this is an appropriate thing to do is not the focus of this study. Similarly, any disquiet at PGD being used for non-medical purposes will not be explored.\textsuperscript{173} Instead, this work will examine the contours of the concept of harm by addressing three overarching questions involving the regulation of IVF and PGD. First, how does the PCWP utilise a harm threshold in practice? Second, how is the harm threshold used to restrict reproductive choice? Third, what does this mean as regards the PCWP as an appropriate regulatory method?

\textsuperscript{171} Oxford English Dictionary (2017).
\textsuperscript{172} Buchanan and others, op. cit, n.167, 24.
\textsuperscript{173} See: Tom Campbell and Laura Cabrera ‘The weak moral basis for strong PGD regulation’ In Sheila A. M. McClean and Sarah Elliston. (eds) \textit{Regulating Preimplantation Genetic Diagnosis. A Comparative and Theoretical Analysis} (London: Routledge 2013) 17.
A frequent source of controversy in the context of ARTs regulation involves the concept of harm prevention.\textsuperscript{174} It is often assumed that in order for state intervention to be perceived as justifiable when prohibiting some action it must show that the action will cause harm – the so called ‘Harm Principle’. But this raises a problem in this area of pre-conception decision making as attempting to characterise the harm arising out of choices made prior to conception are problematic for a number of reasons. This is primarily because the harm in issue is non-physical or intangible. It is far easier to identify or compensate the harm caused by an action when the person who experiences the harm actually exists.\textsuperscript{175} Conversely, it is difficult to resolve when the said harm relates to a theoretical child, as is the case of ARTs regulation and the PCWP. Questions arise regarding how the harm is measured and where is the harm caused. Answering these questions allow us to discover what the policy implications of the harm-based regulatory approach are.

A fraught conflict arises from the clash of ethical principles surrounding harm and respect for reproductive autonomy. A major theme in the literature is that the advancement of ARTs has significantly increased reproductive autonomy for many individuals. In a pluralistic society there is a great deal of emphasis placed upon individual liberty in a legal, moral and political sense. Such is commonly perceived to be in line with the harm principle advanced by John Stuart Mill which states “the only purpose for which power can be rightfully exercised over any member of a civilised community, against his will, is to prevent harm to others”.\textsuperscript{176} Supporters of the Millian utilitarian position on liberty suggests that there should be a presumption in favour of such liberty unless justifying limits can be shown demonstrating harmful effects.\textsuperscript{177}

Given that there are almost 400 genetic conditions which can be tested for using PGD, the number of possible harms that could arise are significant.\textsuperscript{178} Consequently the main philosophical problems which are of concern here involve accounts of harm prevention in


\textsuperscript{175} Anthony Blackburn-Starza. ‘Compensating reproductive harms in the regulation of twenty-first century assisted conception’ In Kirsty Horsey (ed) Revisiting the Regulation of Human Fertilisation and Embryology (Routledge 2015) 153-169.


\textsuperscript{178} The HFEA publish online a table which shows all PGD conditions currently approved and awaiting consideration by the HFEA. This is available at http://www.hfea.gov.uk/pgd-conditions/ Accessed 20.09.17.
cases where the harm is avoided by ensuring that the harmed individual never exists. This is the process of embryo de-selection following PGD permitted by section 13 (9) of the HFE Act. This primarily relates to identity-affecting philosophy and also involves a discussion of cases of wrongful life which Buchanan et al describe as:

A life not worth living is not just worse than most people’s lives or a life with sustained burdens, it is a life that, from the perspective of the person whose life it is, is so burdensome and/or without compensating benefits as to make death preferable.\textsuperscript{179}

While Buchanan et al do not specifically consider the act of embryo selection in the context of this work; they do argue that it is paramount in a liberal and democratic society that people are provided with general purpose means which are things that would be useful to assist with any life plan.\textsuperscript{180} Therefore, assisting in a life plan, such as seeking assistance to conceive, accessing ARTs and selecting an embryo based on its genetic data, for example, all fit into their rationale. In contrast, by drawing on the application of Joel Feinberg’s \textit{Open Future Argument}\textsuperscript{181} in a prenatal context, Dena Davis suggests something which challenges this liberal approach. She states that to select an embryo which is known to be affected by a genetic condition - over an unaffected embryo - violates the future child’s rights in trust.\textsuperscript{182} But for Savulescu, who champions the exercise of reproductive autonomy, any child “cannot be harmed by that act unless it makes their existence so bad that their lives are not worth living”.\textsuperscript{183}

Negotiating the meaning of ‘a life not worth living’ is no easy task. Rebecca Bennett and John Harris argue that “it is quite clear…that most disabilities fall short of the high standard of awfulness required to judge a life to be not worth living”,\textsuperscript{184} which invites a closer examination of application of the “serious harm” threshold in practice demanded by the PCWP considerations. While the effects of some medical or genetic conditions are so serious that they render the description of ‘a life not worth living’ as relatively uncontentious – such

\textsuperscript{179} Buchanan and others, op. cit, n.167 at 224; Rebecca Bennett and John Harris. ‘Are there lives not worth living? When is it morally wrong to reproduce?’ In Donna Dickinson (ed) Ethical Issues in Maternal-Fetal Medicine (Cambridge University Press 2002) 321.
\textsuperscript{180} Buchanan and others, op. cit, n.167 at 206-225.
\textsuperscript{182} Dena Davis. ‘Genetic Dilemmas and the child’s right to an open future’ The Hastings Centre Report (1997) 27:2, 7-15.
\textsuperscript{183} Savulescu, op. cit Bioethics, n.123 at 28.
\textsuperscript{184} Ibid, 15.
as Niemann-Pick Disease (Type A)\textsuperscript{185} - the same cannot be said for all genetic conditions that the HFEA authorise testing for.\textsuperscript{186} In addition, interpreting the phrase ‘a quality of life’ is just as highly subjective and individualistic as the notion of ‘serious harm’ mandated by the PCWP. Stephen Wilkinson rightly stresses that quality of life issues are not confined to disability and disability does not inevitably lead to lower welfare.\textsuperscript{187} Michael Parker, for example, also states “complex concepts, such as those of the good life, the best life, and human flourishing, are not reducible to simple elements or constituent parts which might be identified by the testing of embryos”.\textsuperscript{188} As a consequence, a principle based on assessing a harm which has not yet been caused to an individual who does not yet exist – such as the PCWP - is rendered unworkable. While many of us would prefer our children to be born without a disability and would prefer to live in a society free of disabling harm to members of society, whatever our intuitive preferences are does not determine the moral character of decisions concerning whether or not we can select an embryo affected by a genetic condition.\textsuperscript{189}

The nature of the work explored in this thesis will also necessitate a brief exploration into Derek Parfit’s complex ‘Non-Identity Problem’ in [6.6] onwards.\textsuperscript{190} It is a problem which focuses on our obligations to future individuals who do not yet exist and if they did exist, because of our action, their existence would be harmed. It claims that if existence is worthwhile then the choice to bring to birth that person in the only state of flawed existence she could exist in is not a morally wrong action. For Parfit, an act can only be wrong if that act makes things worse for or harms an existing person or future person.\textsuperscript{191} In addition, acts that maximise well-being for existing or future persons cannot be deemed morally wrong acts.

\textsuperscript{185} This inheritable disease involves the metabolic system where large amounts of fatty material accumulate on organs such as the liver, lungs and brain. Affected infants typically have jaundice, an enlarged liver and profound brain damage. Infant death is typically before 18 months of age.
\textsuperscript{186} The HFEA regulates PGD on a condition-by-condition basis and authorises genetic testing on embryos on that basis. It provides a centralised list of approved genetic conditions which is accessible on its website.
\textsuperscript{191} Parfit, op. cit Reasons, n.190 at 363.
The importance of considering what harm, if any, would constitute a justifiable ground for state intervention is crucial to this thesis. The ‘Harm Principle’ essentially conditions the legitimacy of state intervention via the PCWP. Although it might be intuitively appealing to avoid harm to others, I argue in paper three at [6.7] that when we evaluate the possible ethical foundation of the PCWP, the appropriateness of its current use in practice is problematic. To conclude this section, since it concerns the concept of harm as opposed to the broader application of the PCWP, I advance an argument that such a fundamental principle in regulation should meet stringent requirements for good regulation referred to in [2.4] and focus on producing a defendable position rather than one that has its foundations in abstract concepts and intuition.

2.6 REPRODUCTIVE CHOICE: ACKNOWLEDGING THE IMBALANCE

Reproductive freedom is particularly relevant as regards state intervention in ARTs. But in reality, there is no one version of liberalism to which everyone in society who is broadly liberal would agree upon. The ways in which public policy is used to impose restrictions unearth conflicting accounts of what are morally permissible actions, interventions and choices in human reproduction. Immanuel Kant argued that people must be autonomous and autonomy of the will is the only principle of the moral law. For Kant, morality is not simply concerning what we do but how we do what we do.\(^{192}\) This aspect of the PCWP regulation is interesting because it creates a normative component in the legal construction of harm: an account of moral responsibility and responsible reproduction.\(^{193}\) This means that when we discuss the limitations on reproductive choice, the concept of harm prevention creates an inference that state restrictions are a morally good thing, because it prevents a morally bad choice being made.

A liberal approach offers a clear account on reproductive choice relevant to the issue of genetic intervention for the prevention of harm. It is rarely disputed that the fundamental aim of the criminal law is to prevent harm being caused to others.\(^{194}\) Joel Feinberg identified four candidates which can be used when we address issues regarding the justification of state intervention on liberty. They were harm to others, offence to others, harms to self and legal


moralism. Arguably, though, only the first two of Feinberg’s candidates could provide justification and sufficient reason for restricting reproductive freedom in the context of ARTs. In that sense, on paper the PCWP incites and embodies the very notion of harm prevention even on a simple dictionary interpretation as noted above. As outlined in Buchanan et al, this includes the choice of whether to procreate, with whom, and by what means; the choice of when to procreate; the choice of how many children to have; the choice of what kind of children to have; the choice of whether to have biologically related children; and the social conditions that support reproductive choices. As Tom Shakespeare rightly points out, however, the use of IVF and PGD to deliberately select an affected embryo would be tremendously rare and therefore should be viewed as a private matter for individual decision-making. John Harris argues that the primary job of a liberal state is then to justify any inappropriate restrictions on reproductive choice. Indeed, there are more extreme philosophical arguments which are not strictly followed in this thesis – proposed by Savulescu - advancing why we must not only avoid limiting the use of PGD, but that those people who are aware of a risk of transmitting a genetic condition have a duty to take reasonable steps to avail themselves of biotechnology to avoid harm, maximally benefit their future offspring and society as a whole.

Some commentators suggest that the UK regime is bio-conservative “in the sense that they are based on the assumption that alternatives to existing practice require specific and clear justification in terms of traditional medical or scientific assumptions”. The bio-conservative would say the burden of proof is very much on those who seek to change the status quo with respect to the PCWP and PGD regulation; to show it is a worthwhile and justified change. In contrast, a bio-liberal - such as John Harris who promotes maximal reproductive autonomy in a democratic society - would argue that the burden is placed on the

197 Buchanan and others, op. cit, n.167 at 209-212.
201 Campbell and Cabrera, op. cit PGD, n.173 at 20.
prohibitionists who seek to impose limitations on autonomy.\textsuperscript{202} He articulates a sensible view that:

One of the presumptions of liberal democracies is that the freedom of citizens should not be interfered with unless good and sufficient justification can be produced for doing so. The presumption is that citizens should be free to make their own choices in light of their own values, whether or not their choices are acceptable to the majority.\textsuperscript{203}

The changing nature of human reproduction and ARTs firmly tells us that the time when reproduction was left to chance is in the past. The ability to exercise choice in our reproductive lives is now more complex than ever. Much of the debate centres on the morality of such choices and as reproductive biotechnology advances the decision-making process will become increasingly difficult. But the difficulties it entails are by no means irresolvable if the law shifts its stance toward a more inclusive, considered and contextual approach. A central argument of this thesis is that a shift in attention is demanded in order to ensure individuals in the future can make reproductive decisions autonomously.

3.0 THE STRUCTURE OF THIS THESIS

As necessitated by the nature of any discussion on ARTs, this thesis involves an interdisciplinary examination of work. In \textbf{Part II}, it discusses a variety of topics and subject areas: ranging for example, from the nature of judicial commentary on a child welfare appraisal in healthcare law to a principled based approach to the regulation of ARTs; separating and exploring the practical application of a harm threshold; dismantling a philosophical or theological concept of harm utilised in the current harm-based regime; and unpicking whether the restrictions on reproductive choice are justified or not. The regulation of surrogacy in the UK is also addressed in one of the papers included in \textbf{Part II}, specifically in relation to the pressing need for reform and how disputed surrogacy cases raise the welfare of the born child in order to overlook and override procedural irregularities which would otherwise prevent the granting of a Parental Order.

\textsuperscript{202} Harris, op. cit, \textit{Regulated Hatred}, n.199.
\textsuperscript{203} John Harris. ‘Reproductive liberty, disease and disability’ (2005) \textit{Ethics, Law and Moral Philosophy of Reproductive Medicine} 1:1, 1.
The thesis methodology is called the ‘Alternative Method’, given that part of the contents of this thesis are peer reviewed and published papers, forthcoming papers, or papers currently under review. These are all found in Part II. The papers – both single and co-authored – were researched and written with a unified aim of building up the argument presented in this thesis both together and alone. Each paper in itself seeks to address its own smaller set of questions but taken together, all the questions contribute to the thesis as a whole: addressing the use of the PCWP in regulation and its implications, while exploring regulation, concepts crucial to our understanding of the PCWP in context and advancing an overall argument for abolition of the PCWP.

Part II presents the main body of the thesis, the central argument against regulation of the PCWP. It should be noted that each paper was written according to the specific stipulations of the academic peer-reviewed journals, meaning the length, composition and writing style in each paper was intended to meet the requirements of their destination. Consequently, this thesis does not read as a conventional thesis might, with chapters neatly flowing from start to finish. Nevertheless, the work provides a thorough examination of how the PCWP is regulated in practice and why the principle is problematic and should be abolished. It does so in the following ways: by providing a chronological legislative assessment of the PCWP; by providing an explanation of the assumptions and positions that have been made on the necessity of the PCWP in regulation; by exploring alternative contextual methods of conducting a welfare appraisal in child law or healthcare law; by exploring the benchmark standards of principle based regulation; by analysing prominent philosophical arguments concerning the concept of harm; and by looking at the current regulatory method in order to substantiate an argument that demands improved standards of regulatory practice in the future.

Part III of this thesis provides a critical and concluding analysis of the arguments presented as a whole. It reviews the way in which the overall aim of this work has been achieved and discusses the potential for future research.

3.1 PAPER OVERVIEWS

I will now present a summary of the articles that build upon the assumptions, views and rationales that have been expressed in the previous section. Part II of this work serves as a
reminder of how important it is to recognise what is taking place around us every day in the unnatural world of human reproduction. To realise its goal of establishing a cogent argument against regulation of the PCWP, the thesis has to approach this topic from a fresh angle and provide fresh debate on the relationship between the PCWP, the harm threshold, and reproductive choice. A major theme that emerges when taking the articles here together is the idea that regulation of the PCWP appears at odds with an industry promoting the formation of families and a legislature that offers protections against discrimination to those who are disabled. I hope to lend credence to the idea that despite endemic disagreement regarding the meaning of the PCWP, we need to destroy the mind-set and abandon any suggestions that abolishing it means that we no longer care about the welfare of children born as a result of ARTs. As we steadily walk into an exciting era which will likely present a plethora of genetic choice, it would be wrong to retain a paradoxical principle at the heart of the legislation which conveys the sense of opportunity but in fact features the most prominent control over individuals.

3.1.1 PAPER 1 – A CRITICAL ANALYSIS

The first paper, *The Pre-Conception Welfare Principle: A Critical Analysis* presents an original argument against the regulation of the PCWP by conducting a chronological and comparative legislative assessment of how the law regulating child welfare appraisals has developed. This paper is divided into two parts: Part I is dedicated to an analysis of how the borders of child welfare have been defined by judge-made law in wrongful life cases and cases concerning the withdrawal of life sustaining treatment from sick children. It offers an analogy to the PCWP’s harm threshold and PGD regulation, as well as offering comparative examples of benchmark standards of regulation. Part II traces the development of the PCWP as a powerful regulatory tool; it queries how it is approached in regulation and how its engagement affects individuals seeking access to treatment.

What follows from the earlier discussion of the judicial approach to welfare appraisals is my argument against the PCWP. I argue that much could be learned from the judicial approach to conducting welfare appraisals and in doing so I provide critique of how, when regulating the PCWP, there is a clear departure in practice from the benchmark standards of objectivity,

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transparency and contextual-sensitivity that are proven elements of a successful method for evaluating the welfare of born children.

3.1.2 PAPER 2 – DOING MORE HARM THAN GOOD?

I then present a critical analysis of the application of the harm threshold in practice in the second complete published paper in this thesis entitled, Applying the Pre-Conception Welfare Principle: Doing More Harm than Good? In this article, I move on from the existing debates in the literature by distinguishing the two distinct categories of harm-based regulation mandated by the PCWP in the CoP: the familial harm and genetic harm thresholds. A key element of the PCWP, as is discussed throughout the thesis, is the harm threshold it entails. Therefore, understanding the harm threshold and dismantling its application is of great importance to the research questions outlined in [1.2].

This paper argues against the intuitive aspect upon which the familial harm threshold hinges and explores the existence of current laws which protect the welfare of born children to remedy the risk factors raised in the PCWP assessment. As regards the genetic harm threshold, this paper approaches the harm-based approach from a purely legal sense. Drawing on the key arguments presented in the first paper, I go on to argue here that the PCWP is applied inconsistently, unfairly and absent of transparency.

3.1.3 PAPER 3 - THE PARADOX OF THE PRE-CONCEPTION WELFARE PRINCIPLE

Prevention of harm is the key driving force behind the PCWP and PGD regulation. The framing of harm prevention in harm-based regulation has shaped the way in which PGD has been used in practice. This paper strikes at the heart of the case I am building and in many ways is the key article which links the various arguments presented together. One might assume, as is argued throughout, that the PCWP is a benevolent principle with a morally significant purpose; and that it should be retained in regulation because it prevents or avoids serious harm from occurring in future children, but this is not correct. This paper makes an original case for an ethical rejection of the PCWP.

By distinguishing the PCWP from post conception welfare considerations a fundamental question is raised regarding its use in the regulation of ARTS. Can we justify its use in this way? This paper adopts a unique perspective by bringing the disciplines of law and philosophy together. This allows for a full and proper consideration of the principled approach and an exploration of the conceptual depth of the PCWP.

This evaluation permits me then to consider how appropriate the current use of the PCWP is in a context where regulation of such a fundamental principle should meet stringent requirements for consistency, transparency and contextual-sensitivity noted in the first paper. I suggest that legislation is in need of conceptual justification which common law judges have been far more explicit about in their welfare appraisals. Ultimately, there should be a re-focus on legislation producing a defendable position rather than one that, I argue has its foundations in abstract concepts and intuition.

3.1.4 PAPER 4 – THE LAWS REGULATING SURROGACY

The fourth paper in this thesis is entitled Reforming the law regulating surrogacy: extending the family and is written in partnership with Margaret Brazier. Although this paper was not part of the original plan when this thesis was in the early developmental stages of research, it became apparent that the law regulating surrogacy offered a further aspect of criticism insofar as the regulation of child welfare, including the PCWP, is concerned. This paper demonstrates a different focus on family formation, the extension of family forms and state intervention in a framework which engages child welfare considerations, in a classic sense, for the born child, and also via the PCWP. This paper is, in effect, a case study on the laws regulating surrogacy and we explore an alternative model of regulation for the future which balances the respective needs of individuals involved, while acknowledging that it is incumbent on the state to take account of child welfare of a child born after surrogacy.

The paper raises possibilities of future research which would draw together the main theme of the thesis on evaluating the justification for pre-conception welfare checks and the possibility of pre-conception parental orders being granted subject to fiduciary obligations between the parties. As regards the possibility of future research stemming from this fourth paper and

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linking to the other three papers, I explore this in full in Part III detailing my concluding thoughts.
PART II

PAPERS
PAPER 1

THE PRE-CONCEPTION WELFARE PRINCIPLE: A CRITICAL ANALYSIS


*Law, Innovation and Technology* (Forthcoming 2018)
4.0 ABSTRACT

This article explores the functioning of the PCWP which is located at the core of the framework regulating ARTs. First, it queries how the borders of child welfare have been defined by judge-made law in cases involving wrongful life or withholding/withdrawing treatment from severely sick children. Second, it conducts a chronological and comparative legislative assessment of the development of the regulation of child welfare in the context of the PCWP. It questions how the PCWP is applied in the regulation of ARTs and demonstrates the departure in practice from benchmark standards of objectivity, transparency and contextual-sensitivity that are identifiable in the judicial approach. This article concludes that the regulatory approach to assessing the PCWP is regressive. It is neither fair nor justified and hence, it should not be used.

4.1 INTRODUCTION

The birth of Louise Brown in 1978 changed the landscape of reproductive medicine irrevocably. What was an emergent area of medicine was “singled out as special, as a part of medicine of such particular social concern and significance that the state should have a direct stake in its evolution”. Almost four decades later, ARTs are subject to intense regulation in the UK. The HFE Act 1990 was the first cornerstone in the legislative framework, regulating the creation, use and keeping of embryos or gametes outside of the human body. While some commentators have praised the legislation as standing the “test of time”, others criticised its “paternalistic structure…as outdated”, and some labelled it “a textbook example of regulatory disconnection”. In 2004, given emerging technologies and the rapid advances in the development of human embryology, legislative reform began. The HFE Act 1990 was amended in 2008, resulting in a consolidated HFE Act.

209 Brazier, op. cit Reproduction Business, n.25, at 166.
The main purpose of this article is to explore the inclusion and application of one provision located at the core of the framework, the PCWP. It provides Parliament and the regulator – the HFEA - with the scope to set out the boundaries for what is deemed to be acceptable ARTs, acceptable reproductive choices and gate keep which individuals gain access to treatment.\textsuperscript{215} It is located at section 13(5) of the HFE Act and mandates that prior to offering licensed treatment a clinic must take into account the welfare of any child who may be born as a result and of any other child who may be affected. The considerations undertaken are theoretical, given that they relate to a future child born if treatment is successful, or to any extant child who could be affected by the birth of a future sibling. Thus, given that it occupies such a fundamental role in the framework with unparalleled regulatory strength, it is crucial to reflect on the development of the PCWP, examine its inclusion in the HFE Act 1990, and explore the basis on which it was retained in 2008, albeit in an amended form. Some commentators have already argued it is a haphazard and disingenuous sort of child protection,\textsuperscript{216} while others claim its application to the selection of embryos is problematic.\textsuperscript{217} Whichever the preferred analysis, given its impact on reproductive choice and the potential to impact on the regulation of innovation in science and human embryology, unpacking the function of the PCWP is crucial.

Part I examines the judicial approach to child welfare appraisals in the healthcare context relating to existing children, focusing in particular on case law on wrongful life and that involving the withdrawal or withholding of life sustaining treatment from severely sick children. It will be demonstrated that the paradigmatic common law position on wrongful life and withdrawal of life prolonging treatment provides an equitable legal foundation for a child welfare appraisal which necessitates an exploration into the health and existence of a child in a state of ill-health. By examining aspects of leading judgments, a sense of judicial pragmatism emerges as regards the deconstruction of medical and genetic harm. This pragmatism is highlighted to acknowledge the evolution of judge-made law given the development of a contextual assessment of child welfare based on a balance sheet method and to then compare this to the regulatory framework governing the PCWP.

\textsuperscript{216} Jackson, op. cit, \textit{Conception}, n.4.  
\textsuperscript{217} Elliston, op. cit, \textit{Selecting for Disability}, n.4 at 123.
Part II traces the legislative development of the PCWP, arguing that the law has departed from benchmark standards of objectivity, transparency and contextual-sensitivity which are identifiable components of the judicial approach to a welfare appraisal. In order to substantiate this argument, this critique separates the PCWP framework into two categories of harm-based regulation. One concerns the familial aspects of the PCWP, while the other concerns the medical aspects of the PCWP. The latter, it will be shown, is most directly relevant to the judicial approach to child welfare appraisals outlined in Part I involving considerations of medical harm. Part II will focus on the application of the PCWP in relation to the use of IVF and PGD, as these technologies can determine whether a child is born and in what state of health. PGD is considered an acceptable ART because it detects embryos affected by a genetic condition or abnormality and enables the selection of genetically healthy embryos for implantation. This creates a nexus between the PCWP and the provisions regulating PGD, in the HFE Act and the CoP. This hybrid regulatory approach will be scrutinised in order to reveal the misconceptions and inconsistencies in the current PCWP framework. However, it is also relevant to the former familial aspects of the PCWP given the benchmark standards that are lacking when the PCWP is assessed in the context of access to ARTs. This consideration of the regulatory approach to the PCWP in Part II is relevant for two reasons. First, an important analogy can be drawn regarding the use of the PCWP in the regulation of PGD and the judicial case law concerning a child’s best interests when the assessments both focus on the existence and non-existence of a child in a state of ill-health. Second, the overall comparison of the two approaches exemplifies the identified benchmark standards are lacking in the regulation of the PCWP. It will be argued that far from achieving conceptual clarity, the PCWP is a nebulous concept which should not be used to justify state intervention in ARTs. It is suggested that the PCWP should be abolished. Space does not permit a full exploration of an alternative model of regulation but – if there must be a pre-conception welfare test - it is suggested that the law must be transparent and display a stronger commitment to context.

4.2 THE JUDICIAL APPROACH TO CHILD WELFARE

The CA 1989 is the primary Act that legislates for born children in England and Wales; it provides what is deemed to be the strongest form of a child welfare principle for an existing

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218 Section 13 (9) and (10).
child in need of safeguarding.\textsuperscript{220} In child law, in effect, “children’s welfare trumps and outweighs all other considerations; no other interests or values may affect the decision; children’s interests are the only ones that count”.\textsuperscript{221} It mandates the court and any other party to proceedings to account for a list of statutory welfare factors when making enquiries to safeguard a child.\textsuperscript{222}

In the context of medical law, a judicial appraisal of child welfare for a born child is generally triggered when a conflict arises between parents and healthcare professionals. The first task is for the court to establish its jurisdiction in the case and thereafter, explore the challenges faced by the healthcare professionals in medical decision-making. On its face, the process of a welfare appraisal seems relatively uncontroversial. However, a review of precedent reveals that this is far from the case. Welfare appraisals conducted by judges who have been tasked to determine a claim for wrongful life, or determine whether life prolonging medical treatment for a severely sick child can be withdrawn, unveil the comparative conundrum of a child’s existence and non-existence within an assessment. To what extent the law intervenes in withholding or withdrawing life prolonging treatment\textsuperscript{223} in order to alleviate the burdens of severe illness demonstrates the fine “balance between the pain of prolonged life and the finality of death”\textsuperscript{224} which the courts have resolved. These cases involve both establishing a concept of health and the construction of quantified legal harms as the appraisals question a child’s existence in a state of ill-health. Over time therefore, the concept of welfare and the construction of a welfare appraisal has become an evolving product of judge-made law. The following two sections shed some light on the jurisprudence of a child’s best interests. First, in relation to wrongful life claims, it is clear that the judges believe that life is better than no life and life is, to that extent, in a child’s best interests. Second, it focuses mainly on cases involving the withholding or withdrawing of life-sustaining treatment, in which we see the development of a judicial approach that is responsive to context, objective and transparent.

\textsuperscript{220} No single piece of legislation covers child protection in the UK. In accordance with the inherent jurisdiction of the Court the best interests of the child is the prime concern. The best interests of the child is also the primary consideration in decisions taken affecting a child in accordance with Article 3 of the UNCRC, op. cit, n.52.

\textsuperscript{221} Reece, op. cit, \textit{Consensus}, n.62 at 267.

\textsuperscript{222} Section 1(1) states that when a court determines any question with respect to the upbringing of a child or the administration of a child’s property the child’s welfare shall be the court’s paramount consideration.


\textsuperscript{224} Brazier and Cave, op. cit, 6th edn \textit{Medicine, Patients and the Law}, n.2 at 443.
4.2.1 WRONGFUL LIFE

In the seminal case of *McKay v Essex Area Health Authority*\(^{225}\) in 1982 the plaintiff child, Mary McKay, claimed her actionable injury was life itself. During pregnancy her mother had wrongly been informed that she had not been infected with rubella. As result of the negligent misdiagnosis she had not been advised of the consequences of the infection on the foetus nor had she been given the option of a termination, which she claimed she would have accepted. Mary was born severely disabled as a consequence of the infection. The Court of Appeal dismissed her claim for wrongful life. It held that no action lay where the thrust of the claim was that but for a defendant’s negligence the child would never have been born. Of particular significance, Stephenson LJ remarked, “If a court had to decide whether it were better to enter into life maimed or halt than not to enter it at all, it would, I think, be bound to say it was better in all cases of mental and physical disability, except possibly those extreme cases”.\(^{226}\) While observing a lack of evidence on the extent of suffering experienced, Stephenson LJ stated it “[c]ould not be suggested that the quality of her life is such that she is certainly better dead, or would herself wish that she had not been born or should now die”.\(^{227}\) Ackner LJ took this further by considering the theoretical application of the *Congenital Disabilities (Civil Liability) Act 1976* (CD Act 1976)\(^{228}\) – which came into force a year after Mary McKay was born – and stated there was no comparison to make, in law, between existence and non-existence:

> Her complaint is that she was allowed to be born at all, given the existence of her pre-natal injuries. How then are her damages to be assessed? Not by awarding compensation for her pain, suffering and loss of amenities attributable to the disabilities, since these were already in existence before the doctor was consulted. She cannot say that, but for his negligence, she would have been born without her disabilities. What the doctor is blamed for is causing or permitting her to be born at all. Thus the compensation must be based on a comparison between the value of non-

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\(^{225}\) *McKay v Essex Area Health Authority* [1982] QB 1166 CA.

\(^{226}\) Ibid, at 1182 (Stephenson LJ)

\(^{227}\) Ibid, 1180.

\(^{228}\) The *Congenital Disabilities (Civil Liability) Act 1976* section 1 (1) states: “If a child is born disabled as the result of such an occurrence before its birth as is mentioned in subsection (2) below, and a person (other than the child’s own mother) is under this section answerable to the child in respect of the occurrence, the child’s disabilities are to be regarded as damage resulting from the wrongful act of that person and actionable accordingly at the suit of the child”. Such disabilities are considered “damage” as a result of the actions of the third party.
existence (the doctor’s alleged negligence having deprived her of this) and the value of her existence in a disabled state. But how can a court begin to evaluate non-existence, ‘the undiscovered country from whose bourn no traveller returns?’ No comparison is possible and therefore no damage can be established which a court should recognise.\textsuperscript{229}

The effect of the judgment not only barred any claim for wrongful life where a child is harmed in utero before birth\textsuperscript{230} but, crucially, the Court of Appeal ruled it impossible to quantify a level of damages representative of the difference between a disabled child’s existence versus her non-existence.\textsuperscript{231} In deeming ‘…Life – whether experienced with or without major physical handicap is more precious than non-life’,\textsuperscript{232} the court pronounced a life with defects can never be an injury cognisable at law for three distinct reasons. First, that it would undermine the sanctity of human life in a public policy capacity if a doctor owed a duty of care to a child to ensure she did not exist. Second, if such actions did succeed then doctors may be burdened with a duty to encourage or persuade women to terminate life \textit{in utero}.\textsuperscript{233} Third, that life, however disabled, had to be better than no life.

In over the thirty years since \textit{McKay} the common law position on wrongful life remains intact. Rosamund Scott\textsuperscript{234} criticises the anomalous legal position created by the ruling, claiming it is inequitable, because of a child’s inability to claim wrongful life when conceived naturally when disability is erroneously not detected, in contrast to a child’s ability to claim damages as a result of negligent embryo selection by PGD.\textsuperscript{235} But despite the anomaly, there is a clear and identifiable logic in the judicial rejection of life as a quantifiable damage. First, it opposed a negative endorsement of a harmed or disabled life being

\textsuperscript{229} \textit{McKay}, op. cit, n.225 at 1189 (Ackner LJ)
\textsuperscript{230} In England if a child is injured before birth by a defendant whose conduct caused the child’s disability then there is an action and claim for compensation in wrongful disability.
\textsuperscript{231} \textit{McKay} op. cit, n.225 at 782, 787, 790.
\textsuperscript{232} Ibid, 771 and 782.
\textsuperscript{233} Ibid, 797.
\textsuperscript{235} When the HFE Act 1990 was enacted section 1 of the Congenital Disabilities (Civil Liability) Act 1976 was extended to cover infertility treatments where (a) a child carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination is born disabled, (b) the disability results from an act or omission in the course of the selection, or the keeping or use outside the body, of the embryo carried by her or of the gametes used to bring about the creation of the embryo, and (c) a person is under this section answerable to the child in respect of the act or omission, the child’s disabilities are to be regarded as damage resulting from the wrongful act of that person and actionable accordingly at the suit of the child.
considered as damaging, wrongful, unworthwhile or a life not worth living. Second, it was a positive premise for devising law and public policy surrounding the value of life. Thus, the approach in McKay highlights a key flaw at the heart of the PCWP which compels the application of the very approach rejected by the courts: harm avoidance.

4.2.2 WITHOLDING TREATMENT

Cases involving providing, withholding or withdrawing of life sustaining treatment from an existing seriously ill or severely disabled child reveal an alternative judicial approach towards adjudicating contextual issues on welfare which include an analysis of harm. The case law demonstrates the many dimensions of judicial analysis of child welfare when quality of life decisions surrounding medical treatment in this context are considered. If a child is living in a harmed state because of a medical or genetic condition then sometimes a very difficult question arises as to whether she should continue to live in that harmed state or whether treatment should be withdrawn. By invoking a normative concept of harm – a life perhaps ‘not worth living’ - judges deal with the possibility and legality of withholding or withdrawing life sustaining treatment from a severely ill child, inevitably resulting in death. The welfare considerations which influence an answer to the question of withdrawing treatment are revealed in the contextually-sensitive judicial reasoning. The approach is factual and evidence based, and requires where possible that equal weight be given to the wishes, beliefs and feelings of the parents involved. It demands a collection of multi-agency medical evidence, collating and dissecting it during the proceedings to enable well-reasoned and informed decision-making in every case. The approach is to construct a ‘balance sheet’, weighing the respective benefits and burdens of providing treatment or not while incorporating broader social considerations surrounding welfare. It requires balancing the competing interests where there is pain and suffering, against the prospect of withdrawing treatment and ending life to end the suffering. Thus, in practice, the common

237 Courts will obtain information from Cafcass in each case which is in addition to Local Authority intervention and referral to the Royal College of Paediatrics and Child Health (RCPCH). See: RCPCH, Making Decisions to Limit Treatment in Life-limiting and Life Threatening Conditions in Children: A framework for Practice (2015).
238 Note the case of Re MB [1997] 2 FLR 426 for a best interests determination in a case concerning mental capacity and medical treatment which moves considerations of best interests or welfare beyond only medical care and incorporates broader social, personal and ethical considerations.
239 Re C [1989], op. cit, n223; Re J [1990], op. cit, n.223; Re T [1997], op. cit, n223; Also see: Tony Sheldon. ‘Court Awards Damages to Disabled Child for Having Been Born’ (2003) British Medical Journal 326, 784.
law’s paradigmatic position on child welfare is a product of its own objective judicial reasoning.

In *McKay*, Stephenson LJ cited in the 1981 case of *Re B (A Minor) (Wardship: Medical Treatment)*, in which the Court of Appeal was asked to determine whether a child born with Down’s syndrome (a genetic condition which can be detected by PGD) who was suffering with an intestinal obstruction should undergo invasive surgery or not. The parents refused to authorise the surgery on religious grounds. Without the surgery the baby would die. By balancing the burdens of his condition set against any experience of pleasure in existing, the procedure was judged to be in the child’s ‘best interests’ and the court gave consent to the surgery. More recent case law demonstrates that the court remains reluctant to deem a child’s life to be a “pitiful existence”. In order to justify a decision to stop treatment, on what is framed as a best interest’s analysis, the court conducts an exhaustive consideration of all available evidence, medical and otherwise. Thorpe LJ in *Re A* set out a pragmatic approach to a welfare appraisal in a case concerning the sterilisation of a male who lacked capacity in the following way:

[t]here can be no doubt in my mind that the evaluation of best interests is akin to a welfare appraisal….Pending the enactment of a checklist or other statutory direction it seems to me that the first instance judge with the responsibility to make an evaluation of the best interests of a claimant lacking capacity should draw up a balance sheet. The first entry should be of any factor or factors of actual benefit… Then on the other sheet the judge should write any counterbalancing dis-benefits to the applicant. An obvious instance in this case would be the apprehension, the risk and discomfort inherent in the operation. Then the judge should enter on each sheet the potential gains and losses in each instance making some estimate of the extent of the possibility that the gain or loss might accrue. At the end of that exercise the judge should be better placed to strike a balance between the sum of the certain and possible gains against the sum of certain and possible losses. Obviously, only if the account is in

240 *McKay*, op. cit, n.225 at 1166.
242 *Re K (A Child) (Withdrawal of Treatment)* [2006] EWHC 1007 (Fam) 57.
244 *Re A (Medical Treatment: Male Sterilisation)* [2000] 1FLR 449.
relatively significant credit will the judge conclude that the application is likely to advance the best interests of the claimant.\textsuperscript{245}

Ward LJ in \textit{Re A (Minors) (Conjoined Twins: Separation)}\textsuperscript{246} considered that “every life has an equal inherent value. Life is worthwhile in itself whatever the diminution in one’s capacity to enjoy it”.\textsuperscript{247} In addition, the court made clear that while parents have parental responsibility to give consent to undergo treatment, overriding control is vested in the court to exercise objective and independent judgement in a child’s best interests.\textsuperscript{248} In \textit{Portsmouth NHS Trust v Wyatt and another}\textsuperscript{249} the conflict concerned whether a baby born prematurely at 26 weeks should be ventilated or not if she succumbed to infection. Wall LJ set out “intellectual milestones”\textsuperscript{250} for judges to consider in cases where medical treatment is identified as required, but has been refused. While advocating for paramountcy of child welfare the Court of Appeal held that the best interests of a child in the context of withholding medical treatment were not to be determined by a strongly subjective test of whether the child’s life would be intolerable if treated. It held that although there is a strong presumption in favour of a course of action which will prolong life, the presumption is also not irrebuttable\textsuperscript{251} and the child’s best interests should be broadly interpreted including balancing medical, emotional and other welfare factors.\textsuperscript{252} These intellectual milestones were then elaborated upon in \textit{An NHS Trust v MB (A Child) (represented by CAFCASS as Guardian ad Litem)}\textsuperscript{253} when Holman J stated if a dispute arose between the treating doctors and parents, and the parties have asked the court to make a decision, it is the role and duty of the court to exercise its own independent and objective judgment. He described the best interests test in the widest sense – although he conceded it is impossible to weigh mathematically – to include every kind of consideration capable of impacting on the decision,

\textsuperscript{245} Ibid, 560.
\textsuperscript{246} \textit{Re A (Minors) (Conjoined Twins: Separation)} [2000] 4 ALL ER 961.
\textsuperscript{247} Ibid, 1002. Their Lordship’s relied on the doctrine of necessity to justify the separation of the twins - leading to the inevitable loss of Mary’s life – the analysis of evidence and welfare factors contributed to the decision that a deliberate act was a justified one despite the grave and fatal consequences. The judicial reasoning in this case has been criticised. See: John Harris. ‘Human beings, persons and conjoined twins: An ethical analysis of the judgement in Re A’ (2001) Medical Law Review 9:3, 221-236.
\textsuperscript{248} \textit{Re A (Children) (Conjoined Twins: Surgical Separation)} [2000] 2 WLR 480.
\textsuperscript{249} \textit{Portsmouth NHS Trust v Wyatt and another} [2005] EWCA Civ 1181.
\textsuperscript{250} Ibid, 90-91.
\textsuperscript{251} This wording was expressed by Lord Donaldson in \textit{Re J (A Minor)}, op. cit, n.243 at 46. But the Court has since conceded the sanctity of human life is not absolute. See: \textit{Airedale N.H.S. Trust v Bland} [1993] AC 789, on withdrawal of artificial nutrition and hydration from a patient in persistent vegetative state.
\textsuperscript{252} \textit{Portsmouth NHS Trust} op. cit, n.249 at 87.
\textsuperscript{253} \textit{An NHS Trust v MB (A Child) (represented by CAFCASS as Guardian ad Litem)} [2006] 2 FLR 319.
non-exhaustively including medical, emotional, sensory and even instinctive considerations.254

The law has also confirmed that continued life in a state of ill-health is sometimes judged not to be in the interests of a born child according to the balancing exercise. In Kings College Hospital NHS Foundation Trust v Y and MH 255 MacDonald J rebutted the “strong presumption in favour of a course of action that will prolong life, a strong presumption that flows from the recognition and acknowledgement of the sanctity of life”256 given the “very considerable and weighty factors on the other side of the welfare balance sheet”257 In his reasoning he applied a perspective on welfare by carefully recounting the medical evidence, particularly noting the stark neurological deterioration of Y,258 which allowed him to depart from the dominant rule at law that errs toward the prolongation of life. In this case, given the risk of Y being kept in a permanent vegetative state, MacDonald J determined that re-intubation and intensive ventilation could not be said to be in the patient’s best interests.259 Importantly, the judgment signalled that the legality of withholding treatment is contingent on the highest degree of analysis of the evidence and welfare considerations. It demonstrates that the contemporary judicial approach is contextually sensitive. Moreover, it reinforces the need for a transparent method of welfare determination. Given such cases are inherently complex and demand interpretation of the evidence, information and opinion from multiple disciplines, the parents or interested parties, in a mixed objective and individualistic sense, the law is able to conclude that continued existence in a harmed state is not congruent to the welfare of a child.

The highly publicised case of Great Ormond Street Hospital v Yates and Gard260 goes further still, demonstrating the judicial standards of objectivity, contextual sensitivity and transparency can extend beyond the conventional balance sheet approach when alternative therapeutic treatments are an option to explore. Charlie Gard was born in August 2016 and suffers from a rare inherited mitochondrial disease,261 he has severe progressive muscle

255 Kings College Hospital NHS Foundation Trust v Y and MH [2015] EWHC 1966 (Fam).
256 Ibid, 35.
257 Ibid, 48.
258 Ibid, 50 – 57.
259 Ibid, 55.
261 Infantile onset encephalomyopathy mitochondrial DNA depletion syndrome (MDDS).
weakness and cannot move his arms or legs or breathe unaided. In February 2017 the NHS Foundation Trust for Great Ormond Street Hospital for Children (GOSH) issued an application to the High Court seeking a declaration that it was lawful and in Charlie’s best interests for artificial ventilation to be withdrawn and he receive only palliative care. A second declaration sought was for Charlie not to undergo alternative therapy in America which was favoured by the parents, called deoxynucleoside therapy, which could ameliorate the disease. Charlie’s parents wished to take him to America to receive the alternative treatment. In the High Court, Francis J stated “although the parents have parental responsibility, overriding control is by law vested in the court exercising its independent and objective judgement in the child’s best interests”.

The intellectual milestones from Wyatt v. Portsmouth NHS Trust were recounted and over three days Francis J heard evidence from the healthcare professionals treating Charlie, further evidence from four other UK doctors whom the hospital sought a second opinion and evidence from a fifth doctor instructed by the parents. In evidence, it was suggested that alternative therapy would not only be futile but might well cause pain, thus prolonging suffering and increasing distress to Charlie. Following an astute analysis of the medical evidence Francis J granted the applications brought by GOSH.

The parent’s appealed the decision on five grounds, two of which will be briefly outlined for the purposes of this discussion. For ground one, they sought to distinguish two types of cases concerning medical treatment of severely sick children. They argued their case was distinct from the norm given there was a viable alternative treatment option available. The central issue was whether the parents preferred treatment option would likely cause ‘significant harm’ to Charlie and it arose from the judgement of Baker J in Re King.

262 Constance Yates, Christopher Gard v Great Ormond Street Hospital for Children NHS Foundation Trust, Charles Gard (A Child, By his Guardian) [2017] EWHC 972 (Fam), 11.
263 Portsmouth v Wyatt op. cit, n.249 at 90-91.
265 Grounds 1, 2 and 4 (asserting significant harm, no jurisdiction and a breach of Articles 2, 5 and 8 of the European Convention on Human Rights) were granted permission to appeal. Grounds 3 and 5 (asserting a judicial error on the conventional best interest’s evaluation and procedural unfairness on the parents and their legal team surrounding disclosure of documents) were refused permission to appeal.
266 Note the use of terminology across the legislation: ‘significant harm’ is the key element within the threshold criteria in section 31 of the Children Act 1989 which provides any local authority with the power to intervene in the ordinary care of a child. ‘Significant risk of serious harm’ are the elements contained in the threshold criteria regulating PGD in the HFE Act section 13 (9) and the PCWP assessment in the CoP 8th edn (2009).
267 Portsmouth City Council v Naghmeh King, Brett King, Southampton Hospital Trust, Ashya King (by his children’s guardian, John Mellor) [2014] EWHC 2964 (Fam). This case involved a choice between two types of radiotherapy to treat a child’s brain tumour. The parents disagreed with the treatment plan proposed by the hospital and removed the child so that he could be treated in Spain.
(which focused on a disagreement between the parents and healthcare professionals treating Ashya King - a five year old boy suffering from a serious form of brain cancer – as to the type of radiotherapy to be administered). Charlie’s parents relied on Article 8 of the European Convention on Human Rights (the Convention) to suggest that in the absence of significant harm their parental rights had been interfered with unjustifiably. McFarlane LJ reflected - as per Re King – that the court may not “interfere with a decision by parents in the exercise of their parental rights and responsibilities with regard to their child’s medical treatment, save where there is a risk the parents’ proposed course of action may cause significant harm”. In essence, before the Court of Appeal it was argued that “absent a finding that a course of action preferred by the parents would be likely to cause their child significant harm, it was neither necessary nor proportionate for the state to override the parents legitimate choice of treatment”. For ground two, the parent’s asserted that Francis J had erred in relying on a best interests test alone and not conducting an assessment according to the conventional balance sheet approach. But, after a proclaimed “100 percent, child focused, court-led evaluation” the Court of Appeal unanimously dismissed the parents’ appeal. At the very outset, McFarlane LJ disagreed with the alleged failure of Francis J to correctly attribute weight by not drawing a balance sheet. He declared it was not a conventional balance sheet case given “that all of the evidence, including the opinion of the parents, led to the sad conclusion that it would be in his best interests now to withdraw treatment”. Given the absence of any benefit from the alternative therapeutic treatment which the prospects of success were said to be “effectively zero”, a balance sheet was rendered unarguable. In addition, McFarlane LJ determined that the creation of a new category of case going beyond the category of significant harm outlined in Re King was neither necessary nor appropriate in Charlie’s case. The court concluded that the factual basis for the submissions was undermined and the question of a distinction between cases did not arise. Nevertheless, it stated:

268 Ibid, 5.
270 Ibid, 82.
271 Ibid, 118.
272 Ibid, 48.
273 Ibid, 113.
275 Ibid, 113.
It must follow from that unanimous professional and expert evidence that to move Charlie to America and expose him to treatment over there would be likely to expose him to continued pain, suffering and distress.\textsuperscript{276}

Thus, the incontrovertible consequence was that travelling to America to try alternative therapy was not found to be in Charlie’s best interests.

The Supreme Court similarly declined to grant permission to appeal on the basis that no point of law had been identified.\textsuperscript{277} Lady Hale addressed the issue of an assessment of best interests given that Charlie’s parents argued it was not the right legal test to undertake. The parents claimed “that parents and parents alone are the judges of their child’s best interests”.\textsuperscript{278} Lady Hale stated it was not arguable that the UK courts lacked jurisdiction to make a ruling and make a determination by conducting a best interests evaluation. She reiterated a child’s rights must be the paramount consideration and that the domestic law of the UK accorded with Articles 2 and 8 of the Convention.\textsuperscript{279} Before the European Court of Human Rights (ECtHR) Charlie’s parents argued an unjustifiable infringement of Article 2 (right to life), Article 5 (right to liberty and security) Article 6 (right to a fair trial) and Article 8 (right to respect for private and family life), on the basis that blocking access to alternative treatment deprived Charlie of his liberty and furthermore, the domestic court decisions amounted to an unfair and disproportionate interference in their parental rights. By a majority the ECtHR endorsed the domestic approach, declaring the application inadmissible it stated:

\begin{quote}
Examining the decisions taken by the domestic courts...the Court recalls that they were meticulous and thorough, ensured that all those concerned were represented throughout; heard extensive and high quality expert-evidence; accorded weight to all the arguments raised; and were reviewed at three levels of jurisdiction with clear and extensive reasoning giving relevant and sufficient support for their conclusions at all three levels.\textsuperscript{280}
\end{quote}

\textsuperscript{276} Ibid, 114.
\textsuperscript{278} Ibid, 8 June 2017.
\textsuperscript{279} Ibid.
\textsuperscript{280} Gard and Others v. The United Kingdom (Application No 39793/17) ECHR (2017), 124.
Recounting the process of a welfare appraisal in such complex cases is of relevance here for two reasons. The first, which is legally straightforward, reflects the conceptualisations of a majority culture about the limited circumstances in which the law is permitted to make such fundamental decisions involving existence. Only in extreme cases and with extreme caution can the state involve itself in such matters. The second involves the role of the parents and their power to make decisions about their child’s life-affecting medical treatment, because the judgments signal something interesting regarding residual paternalism in a welfare assessment. Dependent upon the parent’s withdrawal of consent to treat or request for treatment to continue, judges often uphold the contrary view according to the evidence from healthcare professionals. Judicial deference to medical evidence and opinion often conflicts with the more emotive submissions made by parents regarding familial aspects of a child’s welfare, their bond with the child and their parental urge to do what they feel is best. The important part of the process, however, is either the balance sheet analysis or a methodical examination of the evidence when a balancing exercise cannot be undertaken given the facts (as in the case of Charlie Gard above). The overarching purpose is to ensure the appraisals are unique and uncircumscribed. The judicial exercise demonstrably balances welfare considerations by taking into account multiple perspectives. There is no judgment or assertion that the child should never have existed in the state of ill-health and no clear definitive line between a right and wrong decision on a child’s continued existence in a state of ill-health. Overall, the judicial approach demonstrates that the role of the law is to collate the evidence, to be independent, avoid presupposition and provide transparent child focused decision-making in welfare appraisals. Most importantly, the role is not premised in any notion of bias and despite the outcome sometimes being contrary to the parent’s wishes, the sanctity of human life is preserved, including those lives that start out medically harmed.

4.3 THE LEGISLATIVE DEVELOPMENT OF THE PRE-CONCEPTION WELFARE PRINCIPLE

In the following part of this article the legislative development of the PCWP will be traced in five sections. First, I will focus on the initial inclusion of the PCWP in the legislation and its growth as a key regulatory principle in the ART setting. This leads onto the discussion during the reform process surrounding its retention in regulation and the subsequent amendment of the statutory PCWP given the enactment of HFE Act 2008. Finally, the overarching approach conducted by the HFEA in regulating the PCWP is then critically examined.
4.3.1 THE WARNOCK REPORT AND THE HFE ACT 1990

The development of the current framework regulating ARTs traces back to the publication of the Warnock Report. In 1982, the Committee debated a range of moral, legal and ethical issues in the field of infertility and was commissioned to make recommendations on a model of regulation for fertility treatments and embryo research, resulting in the Warnock Report. Although PGD was not available to use then it is clear – and will be shown – that despite the connection of key issues surrounding welfare, the Warnock Committee and Parliament were uninfluenced by the judicial approach to child welfare appraisals when the legislation was crafted. Miola described it as “the defining report of its decade”. Given its gradualist approach to regulation it has underpinned both HFE Acts, resulting in the consolidated HFE Act. Yet despite the Committee’s commitment to covering a range of fundamental ethical topics, the need for a PCWP is not explicitly mentioned within the 103 pages. Instead, focus was placed on “the primacy of the interests of the child and on upholding family values”.

The PCWP was also not included within the 1987 White Paper preceding the HFE Act 1990. It was only by virtue of debate in the House of Lords during the committee stage of the HFE Bill on whether treatment should be provided to lesbians or unmarried couples that the need to include a welfare principle was raised. Emily Jackson, a staunch opponent of the principle, observed its inclusion was “neither challenged nor defended…it was simply assumed to be self-evidently true that their future children’s welfare ought to be taken into account before a couple is offered assistance with conception”. This view is perhaps exemplified by Lord Clyde’s claim that the inclusion of a principle in the legislation resulted in his mind being “substantially set at rest”. When the HFE Act 1990 came into force it devoted little space to the PCWP, occupying only subsection 13(5):

A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the

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282 Miola, op. cit Symbiotic, n.106 at 187.
284 Warnock Report, op. cit n.24 at para 3 (my emphasis).
286 Lords Hansard, 07 December 1989 (Lady Saltoun), Col 1090; Lords Hansard 06 Feb 1990, Col 787.
287 Jackson, op. cit Conception n.4, 177.
288 Lords Hansard, 5 December 1996 (Lord Clyde) Col 812.
need of that child for a father), and of any other child who may be affected by the birth.

Importantly, during the 1990 debates the inclusion of the PCWP within the legislation was unconnected to the health of future children. PGD was not a reproductive technology available in clinics at that time. The Warnock Report described the use of embryo biopsy to detect genetic conditions as “potentially useful” but it was not anticipated that PGD would become a feasible method of detecting abnormal embryos for some considerable time. For that reason the HFE Act 1990 did not include provisions for embryo testing. This means that the PCWP was not inspired by a concept of health or prevention of medical harm, and it was not included with the benevolent motivations one might assume. Its central welfare focus was dissimilar to the aspects divulged in McKay, Re B and Wyatt, where health and medical harm connected to welfare considerations were scrutinised. The PCWP was included for two reasons. First, it alleviated Parliamentary fears of the unknown in ARTs that even Dr. Robert Edwards (who successfully pioneered IVF with Dr. Patrick Steptoe) had declared were “based on the pessimistic assumption that the worst will happen”. Second, it was aimed at restricting who may gain access to ARTs in accordance with the Warnock nuclear model.

Given the lack of debate in the House of Lords surrounding the necessity of the PCWP’s inclusion during the early legislative stages, the principle lacked an ethical underpinning. But by being drafted in broad terms it created an assurance for their Lordships that the potential capabilities of ARTs would not go beyond the preferred parameters of what had been deemed acceptable by the Warnock Committee. It also simultaneously created the impression that an important socio-ethical principle had been included in the legislation with child safeguarding objectives. This then entails a further assumption that its inclusion was consequent to thorough consideration and careful drafting. In reality however, its centrality in the law was to assert control over individuals’ reproductive autonomy, and restrict innovation, rather than promote and resolve a welfare concern for an un-conceived child.

Notwithstanding the bias supporting its inclusion and the lack of a definition in the statute, the status of the PCWP has developed with judicial scrutiny and academic commentary. In

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Evans v Amicus Healthcare Ltd,\textsuperscript{291} a case in which the court determined the fate of stored embryos created by a couple who had since separated, Wall J confirmed that upon a combined reading of the HFE Act 1990 and the CoP,\textsuperscript{292} the principle was considered to be “a twin pillar of the Act”\textsuperscript{293}, alongside consent to treatment. Further still, he claimed it had become one “of the most important principles”\textsuperscript{294} underlying the legislation. Likewise, it established strength in its application before the Grand Chamber of the ECtHR in case law concerning serving prisoners’ access to artificial insemination (AI). In Dickson and Another v United Kingdom the court accepted that child welfare considerations were legitimate considerations to undertake in circumstances which involved a non-serving prisoner, who would be 51 years of age when her partner would be eligible for release from prison, requested to receive AI.\textsuperscript{295}

Interestingly, when focus shifts towards treatment of post-menopausal women, the PCWP is also located at the forefront of socio-ethical critique by attracting debate over a woman’s reproductive responsibility.\textsuperscript{296} The fact that there is debate over whether or not post-menopausal women should gain access to ARTs reveals an important feature about what the PCWP demands and its widespread social impact. Because when the reproductive freedoms and broader implications of becoming an older parent are balanced against the welfare of a theoretical child, there emerges a form of social conscience to the PCWP.\textsuperscript{297} Those who object to the treatment of older women often rely on a welfare argument, suggesting that older women with deteriorating health and mobility who seek treatment are reproductively irresponsible – despite the high variables in age, mobility, parental ability and the social

\textsuperscript{291} Evans v Amicus Healthcare Ltd [2003] EWHC 2161 (Fam). It is worth noting that Wall J’s judgment was not the final court decision.
\textsuperscript{292} CoP 6\textsuperscript{th} edn (2003).
\textsuperscript{293} Evans v Amicus [2003], op. cit, at 293.
\textsuperscript{294} Ibid, at 37.
\textsuperscript{295} Dickson and Another v United Kingdom 920080 (2007) 46 EHRR 41; The Queen on the Application of Mellor v Secretary of State for the Home Department [2001] 3 WLR 533; See: Helen Codd. ‘Prisoners’ access to fertility services’ In Kirsty Horsey (eds) Revisiting the Regulation of Human Fertilisation and Embryology (Routledge 2015) at 50.
acceptance of grandparents raising children. It is also argued that child welfare would be diminished not only by parental limitations but also the likelihood of the child experiencing the death of her mother at a younger than average age. But the use of a welfare argument in this context gives little regard to the fact that older men retain biological ability to naturally reproduce and are less likely to be scrutinised for fathering a child at an older age than their female equivalents. In addition, a child conceived naturally by parents of any age could encounter limitations in their childhood owing to a multitude of external factors, such as parental death, illness or disability, or substandard parenting. The possibilities are infinite. Perhaps the irony lost in this aspect of the debate is that the menopause itself no longer signals the end of a woman’s ability to gestate, yet the welfare of a theoretical child can do.

The crucial point here is this, as the capabilities of human fertilisation and embryology developed the PCWP acquired a powerful, probative and confusing regulatory value. While on the one hand, the laws regulating ARTs are said to engage Article 8 rights to a private and family life, on the other hand, access to treatment is not available on request and can be denied on the basis of a failed PCWP assessment. From the outset the PCWP affected the determination of parentage and it remains the case that theoretical considerations can preclude an individuals’ ability to embark on their private reproductive path.

The original wording of the PCWP also attracted opposition. A body of legal literature examines the principle’s “unashamedly discriminatory” nature towards unmarried, single women and gay couples, due to the prerequisite need for a father. Following the relaxation of social attitudes towards ‘unconventional’ families, and given the advances in science and embryology, it was no surprise that in 2004 the UK government announced it would review the HFE Act 1990. By doing so it demonstrated it was responsive to the proposition that

299 NICE, op. cit Fertility, n.3 recommends women under 43 years of age should be offered treatment. Any decision regarding treatment funded by the NHS in England is made by Clinical Commissioning Groups.
300 Evans v Amicus, op. cit, n.293 at 71.
301 Ms Evans took her case to the ECtHR and lost in the European court of first instance and the Grand Chamber Evans v United Kingdom (Application No: 6339/05) [2006] 1 FCR 585 and [2009] 46 EHRR 34 refers.
302 Gurnham and Miola, op. cit, n.215 at 29; Jackson, op. cit Conception, n.4.
regulation was no longer “up-to-date in light of changing social and familial norms”\textsuperscript{305}. The PCWP was central to the debates on the parenting provision given the preoccupation with parental eligibility\textsuperscript{306}. Subsequently, two individual processes began to explore the function of the PCWP and debated child welfare issues during 2004 and 2005. First in June 2004, the House of Commons Science and Technology Select Committee (HCSTC)\textsuperscript{307} conducted a review of the 1990 Act, reporting in March 2005. This was followed by the HFEA consultation during the same period specifically on the PCWP, entitled ‘Tomorrow’s Children’, reporting January 2005.\textsuperscript{308}

4.3.2 HOUSE OF COMMONS SCIENCE AND TECHNOLOGY SELECT COMMITTEE INQUIRY INTO HUMAN REPRODUCTIVE TECHNOLOGIES AND THE LAW

A large proportion of the Committee’s criticism levied toward the HFE Act 1990 centred on the welfare of the child provisions and the then proposed abolition of donor anonymity, both of which later received the government’s continued support in terms of retention and abolition respectively. The basis of the Committee’s recommendation for the abolition of the PCWP in its then form was as follows:

The welfare of the child provision discriminates against the infertile and some sections of society, is impossible to implement and is of questionable practical value in protecting the interests of children born as a result of assisted reproduction. We recognise that there will be difficult cases but these should be resolved by recourse to local clinical ethics committees. The welfare of the child provision has enabled the HFEA and clinics to make judgements that are more properly made by patients in consultation with their doctor. It should be abolished in its current form. The minimum threshold principle should apply but should specify that this threshold should be the risk of unpreventable and significant harm. Doctors should minimise the risks to any child conceived from treatment within the constraints of available

\textsuperscript{305} McCandless and Sheldon, op. cit No Father Required, n.4.
\textsuperscript{307} HCSTC, op. cit, n.304.
\textsuperscript{308} HFEA, Tomorrow’s Children: A consultation on guidance to licensed fertility clinics on taking into account the welfare of children to be born of assisted conception treatment (2005).
knowledge but this should be encouraged through the promotion of good medical practice not legislation.309

This approach to reframing the PCWP reveals the same pragmatism and situated assessment adopted in the judicial approach to welfare appraisals in the previous discussion. The proposed ‘minimum threshold principle’ specifies the risk of unpreventable and significant harm, which if used would simultaneously empower the individuals receiving treatment and the healthcare practitioners treating them to engage in dialogue surrounding decision-making and relevant welfare concerns. In addition, by acknowledging a scenario could arise in which child welfare risks were present - in difficult cases - the Committee recommended the engagement of existing agencies to protect children from harm, akin to the duties enforced in existing child law.310 Stating “if there is reason to believe that children born as a result of assisted reproduction are at an increased risk then healthcare professionals can alert social services at an early stage”.311 While the Committee’s advocated solution to deregulating the PCWP was pragmatic and realistic, it was not adopted. The government responded to the recommendation by stating that: “[a]tempting to frame these matters in national legislation and guidance which pays due regard to both individual circumstances and the need for objectivity and fairness is extremely difficult”.312 Aside from the modest amendment to the parenthood terminology, there was no attempt to contextually reframe the PCWP, despite the countervailing public interest in transparent regulation of reproductive rights.

4.3.3 HFEA REVIEW: TOMORROW’S CHILDREN

In January 2005 the HFEA commenced a public consultation on the PCWP. Its sole focus was the PCWP, highlighting the inconsistency in which clinics approached the welfare assessment given the unsatisfactory state of regulation. The HFEA declared it was “not within the powers of the HFEA to amend the welfare section in the HFE Act”313 and carefully made clear that the consultation was not intended to solicit suggestions on how the legislation

309 HCSTC, op. cit, n.304 at 107.
310 LA’s have a duty to investigate if there is reasonable cause to suspect that a child is suffering, or is likely to suffer significant harm. Harm is defined as ill-treatment, including sexual abuse and non-physical forms of ill-treatment, or the impairment of health (physical or mental) or impairment of development, including physical, intellectual, emotional, social and behavioural. See the CA 1989 sections 17, 31(2) and 47; also see the Children Act 2004 section 11.
311 HCSTC, op. cit, n.304 at 103.
313 HFEA, op. cit, Tomorrow’s Children n.308 at 02, 1.1.
might be amended, but instead set out a range of different approaches to account for a future child’s welfare. First, the approach adopted could be ‘the maximum welfare principle’, specifically influenced by child law and adoption proceedings it places the child’s welfare as paramount and above all other concerns. This approach places significant responsibility on clinics to ensure any “child born has a good chance of a living a happy and fulfilled life and is not disadvantaged in any foreseeable way…places the burden of proof upon the prospective parents to demonstrate their competence”. Second, the ‘reasonable welfare approach’, noted to reflect a position of compromise between the welfare of a future child and prospective parents’ reproductive liberty. It states the provision of ARTs is acceptable when the child born will have a reasonably happy life. This option would require clinics providing treatment services to satisfy themselves that any child born would have “at least an adequate future, cared for by a ‘good enough’ family. The reasonable welfare principle takes a relatively thorough approach to the welfare of the child, whilst also attaching some importance to the autonomy of the prospective parents.” Or third, ‘the minimum threshold principle’ - which was chosen by the HCSTC in its review - placed greater importance upon parental autonomy and reproductive liberty rather than a future child’s welfare save for cases of “high risk of serious harm”. Its declared emphasis was to protect children from serious harm and suggested “[D]octors should withhold treatment, thereby preventing a child from coming into existence, only where the quality of the child’s life would fall below a minimum threshold of acceptability.” In addition, the document proposed the possibility of the organisation of welfare linked risk factors into three main groups: medical, physical, and psychological and social harm.

Despite what appears to be a genuine attempt, from a practical perspective, to offer some clarification on an ill-defined area of regulation, the consultation failed to deliver on how best to regulate the PCWP and question the underlying value of making this assessment in a pre-conception context. In practical terms, nothing was gained from the review that was not already known or suspected concerning the unsatisfactory regulatory framework at the clinical level. Even in respect of the ‘reasonable threshold’, representing the compromise

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314 Ibid.
315 Ibid, 07, at 2.4.
316 Ibid.
317 Ibid.
318 Ibid.
319 Ibid.
320 Ibid, 11, at 3.3.
position, it conceded the difficulty in determining “exactly what this approach might mean in practice”\(^{321}\). In addition, neither of the thresholds was ever implemented. What it did do successfully, however, is demonstrate that the HFEA were suggesting an air of regulatory discontent but that it would not get heavily embroiled in a contentious aspect of regulation. Whether its lack of philosophical direction “was actually ever part of its brief”\(^{322}\) is a valid point in the HFEA’s defence but, by not committing to any of the three approaches begs the question of how much influence the HFEA has on public policy, and the regulation and determination of the PCWP located at the core of framework. By adopting the non-committal approach the HFEA was certain to avoid any controversy that would have flowed should it have agreed with the HCSTC recommendation of abolition or recommend the lesser ‘reasonable welfare’ threshold. Instead, it focused on a risk based model of regulation, providing threshold criteria with a strong emphasis on medical conditions that might affect a child born and a narrow determination of welfare.

Moreover, the review is disappointing because of how conservative and superficial it was. It lacks a commitment to contextualise any socio-medical ethics underpinning the PCWP. It fails to address what the principle is regulating, and why it is necessary. It also fails to address why, and how, child welfare is theoretically assessed. By not committing to an approach the HFEA simply kept in tune with the UK government and Parliament and avoided clarifying what components support or negate the PCWP’s position in regulation. A question which could have been addressed was what, if any, practical value the PCWP holds. By failing to conduct a comprehensive review which offered critical conclusions or recommendations, it could be argued that perhaps the HFEA is ill-equipped to regulate such a thorny issue. This is troubling given that the PCWP is a central tenet to much debate on the provision of ARTs. If the HFEA deliberately adopted an avoidant approach in order to prevent legislative disharmony with Parliament then it has failed to conduct its principal responsibility as the sector’s regulator.\(^{323}\)

Following the review, the HFEA introduced key changes to the seventh edition of its CoP by removing some vague and subjective questions from the child welfare assessment of the

\(^{321}\) Ibid, 07, at 2.4.

\(^{322}\) Brazier, op. cit, Reproduction Business n.25 at 174.

\(^{323}\) Section 25 (1) of the HFE Act 1990 mandated that the HFEA “maintain a code of practice giving guidance about the proper conduct of activities carried on in pursuance of a licence under this Act and the proper discharge of the functions of the person responsible and other persons to whom the licence applies”.
medical and social history of prospective parents. The deletions from the sixth edition included the ability to provide a stable environment and provide for the needs of a child, the risk of harm to children including multiple births and asking the GP if s/he knows of any reason why patient(s) might not be suitable for treatment. The changes also removed obtaining the patients’ consent to make enquiries of their GPs and consent to approach “any individuals, agencies or authorities for such further information as the centre deems to be required”. The statutory responsibility for conducting the assessments remained with the clinics, although the multidisciplinary assessment noted in the sixth edition of the CoP as the expectation of centres to “take into account views from the staff who have had involvement with the prospective parents” was also removed. The HFEA claimed such changes would allow for an improved system while being keenly focused “on the risk factors that could lead to serious harm…whilst still protecting children’s interests”.

4.3.4 THE HFE ACT 2008 AMENDMENT

After four years of a reform process the HFE Act 2008 received royal assent. In part, its enactment introduced important changes in respect of same sex or single parent families’ ability to access ARTs. The amendment of the preferred family form was a welcome change and the capacity for reproductive choice was extended to accommodate the unconventional family. In effect, the PCWP side stepped the pro-family ideology advanced by the Warnock Committee and their Lordships that treatment services should be provided only “for the married, mortgaged and middle-classes”. In practical terms, the amendment to section 13(5) replaced ‘the need of that child for a father’ from the original wording for ‘including the need of that child for supportive parenting’. Subsequent to the amendment the HFEA

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325 Ibid, 3.12 (ii).
326 Ibid, 3.12 (iv).
327 Ibid, 3.12 (v).
328 Ibid, 3.20 (iiii).
329 Ibid, 3.10 (i)-(iv).
331 HFEA. ‘Improved welfare checks system will be better, fairer and clearer for fertility patients, GPs and clinics’ Press release (2 November 2005).
332 November 13 2008.
333 HFE Act 2008 Part 2; McCandless and Sheldon, op. cit No Father Required, n.4 and Tenacity n.306; Blyth, op. cit Conceptions, n.4 at 17-45.
335 The definition of supportive parenting is included in the 8th edition of the CoP at para 8.11. There is a prescribed presumption in law that supportive parenting will be provided by the prospective parent(s), unless there are justifiable grounds for suspecting the contrary.
revised its CoP in 2009 to include a definition of supportive parenting, thus extending the dynamics of regulated parenthood.

As regards the functional transparency of the PCWP no improvement is recognisable in the legislation. Given that eight hours (within a total of eighty) were spent in Parliament discussing the welfare of the child clause that is perhaps quite surprising.\textsuperscript{336} The HFE Act still does not contain a definition of preconception welfare and there are no legislative “intellectual milestones” on which to base an approach to a welfare appraisal. There is no statutory guidance similar to that attached to the paramountcy principle in child law despite its own contextual success in practice. This means, on a practical level, that the margins of interpretation of the PCWP are as wide as they are long. It indicates that regulatory flexibility is more important than conceptualising a central provision in the framework. This supports the view that the regulatory framework has two distinct roles, one in practice and one on paper. On paper, the PCWP takes centre stage in the statute and has a universal effect on the supply of ARTs in the UK. In practice, its engagement and application fundamentally affects who gains access to treatment and their permitted reproductive choices within that process. The responsibility of providing regulation falls to the HFEA, it regulates the PCWP according to its CoP and how this translates in practice at the clinic level will now be discussed.

4.3.5 THE HFEA APPROACH TO REGULATING THE PRE-CONCEPTION WELFARE PRINCIPLE

Since its inception in 1991 the HFEA has regulated fertility clinics providing licensed fertility treatment services.\textsuperscript{337} Within successive editions of its CoP the HFEA has regulated the PCWP according to the assessment it devises internally.\textsuperscript{338} In practical terms then, it offers the only available insight into the approach for determining pre-conception welfare. In the absence of the “factors to take into account during the assessment process”\textsuperscript{339} contained in the CoP, the interpretation of the statutory PCWP would have to be founded purely on individualistic application by clinicians? Among the eight available editions of the CoP, a concentration on and evolution of risk-based and harm-based regulation is also identifiable.


\textsuperscript{337} HFEA 1990 section 8 details the general functions of the HFEA.

\textsuperscript{338} Section 25, op. cit, n.323.

\textsuperscript{339} CoP 8\textsuperscript{th} edn (2009), 8.10.
In particular, the emphasis and use of a harm threshold in the assessment criteria has developed in the CoP regulating both the PCWP\textsuperscript{340} and the restrictions on embryo testing.\textsuperscript{341}

The CoP reinforces the statutory wording of the PCWP and states that no treatment services regulated by the HFEA may be provided unless account has been taken of the welfare of any child and any other child who may be affected by the birth.\textsuperscript{342} Centres should have documented procedures to “assess each patient and their partner (if they have one) to decide whether there is a risk of significant harm or neglect to any child”.\textsuperscript{343} The current guidance states centres should take a medical and social history from each patient and their partner (if applicable)\textsuperscript{344} with reference to the factors contained at 8.10 of the CoP:

These factors include any aspects of:

a) past or current circumstances that may lead to any child mentioned above experiencing serious physical or psychological harm or neglect, for example:

i) previous convictions relating to harming children

ii) child protection measures taken regarding existing children, or

iii) violence or serious discord in the family environment

b) past or current circumstances that are likely to lead to an inability to care throughout childhood for any child who may be born, or that are already seriously impairing the care of any existing child of the family, for example:

i) mental or physical conditions

ii) drug or alcohol abuse

iii) medical history, where the medical history indicates that any child who may be born is likely to suffer from a serious medical condition, or

iv) circumstances that the centre considers likely to cause serious harm to any child mentioned above.

\textsuperscript{340} The CoP 8\textsuperscript{th} edn (2009) has been revised in April 2010, April 2011, October 2011, April 2012, October 2013, October 2014, April 2015, October 2015, July 2016 and May 2017.

\textsuperscript{341} CoP 8\textsuperscript{th} edn (2009), 10.

\textsuperscript{342} Ibid, 8.2.

\textsuperscript{343} Ibid, 8.3.

\textsuperscript{344} Ibid, 8.9.
This broad harm-based framework separates risks to welfare into two categories: those related to familial harm between 8.10(a)(i) – (iii) and (b)(i)-(ii) and those related to medical or genetic harm between 8.10(b)(iii) – (iv). At first blush this approach provides two main benefits. First, that the framework is non-prescriptive given that it allows for wide margins of interpretation. Second, the PCWP is broadly permissive. But these are both false benefits. The presumption to treat individuals is rebuttable provided any of the criteria in the assessment is engaged. And in practical terms the regulatory model is ill-suited for resolving a theoretical concern over welfare given that the determination of the familial harm criteria is largely intuitive, individualistic and grounded in notions of bias. In addition, the assessment perpetuates a significant person-affecting role that clinic staff undertake when deciding who gains access to treatment.

Isabel Karpin has argued that a “regulatory system based on assessments of risk and benefit to future possible children at the preconception stage has the potential to lead to narrow and discriminatory assessments of health and create burdens on those who are least able to meet them”. Writing in 1998 Julie Tizzard observed the staff conducting the assessments are forced to make value judgements which are patently not just medical ones. Almost two decades later and the approach is unimproved. On the contrary, it denotes a new method of regulated paternalism in ARTs which derives solely from the statutory PCWP. Notably, the approach is inconsistent with the world of natural conception given that fertile individuals do not undergo a preconception assessment. Take for an example, a single woman who discovers she is pregnant after spending one night with a stranger and chooses to embrace motherhood alone. She is not subjected to external scrutiny regarding her capabilities in raising a child. Yet a single woman deliberately planning to become a parent via gamete donation is subjected to an examination of her suitability as a parent and even her “wider family and social networks” could be scrutinised. While the practical assessment displays
key influences from the paramountcy principle in the CA 1989 framework - which is responsive to risk and places the welfare of the born child before any other parties350 - the factors contained between 8.10 (a) (i) – (iii) and (b) (i)-(ii) are symbolically important. They erroneously validate an idealised family environment and represent the preconditions of the ‘ideal parents’ who evade the criteria set out by the HFEA.

Subjectivity - as opposed to objectivity - is a key feature of this potentially prejudicial assessment of individuals seeking treatment. This raises a legitimate concern of inconsistent application of the criteria if the staff conducting the assessment interprets the principle by apportioning different weight to the risk factors or grounding their assessment in intuition and value judgements. It is not a balanced or measured approach. It relies on the speculation of risk to theoretical children in the same terms that child protection laws measure and respond to actual risk to existing children. But it fails to explicitly distinguish the key difference between the preconceived and born child, and it fails to accord the weight to be attached to the risk factors. Regulating the PCWP in this way is disproportionately unbalanced against the individuals seeking access to treatment. Given that there is no empirical evidence available to suggest that individuals seeking access to ARTs present more of a risk to future children than those who conceive naturally, this aspect of the assessment inadvertently facilitates discrimination.

The disclosure or presence of mental or physical conditions,351 or drug or alcohol problems,352 is also problematic given the scope for bias. An individual’s honest disclosure of depression, perhaps previous post-natal depression, or a prior drug or alcohol addiction, can impact on her (and her partner’s) ability to access treatment services.353 But the risk factors simply serve to mandate a further assessment and prediction of parental competence. They are akin to the factors contained in the CA 1989 assessment which determine welfare by inspecting the environment a born child is living in and judging the capabilities of the people responsible for the child’s care in the future.354 The crucial difference between the two welfare appraisals is that the PCWP assessment takes place pre-conception, when the assessed harm does not require legal remedy because it has not occurred and is, at its highest,

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350 Children Act 1989 section 1 (3) (e) and (f).
351 The welfare assessment form notes this at 2.4. The form is accessible online via the HFEA at: http://www.hfea.gov.uk/docs/WelfareofthechildformV2.pdf. Accessed 14.05.15.
352 Ibid, 2.6.
353 CoP 8th (2009) 8.10 (b) (i) – (ii).
354 Children Act 1989 section 1 (3).
a speculative risk. In that sense, the law is anticipatory, in that it preemptively judges the risks to welfare. But in reality such prenatal risks exist in every case of natural conception. In the unfortunate circumstances when familial harm or the significant risk of harm to a child is identified, the law is reactionary. Consequently, it negates the need for a familial welfare assessment which does not meet the standards of objectivity required for better regulation.

Perhaps most striking, and what exemplifies the risk of discrimination, are the risk factors included between 8.10 a (i)-(iii) signifying future harm based on past events. This includes the disclosure of previous convictions which could significantly impact the welfare assessment. Public attitudes towards criminal offending is highly variable and public perceptions of crimes, sentencing and punitive sanctions can differ according to the facts of each case, the individuals involved, the media coverage and political regimes in power. In determining child welfare by reference to previous convictions the HFEA targets individuals seeking treatment. Because it ignores that a criminal antecedent history does not automatically negate an individual’s ability as a potential parent; this reveals the discriminatory undertone of the PCWP.

The question then arises as to what grounds patients are being refused access to treatment. How effective and forceful is the regulation of the PCWP in practice? A report entitled “Assessing Child Welfare under the Human Fertilisation and Embryology Act: The New Law” revealed that while the number of presenting risky parents remained low, clinic staff reported confusion in resolving difficult cases and expressed concerns regarding their role in the process of assessing the PCWP. The report contains examples of “hard cases”, for example, one clinic’s refusal to treat a couple as the male partner had a spent conviction for a violent crime (not committed against a child) recorded against him. The refusal was justified on the grounds that no formal psychiatric diagnosis had been established during the criminal proceedings. This then lead to the assumption that a child’s welfare could be

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355 CoP 8 (2009) 8.10 (a) (i). This is arguably analogous to a risk assessment conducted by the police in respect of detainees in custody. See: Police and Criminal Evidence Act 1984 and the accompanying Code of Practice at Part C.


358 Ibid, 5.

359 A spent conviction is a conviction which, under the terms of the Rehabilitation of Offenders Act 1974, does not need to be disclosed after a specified amount of time. The Act aims to rehabilitate offenders by not making their past mistakes affect their lives.
jeopardised given the male’s background. The gravity of that refusal cannot be underestimated. It shows the heavy hand of state intervention in real terms, resulting in the complete removal of the male’s reproductive freedom to genetically father a child with his partner. Consider for a moment the stark contrast to the Grand Chamber’s decision in *Dickson and Another v UK*, when the incarcerated male and his partner gained access to AI after successfully challenging a refusal based on their Article 8 right to private and family life. This hard case illustrates the harsh reality of the PCWP assessment. The law does not mandate that a defendant in criminal proceedings undergo a psychiatric assessment following a violent conviction. Moreover, the law would not prevent contact between a parent and a child if a father had previously been violent to the child’s mother. Thus, the refusal to treat the male in this example based on welfare grounds is misleading. In truth, the refusal was likely grounded on a discriminatory attitude towards ex-offenders and an inability to recognise a process of social rehabilitation. The example demonstrates an ingrained social bias surrounding criminal antecedence and an explicit failure in the current regulatory model to conduct familial welfare appraisals transparently and fairly.

The section of the welfare assessment contained in 8.10 (b) (iii)-(iv) denotes the genetic harm threshold within the PCWP. It connects the principle to the express provisions regulating PGD in the amended HFE Act. This includes activities that may be licensed under Schedule 2 Paragraph 1ZA of the HFE Act for “establishing whether the embryo has a gene, chromosome or mitochondrial abnormality that may affected its capacity to result in a live birth” and section 13 (9) which specifically states:

(9) Persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop—

(a) a serious physical or mental disability,

(b) a serious illness, or

(c) any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

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360 Lee and others, op. cit, *Full Report* n.357, 8.
361 *Dickson and Another v United Kingdom* (2007) 46 EHRR 41, 78.
This statutory provision - which validates the policy on embryo testing promulgated by the HFEA prior to the HFE Act 2008 - regulates the scope for reproductive choice by imposing restrictions on preference selection between embryos affected and unaffected by genetic conditions. This creates a nexus between the PCWP and section 13 (9). But the limited detail contained in the CoP welfare assessment at 8.10(b) (iii)-(iv) is as far as the genetic harm threshold is explored within the ambit of PCWP. Additional guidance is provided in the CoP specifically for embryo testing and sex selection which then links to broader welfare considerations connected to genetic health.\textsuperscript{362}

First, the guidance recites the statutory framework for embryo testing, interpreting the mandatory requirements as “a particular risk that the embryo to be tested may have a genetic, mitochondrial or chromosomal abnormality, and the Authority is satisfied that a person with the abnormality will have or develop a serious disability, illness or medical condition”.\textsuperscript{363} It specifies that PGD should be considered only where there is a significant risk of a serious genetic condition being present in an embryo.\textsuperscript{364} In addition, the seriousness should be discussed between the individuals and the recommended multidisciplinary team including “reproductive specialists, embryologists, clinical geneticists, genetic counsellors, cytogeneticists and molecular geneticists”.\textsuperscript{365} It continues at 10.9 stating:

The centre should consider the following factors when deciding if PGD is appropriate in particular cases:

(a) the views of the people seeking treatment in relation to the condition to be avoided, including their previous reproductive experience

(b) the likely degree of suffering associated with the condition;

(c) the availability of effective therapy, now and in the future;

(d) the speed of degeneration in progressive disorders;

(e) the extent of any intellectual impairment;

(f) the social support available; and

\textsuperscript{362} CoP 8\textsuperscript{th} (2009), 10 embryo testing.

\textsuperscript{363} Ibid. The guidance also elaborates on gender related serious disability which due to space is outside of the scope of this article.

\textsuperscript{364} Ibid, 10.6.

\textsuperscript{365} Ibid, 10.2.
(g) the family circumstances of the people seeking treatment.

This includes providing information for those seeking PGD on the condition being tested for, the likely impact of the condition on those affected and the family, information about treatment and social support and testimony of people living with the condition. On its face, the factors are broad welfare considerations. It is self-evident that the PCWP is utilised in the HFE Act and the CoP to justify using PGD and the restrictions on embryo selection because both are premised in genetic harm prevention. The regulatory message is clear: avoid genetic harm and you maximise child welfare. But the guidance is flawed. It does not provide a protocol for conducting a welfare assessment of genetic harm, because the HFEA has already determined the outcome according to its own harm threshold assessment. It does so via its centralised list of approved genetic conditions which have been deemed serious enough to warrant genetic testing. There are currently over three hundred and fifty genetic conditions contained on the HFEA authorised list. Further still, the restriction on embryo selection set out in section 13 (9) limits the scope for a contested welfare appraisal. Given that section 13(9) imposes a direct restriction on preferential embryo selection, the factors contained in the guidance have been included in disingenuous terms as, in reality, they would rarely would be considered. A reader of the guidance would be right to assume that these factors are routinely considered in each case. But in practice, these factors only serve to substantiate that assumption of a routine welfare assessment of genetic harm when, in truth, they are redundant and provide a false impression of a contextually-sensitive and objective assessment. Thus, the factors to consider in the CoP at 10.9 above have no practical impact as long as an unaffected genetically healthy embryo is available for selection. Reproductive choice is not a feature in this regulatory framework unless there are no un-affected embryos to select from. Likewise, the multi-disciplinary team noted at 10.6 will have little effect on the process of embryo selection given the statutory restriction on preference. Only when embryos affected by genetic conditions are available for selection and implantation does an assessment of welfare affected by genetic harm come into play. And even in those

366 Ibid, 10.16 (a).
367 Ibid, 10.16 (b).
368 Ibid, 10.16 (c).
369 Ibid, 10.16(d).
370 The HFEA publishes the centralised list of genetic conditions which clinics are authorised to test for. This is available at http://guide.hfea.gov.uk/pgd/ Accessed 19.06.17.
circumstances the unpleasant hierarchical regulatory method – which hinges on almost ranking the available embryos according to the genetic data retrieved - is far from contextually-sensitive.

When one reconsiders the judicial approach to analogous welfare appraisals discussed in the first part of this article – primarily the approach conducted by Thorpe LJ in Re A and his pragmatic balance sheet,\textsuperscript{372} as well as the intellectual milestones outlined in both Wyatt and An NHS Trust v MB (A Child),\textsuperscript{373} and the full exploration of alternative therapeutic treatment in the case of Great Ormond Street Hospital v Yates and Gard\textsuperscript{374} - the current regulatory provisions for PGD fall far below the benchmark standards of transparent, objective and just regulation. The ethico-legal dilemma of adjudicating between a harmed existence versus no existence highlights the significant departure in practice from the expected standards of transparent and fair regulation. It can be argued, therefore, that the PCWP has evolved into an exploitable regulatory device, it has manifested into a form of regulatory control over individuals receiving treatment which does not acknowledge the hallmarks of a democratic society. It is a regressive regulatory approach which is neither fair nor justified and hence, it should not be used.

**4.4 CONCLUSION**

Controversial as such a suggestion may sound; my argument is first that the PCWP does not meet the requisite standards expected of a contemporary model regulating ARTs in the UK. Standards of objectivity, transparency and contextual-sensitivity are prerequisites in the regulation of such a powerful statutory provision. Regrettably, Parliament foreclosed the possibility of the PCWP ever being regulated in a way that balances the competing interests of a future child and the individuals seeking treatment because of one clear failure. It never explored what the principle would demand in practice. Parliament’s avoidant approach resulted in a narrow understanding of the principle at the regulatory level and thus, a misunderstanding of how best to regulate it in practice. Thus, the target of my critique is not only the erroneous interpretation and application of the law, but also the law itself.

The judicially created, and child-focused, balance sheet approach to conducting child welfare appraisals for severely sick children was examined in Part I of this article. The extent of

\textsuperscript{372} Re A, op. cit, n.244.

\textsuperscript{373} Portsmouth v Wyatt, op. cit, n.249 and An NHS Trust v MB, op. cit, n.253.

\textsuperscript{374} Gard, op. cit, n.260, n.262, n.277 and n.280.
judicial energy spent determining the issue of welfare, and all that it entails, demonstrates how contentious and difficult conceptualising child welfare is in practice. Tracing the judicial development of the substantive idea of child welfare also emphasises the need for objectivity and a strong commitment to context within a welfare assessment. My examination of the judicial approach to welfare appraisals served as a meaningful comparator of these benchmark standards. By illustrating a consistency in judicial logic, combined with the reliance on judge-made intellectual milestones and the need for a contextual view of the evidence demanded by the balance sheet approach, this article argues that the judicial approach to welfare appraisals is an equitable method.

Part II of the article examined the development of the PCWP and highlights its departure in practice from the benchmark standards of judicial regulation. The tensions in the normative framework regulating the PCWP were explored via the familial and genetic harm thresholds. The engagement of the PCWP and the familial harm assessment enforces a pro-family ideology that perpetuates legislative supremacy over individuals who wish to become parents. In simple terms, it is an extended version of regulated parenthood. The harsh reality of this regulatory approach is the invisible psycho-social hurdle it imposes in front of individuals to overcome before they gain access to treatment. Far from an objective and contextual assessment, the engagement of the PCWP’s familial harm assessment necessitates that individuals persuade the powers that be, that in spite of this arbitrary criteria positing their perceived flaws, they deserve to receive treatment.

To highlight my concerns about the problematic application of the PCWP and its connection to genetic harm, this article focused on the guidance provided in the CoP on embryo testing and selection. The core concern is that there is no scope for a pragmatic exploration of medical evidence, equivalent to that conducted in judicial law-making, which would allow for a reasoned welfare assessment prior to embryo selection. Individuals undergoing PGD are not awarded with the power of decision-making according to the current criteria. Given the departure from the same benchmark standards in the judicial approach, the overall view of this framework is quite troubling. An analysis of the regulatory framework governing the PCWP, genetic harm threshold and PGD presents quite a different picture. In complex cases involving the detection of serious genetic harm, a transparent, contextual and reciprocal doctor-patient appraisal of pre-selection welfare could be a valid regulatory replacement. This model would balance the reproductive choices of individuals, whilst relying on expert
medical advice and an ethical judgement from the healthcare professionals to refuse to grant treatment in exceptional cases.\textsuperscript{375}

Overall, this analysis demands an important check on the power of the over-zealous state and calls for abolition of the current PCWP. It is essential that the law adopts a more objective and contextual approach to assessing theoretical harms to future children who may be born as a result of ARTs. Much more needs to be done by Parliament and the HFEA to justify the restrictions and impositions on reproductive choice, and there is much to be learned from the way that judges approach questions concerning child welfare.

\textsuperscript{375} The HFE Act includes a conscientious objection at section 38 which states no person who has a conscientious objection to participating in any activity governed by this Act shall be under any duty, however arising, to do so.
PAPER 2

APPLYING THE PRE-CONCEPTION WELFARE PRINCIPLE AND THE HARM THRESHOLD: DOING MORE HARM THAN GOOD?


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5.0 ABSTRACT

This article critically examines the application of the PCWP and the harm threshold engaged in the regulation of IVF and PGD. It separates the harm threshold into two distinct categories of harm-based regulation: familial harm and genetic harm. This article opposes the intuitive aspect upon which the familial harm threshold hinges, and it is argued that the familial aspect of the PCWP assessment should be abolished. It is suggested that the current laws protecting the welfare of existing children are sufficiently response to the welfare risk factors included in regulation. The express provisions regulating PGD are also examined and the engagement of the genetic harm threshold is explored. It is argued that the genetic harm threshold is inconsistently applied and engages unfairly in practice. Given the lack of transparency revealed in the current framework and the draconian engagement of both harm thresholds in practice, this article achieves its overarching purpose of challenging the legitimacy of the PCWP.

5.1 INTRODUCTION

In the UK, access to licensed ARTs is not automatically available on request, but rather depends on the provisions of the overarching statute, the HFE Act, the supporting CoP and the oversight provided by the regulator, the HFEA. Prospective parents require approval from a clinic providing licensed ARTs prior to any treatment being offered and central to that process is a pre-conception consideration of child welfare, as contained in section 13(5) of the HFE Act. This article critically examines the connection between the PCWP and the harm threshold currently applied in the regulation of IVF and PGD. The harm threshold operates under the ambit of the PCWP - the legislative development of which is briefly introduced within [5.2] but in practice and for the purposes of this article the harm threshold contained in the PCWP is separated into two distinct categories of harm based regulation: familial harm and genetic harm. Both categories apply to a theoretical child and, through distinct regulatory provisions outlined in [5.4] and [5.5], purport to identify and assess possible harm with the objective of preventing it and maximising a future child’s welfare. There are a number of concerns about the current framework, including a poorly formed principle in the HFE Act and the CoP, the problematic application of the two harm thresholds in practice, and

376 CoP 8th edn (2009).
377 Section 25, op. cit, n.323. As the regulatory body the HFEA is entrusted to regulate the ethical and practical problems of assisted human reproduction, section 5-10 of the HFE Act refers.
an overall ignorance of the impact the PCWP and the harm thresholds have on prospective parent’s lives. It will be argued that not only is the application of the harm threshold impractical, illogical, inconsistent and unfair, but its nexus to the PCWP demonstrates that the legitimacy of the principle is misconceived in regulation.

This article questions the PCWP’s function as an assessment of harm associated to a theoretical child to be born. It does not seek to re-frame the provisions that are critically analysed. Section [5.4] offers a critique of the familial harm threshold contained in the CoP. It is argued that the familial category of the PCWP’s harm threshold is in fact an assessment demanding clinical speculation on a prospective family dynamic, in addition to an assessment of parental adequacy broadly based on intuition. This article opposes the intuitive aspect upon which the familial harm threshold hinges, arguing that the laws governing the protection of existing children are already sufficiently reactive to the identified welfare risk factors stated in the pre-conception familial harm assessment. Thus the prejudicial familial harm threshold should be abolished.

In [5.5] onwards, the genetic harm threshold is explored in the context of PGD regulation. PGD is the primary technology used to enable parents to have a child without a particular genetic condition thus avoiding “serious medical harm” noted in both the statute and the CoP. Currently PGD can be used to test for 390 widely variable genetic conditions included on the HFEA central list, ranging from life threatening conditions, to chronically debilitating conditions, to late onset conditions and some even indicating an increased susceptibility to cancer. Therefore, understanding the basis on which the genetic harm threshold engages in this context is crucial; especially for prospective parents accessing fertility treatment services given the potential effect it has on their reproductive path. This article examines the initial engagement of the genetic harm threshold criteria and challenges the centralised approach to regulating PGD. The application of the genetic harm threshold will be explored, including permitted and prohibited uses of PGD that are provided for

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378 It is a criminal offence to perform PGD other than in accordance with the terms of a licence, without a licence, or to sex select an embryo for non-medical reasons. Selecting an embryo on the basis of its sex for non-medical grounds is now punishable by 2 years imprisonment, a fine and/or both. See: section 3 (1) – (1A), 11, 41 (2) and Schedule 2, para IZA-B.
379 HFEA, op. cit PGD conditions, n.370.
380 PGD can also be used to sex select between embryos to avoid certain genetic conditions which are sex linked. In addition, it can be used for human leucocyte antigen (HLA) tissue typing in order to identify an embryo that would be an exact tissue match for an existing sick sibling in need of stem cell donation. This article will not examine these two uses of PGD in any depth.
within the strict legislative provisions and the CoP. This article will show that the genetic harm threshold is manipulated in regulation to justify the permitted and prohibited uses of PGD, as well as justifying the restrictions on permitted uses. Moreover, when the genetic harm threshold is broken down, its engagement is also shown to be inconsistent and unfairly applied. This article argues that this model of regulation is draconian and lacks transparency. The retention of the current genetic harm threshold is thus opposed and it is suggested here that the multifaceted way in which the harm threshold is applied in regulation, in both the familial and genetic context, renders the retention of the PCWP as indefensible.

5.2 A VERY BRIEF BACKGROUND OF THE PRE-CONCEPTION WELFARE PRINCIPLE

Section 13 of the HFE Act 1990 stipulated the ‘Conditions of Licences for Treatment’, containing the considerations that clinics must adhere to prior to providing treatment to people who could not conceive naturally. In particular, sub-section 5 detailed the PCWP; commonly considered as the most controversial inclusion owing to its “inherently (and unashamedly) discriminatory nature” towards unmarried couples, single parents and same sex families. When the HFE Act 2008 came into force on 1 October 2009, a modest amendment to the original wording of the PCWP was enacted, eradicating the need for a father and thus liberalising those constraints on parenthood. Now, in its full form, the amended PCWP reads:

A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.

By deliberately excluding any definition of the PCWP, Parliament simultaneously achieved flexibility in regulation whilst ensuring that child welfare considerations were promoted. It also avoided the complexities of trying to establish a consensus on what the PCWP actually meant in practice. The consequence of such a strategic approach was twofold. First, any

381 Schedule 2 3 1ZA.
383 McCandless, op. cit Cinderella, n.336; McCandless and Sheldon, op. cit Tenacity n.306 and No Father Required, n.4.
384 Section 13 (5) HFE Act.
moral connotations attached to the PCWP were left to individual supposition, and second, it generated an understanding that the principle had a moral value ascribed to it. Almost two decades later when the 2008 reforms were debated in Parliament, the basic constitution of the PCWP was similarly never critically explored. The consequence of Parliament avoiding those two opportunities to clarify the constitution of the statutory PCWP, it is argued, is displayed in the development of the principle in regulation. For reasons that will now be revealed, the regulatory approach to the PCWP is problematic.

5.3 CODIFYING THE PRE-CONCEPTION WELFARE PRINCIPLE

By virtue of its CoP, the HFEA provides what could be described as the only insight into a code of ethics in the regulation of ARTs in the UK. It is written and maintained by the HFEA, setting out the rules and criterion for PBR, which includes, but is by no means limited to, the regulation of the welfare of the child. There is a presumption to provide treatment to those who request it, “unless there is evidence that the child to be born would face a risk of serious medical, physical or psychological harm”. Clinics are bound by the CoP and clinic staff must use the criteria set out within it when deciding whether or not the potential risks to welfare are eliminated. The specific PCWP is noted as the fourth regulatory principle in the CoP, and its basic content resembles that of the statutory provision.

A mere three and a half pages of material are dedicated to the welfare of the child within the entire 308 page document. In that sense, the content is relatively brief and non-prescriptive on the underpinnings of the principle. Although the material is also lacking an explicit definition of the PCWP, its constitution is implied via the child welfare assessment material

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385 Evans v Amicus Healthcare Ltd [2003] EWHC 2161 (Fam) at 23, the child welfare principle was noted as one of the most important principle’s underlying legislation of ARTs (Wall J).
387 PBR is a model of regulation based on a set of broad principles governing the norms and ideals of regulation in the particular regulatory framework. See: Julia Black, op. cit, Rise and Fall n.148 at 1-25.
388 See, CoP 8th edn (2009) (version 7.0) ‘User Guide to the Code’. The PCWP is said to be linked to regulatory principles 1, 6, 7 and 10 in the CoP which focus on how to treat patients, gaining consents, clinical conduct and record keeping. The CoP states that the principles inform every part of the Code and that they should be read in conjunction with the guidance notes, also supplied by the HFEA.
389 Principle 4 states “take account of the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth”.
390 CoP 8th edn (2009) at 8.0. The CoP is a large and comprehensive document which regulates all aspects of ARTs. (The content referred to was accurate at the time of writing and submission to the peer reviewed journal. The CoP was updated in May 2017 and now spans over four pages of material).
included within section 8.0. The factors a clinic must take into account when conducting a welfare assessment are as follows:392

a) past or current circumstances that may lead to any child mentioned above experiencing serious physical or psychological harm or neglect, for example:
   i) previous convictions relating to harming children
   ii) child protection measures taken regarding existing children, or
   iii) violence or serious discord in the family environment

b) past or current circumstances that are likely to lead to an inability to care throughout childhood for any child who may be born, or that are already seriously impairing the care of any existing child of the family, for example:
   i) mental or physical conditions
   ii) drug or alcohol abuse
   iii) medical history, where the medical history indicates that any child who may be born is likely to suffer from a serious medical condition, or
   iv) circumstances that the centre considers likely to cause serious harm to any child mentioned above.

It is evident from the criteria that the application of the PCWP pivots between two distinct categories of harm assessment; those being, familial harm considerations, noted between (a) (i-iii) and (b) (i-ii), which relate to the environment into which a child would be born. Which then compare to the welfare factors related to the health of a child between (b) (iii-iv), providing a threshold of harm when a risk of serious harm from a serious medical condition is present or any other circumstances. Both avenues of the welfare assessment incorporates its own distinct threshold of harm, but importantly both thresholds are devolved to the doctors’ clinical discretion via the assessment.393

392 Ibid, at 8.10: “The centre should consider factors that are likely to cause a risk of significant harm or neglect to any child who may be born or to any existing child of the family. These factors include any aspects of the patient’s or (if they have one) their partner’s”.
393 HFEA, op. cit patient history form, n.351.
The patient history assessment is by no means difficult to navigate or complex in nature. In order to gain familial information the first section of the form is completed by the prospective parents and submitted to the clinic. The process then demands a familial harm assessment conducted by clinic staff who are guided by the questions speculating on both direct and peripheral harms within a future family environment. Every child welfare assessment necessitates an interview between clinic staff and prospective parents before treatment can be offered. It requires an exercise of subjective judgement by the staff conducting it - as opposed to more objective or evidence based reasoning that is used to judge the severity of genetic conditions in the genetic harm threshold discussed below - to determine a risk level of familial harms according to the HFEA set criteria. The specific welfare considerations based on historic events within 8.10 (a) and (b) are particularly problematic, as they mandate an assessment of not only the category of risk, but also the task of judging the seriousness of any prior risk which may allude to the possibility of a future risk. The difficulty with this is that such welfare factors are widely variable and based on unpredictable human behavioural patterns, thus creating more doubt as to the predictive accuracy of the assessment criteria. In addition, assessing the stated welfare factors is likely to be largely outside of the range of expertise of the clinic staff conducting the assessment, as they plainly involve other sociological and criminological disciplines if strictly assessed. Given that the assessment necessitates intuitively balancing historic events against current family dynamics, which are then set against projected future family environments, it quickly becomes a convoluted and illogical process. Moreover, despite a clinic being able to confirm that a PCWP assessment has been conducted by clinic staff, it cannot be said that every assessment of familial harm is properly judged or conducted fairly.

In contrast, the criteria in (b) (iii-iv) link to the medical history and provide the genetic harm threshold. Given that clinics are reliant on HFEA approval regarding the mandatory level of seriousness for each genetic condition in order to meet the assessment criteria specific to PGD, the preliminary assessment of genetic harm is more objective than the familial harm threshold. Thereafter, the genetic harm threshold connects the application of the PCWP assessment to separate guidance on embryo testing within the CoP. Notwithstanding a failure by the HFEA to explicitly reference the connection between the PCWP assessment and the guidance on embryo testing, identifying the link between them is simple. Both

394HFE Act 2008 Schedule 2 IZA (1) and (2).
aspects of regulation utilise a harm threshold contained in the CoP at 8.10 to justify the imposition of permissive or prohibitive regulation. PGD is used to detect embryos affected by genetic conditions or abnormalities. It allows parents the option of avoiding implanting affected embryos. In a simplistic sense, given that deselection of affected embryos circumvents serious medical or genetic harm (in that the birth of a child affected by a genetic condition is avoided) the genetic harm threshold central to the regulation of PGD appears grounded in the principle of non-maleficence. The message this generates is that by deselection of affected embryos affected by serious genetic conditions a future child’s welfare is maximised by regulation, as opposed to a diminished welfare if a child was born with a serious genetic condition. If this rationale is accepted, it justifies - in theory -the imposition of points 8.10 (b) (iii) and (iv) in the PCWP criteria assessing medical harm. Once that genetic harm threshold engages, the additional embryo testing provisions contained in the CoP apply. Upon reading those additional provisions, which are detailed and critiqued in [5.5] to [5.5.2], it is evident that a combination of objective and subjective reasoning is required when determining the acceptable parameters in which PGD is authorised. Sarah Elliston rightly observes the issue at this stage:

The idea that the state would involve itself through legal regulation about the genetic makeup of children and intrude on reproductive choices of potential parents in this way raises troubling questions, despite the apparently beneficent motive of preventing children being born with potentially devastating genetic conditions.

Although the familial and genetic harm threshold operate under the one PCWP, the two harm thresholds have distinct roles and engage at different times in the process of seeking access to IVF and PGD. The familial harm threshold is considered in every case before any treatment can be offered to prospective parents, whereas the full extent of the genetic harm threshold engages separately when PGD is sought, though it is possible that both thresholds could be

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396 There is a vast literature exploring the notion of harm connected to the use of ARTs, a full discussion of which is outside of the scope of this article. This article is not intended to provide a philosophical analysis of harm but rather a critique of how harm is framed by the thresholds mandated by the PCWP. See: Julian Savulescu. ‘Deaf lesbians, “designer disability” and the future of medicine’ (2002) British Medical Journal 325, 771.-773; Rosalind McDougall. ‘Parental Virtue: A new way of thinking about the morality of reproductive actions’ (2007) Bioethics 21, 181–190; John Harris. ‘Is there a coherent social concept of disability?’ (2000) Journal of Medical Ethics 26, 95-100; John A. Robertson. ‘Procreative Liberty and the control of conception, pregnancy and childbirth’ (1983) Virginia Law Review 69, 405-465; Guido Pennings, Rik Schots and I. Liebars, ‘Ethical considerations on pre-implantation genetic diagnosis for HLA typing to match a future child as a donor of haematopoietic stem cells to a sibling’ (2005) Human Reproduction 17, 534-538.  
397 Elliston, op. cit Selecting for Disability, n.4 at 90.
considered together in the preliminary stages of seeking treatment. In sections III and IV the two categories of the harm threshold will be consecutively explored. This will provide clarity as to how the two harm thresholds engage and how they are practically applied in regulation. The criticisms of each harm threshold will then be easier to identify in terms of inconsistency, illogicality and unfairness.

5.4 APPLYING THE FAMILIAL HARM THRESHOLD

The majority of the familial harm threshold factors contained in the CoP assessment criteria connects it to the statutory demand of supportive parenting.398 Strictly speaking this entails a prolonged prediction of the family dynamic up to an eighteen year period until that child attains adulthood.399 In the main, the factors listed between 8.10 (a) and (b) assessing both past and current circumstances, are broadly familial aspects of welfare determined by the social environment a child is born into. But by virtue of being included within the child welfare assessment by the HFEA the individual factors can be interpreted as those which are deemed to denote a preferred level of parental adequacy, thus indicative of a preferred family environment in tune with the HFEA structure of supportive parenting. In this context, the concept of regulation imposes a state of influence on what are considered appropriate and inappropriate behaviours of prospective parents. It also implies that the familial harm considerations are the correct considerations to undertake in all pre-conception cases assessing child welfare. Take, for example, the assumption at 8.10 (a) that a lack of previous convictions indicates no risk or a minimised risk of harm to a future child. If accepted, it follows that child welfare would be increased via parental adequacy if parents are of good character. Yet there is nothing to support such an assertion, or anything to suggest that the absence of previous convictions denotes a lack of identified risk to child welfare, those explicitly being a “commitment to the health, well-being and development of the child”400. While initially an assessment of family specific welfare risks may seem intuitively appealing and represent a justified intrusion into prospective parent’s procreative liberty - on the basis that it prevents high risk parents bringing a child into existence in a harmful environment - the familial harm threshold demands a speculative use of potentially discriminatory intuitions. In the recent study conducted by Lee et al it was shown that although the refusals to offer treatment based on child welfare grounds are low, concerns regarding familial harm

398 HFE Act section 13 (5) and the CoP 8th edn (2009) at 8.11.
399 UNCRC, op. cit, n.52. It defines adulthood as 18 years of age (Ratified 12/16/1991).
400 CoP 8th edn (2009) 8.11.
were still raised by some clinics. Ten out of the twenty clinics interviewed indicated welfare concerns in cases where violence had previously been an issue, and eleven clinics raised concerns over criminal convictions. One “hard case” details a young male – and thus his partner - being refused treatment on welfare grounds due to one previous conviction for violence recorded against him demonstrate the scope for bias. Albeit not committed in a domestic setting or upon a child the existence of a violent conviction was relied upon to deny access to treatment on child welfare grounds. Thus the scope and strength of intuition exercised at the clinical level is equally broad and strong, especially given that no additional guidance is provided and the option of adopting a multi-agency approach to adjudicate hard cases is not included in the CoP.

5.4.1 INCONSISTENCY

The familial harm threshold and the demand for supportive parenting can be criticised further in terms of inconsistency. Emily Jackson, a staunch opponent of the PCWP, has previously observed that no such assessment of parental adequacy is conducted for people fortunate enough to conceive naturally, or for couples seeking assistance to conceive via unlicensed medical intervention (such as receiving prescription medication to improve ovulation). Prospective parents travelling abroad for treatment also fall outside of this regulatory framework, in the same way as those who facilitate their own private ‘do-it-yourself’ arrangements for sperm donation and artificial insemination. Though there might be a prescribed presumption in favour of supportive parenting and a presumption to treat, the very essence of the welfare assessment of familial harm subjects those seeking access to ARTs to a level of external scrutiny, which is unparalleled in any other area of healthcare regulation. Even parents who have had a child or multiple children permanently removed

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402 Ibid, Table 2 at 5.
403 Ibid, 8.
from their care due to inadequate parenting or wilful neglect - which would engage 8.10 (a) (i-iii) - are not prevented from conceiving a further child.407

The second difficulty which manifests from a discussion on inconsistency is whether individuals have a right to reproduce and the notion of positive and negative rights.408 The European Court of Human Rights acknowledged in Dickson v United Kingdom409 that Article 8 rights to private life were engaged in laws regulating ARTs. Wall J noted in Evans v United Kingdom410 that the right to found a family “through IVF can only, put at its highest, amount to a right to have IVF treatment,”411 but that this did not extend to a right to be treated with success. Those patients who seek access to treatment require the positive right to be treated in order to fulfil their reproductive choices, contrasted with individuals who conceive naturally and enjoy the negative right of non-interference with bodily integrity. These two categories of rights play a central role in reproductive ethics and, it is argued, respect for the different interpretations of moral rights-based arguments is lost in the current regulatory framework. Consequently, a troubling conflict arises in respect of the PCWP assessment of familial harm and the rights of individuals to gain access to fertility treatment services.

5.4.2 UNFAIR AND UNNECESSARY

A further point here is this; an assessment of familial harm in order to determine a future child’s lifetime aggregate welfare is unfairly speculative. It is reliant on a broad exercise of clinical discretion assessing the current suitability of prospective parents. Previously it has been described as a crude system of prospective parental filtering which is “in simple and crude terms, none of the law’s business”,412 and on reflection has little to do with child welfare but more to do with who are ideal candidates for receiving treatment. In order to function it also unfairly burdens clinic staff conducting the assessment calling on their own moral value judgements. In this context the PCWP represents an indeterminate assessment of potential harm to a child who might exist in the future.

407 Children Act 1989 section 20 provides provisions for the accommodation of children, subsection (4) states a local authority may provide accommodation for any child within their area (even though a person who has parental responsibility for him is able to provide him with accommodation) if they consider that to do so would safeguard or promote the child’s welfare (the paramount consideration in accordance with section 1 Children Act 1989).
409 Dickson v United Kingdom (2007), op. cit, n.361 at 71.
410 Evans v Amicus [2003] EWHC 2161 (Fam), op. cit, n293.
411 Ibid, at 263.
412 Jackson, op. cit Conception, n.4 at 203.
To reinforce this argument, NHS funding eligibility for ARTs has been reported to have a negative effect on the process of assessing the potential nature and presence of familial harm within a family. In particular, “consideration of funding eligibility reintroduces some elements of scrutiny that are no longer carried out in the name of child welfare” but are still intrinsically linked to PCWP considerations surrounding who is a deserving parent when funding is scarce. It has been documented that a patient’s honest disclosure of smoking, or a mere clinical suspicion of smoking, was sufficient information to preclude even a full child welfare assessment being conducted, thus barring the option of NHS funded treatment to prospective parents who honestly disclosed information during a preliminary assessment.

The issue of resource allocation then emerges, a full discussion of which is outside of the scope of this article. But, for the purposes of examining the legitimacy of the PCWP being used in decisions about who gains access to treatment, it is argued that the principle is being utilised in practice beyond the scope for which it was intended. Regardless of any call to the moral responsibility of a reasonable mother-to-be to give up smoking during her pregnancy, it remains her autonomous decision to legally smoke. When we consider that a woman, as an autonomous human being, is exempt from any liability to her child in respect of damage caused before birth from smoking, drinking or otherwise, a refusal to offer treatment on smoking grounds signifies a troubling way in which the familial harm threshold could be unfairly manipulated in practice. Equally, a pregnant woman who chooses to smoke excessively, or is addicted to heroin, or drinks to such excess during the pregnancy that the child is born with fetal alcohol syndrome cannot be sued by the child after birth. A mother is immune from such claims under the Congenital Disabilities (Civil Liability) 1976 Act, and no criminal offence is recognised for a child harmed in utero given that the foetus is not recognised as a person in law. It is argued then, that by virtue of the familial harm threshold, the law imposes an unfair and inequitably higher standard of parental adequacy on prospective parents seeking fertility treatment services than individuals who naturally

413 Sheldon and others, op. cit Supportive Parenting, Responsibility and Regulation, n.4 at 478.
414 Ibid, 479.
415 Lee and others, op. cit Full Report, n.357 at 10; Also note in the Full Report at 73 the necessity of honest disclosure from patients during the familial harm assessment.
416 Jackson, op. cit conception, n.4, between 182 -189.
417 The Congenital Disabilities (Civil Liability) Act 1976 provides a code of liability for disabled children. Section 2 states a mother is only liable for injuries caused through negligent driving of a vehicle on a road.
conceive. An expectant mother is able to smoke twenty cigarettes a day, while a woman seeking access to IVF could be criticised on PCWP grounds for simply being espoused to a smoking man.\footnote{Julian Laubenthal and others. ‘Cigarette smoke-induced transgenerational alterations in genome stability in cord blood of human F1 offspring’ (2012) Journal of the Federation of American Studies of Experimental Biology 26, 3946-3956.} In effect, it demands that at all times a woman should morally behave as if she were already pregnant in order to prevent the engagement of the familial harm threshold.\footnote{Sheila A.M. McLean. Old Law, New Medicine (Pandora Press 1999) 66.}

When we consider the multi-agency streamlined approach taken in child law for assessing an existing child’s welfare, governed by the Children Act 1989 or the Adoption and Children Act 2002 for example,\footnote{HM Government ‘Working Together to Safeguard Children: A guide to inter-agency working to safeguard and promote the welfare of children’ (March 2015). Available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/419595/Working_Together_to_Safeguard_Children.pdf Accessed 25.08.16.} the contrast to the subjective approach in pre-conception cases assessing familial harms could hardly be starker. When applying the child welfare principle in regulatory frameworks relating to existing children, the process demands a unique evaluation of each particular case. Each assessment of an existing child’s welfare is then determined by an individualistic view of parental responsibility, combined with an idealistic view of a preferred family dynamic and home environment in which to raise that child in.

In the context of gaining access to IVF, the familial harm assessment is not based on any reliable or well-reasoned assessment tool.\footnote{This argument can be further explored in the context of families who seek to conceive a matching sibling donor for an existing sick sibling. The argument that the harm principle is the underlying feature in legislation in western society is thoroughly explored by Malcom Smith. Saviour Siblings and the Regulation of Assisted Reproductive Technology: Harm, Ethics and Law (London: Routledge 2015).} In acknowledging the complexity of the PCWP demand for supportive parenting, Sheldon et al articulated:

...it is important to remember that regulation does not operate in a vacuum. Professional practice is rather determined by a broad range of influences including the ‘residue’ of earlier legal provisions, institutional pressures, professional cultures, the individual’s own moral views and emotional reactions, and economic constraints.\footnote{Sheldon and others, op. cit Supportive Parenting, Responsibility and Regulation, n.4 at 462.}

Noting these competing values strengthens further the argument against the application of the familial harm threshold. Given that in reality there is no objective criterion for assessing an
ideal parent or an ideal family, it begs the question of why prospective parents seeking assistance to conceive are forced to endure such external scrutiny.

A further crucial point is that any harm caused to an existing child after birth is adequately redressed by both criminal and family law.424 Of particular relevance, the Children and Young Persons Act 1933 states that if any person who has attained the age of 16 and is responsible for a child or person under that age:

…wilfully assaults, ill-treats, neglects, abandons, or exposes him, or causes or procures him to be assaulted, ill-treated, neglected, abandoned, or exposed, in a manner likely to cause him unnecessary suffering or injury to health (including whether the suffering or injury is of a physical or a psychological nature) he is guilty of an offence425.

The recent enactment of what has become known as the ‘Cinderella Law’426 extends the criminalisation of causing harm to a child to include suffering or injury, which is physical or psychological.427 This is in addition to the powers of the Court to remove a child from a harmful family environment,428 and in addition to the requirements imposed by the Sexual Offences Act 2003429 protecting the general public or any particular member of the public from serious sexual harm by a person who has been convicted of a sexual offence.430 Given that the law is sufficiently responsive to the familial harm threshold criteria in the event of criminality, and that it provides sufficient safeguards for an existing child’s welfare as the paramount consideration,431 it can be argued that those avenues of legal redress adequately rebut the need to retain the familial harm threshold as contained in the PCWP assessment. After all, if the law is sufficiently responsive it ought not to be prejudicially pre-emptive.

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424 HCSTC, op. cit, n.304, recommendation 103.
425 Children and Young Persons Act 1933 section 1.
427 Serious Crime Act 2015 section 66 (1)- (3) amends the Children And Young Persons Act 1933 to reflect child cruelty cases by causing psychological harm to a child under 16 years of age.
428 Children Act 1989 section 20.
429 The Sexual Offences Act 2003 Part 2 replaced the Sex Offenders Act 1997 with the Sex Offender Register (section 80) and Sexual Offences Prevention Order (section 104).
430 Including but not limited to sexual offences involving children. Refer to Schedule 3 Sexual Offences for the purposes of Part 2 of the Sexual Offences Act 2003.
431 Children Act 1989 section 1.
5.4.3 ILLOGICAL

Another very significant point has also been consistently missed here, which offers a brief introduction of the role of philosophical thinking in the regulation of the familial harm threshold. Even though the application of the familial harm assessment is largely intuitive and necessitates discretionary decision making, it demands the impossible. The comparative task underlying a moral assessment of welfare implies that a child’s welfare is maximised if it is born in ideal circumstances. It has previously been advocated by Emily Jackson that this aspect of regulation suggests that if a child is not born in the ideal sense, then it might be better for it to not to been born at all. But strictly speaking, that is an impossible comparison to undertake, for the same child could not be born in alternative settings, to alternative parents and at an alternative time. Very basic human biology supports this philosophical argument, as only one child could be born from the gametes that she originated from, at the time she was born and in the family that she was born into. This serves to strengthen a rejection of the familial harm threshold, on the basis that an assessment of projected aggregate welfare is both practically impossible and a philosophically illogical task. It crucially lacks an appreciation of a very complex philosophical aspect of pre-conception harm and what is familiarly known as Parfit’s time dependency claim. This argument asserts if any person had not been conceived at that exact time, then she never would have existed. The argument assumes that each gamete entails a different person, and “if any particular person had not been conceived when he was in fact conceived, it is in fact true that he would never have existed”. Stephen Wilkinson then rightly claimed a “different gamete entails ‘different person’”. It follows, therefore, that theoretical child welfare cannot be assessed. Although it is theoretically possible to discuss different children who may exist in the future, it is nothing higher than theoretical possibility. To then attempt to predict a future child’s welfare is illogical when an individual person’s existence is so largely variable in itself. The illogicality goes further when we consider the impossible task of guessing how sensitive a future child might be to potential welfare affecting factors. While this identified philosophical confusion does not preclude conducting comparative assessments of the quality

432 Jackson, op. cit Conception, n.4 at 203.
433 Parfit, Reasons op. cit, n.190; Gavaghan, op. cit Regulating after Parfit: Welfare, n.190 at 147-164.
434 Ibid, Reasons and Persons at 351.
of life that born children enjoy – especially given that the application of a welfare assessment for an existing child is comparatively more contextual in child law\textsuperscript{436} - in a pre-conception context the lack of logic supports the argument against the familial harm threshold.\textsuperscript{437}

But the criticism here of the HFEA is not in failing to consider philosophical concepts of harm, but rather its reluctance to recognise that the comparative task of assessing the familial welfare of existing children is distinct from its own \textit{pre-conception} harm assessment model. In the latter, clinics are tasked to conduct nothing more than a subjective guess. In addition, the HFEA has failed to recognise that, by virtue of these regulatory provisions, the harm caused to wishful parents embarking on their endeavour to start a family who are then denied access to ARTs. Despite the familial harm threshold seeming intuitively attractive, this model of regulation cannot be reconciled with the reproductive freedoms of prospective parents given the unjustified barriers it erects in their path.

The genetic harm threshold to which I now turn is still a relatively new area of regulation insofar as the law regulating PGD is concerned, and the basis in which it applies is important given the significant expansion of the permitted uses of PGD in recent years. In order to understand the regulation of PGD, a combined reading of the HFE ACT and the CoP is required. The genetic harm threshold is contained in both, and it will now be demonstrated that the same genetic harm threshold has been manipulated in the statutory and regulatory provisions. In doing so, the genetic harm threshold can be criticised, in that it is ill-defined, applied inconsistently and the motivation behind it lacks regulatory transparency. Moreover, it further erodes prospective parent’s capacity to exercise reproductive choice, a shortcoming of the overarching PCWP.

\section*{5.5 APPLYING THE GENETIC HARM THRESHOLD IN PGD REGULATION}

Prior to the 2008 reforms, the HFEA, as the sole architect of the CoP, exercised carte blanche in deciding the appropriate uses of PGD.\textsuperscript{438} The HFEA decided in what circumstances PGD

\textsuperscript{436} Children Act 1989 section 1 and 7 allow the court to order the preparation of child welfare reports for assessing an existing child’s welfare.

\textsuperscript{437} For an anti-natalist argument on the harm of coming into existence see the work of David Benatar. He argues that every person is harmed by existing and by bringing a person into existence you are impermissibly harming that person. See: David Benatar. \textit{Better to never have been: The harm of coming into existence} (Oxford: Oxford University Press 2006). Benatar’s work is discussed in more length in [6.5] onwards.

\textsuperscript{438} It should be noted that prior to the enactment of the HFE Act 2008 the HFEA had received unanimous support by the House of Lords in licensing embryo testing as per the case of \textit{Quintavalle (Comment of Reproductive Ethics) v. Human Fertilisation and Embryology Authority} [2005] UKHL 28.
could be used and whether a clinic should be granted a licence to use it. It devised the entire licensing framework for PGD in successive editions of its CoP. Such criteria evolved from PGD being available only where there was a “significant risk of a serious genetic condition” to a “substantial risk,” and in the current CoP “only where there is a significant risk of a serious genetic condition being present in the embryo.” When the 2008 Act amendments came into force, the codified system regulating PGD was simply placed on a statutory footing. The only real practical difference to take effect from October 1st 2009 was that PGD was no longer regulated on a case specific basis, but rather a condition-by-condition basis for genetic conditions approved by the HFEA and included on a formalised central list of genetic conditions.

5.5.1 ILL-DEFINED

A clear objective of the HFE Act 2008 was to establish parliamentary authority over the use of PGD. Although the HFEA retained discretion to approve a genetic condition as sufficiently serious to warrant the use of PGD, it does so now according to the following statutory criteria:

Schedule 2 IZA (1) and (2) read:

(1) A licence under paragraph 1 cannot authorise the testing of an embryo, except for one or more of the following purposes:

(a) establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth,

(b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,
(c) in a case where there is a particular risk that any resulting child will have or develop:

(i) a gender-related serious physical or mental disability,

(ii) a gender-related serious illness\(^{445}\), or

(iii) any other gender-related serious medical condition,

establishing the sex of the embryo.

(d) in a case where a person (“the sibling”) who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of those persons) suffers from a serious medical condition which could be treated by umbilical cord blood stem cells, bone marrow or other tissue of any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling, and

(e) in a case where uncertainty has arisen as to whether the embryo is one of those whose creation was brought about by using the gametes of particular persons, establishing whether it is.

(2) A licence under paragraph 1 cannot authorise the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) unless the Authority is satisfied:

(a) in relation to the abnormality of which there is a particular risk, and

(b) in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b),

that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

The HFE Act does not include a definition of a significant risk of serious harm. When the House of Lords debated the use of terminology in the statute Baroness Royall made it clear

that a definition of “serious” was deliberately excluded from the statute with a view to ensuring that the HFEA was able to exercise appropriate flexibility to make licensing decisions. Consequently, the HFEA provided additional guidance in the form of explanatory notes for its Licence Committee (the Committee) specifying whether a risk exists as per the criteria set out in paragraph IZA (1)(b). That guidance provides the entire framework for how a Committee should determine both the ‘significance’ of the risk and the level of ‘seriousness’ for any genetic condition, and on closer examination it provides a surprisingly lower harm threshold than that which is contained in the statutory provisions and the CoP. The guidance specifically covers issues of penetrance levels in various genetic mutations, and although the potential variability in symptoms is noted, the document is clear in its recommendation that in making a decision on the harm threshold a Committee should assess penetrance according to the *highest* possible risk on the penetrance figure, while presuming the *worst* symptoms and the “worst case scenario” in each case. A “significant risk of serious harm”, is thus a misleading use of terminology.

### 5.5.2 INCONSISTENCY

Many genetic conditions self-evidently meet the serious harm threshold. It is reasonably safe to assume that there would be little criticism on the morality of a decision made by prospective parents to wish to avoid the birth of a child who would endure intolerable suffering by being born with a serious genetic condition. Tay-Sachs disease or Spinal Muscular Atrophy, for example, are both undeniably serious genetic conditions involving significant suffering and often resulting in infantile death. But they are relatively uncontroversial examples. There are currently 390 genetic conditions included on the central list and of course not all of them are as easily categorised.

More controversy surrounds the detection of perhaps less serious conditions included on the HFEA central list such as Cystic Fibrosis (CF), a life limiting condition where the potential

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446 Lords Hansard 21 January 2008: Column 30 (Baroness Royall).  
448 Ibid, 4.  
449 Ibid, 5.4.  
450 Ibid, 5.5.  
452 An authorised genetic condition remains on the central list and the entire list is subject to review every 5 years.
degree of suffering is so widely variable given the different classifications of the CF mutation. While there are six classifications of the CF-transmembrane conductance regulator (CFTR) gene, there are more than 1,800 mutations; some are common and others are rare and found only in a few patients. Each one of the varying CF mutations is independently classified depending on the level and functions of the CFTR gene. This means that the Committee’s genetic harm threshold mandating the highest possible risk in the worst-case scenario is not entirely coherent when applied to CF. The “worst case scenario” approach cannot be accurately applied to a genetic condition where the symptoms and prognosis are so widely variable and unpredictable in each patient. In addition, such an approach in assessing genetic harm takes no account of several significant exterior non-genetic factors affecting the level of harm and suffering of a CF patient, such as air quality, the level of care received, nutritional status of the individual and the patient’s age on diagnosis.

A further problematic example of inconsistency in regulating a genetic harm threshold is evident when you consider its implications for ‘carrier status’ embryos. Those embryos detected as carrying a single copy of the CF protein gene, indicating an unaffected carrier of CF if brought to birth, also strictly fall within the statutory genetic harm threshold criteria set out in IZA (1)(b) “where there is a particular risk that the embryo may have any gene” permitting the use of PGD to test for CF. Yet the only circumstance where being a CF carrier has any potential physical effect, is if two carriers of the gene were to procreate. Only then would there be 25% chance that their child would be born with CF, or a 50% chance of their child being another carrier of the CF mutation. Prior to the act of procreation, both CF carriers would live their lives unharmed by the gene. Given that one person in twenty five is said to be a carrier of CF in the UK, the possibility of CF affected children being born remains a point of consideration. PGD presents the possibility of eradicating that possibility by virtue of de-selection justified on the basis of the genetic harm threshold. But strictly speaking, there is nothing to suggest that the aggregate lifetime welfare of a CF carrier is

454 Cystic Fibrosis Foundation. Available at: https://www.cff.org/What-is-CF/Genetics/Know-Your-CF-Mutations/ Accessed 20.08.16.
456 Ibid.
diminished due to their carrier status. There is no plausible argument corroborating the Committee’s endorsement of a “worst case scenario” when an embryo carrying the single CF gene is identified in a cohort of embryos. Despite paragraph IZA (2) stating that a licence for the purpose of paragraph IZA (1)(b) cannot be issued for embryo testing unless the HFEA is satisfied “there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition”, the difficulties in interpretation are self-evident. It follows that, given the inclusion of CF on the central list, a decision could then be legitimately made by a clinic to detect a CF carrier embryo by PGD and de-select it because of the genetic harm threshold.

While it is not explicitly stated within the HFE Act or the CoP that the genetic harm threshold is linked to PCWP considerations, it is clear that the rationale underpinning the provisions use child welfare as a means of justifying the testing. The approach to harm prevention insofar as de-selecting embryos affected by a genetic condition demonstrates the regulatory position: prevention of genetic harm equates to maximised child welfare. But this example of detecting CF serves to highlight two salient points countering the use of a genetic harm threshold in the regulation of PGD. First, that although licensing PGD to identify CF is perhaps not contentious per se - as the condition is one with life affecting symptoms of variable severity - its inclusion on the HFEA central list demonstrates that the genetic harm threshold is open to exceptionally wide interpretation that has been deliberately manipulated beyond the basic parameters of harm prevention. It is not a consistent or transparent model of harm based regulation. Second, when the statutory restrictions preventing preference selection of affected embryos contained in section 13 (9) and (10) of the HFE Act are considered, the genetic harm threshold model has extremely problematic overtones. It is perhaps less to do with the prevention of serious genetic harm, and more to do with eradication of genetic disease. With a strict application of the genetic harm threshold what transpires is the force of regulation; it triumphs in the face of reason, the need for transparency and a respect for reproductive autonomy, in equal measure.

The inclusion of the BRCA 1 and BRCA 2 gene mutations on the HFEA central list invite similar concerns regarding the appropriateness of the genetic harm threshold criterion as a

457 Schedule 2 paragraph IZA (2).
458 The possible ethical underpinning of these provisions is discussed in detail [6].
459 BRCA 1 and 2 mutations indicate an increased risk of developing a cancer
guide for the moral use of PGD. Criticism surrounds issues of necessity given that serious genetic harm is not absolute, but rather a very high possibility. But if the rationale of serious harm prevention underlying this approach is accepted, then the potential expansion of the genetic harm threshold is on the horizon. Recent research has discovered 93 genes that, if mutated, can cause normal tissue to become cancerous and increase the risk of susceptibility to aggressive cancers. It was stated by the NHS that this “landmark research paves the way for new and better treatments…as well as ways of preventing the disease ever occurring”.

If such discoveries follow suit insofar as susceptibility to serious harm are concerned, thus engaging the genetic harm threshold, then we are crucially forced to question whether the current genetic harm threshold is an appropriate means to regulate PGD. It fails to measure the variable severity of genetic conditions given the uncertain development of some genetic mutations, the variability of prognosis in different people, the effect that age can have on diagnosis and, of course, the increasing prospects of successful therapeutic treatments.

Huntington’s disease (HD) is also included on the central list and is categorised as a late onset genetic condition. It is dissimilar in nature to CF or BRCA 1 and 2, notably because it is an autosomal dominant disorder, meaning that a person needs only one copy of the defective gene to definitely develop HD in their lifetime. It commonly takes effect in later years and most significantly it is incurable. In an objective assessment of genetic harm it qualifies as a serious genetic condition with a wide spectrum of aggressive symptoms usually causing movement, cognitive and psychiatric effects. But the issue in contention is not with HD itself as a serious genetic condition, more so with the application of the genetic harm threshold primarily contained in the PCWP assessment 8.10 (b) (iii). First, the genetic harm threshold is nothing to do with child welfare considerations when a genetic disease is late onset. Second, the legislative restrictions prohibiting the selection and implantation of an embryo detected as carrying a late onset condition disregards the intervening years a person lives for prior to being symptomatic and diagnosed. While objectively a late onset condition can be categorised as sufficiently serious to satisfy a genetic harm threshold, the application of the genetic harm threshold in this context is problematic. Given that late onset genetic

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462 HFE Act section 13 (9) and (10).
conditions provide a time frame for life before diagnosis, the worst-case scenario licensing threshold becomes as nonsensical as child welfare considerations are in this context.

When prospective parents seek PGD, the embryo testing provisions contained in the CoP take practical effect alongside section 13 (9). The guidance notes on embryo testing contain additional welfare based factors for clinics to consider prior to agreeing to provide PGD to prospective parents, such as the likely degree of suffering associated with the condition, set against the availability of fast growing effective therapies and the views of the people seeking treatment including their previous reproductive experience. Given that the range of factors can be judged objectively, for example, the speed of degenerative progressive disorders, compared to individual family experiences which are subjectively judged, such as the personal views from parents who are at risk of having another child with a serious genetic condition, this regulatory approach has been labelled as “a mixed objective – subjective ‘seriousness’ test” for applying the genetic harm threshold in practice.

It is worth noting, however, that due to the HFE Act 2008 amendments to the standard conditions placed on licences, the codified mixed objective-subjective test contained in the CoP becomes obsolete. In some scenarios the personal views of the prospective parents are simply irrelevant when the statutory restrictions are properly considered. The very clear overriding objective for introducing section 13 (9) into the HFE Act was to prevent PGD being deliberately used to positively select for genetically disabling traits or conditions. In general, section 13 specifies the licence conditions authorised by the HFEA, and subsection (9) is specific to PGD. It provides the following:

(9) Persons or embryos that are known to have a gene, chromosome, or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop-

(a) a serious physical or mental disability,

(b) a serious illness, or

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463 CoP 8th edn (2009) 10.7 (b).
464 Ibid, 10.7 (c).
465 Ibid, 10.7 (a).
466 Emily Jackson. ‘Statutory regulation of PGD in the UK: unintended consequences and future challenges’ In Sheila A. M. McLean and Sarah Elliston (eds) Regulating Pre-Implantation Genetic Diagnosis. A comparative and Theoretical Analysis (Routledge: 2013) at 76.
must not be preferred to those that are not known to have such an abnormality.

Once sub-section (9) came into force, the HFEA was stripped of its discretionary power to respond to a request to positively select an embryo with a genetic condition. This statutory restriction extends to the positive selection of donors and donor gametes to prevent an attempt to increase the possibility of having a child with a disability. Though there may be tactical avenues to circumvent these legislative amendments, on the face of the HFE Act prospective parents are now prohibited from deliberately selecting an embryo affected by a genetic condition based on the statutory version of the genetic harm threshold. Even if prospective parents articulated a case that the PCWP was not violated, and supported their case by either their own reproductive experiences of having a child with a particular genetic disease or based on their own experience of living with a genetic disease, they would be unsuccessful provided at least one unaffected embryo offered an alternative option. The interesting aspect of these provisions is that they are not discretionary provisions but they are not completely prohibitive either, for only preferential selection is prevented for positively selecting for disability. The position is further qualified in the CoP where a blanket prohibition on transferring affected embryos is precluded.

On that basis the genetic harm threshold quickly loses coherence and, of more practical importance, it becomes difficult to reconcile a pragmatic ethical solution within the basic parameters of the current statutory provisions. The provisions prohibit the deliberate selection of an embryo affected by factors listed in section 13 (9) (a) - (c) and that prohibition extends to a chance selection between a combination of affected and unaffected embryos. However, in the event that only affected embryos are available for selection, the genetic harm threshold then ceases to apply. In that scenario, prospective parents are allowed to exercise their reproductive liberty and select an embryo regardless of the genetic condition affecting it. There are no additional prohibitive caveats contained within the HFE Act or the CoP restricting such a choice in those specific circumstances. In this context, regulation institutes a rather unpalatable hierarchy of embryo selection based on the genetic information from the

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468 Elliston, op. cit Selecting for Disability, n.4 at 136-189.
469 CoP 8th edn (2009) 10 C states of section 13 (9) and (10) “where there is no other embryo suitable for transfer, an embryo with these characteristics may be transferred”.
470 Ibid, 10 C.
cohort of embryos. Insofar as the scope of choice is concerned the application of the genetic harm threshold divides in three separate categories each demanding or relinquishing a level of regulatory engagement depending on the circumstances. First, where only unaffected “healthy” embryos are available for selection, prospective parents can select any embryo. Second, where a combination of affected and unaffected embryos are available for selection the scope for choice is then limited. Third, where only affected embryos are available for selection, the hierarchical system of embryo selection evolves. The first scenario is unproblematic insofar as that particular autonomous choice is concerned. The second scenario empower the genetic harm threshold and simultaneously minimises reproductive choice by prohibiting preferential or chance selection. In contrast, the third scenario empowers prospective parents with reproductive autonomy just as the genetic harm threshold disengages. This represents a significant concession in the regulation of a genetic harm threshold endorsed by the PCWP. It demonstrates that the genetic harm threshold which is central to the promotion of the health related concerns of the PCWP is not solely focused on child welfare or health. Notwithstanding the lack of transparency in the restrictive provisions, it is easy to discern a hidden agenda contained in regulation that is justified on a loose harm prevention model.

The fact that genetic harm of any magnitude could affect an embryo and that embryo could be selected for implantation when no other embryos were available for selection, demonstrates the inconsistent utilisation and application of the genetic harm threshold. In turn that amplifies the inherent problems in the PCWP. Similar to the way in which a familial harm threshold imposes a state of influence on appropriate behaviours, the genetic harm threshold problematically endorses a form of parental reproductive responsibility insofar as the scope for reproductive choice is concerned. The underlying rationale is that if regulation restricts that particular reproductive choice, then by implication it is not the right reproductive choice to make. In regulating PGD in this way, Parliament and the HFEA have effectively empowered themselves to act in loco parentis by assuming the fundamental rights of prospective parents embarking on what should be their private reproductive path.

5.6 CONCLUSION

This article sought to address two main questions. First, how does the PCWP’s harm threshold apply in the regulation of IVF and PGD? Second, how does its engagement reflect on the overall legitimacy of the PCWP? These two questions are intrinsically linked because
the harm threshold operates under the ambit of the PCWP as contained in the HFE Act and as divulged in the CoP. However, this article has shown that this hybrid regulatory approach is unsatisfactory and that the current framework regulating a harm threshold in accordance with the PCWP is problematic for a variety of reasons.

It is argued that the way in which the statutory PCWP found its place in the regulation of ARTs has contributed to the unsatisfactory state the principle remains in today. The absence of a statutory definition of the PCWP has resulted in inevitable confusion regarding the constitution of the principle. The task of developing the principle has always fallen to the HFEA and the harm threshold is an integral part of the assessment. In order to answer the first question posed by this article, the function of the harm threshold was divided into two distinct categories of harm based regulation: familial harm and genetic harm. The intention was to demonstrate not only the process of applying each threshold in practice but also, crucially, to emphasise the impact each harm threshold has on prospective parents seeking access to fertility treatments, such as IVF and PGD.

An argument for deregulation of the familial harm threshold was advanced in [5.4]. Given that this aspect of the familial harm threshold occupies such a pivotal role in the assessment process - in that it is the gatekeeper to accessing fertility treatment services - the dangers of subjectivity on the part of clinic staff unraveling the criteria and conducting the assessment lends significant doubt as to the appropriateness of its retention. This article represents an attempt to oppose the intuitive appeal of the familial harm threshold. I have argued that the value of such intuition is significantly outweighed by the discriminatory dangers outlined in terms of inconsistency, unfairness and illogicality. The notion that regulating a PCWP offers justification for vetting prospective parents is rejected because of those three combined arguments. My contention is that the current codified approach to regulating the PCWP’s familial harm threshold, despite an apparent presumption to offer treatment, lacks parity with the unregulated world of natural conception and places prospective parents seeking assistance to conceive in an unfair position.

This article has demonstrated that the genetic harm threshold engages in practice on multiple levels. In 2007 when Lord Darzi introduced the HFE Bill to the House of Lords he stated that
the Bill was to “make explicit the basic parameters for screening and selecting embryos”.

What followed was the adoption of the existing codified system of public policy promulgated by the HFEA in the preceding years. By way of examples I have shown that the use of “basic parameters” regulating a genetic harm threshold is problematic on grounds of inconsistent application, incoherence and a lack of clarity in the express provisions regulating PGD. My purpose has been to identify the reasons why continued regulation of the current genetic harm threshold is open to challenge. I suggest that perhaps it is time to achieve regulatory transparency, seek greater clarity on the restrictive provisions, and revisit the legitimacy of regulatory powers of Parliament and the HFEA which systematically erode reproductive choice. By outlining the problems in applying the genetic harm and familial harm thresholds an answer to the second question posed by this article is revealed, in that an argument declaring that the continued retention of the current PCWP is indefensible in law.

471 Lords Hansard 19 November 2007: Column 666 (Lord Darzi)
PAPER 3

REGULATING FUTURE PEOPLE: THE PARADOX OF THE PRE-CONCEPTION WELFARE PRINCIPLE
6.0 ABSTRACT

The PCWP has a powerful role in the way that ARTs are regulated in the UK. Contained in section 13(5) of the HFE Act 1990, it requires clinics providing licenced fertility services to consider the welfare of future individuals before their conception. As such this provision is very different from a consideration of an existing child’s welfare in healthcare or child law. By distinguishing this provision from post-conception welfare considerations a fundamental question is raised which is the focus of this article: How is the PCWP used in the regulation of ARTs? And can we justify its use in this way? While there is a body of ethical and legal literature which has discussed the use of the familiarly known ‘welfare of the child’ in ARTs before, this article adopts a unique perspective by bringing these disciplines together. This means we can a) be much clearer about what the PCWP is asking decision makers to do in practice; b) evaluate the possible ethical foundation of the PCWP; and c) in light of this evaluation, consider the appropriacy of the current use of the PCWP. It is suggested that regulation of such a fundamental principle should meet stringent requirements for consistency and transparency and focus on producing a defendable position rather than one that has its foundations in abstract concepts and intuition. As a result this analysis calls into question the overall legitimacy of the use of the PCWP and it is argued that the involvement of the principle in the regulation of PGD - and ARTs broadly construed – is indefensible.

6.1 INTRODUCTION

This article critically examines the PCWP in the regulation of ARTs. The PCWP plays a powerful role in the way that ARTs are regulated in the UK and mandates the clinics providing licensed services to consider the welfare of future individuals before treatment can commence. As such this provision is very different from a consideration of an existing child’s welfare in healthcare or child law. Distinguishing it from post conception welfare considerations gives rise to a fundamental question which is the focus of this article: How is the PCWP used in regulation? In answering this question, I will respond, in particular, to an erroneous assumption that the PCWP is conceptually clear and has a coherent ethical

472 Section 13 (5) states: “A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth”.
473 HFE Act section 2 (1) states “treatment services” means medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children.
underpinning. This critique offers a robust analysis of the application of the PCWP in practice; it points to weaknesses in state regulation and challenges the reasoning supporting restrictive control on reproductive choice.\textsuperscript{474} The argument is based on the law’s framing of serious harm and the embryo selection restriction set out in section 13 (9) of the HFE Act. I argue that the law, when properly understood, misconstrues the intractable problem of avoiding pre-conception harm.

The principal technique under consideration here is PGD, involving genetic testing of embryos to ascertain which are affected by a genetic condition. PGD is the primary reproductive technology which allows for embryo selection based purely on genetic data. While the availability of PGD could be considered as enhancing individuals’ reproductive autonomy – in that it provides them with the choice to test their embryos for a genetic condition that they wish to avoid having a child born with – in the aftermath of genetic testing, individuals’ ability to exercise autonomous choices on embryo selection are restricted on grounds inextricably linked to the PCWP and the harm threshold it mandates in respect to genetic testing. In order to function in a regulatory capacity the PCWP utilises a genetic harm threshold criteria, set out in the overarching statute, the HFE Act and the CoP.\textsuperscript{475}

Section [6.2] will recount the development of the statutory and regulatory provisions which obstruct individuals’ autonomy to decide which of their embryos they can select for implantation. This article seeks to challenge the restriction on embryo selection by highlighting the weak basis on which the restrictions rely. The justification lies primarily in the PCWP considerations contained in the HFE Act at section 13(5) and the accompanying provisions in subsections (9) and (10) which specifically relate to PGD. Such considerations, it is argued, are grounded on a problematic notion that preventing children being born with genetic conditions is a legitimate reason to include the PCWP in the law and regulation of PGD. By constructing a harm based approach to justify the use of PGD and subsection (9) restriction, a link is created between harm prevention and the maximisation of a future child’s welfare.

\textsuperscript{474} For the purposes of this work, reproductive autonomy is the ability to be self-determining and to act according to one’s own values in reproductive decision-making. See: Emily Jackson. \textit{Regulating Reproduction: Law, Technology and Autonomy} (Oxford: Hart Publishing 2001) between 2 -9; Erin Nelson. \textit{Law, Policy and Reproductive Autonomy} (Hart Publishing 2013) 235-254.  
\textsuperscript{475} CoP 8\textsuperscript{th} edn (2009).
This article challenges that notion, and it does so by first outlining the development of the provisions regulating PGD in Part I. Section [6.5] then explores a range of ethical perspectives on harm – given that serious medical harm is mandated by the PCWP assessment – and it examines its connection with, and relevance to, PGD regulation. The connection in regulation between the PCWP and PGD has been explored in the literature by both supporters and critics. But despite the extent to which scholars have criticised the application of the principle, given the tensions between their analyses, no consensus has been reached. Thus, this article will approach the question posed above from a different angle. First, it will offer a critical analysis of the development, legitimacy and ethical plausibility of the current harm based approach in regulation in respect of the restriction contained in section 13 (9) and highlight the problems entailed with the PCWP specifically in the context of restrictive PGD regulation. Then it will argue that whilst the PCWP is a major influence on the morally acceptable uses of PGD and thus its legal boundaries, when its ethical constitution is explored, a rebuttal argument emerges. This argument rejects the idea that the PCWP has any cogent bioethical foundation and simultaneously champions the reproductive freedom of individuals embarking on their right to found a family of their choosing. It further rejects the idea that the PCWP is beneficently motivated towards unborn children, prospective parents, wider family units and society in general through the avoidance of children born with genetic conditions. A selection of prominent ethical approaches to the PCWP will be discussed to substantiate my rejection of the PCWP. Critically, this rejection is not advanced from a disability rights perspective challenging the morality of the genetic testing, as the desire to genetically test embryos is advanced here as an entirely individualistic reproductive choice. Rather, the rejection draws on a range of ethical interpretations of harm which demonstrate there is no proper foundation for the PCWP’s harm based approach.

On exploring various ethical approaches to the harm threshold, it becomes clear that there is no coherent philosophical or theoretical substance underpinning it and, I argue that the PCWP is a paradox involving complex and conflicting interpretations which are impossible to

477 Jackson, op. cit conception, n.4; Blyth and Cameron, op. cit Welfare of the Child, n.404; Blyth, Burr and Farrand, op. cit Welfare Assessment, n.404; Sheldon and others, op. cit Supportive Parenting, Responsibility and Regulation, n.4; Harris, op. cit Welfare n.4; Reece, op. cit Consensus, n.62.
reconcile fairly in regulation. While it is right for the state to safeguard existing children’s welfare, its interference in governing the genetic makeup of children who might not ever exist by limiting the scope of reproductive choice is a troubling aspect of the currently permissible scope of PGD. Moreover, it is argued, that state intervention of this kind displays a concerning message regarding what are right and wrong choices in embryo selection. Given a widespread assumption that state intervention is legitimate, I argue that there should be regulatory transparency as regards the underpinnings of such restrictions. Overall, these concerns call into question the legitimacy of the PCWP and it is argued that the involvement of the PCWP in the regulation of PGD – and ARTs broadly construed - is morally indefensible and should be abolished.

6.2 THE BACKGROUND TO PGD REGULATION AND ITS UNDERLYING PREMISES

PGD was developed to provide an alternative option to prenatal diagnosis (PND). Whereas PND involves testing a foetus to determine whether any abnormalities are present prior to birth, PGD occurs ex vivo, prior to an embryo being selected for implantation. Since the early 1990s PGD has provided individuals with the option to select an embryo on the basis of its genetic makeup.478 Given the Human Fertilisation and Embryology 1990 Act (the HFE Act 1990) did not legislate for PGD the task of regulating it fell entirely to the regulator, the Human Fertilisation and Embryology Authority (the HFEA). At that time, the HFEA was influenced by the circumstances in which PND was being used in practice – which was subject to clinical discretion on a case by case basis – and the ground of foetal abnormality to terminate a pregnancy as contained in section 1(1) (d) of the Abortion Act 1967. That ground specified that, in order to receive an abortion, the opinion of two practitioners formed in good faith was required and “that there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped”.479 The critical convergence of the two threads of regulation - the PND model and the abortion model - provided the HFEA with the basis of its own regulatory framework for PGD. It did so via the sixth edition of its CoP, published in 2003. The terminology included in the CoP reflected the two models of regulation, albeit in an unsatisfactory form. It described PGD as

479 Section 1 (1) (d).
equivalent to the “current practice in the use of prenatal diagnosis”. But from the outset, the HFEA only licensed PGD when there was a substantial risk of suffering from a serious genetic condition. Unlike PND where there are no limitations on testing. Therefore, the initial governance of PGD – in accordance with the statutory criteria to lawfully terminate a pregnancy – was less than perfect. Moreover, it lacked transparency and failed to provide consistency in regulation.

In 1999 the HFEA and the then Advisory Committee on Genetic Testing conducted a public consultation on the clinical use of PGD. Thereafter, the HFEA and the Human Genetics Commission established the Joint Working Committee, producing recommendations for when PGD could be performed but significantly this rejected the proposal for a list of serious genetic conditions for which PGD was thought to be appropriate. The HFEA then incorporated the recommendations into the architecture of its CoP in 2003. That was almost ten years after the first pregnancies and births were reported when PGD was used to identify the gender of embryos from couples at risk of having children with a sex-linked inherited disease.

At that critical stage the HFEA formulated its genetic harm threshold which determined the limitations of permissible genetic testing of embryos, mandating a risk of a serious harm in each case before PGD could be used. It was originally licensed on a case-by-case basis, meaning clinics had to apply to the HFEA for a license in respect of each proposed application of PGD. That approach limited PGD to strictly health-related motivations for using it and circumvented the fear of PGD being propelled down a slippery slope creating ‘designer babies’. This case by case approach served to prevent the deliberate selection of embryos for implantation affected by a genetic condition. Prior to restrictions on conditions

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481 Ibid, 14.22.
482 HFEA and ACGT, Consultation document on Pre-implantation Genetic Diagnosis (1999).
483 HFEA and HGC, Outcome of the Public Consultation on Pre-implantation Genetic Diagnosis (2001) 23.
487 This term is used to describe circumstances in which embryos are tested and deliberately selected for non-medical related traits such as eye colour, intelligence, athleticism. Such choices are not legally permissible in the UK. The term was coined in 2002 by Julian Savulescu in op. cit Deaf lesbians, n.396.
for licences which came into force with the HFE Act 2008, the HFEA and clinics had the discretion to permit such choices. The HFEA prevented non-medical sex selection save for only particular circumstances where identifying sex-linked disorders or when PGD for embryonic human leucocyte antigen (HLA) tissue typing was requested, commonly referred to as creating ‘saviour siblings’. Embryo selection based on any identifiable non-medical traits was also banned. Thus, a clear dichotomy between acceptable medical uses and unacceptable social uses of PGD was quickly established via the regulatory provisions mandating a genetic harm threshold for PGD use.

6.3 THE 2008 REFORMS

During the run up to the enactment of the HFE Act 2008, there was a clear Parliamentary intention to clarify the acceptable uses of PGD and place these on a statutory footing. Schedule 2 of the amended HFE Act specifies activities that may be authorised by a licence, including creating, testing and implanting a ‘permitted embryo’ in a woman. The statutory provisions relating to authorisation for genetic testing are located in Schedule 2 S1ZA, which permits testing in the following circumstances:

(a) establishing whether an embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth,

(b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality.

Once the broad statutory criterion is met, and provided the HFEA Licence Committee has approved of the genetic condition as being sufficiently serious, then any embryo within a

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488 Section 14 of the HFE Act 2008 amended the conditions for licences.
489 HFE Act section 13 (10) – (11) for restrictions where testing involves gender related genetic disorders and Schedule 2, S1ZA (1) (C). Turner syndrome is a genetic condition which affects only girls. The common characteristic features of the syndrome are shortness in height and ovaries which do not function correctly.
490 Schedule 2 Paragraph 1ZA (1) (d) sets out the statutory criteria for tissue typing. The HFE Act also prohibits certain activities absolutely including non-medical sex selection, criminalising performing activities without a licence with a penalty of imprisonment up to ten years or a fine or both, section 41; Merle Spriggs and Julian Savulescu. ‘Saviour siblings’ (2002) Journal of Medical Ethics 28:5, 289.
491 HCSTC, op. cit, n.304.
492 HFE Act section 3ZA (4) states an embryo is a permitted embryo if (a) it has been created by the fertilisation of a permitted egg by permitted sperm (b) no nuclear or mitochondrial DNA of any cell of the embryo has been altered, and (c) no cell has been added to it other than by division of the embryo's own cells.
cohort of embryos can be tested for any condition contained on the HFEA centralised list.\textsuperscript{493} Given there is no definition of harm or risk contained in the HFE Act the HFEA provided an explanatory note for the Licence Committee determining the significance and severity of the risk for a genetic condition. The guidance indicates the penetrance for the relevant condition is assessed according to the highest risk for the applicable range in terms of significance,\textsuperscript{494} while presuming “the worst possible symptoms” is recommended for a determination how serious a disability is.\textsuperscript{495}

Significantly, subsection (b) permits multiple testing for \textit{any} genetic or chromosomal abnormality, meaning that the testing is not strictly limited to the relevant genetic conditions in each particular case. This prompted the process of testing being provided according to individual needs, and the general licensing of PGD altered to a more lenient condition-by-condition basis since 2009.\textsuperscript{496} Additional extensions of PGD are framed as ‘PGD with non-disclosure’ and ‘exclusion testing’.\textsuperscript{497} This provides individuals who do not wish to know their own genetic status to test their embryos without having the test results disclosed to them.\textsuperscript{498} For example, someone who thinks they are at risk of developing a serious late onset genetic condition – such as Huntington disease (HD) – has the option of testing their embryos to ensure they do not select an embryo with HD but, crucially, they preserve their right not to know whether they have HD.\textsuperscript{499} The incremental relaxation of the restrictive approach in PGD regulation reveals one important point concerning PCWP considerations: the availability of PGD with exclusion testing or non-disclosure is not focused solely on the PCWP considerations.

A shift in the regulation of PGD is further evidenced by two available options now documented in the latest version of the 8\textsuperscript{th} edition of the CoP which was published in May 2017.\textsuperscript{500} First, as outlined at 10.7, when PGD is being used to detect heritable conditions a clinic can offer PGD for “additional conditions that do not meet the particular risk

\begin{itemize}
\item \textsuperscript{493} HFEA, op. cit, n.370.
\item \textsuperscript{494} HFEA, op. cit, \textit{Explanatory Note on PGD}, n.447, at 5.4.
\item \textsuperscript{495} Ibid, 5.5.
\item \textsuperscript{496} It should be noted that the policy position on PGD for tissue typing remains on a case by case basis.
\item \textsuperscript{497} The CoP 8\textsuperscript{th} edn (2009) 10.10 – 10.11 now specifically deals with PGD with non-disclosure and notes that ethical implications of such have been raised. However, the CoP does not contain any further analysis of the ethical implications mentioned in 10.10.
\item \textsuperscript{498} Ibid, 10.10 – 10.12.
\item \textsuperscript{500} The CoP 8\textsuperscript{th} end (2009) was updated in May 2017 to include new provisions between 10.10 – 10.17.
\end{itemize}
requirements that have been deemed, by the Authority, to be of significant risk”. In the explanatory note for the Licence Committee, the HFEA distinguished a “particular risk” as an “objectively measurable criterion” compared to the significant risk which refers to the “highest penetrance” of a condition. The CoP also states:

Where patients seek PGD, but do not wish to be given any additional genetic information that may be found via sophisticated genetic testing methodologies (e.g. segmental aneuploidies), the centre should offer, where possible, PGD with exclusion testing.

Thus, not only is the risk criteria included in regulation confusing and contradictory; but also using PGD with non-disclosure is the only occasion in PGD regulation that a patient’s choice ‘not to know’ overrules the PCWP considerations of familial harm which could have an impact on child welfare in years to come. Second, a clinic is entitled to apply directly to the HFEA to test for a genetic condition which is not yet included on the HFEA list of conditions. Given the extraordinary fast pace at which genetic conditions and mutations are identified, the HFEA provides clinics offering PGD with an element of regulatory ‘wriggle room’ insofar as its ability to consider the permissibility of testing for new genetic conditions is concerned. The approved list of genetic conditions is by no means static; it consistently grows and is subject to review by the HFEA Statutory Approvals Committee. But if a condition has not yet been approved, a clinic can request the HFEA to consider whether it meets the risk criteria to be included on its centralised list. These options demonstrate that regulatory flexibility - in the sense of sophisticated testing methodologies and the continual expansion of the central list - endorses the liberalised approach to a preventative model of PGD regulation that circumvents genetically harmed children being born by determining the contemporary permissible uses of PGD.

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502 HFEA, op. cit Explanatory Note on PGD, n.447.  
504 For example, if a parent suspected she could have HD but used PGD with non-disclosure to reserve her right ‘not to know’ about her own genetic status.  
505 The HFEA publish information online surrounding genetic conditions awaiting approval and how to apply for a condition to be considered.  
506 Clinics or interested patients can contact the HFEA via pgd@hfea.gov.uk for information on authorised genetic conditions and those which are awaiting approval.  
507 HFEA, op cit Explanatory Note on PGD, n.447.
6.4 APPLYING THE GENETIC HARM THRESHOLD

By utilising harm based regulation in the PCWP assessment and to justify genetic testing; Parliament and the HFEA inadvertently frame genetic harm prevention with the promotion and maximisation of child welfare via the PCWP assessment.\(^{508}\) Despite the HCSTC\(^{509}\) recommendation in 2005 for increased clarity in the appropriate statutory regulation of PGD,\(^{510}\) the desire for regulatory flexibility prevails. The HCSTC saw “no reason why a regulator should seek to determine which disorders can be screened out using PGD…clinical decisions should operate within clear boundaries set by Parliament and informed by ethical judgements”\(^{511}\). Moreover, in advocating for reproductive choice and a general decreased level of state intervention of regulated fertility treatments, the HCSTC indicated “the State should intervene only in carefully defined and justified circumstances”\(^{512}\). But when Lord Darzi introduced the Human Fertilisation and Embryology Bill 2007 in the House of Lords, he announced the intent was “to make clear the basic parameters for screening of selecting embryos”.\(^{513}\) This was furthered in a later statement by Baroness Royall when she explained why a definition of “serious” had not been included in the Act “in order to allow the HFEA and clinicians appropriate levels of flexibility…because of regulatory oversight from the HFEA”\(^{514}\). Thus, the parameters of the categories of conditions for which PGD can be used have never been fixed by law or regulation, but rather depend on what occurs in biology, embryonic science and the development of diagnostic testing.

Critically, section 14 of the HFE Act 2008 amended the existing conditions stipulated in section 13 of the HFE Act 1990, covering licences for treatment services not wholly dependent on the PCWP but intrinsically linked to it.\(^{515}\) Section 13 (9) of the consolidated HFE Act now contains the restriction which is then mirrored in section 13 (10) relating specifically to a restriction of embryo selection on grounds of gender.\(^{516}\) Section 13 (9) is of

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\(^{509}\) HCSTC, op. cit, n.304.  
\(^{510}\) Ibid, 140 para 315.  
\(^{511}\) Ibid, 58 para 124. It must be noted that in Quintavalle v HFEA, op. cit, n.438 the House of Lords unanimously supported the role and function of the HFEA as decision-maker regarding PGD use.  
\(^{512}\) Ibid, 40 para 8.  
\(^{513}\) Lords Hansard, op. cit, n.471 (Lord Darzi) (my emphasis).  
\(^{514}\) Lords Hansard, 21 January 2008: column 30.  
\(^{515}\) HFE Act 2008 section 14 amended section 13 of the 1990 Act regarding conditions of licences for treatment, including an amendment of the PCWP, counselling provisions, consent and restrictions on embryo transfer.  
\(^{516}\) Section 13 (10) states embryos that are known to be of a particular sex and to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop (a) a gender-related
relevance here not only because of its utilisation of the HFEA harm threshold, but the restriction it imposes on embryo selection. It reads:

[p]ersons or embryos that are known to have a gene, chromosome, or mitochondrion abnormality involving significant risk that a person with the abnormality will have or develop-

(a) a serious physical or mental disability,
(b) a serious illness, or
(c) any other serious medical condition,

must not be preferred to those that are not known to have such an abnormality.

The restriction is premised on an assumption that the state has a legitimate role to play in such a private area of reproductive choice, an assumption that drastically undermines individual preference. Marleen Eikholt examines the concept of procreative autonomy in the context of the HFE Act 2008 and argues that the legislation “is not built on any coherent conception of procreative autonomy”.\(^{517}\) She distinguishes between the more and less inclusive interpretations of procreative autonomy and demonstrates how the interpretation of what constitutes harm impacts on the legislative provisions restricting autonomous choice. Crucially, she highlights that certain provisions in the legislation - such as section 13 (9) - only permit the use of reproductive technologies for strictly therapeutic or medical reasons. Thus, the use of the same technologies for any other reason which individuals may choose is prohibited and, as a consequence, she argues that:

Autonomy is defined by a focus on the decision-making. By requiring that therapeutic necessity underpins the exercise of choice under the Act, the Act cannot be said to endorse even a moderated version of reproductive autonomy.\(^{518}\)

While section 13 (9) is not entirely prohibitive - given that it restricts preferential selection of an embryos affected by a factor listed between (a) – (c) when unaffected embryos are available to select – nonetheless it restricts choice based on the genetic harm threshold.

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\(^{517}\) Eijkholt, op. cit Procreative Autonomy, n.371.

\(^{518}\) Ibid, at 115.
originating from the PCWP assessment of harm. The effect of section 13 (9) is that it sanctions automatic de-selection of affected embryos when unaffected embryos are in the same cohort, irrespective of the severity of the conditions detected. Only when there are no unaffected embryos to select from does section 13 (9) permit selection and implantation of an embryo affected by the options noted between (a) – (c).

The CoP guidance reinforces section 13 (9) and adds that positively selecting an affected embryo where “at least one other embryo suitable for transfer is not known to have the characteristics” is prohibited. Although a link is not explicitly stated in the guidance, it undoubtedly connects to the PCWP assessment in the CoP which mandates a medical and social history be taken from each patient and their family for considering the risk of significant harm. The factors of relevance here are noted in the CoP child welfare assessment at 8.10 (b) as follows:

(b) past or current circumstances that are likely to lead to an inability to care throughout childhood for any child who may be born, or that are already seriously impairing the care of any existing child of the family, for example:

(i) mental or physical conditions

(ii) drug or alcohol abuse

(iii) medical history, where the medical history indicates that any child who may be born is likely to suffer from a serious medical condition, or

(iv) circumstances that the centre considers likely to cause serious harm to any child mentioned above.

While there is intuitive appeal to the selection restriction – given its aim appears to be preventing future harm - it is apparent that the ideas expressed are not objective. This hybrid style of regulation carries with it two important but presumably unintended consequences of the welfare based framework. First, which is legally straightforward, it only enhances the reproductive autonomy of individuals if they are choosing between affected embryos. The only circumstances in which a positive preference to select a particular embryo is compatible

519 For a compelling argument on possible legislative loopholes to the prohibition on selecting for disability see Elliston, op. cit Selecting for Disability, n.4.

520 CoP 8th edn (2009)10.C.
with the PCWP factors and section 13 (9) is when individuals can only select an unaffected embryo. Only in that scenario can the impact of the genetic harm threshold entailed within the PCWP considerations be evaded. Second, it creates a hierarchy in embryo selection based on genetic determination, which as Jeanne Snelling and Colin Gavaghan state, “not only conveys a problematic attitude to the value of disabled persons’ lives, but also codifies a particular concept of reproductive responsibility, one with extremely problematic overtones”. Although the assumed reasoning here might be intuitively appealing, it is argued that the restriction is troubling not only because it prohibits deliberate preferential selection of an affected embryo without justification, but it also implies a morally preferable action to be taken by individuals during the selection phase. As it specifically prohibits a ‘negative’ preference selection, it simultaneously questions whether, and arguably infers that, such deliberate choices between embryos would represent ethically problematic reproductive choices. What this tells us is that the prevailing assumption being made is that being born with a genetic condition, illness or disability equates to harm and conflicts the PCWP considerations. The highly publicised case of Sharon Duchesneau and Candy McCullough, where a deaf couple ensured the birth of two congenitally deaf children via a deaf sperm donor and artificial insemination, illustrates that point. Their deliberate choice in gamete selection attracted widespread scholarly debate regarding appropriate constraints on reproductive choice, reproductive responsibility and avoidable harm. This further tells us that the developing force of a PCWP in connection with restricting such desired reproductive choices is worthy of exploration.

The issue becomes on what grounds these restrictive statutory provisions are justified. Why are individuals restricted in their ability to select between their own embryos? In the same manner that the PCWP’s demand of supportive parenting can unfairly interfere with their ability to access ARTs; section 13(9) overrides the autonomous choice of individuals in embryo selection. The restriction also impacts on selection being simply left to random chance in the event that the individuals were not troubled by any of the genetic information retrieved from their cohort of embryos. Such a restrictive policy approach not only eradicates individual’s ability to make maximally autonomous choices about their future family, but it is

521 Snelling and Gavaghan, op. cit PGD, n.193 at 86.
522 Spriggs, op. cit Lesbian Couple, n.467.
523 The HCSTC also stated the principle “discriminates against the infertile and some sections of society, is impossible to implement and is of questionable practical value in protecting the interests of children born as a result of assisted reproduction”. HCSTC, op. cit, n.304 at 52, para 107.
also akin to the ‘principle of procreative beneficence’ advocated by some ethicists.\textsuperscript{524} The notion of procreative beneficence and related arguments suggest that we have a moral obligation to avoid having a child born with a particular disability if the specific outcome is preventable.\textsuperscript{525} Those arguing for such an obligation, such as Julian Savulescu,\textsuperscript{526} question why one would choose to have a child born with a disability if that child can be substituted with a different child without a disability. It asserts the latter course of action is the morally preferable path because it avoids harm. The argument that we should bring to birth the ‘best’ children possible has widespread intuitive appeal and these intuitions fit with the current legislative and regulatory focus on avoiding serious harm by choosing which children will be born as a result of PGD by embryo de-selection. Nevertheless, there have been strong criticisms of the justification behind it.\textsuperscript{527} As we will see, if it is difficult to provide strong reasons to justify this focus on creating the best children possible, then it becomes questionable whether the PCWP, which arguably relies on this premise, is an appropriate measure to govern acceptable uses of PGD.

Looking back then at the current regime, the justification for the regulatory intervention starts and ends with the PCWP, which is hinged on a widely accepted view that it is a benevolent principle included in regulation to prevent serious harm being caused to future children born as a result of ARTs. To what extent the PCWP is an appropriate measure to govern acceptable uses of PGD is now explored in the sections that follow.

\textbf{6.5 WHAT SUPPORTS THIS STATE INTERFERENCE WITH PRIVATE CHOICES?}

Notwithstanding that the PCWP is not paramount in the regulation of ARTs (as it is in child law relating to children after birth, for example),\textsuperscript{528} it has unrivalled strength in the current regulatory model that focuses on a theoretical child. In connection with its utilisation of supportive parenting and the broader context in which the family environment is scrutinised,

\begin{itemize}
\item \textsuperscript{524} Savulescu, op. cit \textit{Procreative Beneficence}, n.200.
\item \textsuperscript{526} Ibid, Savulescu and Kahane.
\item \textsuperscript{527} Rebecca Bennett. ‘When Intuition is Not Enough. Why the Principle of Procreative Beneficence Must Work Much Harder to Justify Its Eugenic Vision’ (2014) Bioethics 28, 447–455; Parker, op. cit \textit{Best Possible Child}, n.188.
\item \textsuperscript{528} Children Act 1989 section 1 as discussed in [2.1].
\end{itemize}
the clear and fundamental objection to it is that it is based entirely on intuitive appeal.\textsuperscript{529} While the statutory restrictions on embryo selection do not explicitly rely on the PCWP as a means to justify the intrusion into individuals’ reproductive liberty, it is undoubtedly the premise on which the restrictions in section 13 (9) and (10) are based. During the reform process the UK government even confirmed:

The welfare of children who may be born as a result of assisted reproduction treatment is a central tenet of the HFE Act, and one of the key guiding principles which informs the operation of the HFEA and the content of the Code of Practice. This recognises that whereas patients are entitled to sensitive consideration of their wishes, the welfare of children cannot always be adequately protected by concern for the interests of the adults involved.\textsuperscript{530} This affirmation makes clear that there was a deliberate legislative imbalance in favour of the welfare of a theoretical child over the reproductive freedom of individuals seeking treatment. This was despite the HCSTC recommending the PCWP should be abolished in its review of the law governing ARTs.\textsuperscript{531} Even though the government conceded the “difficulty in attempting to frame these matters in national legislation and guidance”,\textsuperscript{532} it failed to undertake the task. Parliament avoided addressing the PCWP’s ethical underpinning and side-stepped the thorny issue of establishing a unified legislative perspective on what was meant by pre-conception harm for the purposes of the PCWP and PGD regulation.\textsuperscript{533} When Sarah Elliston explored the legislative loopholes for positively selecting for disability she stated that the “principle therefore operates on two levels: as both a general condition for offering any assisted reproduction governed by the HFE Acts and now, in addition, as an implicit justification for the specific provisions concerning treatment involving PGD”.\textsuperscript{534} And yet - given the systemic failure of Parliament to address or substantiate its meaning – it is difficult to be clear on what justifies the interference in reproductive choice.

\textsuperscript{529} CoP 8\textsuperscript{th} edn 2009 at 8.11.\textsuperscript{530} Department of Health, op. cit Report on the HFE Act, n.26 at 39 – 40.\textsuperscript{531} HCSTC, op. cit, n.304, recommendation 24.\textsuperscript{532} Department of Health, op. cit, n.26 at 39 – 40.\textsuperscript{533} When the 2008 Act provisions were debated in Parliament the conventional use of PGD was deemed unproblematic, unlike PGD for tissue typing or sex selection which dominated the extent of the debates in the House of Lords. See: Emily Jackson. ‘Statutory Regulation of PGD in the UK: unintended consequences and future challenges’ In Sheila A. M. McLean and Sarah Elliston (eds) Regulating Pre-Implantation Genetic Diagnosis. A Comparative and Theoretical Analysis (London: Routledge 2013) at 78-79.\textsuperscript{534} Elliston, op. cit Selecting for Disability, n.4 at 109.
To be clear, this article does not challenge the use of PGD; it is accepted that many genetic conditions are serious enough to justify testing given the potential impact a condition can have on the life of a future person and the wider family unit. The reason why individuals decide to test their embryos is a matter of private reproductive choice. The issue in contention here surrounds the connection of the PCWP to the selection restriction set out in section 13 (9), and the erosion of the capacity of choice. In the sections that follow my argument highlights a selection of prominent ethical theories which provide an understanding of the concept of harm. Given that section 13(9) is framed in harm avoidance terms, it is important to understand the basis on which preferential selection of an affected embryo is restricted. By examining a selection of ethical theories, this article argues that the law, when properly understood, is problematic for two reasons. First, it demands the impossible insofar as the interpretation of PCWP’s harm threshold is concerned. Not only is arriving at a consensus on the notion of preventing preconception harm unachievable, but there is no one single philosophy underpinning the mandate for harm contained in the PCWP assessment. There is no one unified approach to unraveling the concept of preconception harm. Rather, subjectivity and individualistic presupposition are key features of the current PCWP framework mandating a genetic harm threshold. Second, and more importantly, this calls into question the restriction set out in section 13 (9) given that it unjustifiably restricts preferential embryo selection based on a nebulous concept of harm.

6.6 A CHOICE BETWEEN DIFFERENT LIVES?

It is important to be clear about what we are deciding when we use PGD to choose between embryos for implantation. We are not choosing to bring to birth one individual either with or without impairment but we are choosing which, of a number of possible lives, to bring into existence. Of course, with PGD there is a sense in which harm can be avoided in rare cases where lives are likely to be completely dominated by overwhelming suffering and deemed to be ‘unworthwhile’ lives. These cases represent the type of serious harm that should, where possible, be avoided. But in reality these cases are fortunately rare and the more frequent decisions being made regarding embryo selection are perhaps not as straightforward. The practical process of selecting between embryos presents three stark alternative scenarios resulting from the process of PGD:

1. whether the embryo becomes a child born with a genetic condition or abnormality;
2. whether it is never born at all; or
3. whether a different child is born without a genetic condition.

In a practical sense it is a relatively uncomplicated set of scenarios and a preference to implant an unaffected embryo over an affected embryo is one that many of us would have. However, it is quite another thing to say that this is clearly the morally preferable course of action, or even that this is the course of action that must be legally enforced. To take this further step, which inevitably interferes with the procreative autonomy of those accessing PGD, we must have a justification over and above preference or intuition included in public policy promulgated by the HFEA.535

Providing this justification has proved problematic, partly because the concept of preventing harm to someone that does not exist is very difficult to grasp and evaluate. This introduces the concept of ‘impersonal harm’; harm where there is no definite person to whom harm can be assigned. But understanding this concept has to be achieved if a principle of harm prevention guides the law and allows the state to intervene in reproductive choice. The overarching question we have to ask ourselves is: where is the identifiable harm? In other words, in the absence of evidence of harm, the burden of proof should reside with those restricting reproductive decisions. While it is conceded that the law regulating PGD is not just about setting out moral rules given that the law in a broader sense is a large scale political instrument, it is concerned with allowing for reproductive possibilities within the confines of justifiable policies. The issue here is that the law is framed and constructed in terms of pre-conception harm and this, it is argued, is an unjustifiable intrusion given the weak basis upon which it hinges. That means any speculation about the welfare of a theoretical child is an uncertain basis for reproductive restrictions and, in reality, is perhaps more revealing of an ideological objection to some individuals’ motives for procreative choices.536

6.7 WHAT COUNTS AS HARM?

An important philosophical literature has explored the principle of harm. It was first articulated in John Stuart Mill’s influential maxim in On Liberty which said that:

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535 It is noted that one justification for state intervention in the context of assisted reproduction is the involvement of a third party and questions whether individuals have a right to reproduce. This involves the notion of positive and negative rights which are not discussed at length in this article. See, HCSTC, op. cit, n.304 at para 35.
536 Pennings, op. cit Ethics of PGD, n.396.
The object of this Essay is to assert one very simple principle...that principle is, that
the sole end for which mankind are warranted, individually or collectively, in
interfering with the liberty of action of any kind of their number, is self-protection.
The only purpose for which power can be rightfully exercised over any member of a
civilised community, against his will, is to prevent harm to others.\textsuperscript{537}

On its face, when applied to ARTs, a Millian libertarian harm principle maximises freedom
and individual reproductive choice. There must be a presumption in favour of liberty in the
Millian sense. But what must not be forgotten is that liberty in this Millian sense relates to an
extant “human being(s) in the maturity of their faculties. We are not speaking of children or
young persons below the age which the law may fix as that of manhood or womanhood”.\textsuperscript{538}

Mill was a utilitarian and his harm principle was focused on maximising utility. This means
that the welfare, preferences and interests of conscious beings are the only things that matter.
It does not relate to an embryo which is, in strict terms, the theoretical child contained in the
statutory PCWP. Thus, it fails to convincingly justify the imposition of the selection
restriction set out in section 13 (9). Logically there can be no such thing as impersonal harm
as things that are not persons or conscious beings do not have welfare interests that can be set
back. Mill’s harm principle requires perceptible evidence of harm in order to justify a
restriction, which means a deeper analysis of what constitutes ‘harm to others’ is required to
consider whether it is applicable in the pre-conception context. Discerning a tangible harm to
a theoretical child – whether physical or psychosocial - is far from self-evident and is
demonstrably illogical on even a cursory examination of the concept. Sheila McLean, who
acknowledges her libertarian views on reproductive choice are largely influenced by Mill,\textsuperscript{539}
has argued “the embryo is not an “other” it cannot be harmed, and the child it may become
will generally not be harmed by the fact of being born”.\textsuperscript{540} It is therefore argued that, while a
Millian approach to interpreting harm might be favourable to society as a whole; it lacks
practical logic when attempts are made to connect it to children who do not exist.

\textsuperscript{537} David Bromwich and George Kateb. \textit{On Liberty (Rethinking the Western Tradition): John Stuart Mill} (Yale
\textsuperscript{538} Ibid, 81.
\textsuperscript{539} Sheila A. M. McLean. \textit{Modern Dilemmas Choosing Children} (Edinburgh: Capercaillie Books 2006) 211.
\textsuperscript{540} Ibid, 219.
The principle of non-maleficence – which asserts not inflicting harm intentionally – is a key precept of medical ethics and often invoked in debate regarding medical decision-making.\textsuperscript{541} As implied in the Hippocratic Oath, the principle to ‘do no harm’ alludes to the common practice of doctors and resonates with our moral norms. But the ethical stakes involved in embryo selection - as regards a doctor’s compliance with the principle of non-maleficence in PGD cases – more neatly relates to their role as the treating physician. This entails balancing the patient’s rights, the welfare interests for an unborn child and the effects such treatments could have on society as a whole. Thus, the principle of non-maleficence is not solely focused on PCWP considerations and in practical terms its reach is broader. Doctors are equally prohibited in permitting preferential embryo selection which would fall foul of section 13 (9), irrespective of their own medical judgement regarding an individual’s preferred choice on embryo selection.

The attempt to justify our intuitions in this area has generated a great deal of complex philosophical argument surrounding the preconceived child, most notably in the work of Derek Parfit.\textsuperscript{542} The problem that Parfit attempted (but failed) to solve is this. We know that if we are choosing between which embryos to implant, or whether to assist an individual or couple to procreate, we are choosing whether this particular individual who will result from this action should be brought to birth. We also know that in all but the very extreme cases\textsuperscript{543} those people brought to birth with suboptimal circumstances, with disabilities like deafness,\textsuperscript{544} or with genetic conditions that are life affecting to a lesser extent than extreme cases, can lead relatively normal lives.\textsuperscript{545} Children born to parents some might consider less than ideal parents - perhaps older, single, with mental health issues or learning difficulties for example - are probably as likely as anyone else to have a life that they value and consider to be worthwhile. As a result, it is very difficult to marry the fact that allowing a deaf child to be born or a child to be born to an older mother,\textsuperscript{546} for instance (where the child has the only

\textsuperscript{541} Tom Beauchamp and James Childress. \textit{Principles of Biomedical Ethics} (New York: Oxford University Press 2008).
\textsuperscript{542} Parfit, op. cit, \textit{Reasons} n.190; Gavaghan, op. cit, n.190.
\textsuperscript{543} Tay-Sachs disease is a rare recessive genetic disorder that progressively destroys nerve cells in the brain and spinal cord. It often leads to infantile death. A further example is Sanfilippo Syndrome, a rare genetic condition that causes fatal brain damage and often causes childhood premature death.
\textsuperscript{545} Turner syndrome is a chromosomal genetic disorder which affects only females. There are a range of symptoms including under developed ovaries and shorter than average height. There is no cure for Turner syndrome but most of the characteristics are treatable.
\textsuperscript{546} Brazier, op. cit \textit{Liberty}, n.296.
chance at life she can have with the circumstances that she has, and most likely a life she values), with the intuition that to allow these individuals to be born is morally problematic or wrong and should be legislated against. If we allow a ‘deaf’ embryo to be implanted, for instance, that child will be born in the only state she could be born in, and is likely to value her life as much as any of us. Choosing a different embryo to implant will not improve anyone’s welfare but just enable a different child, who is likely to value her life too, to be brought to birth. Thus, while we might feel that it is wrong to implant the impaired embryo, as this action harms no-one and creates a life of value, it is difficult to understand on what basis this action is wrong rather than simply counter-intuitive for many.

Parfit called this conundrum the ‘Non-Identity problem’: while we intuitively feel that the right thing to do is to choose the unimpaired life, it is difficult to understand why to do otherwise is wrong or where the harm of doing so might lie. The argument rests on the notion that being alive and living a worthwhile life is a good thing. Given the majority of lives would be considered to be worthwhile - even the lives of people born with genetic conditions, disabilities or impairments – then those people benefit from existing. As Parfit explains, “where a child could not have existed otherwise than in his suboptimal state…he has not been harmed by being born in his damaged state”. This approach utilises a counterfactual definition of harm, which implies that provided a child would have a worthwhile life, an impaired child is not harmed by being brought into existence in their impaired state because that is the only condition they could have existed in. If followed, this means that regardless of the motivations of the prospective parents to select an embryo affected by a genetic condition or abnormality, or the decision to leave selection between unaffected and affected embryos to chance, harm cannot be said to have been inflicted upon a child by bringing it into existence in the only condition it could have ever been born into and existed in.

Thus, it has been suggested that the act of embryo selection in either scenario, or leaving selection to chance, is not a morally wrong act and the philosophical shortcomings of the PCWP – which provides the moral justification for the legislative restrictions on embryo

547 Parfit, op. cit Reasons, n.190.
549 Parfit, op. cit Reasons, n.190 at 359.
selection - are then revealed. The argument is that there is no justification for the notion of selecting the ‘best’ lives to bring to birth; it is supported by preference and intuition that simply fails to validate it. If we accept this argument, then the restriction imposed by section 13 (9) on reproductive autonomy is difficult to defend, as it enforces a moral obligation that has no clear justification. Albeit it is accepted that there is not an absolute right to procreative autonomy given that some women are still unable to conceive even with the assistance of ARTs. Sally Sheldon and Stephen Wilkinson deal with the philosophical response to the PCWP considerations involved in selecting an embryo by clarifying “we are not choosing to make one determinate future person better (or worse off). Rather we are choosing to create one person rather than a different person”. While they do not explicitly object to PCWP considerations, they do highlight that it is “almost impossible to construct a child welfare argument against creating a child whose welfare is under consideration”. Their argument raises very practical problems regarding the construction of a pre-conception harm and welfare assessment: not only does it involve incomparable notions of harm but it demands a broad speculation of aggregate welfare according to the HFEA criterion.

A common argument which does support selective reproduction (save for the exception of a life deemed not worth living) is based on Joel Feinberg’s concept of harm in wrongful life cases, which demands a counterfactual test. Feinberg addressed the notion of harm where the assessment involved an existing child living with a form of disability as a result of injury or negligence. He questioned whether a child is harmed if she is caused to be worse off than she otherwise would have been had there been no injury. It relies on Parfit’s non-identity problem and states that if harmed existence is accepted as better than non-existence, existence cannot harm the child who is born because the alternative is not a different life but non-existence. In this sense rationality is stretched beyond breaking point because the comparison is between the impaired state and non-existence. Herein lies the crucial point: the purpose and timing of the harm evaluation in the context of the PCWP and PGD regulation is entirely different to this counterfactual test; it arises prior to conception during the PCWP assessment.

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550 Bennett, op. cit, Intuition n.527.
551 Wall J noted in Evans v United Kingdom [2003] EWHC 2161 (Fam) at 263 “The right to found a family through IVF can only, put at its highest, amount to a right to have IVF treatment. Self-evidently, it cannot be a right to be treated successfully”.
552 Sheldon and Wilkinson, op. cit Hashmi, n.215.
553 Ibid, 152.
If you were to ignore the fundamental difference between notions of harm – for the born child and the embryo – the result is that outlined by David Benatar:

[T]he problem is that a number of people have employed the present life sense and applied it to future-life cases, which are quite different. When they distinguish between impairments that make a life not worth living and impairments that, though severe, are not so bad as to make life not worth living, they are making the judgements in the present-life cases… In this way we are led to make judgements about future life cases by the standards of present-life cases.555

Benatar’s argument makes practical sense. Comparing existence with non-existence is, strictly speaking, an impossible task. Moreover, drawing hypothetical analogies of harm based on present-life cases and future-life cases does not provide a reasonable justification for the prohibition on preference selection. If it cannot be proved that there is a real risk of serious harm to anyone the PCWP cannot be said to be violated and the restriction on reproductive choice is unjustifiable. Thus, it can be argued that the harm threshold assessment mandated by the PCWP is an unduly burdensome model of regulation given that it disproportionately favours the welfare of the theoretical child over the reproductive freedoms of individuals.

Interestingly, Benatar also argues that all reproduction creates avoidable harm and thus should be avoided. He advocates an anti-natalist view on procreation which is bound up in concepts of pain and suffering involved in living. It is a philosophical stance that resists attributing a value to birth or living, by espousing that it is better to never come into existence at all. His theory is that being brought into existence is not a benefit, but conversely it is always a harm to exist.556 In stark contrast to Harris, who has stated “procreation is something universally acknowledged to be not only one of the most important and worthwhile of human activities”, 557 Benatar argues – somewhat extremely - that procreation is always wrong because it is inevitably a harm despite what might feel like a civic drive to reproduce. He relies on a fundamental asymmetry to determine the relative advantages and disadvantages of coming into existence558. In very simple terms, in order to evaluate whether it is better not to be born one should quantify the presence and absence of pain and pleasure

555 Benatar, op. cit, n.437 at 22-23.
556 Ibid.
557 Harris, op. cit, Welfare, n.4 at 32.
558 Benatar, op. cit, n.437 at 40-41.
in existing, broadly construed, to arrive at a conclusion that presence of pain is worse than the absence of any pleasure, and therefore, not existing is better than existing because of the harm embroiled in existence. If accepted, then this radical consequentialist view of harm leads to only one fatal conclusion: that non-life is less harmful than life. It is an extreme view which goes significantly beyond the statutory restrictions in contention here and is plainly not congruent with the global supply of ARTs. It demonstrates the extremity of an argument surrounding the same issue of harm and shows the margin of interpretation of what constitutes harm is wide. But if we believe that coming into existence is usually a good thing, as opposed to Benatar, then it seems difficult to understand why bringing to birth an impaired life but one that is valued by the person living that life is a morally unacceptable action, and one we should legislate to avoid.

If we turn back for a very moment to Feinberg’s work on the concept of harm, his other ‘open future argument’ suggests that a child possesses derivative rights in trust from an adult’s rights to choose their own path in society. In brief, the child’s right protects her from having important decisions determined by others before she can make them for herself. But, while it is correctly cited in discussions of issues such as vaccinating born children or genetically testing children, it is also inapplicable in the pre-conception context when considering the PCWP and theoretical problem it represents. In that sense, it serves to highlight the very problem Benatar articulates regarding the crucial difference between present-life cases and future-life cases. Because being born with a genetic condition or abnormality is a condition relevant to that individual person’s existence, it does not affect that individual’s right to an open future within the parameters of their genetic limitations.

Having now outlined a selection of eminent philosophical interpretations of the concept of harm and having applied these in the context of the PCWP assessment of genetic harm, I will now turn to consider the act of embryo selection and question whether the genetic harm threshold and the statutory restriction on preferential selection actually determine whether the best embryo – if there is such a thing - is selected.

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6.8 SELECTING THE BEST?

While there have been attempts to justify the notion that there is a moral obligation to choose to bring to birth the ‘best’ child possible these attempts have, thus far, failed to provide the robust justification needed. The main difficulty lies again in identifying the harm that is caused by a choice to bring to birth a child who we think may not have as good a life an another alternative child. Those suggesting we have an obligation to produce the best children possible draw on Mill’s harm principle of preventing harm to others, but the problem is that the harm principle fails to convincingly justify the imposition of section 13 (9) restrictions in this context if we cannot identify the harm done to an individual. Parfit, Savulescu and John Harris have attempted to identify the harm that is done by a choice to bring to birth an impaired rather than an unimpaired life. Parfit spoke of the possibility of bad acts being bad because they are cumulatively bad in terms of life quality. He articulates a ‘No-difference view’ which relies on total utilitarianism and states the best outcome is the one which results in the greatest quality of the factors that make a life worth living. Harris argued that being “born with any impairment that one could have a rational preference to be born without” is to be harmed. Although he later conceded there are morally good reasons to procreate provided the “lives are predictably well worth living” Savulescu has argued for two principles: procreative beneficence and reproductive autonomy. As regards genetic testing he argues that, “couples should employ genetic tests to have a child… who will have the best opportunity of the best life”. Furthermore, that people should be “free to do what others disapprove of or judge wrong, provided the exercise of freedom does not harm others”. Crucially, though, Savulescu does not argue that choosing a child other than the best possible child, even if the chosen child is born with a condition, would harm the selected child because that is the only child who could exist in that situation. He accepts any deviation in reproductive choice would result in a different child existing. But the problematic part of his argument, and the troubling endorsement of the restriction set out in

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560 Parfit, op cit, Reasons n.190; Harris, op. cit Concept of Disability, n.396.
561 Bromwich and Kateb, op. cit, n.537.
562 Parfit, op cit Reasons, n.190 at 367 -387.
563 Harris and Bennett, op. cit Lives Not Worth living?, n.179.
565 Savulescu, op. cit Deaf lesbians, n.396 at 771.
566 Ibid.
567 The caveat to this position is when the condition is so serious that it would be better to not exist.
section 13 (9) (which when strictly interpreted is contrary to the reproductive freedom he inspires), is that he suggests circumstances may arise in which it would be reasonable and justified to say it is wrong to have a particular child.\(^{568}\) This raises the same important point about what the restriction in section 13 (9) implies regarding what is reproductively responsible decision-making according to the PCWP framework for avoiding pre-conception harm.

Thus, avoiding the creation of worthwhile but impaired lives, lives that may be viewed as suboptimal but valued by those who live them, does not seem to avoid harm to any identifiable individual. That individual has a life she values and could not be born without the impairment she has. There have been attempts to convince of a notion of harm that does not affect individuals (impersonal harm),\(^{569}\) but such a notion is not only counter-intuitive, it also lacks plausibility.\(^{570}\) Michael Parker is critical of Savulescu’s principle of procreative beneficence, arguing against the concept of the best child possible given we cannot know what the best child is.\(^{571}\) He asserts “the best possible life is not necessarily, indeed could not be, one lived by a person with no flaws of character or of biology”.\(^{572}\) Further, that Savulescu’s account is underdetermining, paradoxical and self-defeating because “it does not consider the social embeddedness of the concept of the good life and related concepts, and ignores the political dimensions of reproductive choice and of reproductive ethics”.\(^{573}\) What Parker helps us to grasp is that it is not possible to rank embryos according to genetic determination and no one is harmed if an impaired but valuable life embryo is selected or if a different embryo is chosen. This is because the concept of ‘the best child’ is uncertain and includes the possibility that the best child might be the impaired child.

Rebecca Bennett also criticises Harris and Savulescu for alluding “to this notion of impersonal harm in their work, albeit in a superficial and fleeting way”, by arguing that:

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569 Parfit, op. cit *Reasons*, n.190; Harris, op. cit *One principle*, n.525 at 27; Jonathon Glover. *Future People, Disability, and Screening*. In Peter Laslett and James Fishkin (eds) *Justice Between the Age Groups and Generations* (New Haven: Yale University Press 1992); Savulescu and Kahane, op. cit, n.525.
571 Parker, op cit, *Best Child*, n.188.
572 Ibid, 281.
573 Ibid, 283.
[t]he very intuitions that attract us to this possible explanation also repel us from this explanation. Intuitively we find it difficult to understand how something can be wrong when it doesn’t affect the welfare of individuals. Do we really care about benefit or harm that doesn’t benefit or harm anyone?\textsuperscript{574}

Bennett, a staunch opponent of Savulescu’s principle of procreative beneficence,\textsuperscript{575} asserts that the principle’s theoretical foundation – which relies on the notion of impersonal harm – is an illegitimate and indefensible eugenic vision.\textsuperscript{576} She states “[I]f it is true that no particular person is harmed by a choice…then this choice is outside the realms of morality; it is a morally neutral choice, a preference”.\textsuperscript{577} Peter Herissone-Kelly disagrees with Bennett’s thesis by claiming a “non-person affecting wrong…is no more than giving a voice to a mere preference that the world be a certain way”.\textsuperscript{578} He suggests it is better “to jettison talk of impersonal harm altogether, and to cut ourselves free of the lingering suspicion, enshrined in that talk, that all wrong must involve harm”.\textsuperscript{579} Speaking plainly, he unconvincingly attempts to advance a position of compromise by rearticulating procreative beneficence and downplaying it as a ‘mere preference’ as opposed to upholding Savulescu’s duty. In attempting to rationalise the concept of impersonal harm altogether, Jonathon Glover conceded that although many find the idea counterintuitive – for “it is a natural progression to think that for an action to be right or wrong someone must be better or worse because of it”\textsuperscript{580} – nevertheless he asserts the notion of impersonal harm is required for plausibility in reproductive ethics.

What Bennett and Glover combined help us to understand is that genetic determination is harmless, no child born after PGD could have a legitimate complaint because save for the choice made to bring them to birth they would not exist in an alternative life. The diversity of preferences, the subjectivity involved in the decision-making process, the wide range of social influences and belief systems, all demonstrate that the concept of harm mandated by the PCWP is deeply paradoxical. The important point is that section 13 (9) denies individuals reproductive choice based on counter-intuitive notions of harm that does not affect

\textsuperscript{574} Ibid, 441.
\textsuperscript{575} Savulescu, op. cit, Procreative Beneficence n.200; Savulescu and Kahane, op. cit, n.525.
\textsuperscript{576} Bennett, op. cit, Intuition n.527.
\textsuperscript{577} Ibid, 269.
\textsuperscript{578} Peter Herissone-Kelly. ‘Wrong, preferences, and the selection of children: a critique of Rebecca Bennett’s argument against the principle of procreative beneficence’ (2012) Bioethics 26:8, at 448.
\textsuperscript{579} Ibid, 450.
\textsuperscript{580} Glover, op. cit Future People, n.570 at 443.
individuals. It is argued therefore, in the absence of robust reasoning and when weighed against more tangible harms to reproductive freedoms, the burden of proof rests with the legislature to validate the imposition of the PCWP and section 13 (9).

My analysis of the concept of harm in the previous sections had one central aim: to demonstrate that harm that is done without there being an identifiable person to whom it is done is an impossible concept to reconcile in regulation. It is impossible to determine, to agree upon and to discern the impact of harm on potential future people even twenty years from now. It is also important to note that even if we do accept that there is something that we call impersonal harm that is caused by making a choice to create an impaired rather than unimpaired child, and then it is something which would impact at a population level rather than an individual level. In reality, very few cases would be affected if the legislative restrictions in section 13 (9) and the PCWP harm threshold were to be abolished. While it might make intuitive sense to say that we have a moral imperative to create future generations who have unimpaired and ‘better’ lives, there is less sense to be made of the notion that allowing a woman to bring to birth a child with an impaired but worthwhile life has failed in her reproductive responsibility, or has caused any harm to an individual or decreased the worth of the population as a whole.

Without a clear sense of why it might be morally wrong to choose to bring to birth an impaired child or a genetically healthy child perhaps to what are considered to be less than ideal parents, it is unsatisfactory that the law and regulation of PGD has the power to frustrate the strongly held reproductive choices of some individuals on the basis of the preferences or intuitions held by (some) others. Utilitarianism is not necessarily a foundation of morality and the lack of something clearly wrong which legislation can hang on is problematic. The legal position should not be one where consideration of deregulating the PCWP and section 13 (9) only occurs where good reason is found. The opposite should be true; the state should not impose a totalitarian principle in the law without good reason to curtail reproductive choice. If we accept that Benatar is wrong and procreation is generally not a bad thing – as long as worthwhile lives are created, no one is harmed by it and it is good for human flourishing - then it inherently involves a fundamental right to procreative autonomy. This leads to the intractable problem of whether individuals have the right to reproduce and of course, if that right exists, what it includes. Whether it entails unlimited access to ARTs, unlimited attempts at IVF, or immediate access to surrogacy or adoption in the event of failure, is outside of the scope of this article. But what is clear as a result of this ethical
examination of legally constructed harm in a preconception context, is that finding reasons to justify the current use of the PCWP in the regulation of PGD is problematic.

6.9 CONCLUSION

The way in which the law applies the PCWP in unison with PGD regulation imposes a major intrusion into the reproductive autonomy of prospective parents. In order to diminish or interfere with such fundamental reproductive liberties, the state must show sufficient and justifiable reasons for the intrusion. To an extent, given that there is no statutory definition of preconception child welfare or any legislative elaboration on preconception harm in PGD regulation, my attempt here to examine the ethical underpinnings of the principle and the concept of pre-conception harm was dialectical. I argue that the restrictions and interference flowing from section 13 (5) and (9) are unsupported in the current framework and, more equally, the statutory provisions fail to provide any ethical reason for the limitations and restrictions that they impose on reproductive choice. There is little, if any, conceptual clarity underpinning the statutory PCWP and, while the notion of the principle may be intuitively appealing, it does not stand up to scrutiny. Writing in 1999, Margaret Brazier argued that “[B]ritish law…displays contradictions, no single, coherent, philosophy underpins the law’s response to reproductive medicine”. That statement, I claim, still resonates strongly today. The PCWP is paradoxical: it does not provide any justifiable sense of what harm is caused or prevented if certain reproductive choices are made or not in terms of embryo selection.

Once the misconception of the PCWP is revealed, the implications of its strength in practice become more troubling. As section 13 (9) governs the use of PGD and the process of embryo selection, it erodes the procreative autonomy of people receiving treatment in the absence of any justifiable reason, which is difficult to accept. What is more, the fact that section 13 (9) is not entirely prohibitive and allows for selection of an affected embryo when no other genetically unaffected embryos are available reinforces the argument against the notion of impersonal harm justifying the imposition of PCWP considerations. The truth is that the current regulatory framework is based only on preference and intuition. There is no identifiable and convincing argument to substantiate the current restrictive legislative approach to embryo de-selection following PGD. Hypothetically speaking, it is true that without such a restriction some choices which could be exercised by prospective parents may

feel unpalatable; but the vague engagement of section 13 (5) purporting to protect or promote a theoretical child’s welfare on the basis of harm prevention does not amount to a morally relevant consideration, or one which is able to convincingly justify the imposition of restrictions. This is not to say that there are no valid reasons for imposing some restrictions on access to treatment, but the utilisation of the PCWP in this way, in the absence of empirical evidence to support the assertions of harm, is prejudicial and unjustifiable. However disagreeable a reproductive choice may feel to some, such choices should not be prevented because of a PCWP that is vague and ethically incoherent. It is a consideration that I have claimed to be fundamentally flawed in the context of preconception cases.

Returning to the general questions posed by this article: How is the PCWP used in the regulation of ARTs? And can we justify its use in this way? I argue that the present unsatisfactory legislative position is a direct consequence of Parliament’s failure to address the concept of pre-conception harm on both occasions when the legislation was debated. Parliament simply avoided the nature or applicability of the philosophical issue. The inevitable consequence of an avoidant approach to the ethical dimensions of a PCWP has been a misunderstanding of the moral value ascribed to it. Just as critically, it has given rise to a misunderstanding of the inability to prevent pre-conception harms, which means that there is no clear sense of ethically appropriate uses of PGD and embryo selection. The sensible conclusion may well be that reached by Ackner LJ in the seminal case of *McKay* in 1982: the conundrum of existence and non-existence is impossible to reconcile in regulation. If that pragmatism is strictly followed, then reproductive freedoms would not be violated and individual’s reproductive choices to preferentially select between their embryos - regardless of genetic data - could not be legitimately or ethically refused. But of course there might be difficult cases which involve difficult decisions. In such cases legislation should optimise opportunities for prospective families while remaining mindful of ordinary best interest assessments of possible future children and the prospective parents, who are, lest we forget, important stakeholders in the process. This ideal can only be achieved if the laws regulating the PCWP and its relationship to the provisions regulating PGD are revisited and consideration given to reframing regulation. There is no plausible ethical argument to support the intrusion of the PCWP and current restrictions on the reproductive freedoms of individuals legitimately seeking access to PGD.

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582 *McKay v Essex Health Authority*, op. cit, n.225 at l.183.
583 Ibid, 1189.
The collaborative and cooperative manner of writing this paper does not lend itself to identifying the specific contributions of each author by section or word count. Each contributor has agreed an equal share of authorship of the paper, i.e. 50%.


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7.0  ABSTRACT

This paper considers the current law relating to surrogacy and re-emphasises the need for urgent reform. It starts by reflecting on how we got where we are and notes that the legal framing of surrogacy debates has forced us into the legislative and regulatory position we are now in. We argue that a review of the law regulating surrogacy should be comprehensive and we look at a potential model of regulation in the future. We suggest surrogacy regulation should be inspired by a fiduciary model recognising relationships between families, extended families and surrogate women. The model we suggest is one of mutual fiduciary obligations owed by intended parents to surrogates and vice versa, supported by pre-conception agreements reflecting such mutual duties while recognizing the overriding concern for the welfare of a child born as a result of a surrogacy arrangement. We lack space in this paper to argue for the law to give full status to legally enforceable fiduciary obligations in surrogacy. We simply contend that the concept offers a helpful model in thinking about the future for regulating surrogacy.

7.1  INTRODUCTION

This paper was first delivered by Margaret Brazier as the keynote address at the seminar which formed the basis of this special issue. As Kirsty Horsey notes in her Introduction, one of the objectives of the seminar was to press for reform of the law regulating surrogacy. Much has changed since that sunny day in May. The Law Commission's consultation on its Thirteenth Programme for law reform asks whether the Law Commission should include in that programme a review of the law relating to surrogacy. The answer in our view is ‘yes’ and the review must be comprehensive. After decades of inaction, despite calls for law reform, it seems that the chaotic state of UK law relating to surrogacy may at last be addressed. Thus the original title of this paper ‘Jam Tomorrow Will Not Do’ is (we hope) no

585 13th Programme of Law Reform, Law Commission (2016)
586 In the wake of evidence of changing attitudes to surrogacy and a highly publicised case where an arrangement broke down in a blaze of media publicity, the government commissioned a review of payments and regulation of surrogacy arrangements. The review team reported in 1998 but none of the recommendations for reform were implemented: see Surrogacy: Review for Health Ministers of Current Arrangements for Payments and Regulation Cm 4068 (1998) hereafter Surrogacy Review.
588 Lewis Carroll Alice in Wonderland the White Queen declared ‘The rule is, jam tomorrow and jam yesterday - but never jam today’.

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longer apt. ‘Jam’, that is to say proposals for reform with a reasonable chance of success, may be on its way.

Other papers in this collection address many aspects of surrogacy and set out the authors’ proposals for law reform. In our paper, we first re-iterate why comprehensive reform of the law relating to surrogacy is so urgently needed to protect the well-being of children born as a result of surrogacy arrangements, and reflect about how and why we reached this current impasse on surrogacy. We then note how the legal framing of surrogacy debates has created problems of its own and suggest ways of thinking about surrogacy inspired by a fiduciary model representing a relationship between families, new ways of creating and recognising extended families, rather than a commercial model of babies for sale grown in carriers who happen to be women. Intended parents, couples and individuals seek surrogacy arrangements because they passionately wish to found a family. Most women who choose to become surrogates do so because they have a strong desire to help others found their own family.\(^{589}\)

### 7.2 THE NEED FOR REFORM NOW\(^{590}\)

One objection to embarking on what will be a complex and costly review of surrogacy laws might be that even at the most expansive estimate of the number of surrogacy arrangements, that number, and thus the number of children born of surrogacy, is relatively small.\(^{591}\) The bald number of children at risk should not matter when the potential consequences for children (and their parents, genetic, gestational, social or psychological)\(^{592}\) may be dire. A response to calls for law reform that simply asserted that only a few children faced risk of harm would be swiftly attacked.

Imagine this scenario:

Twins are born in the UK to an unmarried couple, Ana and Ben. Ana is from the Ukraine and a student in the UK. Ben is a refugee from Somalia. Ana dies in a road accident on the way home from hospital. Ben is unable to cope with grief and two new born babies. The infants

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\(^{591}\) Ibid; another factor to consider is the cost in terms of legal fees and court time of the sheer number of cases now heard in the Family Division.

\(^{592}\) *Re G* [2006] UKHL 43 at 32-37 (Lady Hale), op. cit, n.99.
look dirty and malnourished. Neighbours become concerned. Social services tell them they should contact the Ukrainian and Somalian embassies. ‘Foreign babies’ are not their concern. The Ukrainian embassy replies that unmarried women do not transmit Ukrainian nationality to their children. The Somalian embassy says that Ben has forfeited his citizenship and bars Ben’s sister from coming over to the UK to help Ben care for the twins. Ana’s brother is also refused a visa to come to help.

The twins’ fate is raised in Parliament. Ministers express regret, pointing out this is an unusual case involving only two babies. The case will be carefully examined in due time.

Of course no local authority social services department would simply leave two infants physically in the jurisdiction to starve to death. Something will be done about the immediate risks to the babies whatever their nationality. The media would have a field day if a Minister responded ‘only two babies’ were abandoned by the state – the fact that it was only two babies at risk would cut little ice.

The risks to children arising from the inadequacy of UK law in relation to surrogacy arrangements are not as stark as the risks to our hypothetical twins. There are nonetheless significant risks to the well-being of children when surrogacy arrangements go awry, often but not always arrangements with a foreign aspect. The complex and inadequate state of the law (or a toxic mix of UK and foreign laws) may mean that a baby (or babies) risks to quote Hedley J, being ‘marooned stateless and parentless’ and, were the letter of the law to be applied, babies could not be united with the parent or parents who sought their birth. In rare cases wholly unsuitable arrangements create chaos on breakdown and may involve outright fraud.

In relation to overseas surrogacy arrangements, judges are regularly asked to approve a parental order in cases involving the exchange of sums of money which are hard to see as even generous expenses. While UK law makes it a condition of the grant of a parental order that only reasonable expenses may be paid to the surrogate, many foreign jurisdictions allow surrogates to be paid for their services and to make a profit on the arrangement. Time and again judges are asked to approve payments already made to the foreign surrogate of the

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593 *Re X and Y (Children) (Parental Order: Foreign Surrogacy)* [2008] EWHC 3030 (Fam), 10.
594 *R v Pollard*, Bristol Crown Court (June 2014); also see *Re A v X* [2016] EWFC 34 for an illustration of the problems encountered with Facebook and social-media.
equivalent of £15,000 and more. The payment may well be in addition to a payment to a foreign agency and the agreement to make the payment may be framed in such a way that if interpreted literally, it cannot be seen as other than a straight deal to pay the surrogate for handing over the child.\footnote{596}{Re X and Y, op. cit, n.593 at 16.} If the letter of UK law were followed, the intended parents would be denied a parental order and might be unable to acquire the status of the child’s legal parents.\footnote{597}{Note that the payment may also in theory preclude the couple from adopting the child; see section 95 of the Adoption Act 2002; see C v S 1996 SLT 1387.}

Different laws governing legal parenthood at birth often mean that while UK law regards the birth mother and her husband as the legal parents at birth whose consent is needed for the parental order, the foreign law confers parental status on the intended parents. When the child is born abroad to a Ukrainian mother and her husband that child will not have UK nationality nor any right to enter this sceptre’d isle.\footnote{598}{Re K (Minors) [2010] EWHC 1180 Fam.} With some help from the Borders Agency judges find ways of settling the infant with the parents who sought his existence. In many of these cases, absent judicial creativity, children might languish in orphanages overseas. It is unsurprising that the judges have for many years called for Parliament to intervene. Nearly a decade ago in Re X and Y (Children) (Parental Order: Surrogacy),\footnote{599}{Re X and Y, op. cit, n.593.} a married couple domiciled in England entered into a surrogacy arrangement with a married Ukrainian woman. She had been implanted with embryos derived from donor eggs fertilised by the husband’s sperm and gave birth to twins. Under Ukrainian law once the twins had been handed over to the intended parents, the woman had no parental rights or duties to the children and the children had no right to Ukrainian nationality or rights of residence in Ukraine. As far as Ukrainian law was concerned the intended parents were for all purposes the legal parents of the twins. Under UK law, the surrogate and her husband were the legal parents and the twins had no claim to British nationality. The children were at the time of the application for a parental order ‘effectively legal orphans’ and stateless.\footnote{600}{Ibid, 9.} As was to happen many times in later cases, Hedley J exercised judicial ingenuity to enable him to secure the welfare of the children in granting a parental order to the British couple. He commented fairly mildly that the government had ‘indicated that it was minded to review the law and regulation of surrogacy. It is no part of the court’s function to express views on that save perhaps to
observe that some of the issues thrown up in this case may highlight the wisdom of holding such a review.’ Moylan J was more forthright in 2014:

There is in my view a compelling need for a uniform system of regulation to be created by an international instrument in order to make available an appropriate structure in respect of what can only be described as the surrogacy market.  

Problems with surrogacy posing risks to the well-being of the child are not limited to overseas surrogacy arrangements. Consider Re N (a Child). P agreed to carry a child for a married couple, SJ and TR. She underwent artificial insemination with the husband’s sperm. She became pregnant but later told the couple untruthfully that she had miscarried. She gave birth to and kept the child, N. The couple later discovered the fraud and when N was eighteen months old the Court of Appeal upheld the decision by Coleridge J that N’s biological father, SJ should be granted a residence order. It further emerged that some years earlier P had practiced a similar deceit on another couple. It was agreed that the child C, now nearly six, should remain with P and her husband but at some later time should be told about her genetic paternity. To put it at its lowest, C experienced the loss of her sibling and at some stage must come to terms with her mother’s extraordinary behaviour.

Data on surrogacy is thin. A number of arrangements take place ‘beneath the radar’ - with no formal legal process at all. The dangers of such informality are illustrated by JP v LP and others. A married couple agreed with a friend that she would act as a surrogate. She became pregnant after self-insemination with the husband’s sperm. No attempt was made by the couple to apply for a parental order and some months after the birth the marriage broke down and the wife JP left the couple’s home. JP absent a parental order had no claim to legal parenthood although she was the child’s primary carer. The surrogate was the legal mother and the husband the legal father. After years of legal wrangling Eleanor King J made the child a ward of court and granted the former couple a joint residence order. This order gave JP parental responsibility. The surrogate remained the legal mother also enjoying parental

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601 Ibid, 29.
602 Re D (A child) (Surrogacy) [2014] EWHC 2121 Fam [1].
603 [2007] EWCA Civ 1053.
605 [2014] EWHC 595 (Fam); Also see: Re A v X [2016] EWFC 34
responsibility though forbidden by court order from any attempt to exercise parental responsibility without the leave of the court. Eleanor King J warned of:

[T]he real dangers that can arise as a consequence of private ‘partial’ surrogacy arrangements where assistance is not sought at a licensed fertility clinic (or indeed of full surrogacy arrangements where the child is born abroad). At a licensed clinic consideration will be given to the welfare of a child born as a result of a surrogacy arrangement and counselling services will be provided to the parties which will include the provision of information about the likely repercussions of a surrogacy arrangement and the importance of obtaining a parental order.  

Agreeing ‘something must be done’ is easy. Determining what can and should be done is harder and the difficulty of formulating sensible proposals for law reform helps explain why successive governments have turned a deaf ear to judicial and other calls for reform of the law and left the mess for judges to sort out case by case.

The challenge for those working to change the law is to create a framework that will incentivise better practice and reduce the hard cases which now beset the courts ensuring the best possible outcome for the children of surrogacy and their families. No framework will be perfect. Even if within the UK we create a system of regulation that makes home-grown surrogacy the most attractive option to most intended parents and potential surrogates, some will still resort to access abroad or informal ‘under the radar’ arrangements. Regulation may be off-putting to some people seeking surrogacy and an incentive to avoid domestic regulation. That is why ideally a solution to the problems of surrogacy law should be international.

7.3 BACK TO BASICS

We need to start by going back to the beginning. In 1984, the Warnock Committee noted that surrogacy presented them with ‘some of the most difficult questions we encountered’.  

Public opinion was sharply divided on many of the other issues addressed by the Committee. In relation to surrogacy the Committee found that that there were ‘strongly held objections to

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606 JP v LP, op. cit, n.605 at 39.
607 Surrogacy Review, op. cit, n.586.
609 Warnock Report, op. cit, n.24 at 8.17.
the concept of surrogacy, and it seems from the weight of evidence submitted to us that public opinion is against the practice.\textsuperscript{610} The Committee proposed measures designed to discourage surrogacy. At the time the Chair of the Committee, then Dame Mary Warnock, joined the majority of the Committee in rejecting the minority view that surrogacy should be regulated by an official agency which would oversee and approve surrogacy arrangements and facilitate the handover of the child. Baroness Warnock later changed her mind.\textsuperscript{611} In 1984, however, when the Warnock Committee published its Report, opposition to laws facilitating surrogacy was, as the Committee found, fairly widespread. In 1978 in \textit{A v C}, the first surrogacy case to come before a British court, the Lord Justices of Appeal declared surrogacy arrangements to be ‘irresponsible, bizarre and unnatural’.\textsuperscript{612}

After \textit{Warnock} and before the Human Fertilisation and Embryology Act 1990 became law, Kim Cotton gave birth to a child for an overseas couple receiving a payment of £6500 with a further £6500 paid to the agency that arranged the surrogacy. Mrs Cotton was content to hand over the child as agreed.\textsuperscript{613} Social services intervened and Latey J was entrusted with the task of determining if the couple could take custody of the baby. In a highly pragmatic judgment which was to set the precedent for later judicial interventions focusing on the welfare of the child, Latey J granted custody to the intended parents.\textsuperscript{614} The Kim Cotton case however highlighted the role of agencies and dubious practices in the USA. A picture emerged in the media of surrogacy as a crude commercial transaction. Women were seen as being lured into selling their babies. The women themselves might be vulnerable and ripe for exploitation. At the end of the process they might be forced to hand over the child against their will. Stories of variable authenticity circulated about women able to carry a child choosing to opt for surrogacy to avoid ruining their figures or damaging their careers. The emergence of aggressive US surrogacy agents (salesmen) reinforced a dystopian vision of a commercial baby market. The Warnock Committee suggested that it would be degrading for a child to be ‘bought for money’.\textsuperscript{615}

\begin{itemize}
\item \textsuperscript{610} Ibid, 8.10.
\item \textsuperscript{611} Mary Warnock, op. cit \textit{Making Babies}, n.71 at 87-93.
\item \textsuperscript{612} \textit{A v C} [1985] FLR 445 (decided in 1978 but not reported until 1985).
\item \textsuperscript{613} Kim Cotton. ‘The UK’s antiquated laws on surrogacy: a personal and professional perspective’ (2016) \textit{Journal of Medical Law and Ethics} 4.3, 229-235.
\item \textsuperscript{614} \textit{Re C (A Minor) (Wardship: Surrogacy)} [1985] FLR 846.
\item \textsuperscript{615} Warnock Report, op. cit, n.24 at 8.11.
\end{itemize}
In this climate, the Surrogacy Arrangements Act 1985 was rushed through Parliament. Payments to any third party for arranging surrogacy were banned and ‘contracts’ for surrogacy made unenforceable. More general disapproval of the practice also led the Committee to rule out any non-profit making state service. Fear of a child being born ‘tainted with criminality’ meant that while much of the Surrogacy Arrangements Act was reinforced by criminal sanctions, if an ‘illegal’ payment was made directly from the couple to the surrogate no crime was committed but the original provision in section 30 of the 1990 Act relating to parental orders set the condition that no order should be granted if the surrogate received more than reasonable expenses. Surrogacy in the UK became a kind of ‘hold your nose’ practice – not to be encouraged, but not to be banned as in France.

Surrogacy has not ‘withered on the vine’. Some of the dystopian visions of the Warnock Committee and Parliament during the passage of the 1985 Act have proved groundless. There is no evidence that wealthy career women contract out pregnancy to advance their careers or that the rich and beautiful do so to save their figures. In the UK, in successful arrangements with no overseas element, the crude commercial model of surrogacy has not materialised. In many (but by no means all) cases surrogacy is a relationship between families or enduring friends. It is this model of relationship which we argue should drive reforms of the law.

There are those who would have no objection to a regulated surrogacy (baby) market, a controlled commercial model. For those uncomfortable with such a market the irony is that the dystopian vision of a surrogacy market has come to be largely as a result of attempts to ban it. Payments are made that look excessive, children risk being ‘marooned stateless and parentless’. Poor and powerless women may well be being exploited, but not British women. A largely unregulated international market has sprung up. The objectification of surrogates defined primarily as outsourcing a womb to rent has developed in the USA. The term ‘surrogate mother’ often gives way to the notion of a ‘gestational carrier’. In this model, couples (especially but not solely gay couples) will seek woman A as an egg donor chosen for her genetic strengths of intelligence and beauty and a gestational carrier woman B is chosen perhaps for her childbearing hips and successful record in prior pregnancies. Enforceable contracts grant a high level of control to the couple or individual commissioning

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616 Surrogacy Review, op. cit, n.586 at 3.44
617 Smith, op. cit, n.589; Prosser and Gamble, op. cit Modern Surrogacy, n.70.
618 Jackson, op. cit commercial, n.608.
the pregnancy. As commercial surrogacy was practised until recently in India and Thailand, similarly egg donor and gestational carrier were separate roles. The carrier was subject to intensively monitored terms of service. Measures to minimise the chance of bonding between the surrogate and the child are put in place. In terms that we cannot better, Julie Wallbank warned intended parents ‘to be aware that they are collaborating with a woman not a womb’. Those who engage and those who manage gestational carriers on a commercial basis are, we suggest, wanting to contract with a womb rather than engage with a woman.

A dilemma emerges. Banning payments, outlawing contracts and trying to keep the lid on home grown surrogacy has given rise to the very evils we sought to rule out. Is there a way out? Should we join Lady Warnock in seeking to rethink our understanding of surrogacy and acknowledge that intended parents resorting to surrogacy in the ‘Dark Ages’ of the 1980’s got a raw deal? In those early years, the focus of debate on the emerging reproductive technologies was more one of beneficence to those unable by virtue of medical misfortune to have children rather than on autonomy or the expansion of assisted conception to those seeking alternative family structures. Moreover, the focus was principally on infertile women. IVF helped those who, like Lesley Brown, had blocked tubes, gamete donation helped couples where the man lacked viable sperm, and women who did not ovulate. Surrogacy was the only source of help for women unfortunate to have been born without a womb or lost that womb to disease, women who did not wish or were not able to adopt. In such cases the infertility was absolute; there was no chance of the woman being able to carry a child. The plight of the wombless did not render them less worthy of help especially as clinically the process of DI and partial surrogacy was so simple that medical help was not strictly necessary (with respect to the Court of Appeal in A v C, partial surrogacy is less ‘unnatural’ than most forms of assisted conception). Even full surrogacy requiring IVF is on the lower level of complexity in the spectrum of fertility treatments. Did the very fact that surrogacy is not an exclusively medicalised procedure contribute to its controversy? Having a child via partial surrogacy was something willing parties could achieve for themselves, unsanctified by the cloak of the medical ‘permission’. In 2016, as a result of developments on the internet, ‘Do-It-Yourself’ private surrogacy arrangements allow intended parents and

surrogates to avoid the regulatory regime that arises when treatment is received at a licensed centre. While there may appear to be benefits to strictly private arrangements, such are equally met with risks given the lack of clinical control for simply testing sperm to ascertain it is suitable for treatment or conducting a pre-conception assessment of prospective child welfare.

Fears of adverse consequences arising from facilitating surrogacy led the UK to ban payments and make contracts unenforceable. At this point the first named author must make a humble confession. In agreeing with the ban on payments in 1984 when Warnock reported and in 1998 when she chaired the Surrogacy Review, she was wrong and Michael Freeman was right. She has not changed her mind about the dangers of the commodification of children or in some cases women who agree to act as surrogates. ‘Commercial’ surrogacy, where acquiring a child is legally and socially conceptualised as akin to buying a high performance sports car, is not a model that fits with the value society ought to accord to children.

### 7.4 THE WELFARE OF THE CHILD

Judges struggling to avoid adverse consequences to children arising from apparent breaches of the law on expenses, or incompatible laws on parenthood at birth, or failures to take formal measures to grant parental status to one or both of the intended parents emphasise that the court’s highest priority is the ‘welfare of the child’. The Human Fertilisation and Embryology (Parental Orders) Regulations 2010 now mandate that the welfare of the child is the ‘paramount consideration’, introducing a welfare checklist which a court must take into account on every application for a parental order. As Hedley J stated in *Re X and Y*:

> [I]t is almost impossible to imagine a set of circumstances in which by the time the case comes to court, the welfare of the child...would not be gravely compromised at the very least by a refusal to make a [parental] order.

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623 Jackson, op. cit DIY, n.405 at 31 - 49.
624 Freeman, op. cit, n.587.
626 *Re X and Y*, op. cit, n.593.
627 *JP v LP*, op. cit, n.605.
630 [2008] EWHC 3030 Fam [24].
In the context of many other ARTs, section 13(5) of the Human Fertilisation and Embryology Act 1990, which required that before any licensed treatment can begin, the clinics must take account of the welfare of ‘any child who may be born as a result of the treatment’ has been roundly condemned. The modest amendment of the section in the 2008 Act that replaced the requirement to consider ‘the need for a father’ with the need of that child for ‘supportive parenting’ did little more than dilute criticisms that the provision is discriminatory. So is it right that in the context of surrogacy arrangements, the child’s welfare should be centre stage?

Section 13(5) has been attacked on several grounds. First, a principal philosophical criticism is that in most of the decisions about whether or not to offer ARTs to the patient, if treatment is refused because of the perceived risk to the welfare of an as yet hypothetical child, the choice is whether that child be born or never exist. For non-existence to be worse than existing, the potential harm to the child to be would need to be ‘serious’ while presenting a ‘significant risk’. Secondly, it entrusts decision about potential welfare to clinicians who lack the expertise, training and facilities to make such welfare judgements. Thirdly, clinics asked to address complex medical and moral considerations about a theoretical child’s welfare may well fall into dangerous realms of clinical speculation and intuitive appeal. For example, if prospective parents seek pre-implantation genetic diagnosis and tissue typing to bring about the birth of a ‘saviour sibling’, if the treatment is refused the saviour baby will never be born. Clinicians are asked to judge not just the medical prospects of treatment, but also to speculate whether the parents will be able to love and care for the saviour rather than seeing her as just the means to an end. What will be the effect be on the saviour child maybe ten or more years on if the donation of cord blood or bone marrow later fails and the elder sibling dies? Such child welfare considerations are evidently complex and fraught with ethical wrestling.

Surrogacy is different. The question is not shall this child be born, would he be better never born, but how can the law ensure that the child (any child) once born is cared for in the most favourable environment to allow him to flourish, that he is not a ‘legal orphan’, a bargaining factor between warring ‘parents’, at risk of being separated from the social mother he has

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631 Jackson, op. cit Conception, n.4; HCSTC, op. cit, n.304 at para 101.
632 For a summary of these arguments see Colin Gavaghan, op. cit Regulating after Parfit, n.190.
634 Elliston, op. cit Selecting for Disability, n.4.
bonded with. The questions about welfare are practical; surrogacy, unlike other ARTs, raises few significant medical questions, or fundamental moral questions about the nature of the embryo. Decisions about the implications and implementation of arrangements in the light of child welfare considerations will be made not by clinicians but by experienced judges, or in a reformed legal framework perhaps by a dedicated surrogacy approvals authority. In either case the decision makers will have access to skilled advice. Placing the welfare of the child at the heart of laws relating to surrogacy does not ask that we decide should this child be born at all but rather how can the law make arrangements more likely to work, how risks of breakdown can be reduced? What steps can the law legitimately take to maximise the aggregate lifetime welfare of the child born into a surrogacy arrangement? How can a new family be founded that reconciles the needs and wishes of the adult parties and the best chances to promote the well-being of the child?

UK law is muddled and contradictory. The 2010 Regulations governing parental orders require that it is the interests of the child that must take priority in regulating surrogacy. The broader legal framework governing surrogacy fails to support the good intentions of the 2010 Regulations. The difficulty in the law as it stands, the 1985 Act outlawing contracts, the conditions for the grant of a parental order banning payments and the rules defining parental status at birth, make it near to impossible for judges hearing applications for parental orders to prioritise welfare without flagrantly flouting other provisions of the law. Judicial creativity has so far found a way to avoid disastrous outcomes for children at the cost of making the law look like an ass, and because any scrutiny of the arrangement is ex post facto, sometimes preventing any substantial evaluation of the initial agreements. The historical aversion to encouraging surrogacy means that regulation to attempt to facilitate good practice in surrogacy remains absent.

7.5 RETHINKING REGULATION

We now make tentative suggestions for a conceptual framework within which reform of the law might be located if surrogacy is recognised as a legitimate means of founding families, but a model of a surrogacy market based on consumer law is rejected. Such a framework would (as argued above) place the welfare of the child at the centre of the law and also protect and honour the interests of other parties to the arrangement. We argue that the law

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635 We are unaware of the data on this aspect but we do note that albeit the risk of breakdown is small the costs of breakdown are inevitably traumatic.
should be based on a fiduciary model, seeking to endorse and protect relationships of trust between the adult parties and enforcing an obligation of trust in relation to the child. Surrogacy would become part and parcel of modern family law. Such a model would permit (though not mandate) a moderate payment to the surrogate, encourage clear agreements between the adult parties, allow accredited agencies to facilitate surrogacy\textsuperscript{636}, and make the transfer of legal parental status much simpler\textsuperscript{637}. The law should seek to make surrogacy work based on the models of good practice garnered from evidence of successful surrogacy practice in the UK today.

We first look at how the especially thorny problems illustrated in those cases where the judges have had to stretch the letter of the law near to breaking point might be addressed within a framework based on such a fiduciary model. Then we explore a little further the broader implications of such a fiduciary model.

7.6 ‘CONTRACTS’, AGREEMENTS AND PAYMENTS

Contracts and payments have been perhaps the most divisive questions besetting debates on surrogacy and hindering consensus on law reform. At first glance endorsing either seems to steer surrogacy firmly into the commercial arena. This does not need to be the case. Legal language and classifications have not helped. The word ‘contract’ invokes the picture of the market, of sale of goods and buying and selling babies with attendant legal rules about ‘satisfactory quality’ and ‘fitness for purpose’. In the international commercial surrogacy market operating in some parts of the world this picture has reality. Contracts control the surrogates’ behaviour, for example, specifying that in certain circumstances should ante-natal tests show the foetus suffers from some form of disability the pregnancy should be terminated. The vendor must hand over the ‘goods’ if the terms of the contract are met. The buyers may reject faulty goods.\textsuperscript{638}

Are contracts and a trust based model of surrogacy prioritising the welfare of the child thus incompatible?\textsuperscript{639} Not necessarily if we reflect on the language and meaning of contract in everyday language. In the common law, agreement alone does not create a legal contract. Both parties must provide consideration, something of value in return for the promise of the

\textsuperscript{636} This would include consideration of the appropriate extent to which agencies could advertise surrogacy services.

\textsuperscript{637} Discussed in detail in Alghrani and others, op. cit, \textit{Piecemeal Tweaks} n.590 at 425-453

\textsuperscript{638} Sascha Callaghan and Ainsley Newson. ‘Surrogacy, motherhood and Baby Gammy’ (2014) \textit{BioNews} 766.

\textsuperscript{639} Jackson, op. cit, \textit{Regulating Reproduction}, n.621 at 308-315.
other party. Legal contracts at common law are *bargains* so at first glance the language of contract seems to envisage surrogacy as bargaining for baby. Strip away the bargain element and focus on popular understanding of contracts as agreements (as is the case in most civil law jurisdictions) and there will be few people who would not agree that the surrogate and the intended parents should negotiate a clear agreement setting out mutually agreed expectations, what the Surrogacy Review termed a Memorandum of Understanding. The Surrogacy Review however recommended that a surrogacy agreement should not permit any payment over and above reasonable expenses. Does paying the surrogate tip the agreement over the threshold of an agreed relationship based on trust and into the jaws of the market?

Opponents of paying surrogates will say, call the contract what you will, if a surrogate is paid a greater sum than the expenses she has incurred, the intended parents are buying a baby. As Michael Freeman and many others have argued, the payment can rightly rather to be regarded as payment for the surrogate’s services, akin to paying the doctors at a fertility clinic in the private sector for their services. The payment is not for the sale of goods (babies) but for reproductive labour. The surrogate woman is paid for her services as the fertility doctor is paid for hers. A lawyer would not draft a contract without expecting an appropriate fee. The professional status of the service provider only alters the essential nature of the assistance rendered, if we regard labour done by the hands and brain of the doctor as different from the work done by the surrogate in permitting the use of her body. Perhaps the question provokes uncomfortable feelings about the intimate use of women’s bodies? Most women who struggled to feed their baby would have few qualms about the baby being fed by bottle or tube from a breast milk bank. Having another woman breast feed your child may feel uncomfortable albeit the same end is attained.

One immediate difference between the surrogate who allows her body to be used to gestate the baby and professionals who use brain and hands to create the embryo is obvious. The private patient must pay the clinic whether or not a take home baby is safely delivered. If we

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641 Freeman, op. cit, n.587.
642 Jackson, op. cit, Regulating Reproduction, n.621.
conceptualise the surrogate as a ‘human clinic’, payment would be due independently of the
transfer of the infant, just as fees must be paid to the clinic for fertility treatment even if
treatment was unsuccessful. Intended parents are unlikely to agree to pay the surrogate’s fees
if she is free to change her mind and keep the child. Framing the agreement as for services
not sale will not remove the reality that what intended parents seek is ‘their’ child. So do we
return to the scenario of a dystopian market and a woman having the child she has carried
torn from her arms, even when she may have grounds to be concerned about the welfare of
the child if she relinquishes her as agreed?

We should note that even traditional contract rules would not necessarily result in the
surrogate being obliged to comply with a contract of sale. Contracts for personal services are
not subject to specific performance.\(^\text{645}\) If you engage a nanny and your views on child care
prove irreconcilable, or he just does not like you, you cannot get an order that he continues to
work for you. There may be liability in damages for breach of contract so on traditional
contract rules the surrogate who refuses to surrender the child might be liable for the cost to
the couple of a further surrogacy arrangement. Nor is the analogy with the nanny a complete
fit. The nanny walking out causes domestic disruption but does not deprive parents of ‘their’
child.

7.7 PARENTAL STATUS AND A FIDUCIARY MODEL

And there lies the thorny question, whose child is the baby? Current UK law is clear on
maternity; at birth the child is the child of the surrogate.\(^\text{646}\) At least in relation to gestational
surrogacy arguments are advanced that the intended parents should be the legal parents of
‘their’ baby from birth.

Practical considerations offer some support for such a change. English law provides for a no
more than two parent model, the surrogate mother is the legal mother\(^\text{647}\). In the most
common case where the surrogate is part of a married heterosexual relationship her husband
is the legal father. Complex provisions govern legal fatherhood in other cases but it remains
the case that no provision is provided in law for anything other than two legal parents.\(^\text{648}\).
Intended parents can acquire parental responsibility only via a parental order, which cannot

\(^{645}\text{De Francescov Barnum (1890) 45 Ch D 430; Jackson, op. cit Regulating Reproduction, n.621 at 312.}\)
\(^{646}\text{HFE Act 2008 Part 2 section 33 (1).}\)
\(^{647}\text{Ibid, Part 2 section 35 (1).}\)
\(^{648}\text{Brazier and Cave, op. cit 6th edn Medicine, Patients and the Law, n.2 at 387-398.}\)
be applied for until the child is at least six weeks old, or via adoption. In the interim, decisions about, for example, necessary medical treatment in theory remain with the surrogate even if she has handed over the child. The child and all possible ‘parents’ exist in a legal limbo that does not square with the paramountcy of the welfare of the child in surrogacy arrangements.

We acknowledge that there are sound arguments to consider changing the law on parental status at birth in surrogacy arrangements but not on the basis of whom the child ‘belongs’ to. She ‘belongs’ to no-one in the sense we usually use that word. In another sense she ‘belongs’ to us all as do all children whose welfare in a modern state is not solely the business of parents even when there is no dispute about who those parents are.

How might a fiduciary model of surrogacy approach parental status and parental rights? Parental rights derive from parental responsibility, a responsibility usually but not always derived from biological parenthood. Where parents are dead or incapacitated, guardians act for a child and care for the child in her minority. Guardians undoubtedly owe fiduciary duties to the child. Guardianship offers another way to think about the triangular relationship between the surrogate, the child and intended parents. During her pregnancy the surrogate is de facto the ante-natal guardian of the child she carries, regardless of whose gametes created the child. She is a trustee for the welfare of the child. It will be envisaged by all parties that at birth she will surrender both the child and its guardianship and formal parental responsibility will be conferred on the intended parents. The relationship between surrogate and child cannot be extinguished at the cutting of the umbilical cord. A guardian who had grounds for serious concern about the welfare of the child she carried would have a moral obligation to take some action. A couple who regarded the surrogate as a partner in their reproductive enterprise would take care to ensure her welfare as well as the child’s, and vice versa. Each adult party is a ‘trustee’ for the well-being of the others. We envisage surrogacy as a ‘marriage’ with sometimes three or more people in it. Such a relationship will be complex at times. Different people will want different things from the relationship as do partners in a marriage. Agreement on what this relationship should entail, clarity and trust are essential.

Concepts of guardianship and trusteeship open the door to consideration of pre-conception agreements which, based on sound advice, would address the welfare of the child, the

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649 Alghrani and others, op. cit *Piecemeal Tweaks*, n.590.
agreed expectations of the adult parties and provide that the intended parents be presumed to obtain parental responsibility at birth. Pre-conception agreements might be likened pre-nuptial contracts in *Radmacher (formerly Granatino) v Granatino*.\(^{650}\) The analogy is less than perfect and we use it simply to show that agreements can carry weight while allowing for concerns about any suggestion of coercion or limited understanding on the part of any of parties or those affected by the ‘contract’ to be being given full scrutiny.

Given societal interests in child welfare, to take legal effect the agreement would require prospective scrutiny by a court or a regulatory authority.\(^{651}\) The parties to the agreement would need to demonstrate that they have addressed the matters of concern to each of them, including the relationship between the surrogate and the child and her family after birth, payments and expenses, health care provision and what might ensue in certain contingencies, for example if intended parents separate or one partner dies. The agreement must be one entered into wholly voluntarily, fully informed, with all parties having had time to reflect. The approving authority must be satisfied that the agreement meets the needs of the child.

Such an agreement would be scrutinised before conception and the intended parents granted a provisional parental order with the caveat that the surrogate has a set time, normally expiring before the birth, to register an objection relating to changed circumstances and/or risks to the child triggering a full re-hearing. In the absence of objection from the surrogate or other concerns being expressed about the welfare of the child once born, the provisional order could be simply confirmed, rather as a decree nisi becomes a decree absolute.

### 7.8 FIDUCIARY OBLIGATIONS

Once the reproductive enterprise is embarked on and pregnancy established, the relationship between surrogate and intended parents should continue to be based on a fiduciary model, one grounded in trust and utmost good faith. English courts have been reluctant to expand the legal categories of fiduciary relationships, notably in refusing to extend fiduciary relationships to the doctor/patient relationship.\(^{652}\) We lack space here to argue for the law to

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\(^{650}\) [2010] UKSC 42.


\(^{652}\) *Sidaway v Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1984] 1 All ER 1018 at 1029 (Dunn LJ) (CA); and [1985] 1 All ER 643 at 651 (Lord Scarman).
give full status to legally enforceable fiduciary obligations in surrogacy. We simply contend that the concept offers a helpful model in thinking about surrogacy.\[653\]

Classical fiduciary relationships such as trustee and beneficiary, solicitor and client, parent and child, or husband and wife require that the fiduciary acts to promote the interests of the vulnerable party in the relationship, the beneficiary, client, or child, usually in relation to the management of the latter’s property. He enjoys a position of trust and must act in utmost good faith. MacLachlin J, supporting the extension of fiduciary relationships to doctors and patients in the Canadian Supreme Court, made it clear that it is not enough to abide by the letter of the law: in making decisions about the welfare of the other party the fiduciary must act ‘to the highest standard of dealing with their patients which the trust accorded to them requires’.\[654\]

The reluctance of English judges to extend the categories of fiduciary relationships to doctors arose in part from what was perceived as dissimilarity between classical fiduciary relationships and doctor/patient relationships. Fears were also expressed that imposing a fiduciary character on doctor/patient relationships would ‘entrench the power balance’ between doctors and patients.\[655\] A model of fiduciary relationships in surrogacy arrangements is less of a departure from the established notions of fiduciary duties than their extension to doctors. Parents already owe fiduciary duties to their minor children, guardians to their wards and spouses to each other. Within surrogacy, we might argue that all candidates for legal parenthood and/or guardianship owe such a duty to the child. That duty requires that they prioritise the interests of the child in hard cases above their own interests.

From such a duty it follows that unless there are overriding concerns about the welfare of the child coming to light after an approved pre-conception agreement, the surrogate will as soon as possible hand over the child and relinquish any claim to retain ‘custody’ of the child, allowing the child to settle with and bond with the intended parents as soon as possible. Equally, however, should information come to light casting doubt on the capacity of the intended parents to care for the child, the fiduciary duty to the child requires that the surrogate (as guardian of the child) ensures those concerns are addressed. On their part

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\[653\] For a similar argument in relation to doctor/patient relationships in screening for HIV see: Margaret Brazier and Mary Lobijot. ‘Fiduciary Relationship: An Ethical Approach and a Legal Concept’ In Rebecca Bennett and Charles A. Erin HIV and AIDS: testing, screening and confidentiality (Oxford University Press 2001) 179.


intended parents have an obligation of utmost good faith that, for example, requires then to disclose any information relevant to the welfare of the child. For example if a provisional parental order is made in favour of A and B, and later A becomes aware that B’s violent temper and impatience create a risk to the child, A has a duty to disclose that information. If when the child is born, he is born with significant disabilities the intended parents nonetheless have a duty to honour the arrangement and undertake parental responsibility for her. They cannot simply walk away.

It might further be argued that a fiduciary model that imposes a duty to the child on all the adult parties means that in the above example of the birth of a disabled child, the surrogate too retains an obligation to the child that becomes highly relevant if the intended parents renege on their agreement. Such an obligation does not compel her to raise the child herself but does require that she ensure that the child is cared for. The intended parents again cannot be compelled to accept the child but their fiduciary duty demands that they provide financial support for the child should the surrogate decide that she will raise it.

Our concept of a fiduciary model for surrogacy extends beyond the extension of the established fiduciary category of parent and child to both the surrogate and the intended parents to suggesting a model of mutual fiduciary obligations owed by intended parents to surrogates and vice versa. Pre-conception agreements should reflect such mutual duties of care ensuring for example that the surrogate will be provided with all she needs for a healthy, happy pregnancy, that the parties agree on such matters as post-birth contact, and that all agree on the nature of the intended parents’ involvement with the pregnancy. Should the agreement not cover points of later dispute the mutual notion of fiduciary obligation can fill the gaps. So, for example, assume A and B enter into an arrangement with C who at the time of the arrangement plans to emigrate with her husband, and so no provision is made for contact. C’s husband dies suddenly and she and her children remain in the UK. C now wishes to retain some connection to the child and the parents. Both her welfare and that of the child should be considered, not simply the terms of the agreement.

Extending a fiduciary model to the adult parties can be supported on at least two grounds. First, as with any child the welfare of a child born as a result of a surrogacy arrangement can in practice never be wholly divorced from the welfare of the adults on whom she is dependent. The health and well-being of the surrogate during pregnancy and the parents who will care for her after birth affect the child. A constructive relationship between all the adults

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benefits the child. Second, fiduciary relationships seek to protect a vulnerable party in a relationship from misuse of power by the fiduciary. In surrogacy arrangements, both parties are vulnerable to misuse of power by the other. The risks of exploitation of surrogates are well rehearsed. Surrogates too have power to ‘exploit’ intended parents demanding more money or deceiving the intended parents about the outcome of a pregnancy.656

7.9 CONCLUSION: NO EASY TASK

Reforming UK law on surrogacy will not be easy. It may be tempting to seek a ‘quick fix’ of obvious problems. The challenge is to create a framework of laws and regulation that protects the extended family that surrogacy creates and reduces the risks of breakdown and legal wrangling. UK law should offer incentives to opt into domestic regulation and reduce the numbers who seek surrogates overseas. A fiduciary model emphasising the centrality of trust may help inform lawmakers. One question, however, we have not even asked. Is surrogacy now regarded as a responsible and legitimate way to found a family? Has evidence of how surrogacy can work dispelled the deep suspicions of the Warnock Committee? Our answer is ‘yes’, but unless there is first a clear articulation that surrogacy is acceptable, half-hearted measures may again result in hazy laws.657

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656 R v Pollard, op. cit, n.594; Re N, op. cit, n.603.
657 Horsey and Sheldon, op. cit Still hazy, n.69 at 67.
PART III

CONCLUSION
[A]ll too often crucial issues of individual rights and public policy, and issues of conflicting rights are skated over. There is little conceptual depth underpinning British law. The result is that again and again, as new medical developments emerge, we debate the same issues in different disguises…British law displays too many contradictions, no single coherent philosophy underpins the law’s response to reproductive medicine.\(^\text{658}\)

### 8.0 IN REVIEW

The ideas driving the preceding papers illustrate a novel and nuanced foundation for rethinking the legal approach to assessing the pre-conceived child’s welfare in the context of ARTs regulation. The principal argument advanced in this thesis is that the PCWP and the harm threshold it mandates should be abolished. This argument inevitably impacts on PGD regulation given the connection between the PCWP and the genetic harm threshold utilised in section 13 (9) of the HFE Act. In order to address and develop this argument I have advanced a number of critical conclusions regarding the legislative development of the PCWP, its application in practice and what I have distinguished as two distinct categories of harm based regulation that it endorses: the familial harm and genetic harm thresholds.

Although the final paper at [7.0](#) provides a different analysis of state regulation of surrogacy arrangements, in Part III it is both important and valuable to review the commonality between all of the papers provided in this work. Overall, as a collective of papers this includes the need to use non-inflammatory and transparent language in regulation; the need to divorce our thinking of child welfare considerations for the born child from the pre-conceived child; the need to disconnect the relationship between ‘welfare’ and ‘harm’; the need to acknowledge the importance of motive in determining what reproductive choices are legislated against; as well as promoting transparency, objectivity, contextual-sensitivity and consistency as the most important benchmark standards of better regulation. These combined standards provide the tools for any debate on attempting to frame future public policy in this area.

For now, I present a brief review of the structure of the thesis and the need for the arguments mentioned above.

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\(^{658}\) Brazier, op. cit Reproduction Business, n.25 at 167.
8.1 PRESENTATION OF THE THESIS

The critical conclusions I draw are largely drawn from the four papers in Part II that comprise the body of this thesis. In order to present a cogent case against the PCWP, and present a novel argument which adds to the existing literature in the field, I first had to deliver the background. Thus, in Part I, the development of the welfare principle in child law and surrogacy law was outlined and the legislative chronology of the PCWP and PBR was discussed. This entailed setting out a number of assumptions, arguments and debates surrounding the concepts of welfare and harm avoidance. Such are vital for understanding the basis on which this work challenges the suitability of the PCWP in the current regulatory framework. In that sense, Part I is key to understanding the nature of the problem. By highlighting the themes and setting out my position I was able to develop my argument moving beyond the existing literature criticising the inclusion of the PCWP in regulation. Part I specifically lays out the research questions which I set out to address in the material included in Part II and it clarifies why the questions warrant attention.

Part II of the thesis is the main body of work; it includes three peer-reviewed papers as they were accepted for publication and one paper which is currently undergoing peer-review. Two of the papers available at the time of submission can be found in their published forms in the Appendix. The overall aim of Part II is to present the central argument of the thesis and answer the research questions set forth in Part I. Each of the papers were written for their own purpose and aimed to dismantle an individual aspect of either the legislative development of the PCWP; the application of the PCWP in practice; the engagement of the familial harm threshold; the engagement of the genetic harm threshold; and challenge the legitimacy of state interference in reproductive choice. Thus, each paper works as an individual piece, as well as with the intent of being combined to form a collective and cohesive body of work. The very nature of a thesis by publication lends itself to conducting a thorough review of the literature in Part I to make the links explicit within the papers in Part II and set out the way in which, as a combined piece, the work provides the larger argument.

Naturally, there are further tensions that ought to be explored in key areas of future research if the contribution of this thesis is to be advanced. The questions that the combined papers provoke will be dealt with after I have examined the contribution of the papers in a thematic overview.
8.2 RESEARCH QUESTIONS

The title of this thesis -The Pre-Conception Welfare Principle: A Case-Against Regulation – is an evocative one. While it encompasses all of the elements of this work – in that it is indicative of the simple argument for outright abolition of the principle from regulation – it incites a sense of anxiety regarding a future regulatory method if the PCWP was repealed. As mentioned previously, the aim of this thesis is to present an original case for abolition of the PCWP which adds to the existing body of legal literature. I argue that the PCWP’s inclusion and retention in regulation is, has been, and will continue to be a direct product of unsubstantiated assumptions and misconceived notions of harm avoidance. Its position in regulation is symbolic of the actions of an over-zealous state. In a pluralistic and liberal democratic society one central question emerges from this discourse: how is the insertion of the PCWP in legislation justified? Even if one were to agree that it is grounded on intuitive appeal to notions of responsible parenthood, but still afford the PCWP with the benefit of doubt, none of the so-called risks it purports to address are abated by its inclusion. Though such intuition may be viewed as a good objective, I argue that the PCWP is an inappropriate regulatory method given that it inadvertently asks people’s unconscious bias to flourish. Speaking plainly, the PCWP is a blunt instrument used in a dictatorial model of regulation, included to achieve three particular outcomes: state control over the future family formation; state control over genetic determination of future children; and state control over innovation. In that regard, the work explored in this thesis moves beyond the small confines of section 13 (5) of the HFE Act. It suggests that retaining the PCWP should be open to new debate. As reproductive biotechnology advances we are fast approaching a turning point whereupon similar assumptions could readily and mistakenly be made about the importance of the pre-conceived embryo or the pre-conceived child if we do not directly address the current tensions, failings and imbalance in regulation now. It would be wrong to retain the PCWP as a type of regulatory safety valve to ensure state control over ARTs which are (erroneously) viewed as a public, not quintessentially private, matter. To be concise, the thesis aims to evidence the argument for deregulation in order to redress the imbalance in favour of reproductive choice.

The means of doing so was provided by the broad research questions which were set out in Part I. Namely:

1. How is the PCWP used in the regulation of ARTs?
2. What is the PCWP asking decision-makers to do in practice?

3. What is the harm threshold?

4. How is the PCWP used in practice to restrict reproductive choice?

5. On what basis is this state interference justified?

6. What does this mean regarding the PCWP as an appropriate regulatory method?

By answering these questions the peer-reviewed articles in Part II build a case-against the PCWP. The questions allowed me to consider a different approach to conducting a welfare appraisal in healthcare law and observe the standards maintained in a judicial approach. This then allowed me to develop an argument against the utilisation of the familial and genetic harm threshold. This argument challenges the status quo and calls into question the entire regulatory approach in the dynamic field of ARTs. Naturally these questions enabled me to produce answers which are pertinent to the formation of law and public policy regulating the PCWP, which includes ethics and policy, and illustrate the tensions in the current regulatory framework to which we must give consideration.

8.3 PRINCIPAL ARGUMENTS

I shall now turn to each of the papers contained in Part II and set out how they form a collective body of work in order to achieve the stated aims of this thesis.

8.4 PAPER 1 - A CRITICAL ANALYSIS

*The Pre-Conception Welfare Principle: A Critical Analysis* included at [4.0] comparatively queried how the borders of child welfare appraisals have developed and been defined in judge-made law. Highlighting the judicial approach to adjudicating child welfare appraisals in cases involving wrongful life or withholding or withdrawing life sustaining treatment from severely sick children proved to be a theoretically and practically important way of challenging some of the ingrained prejudices which underpin the PCWP and PGD regulation. In utilising a contextually focused model the judicial approach achieves transparency and objectivity which meets the benchmark standards of regulation identified in Part I in [2.4]. In ARTs regulation, instead, we are faced with a PCWP that, although appearing user

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friendly on the face of the Act, rouses confusion as regards its vague meaning and practical application. This is an issue because when there is ambiguity of meaning there is a fundamental problem identifiable throughout the entire regulatory framework. This is a peril of PBR.\textsuperscript{660} The use of principles means that regulation is open to interpretation, as opposed to a conventional rules based method used for appraising a born child’s welfare in child law.\textsuperscript{661} For PBR to work successfully in practice as regards the PCWP there must be conceptual clarity of meaning, a response to context and a transparent method for interpreting the approach so that the system is not open to abuse.

This paper argued that the PCWP does not meet those standards and this is reflected in the myopic approach conducted by the HFEA in assessing welfare via its harm threshold. The most relevant argument presented in this paper against the PCWP relates to the departure in practice from the benchmark standards of objectivity, transparency and contextual-sensitivity. The critical convergence of the statutory PCWP and the CoP guidance provides the hybrid model of regulation which detracts from legitimate concerns for the welfare of a born child and primarily shifts focus onto the individuals seeking access to treatment. This permits two problematic examples of unjustified state intervention in reproductive choice because of the PCWP assessment. The first problem is the opportunity it presents for discriminating against certain individuals seeking access to ARTs. The second is that the departure from better regulation exemplifies the shortcomings of the PCWP as regards the genetic harm threshold and PGD regulation.

The comparative analysis of approaches undertaken in this paper helped to create a nexus between the PCWP’s medical harm threshold and the restriction on embryo selection contained in section 13 (9). In particular, the hidden contention that avoiding genetic harm will increase a child’s aggregate life time of welfare. This assertion – although not explicitly documented in the hybrid model - provides the justification for the restrictions on embryo selection. This paper argued against this rationale by relying on the departure from the benchmark standards of regulation. The argument is made that the lack of attention given to the meaning of the PCWP has resulted in a catalogue of missed opportunities\textsuperscript{662} to provide a

\textsuperscript{660} Black and others, op. cit, n.165; Black, op. cit \textit{Rise and Fall}, n.148.

\textsuperscript{661} Children Act 1989.

\textsuperscript{662} Amel Alghrani. ‘The Human Fertilisation and Embryology Act 2008: a missed opportunity for clarity’ (2009) \textit{Journal of Medical Ethics} 35:12, 718; Sally Sheldon and Julie McCandless. ‘Genetically challenged: The determination of legal parenthood in assisted reproduction’ In Tabitha Freeman and others (eds)
discernible regulatory framework governing ARTs, rather than regulation built on eugenic idealism and poorly formed notions of principalism.

Overall, this is indicative of the framing in legislation that was alluded to in Part I at [2.3]. This general framing in the hybrid model connects the two notions of welfare and harm prevention, which although seeming to promote a version of reproductive choice in ARTs legislation, in many ways framing fails individuals by imposing unwarranted restrictions based on unexplained frames. Sheila Jasanoff clarifies that:

> Experts arrive at a consensus in part by demarcating, or framing, the domains they consider relevant to the problem at hand, or simply as tractable to analysis. What lies within the perimeter of the expert competence tends to be labelled ‘science’ or ‘objective’ knowledge; what lies outside is variously designed as values, policy or politics. Yet, the very act of performing this ‘boundary work’ is laden with value judgements and reflects the limits of the experts’ knowledge, training and imagination.  

This process displays a form of vulnerability in the PCWP because it is not dependent on epistemic strengths, but on social construction. A much sharper focus is required which is contextually-sensitive and focused on balancing the interests of the individuals receiving treatment, as well as acknowledging the potential child who may be born if treatment is successful. The analysis divulged in this paper allows me to advance an argument for change based on a more responsive model of regulation that “values trust, transparency and professionalism” in the contexts of ARTs regulation. There is a need to enact more responsive laws and public policy in the context of ARTs; and in the process of doing so, I suggest there is a lot to be learnt from the judicial approach in conducting a balanced welfare test in complex cases.

This paper provokes future research analysing the most appropriate model of regulation governing ARTs. But before I embark on that line of inquiry, it is important to understand

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the overall purpose of regulation. Tony Posser succinctly describes regulation in the following way:

Regulation is best thought of not as the application of rules laid down by a principal for the regulatory agent to enforce, but as part of a regulatory enterprise which will involve collaboration between different levels of government, including the regulator.665

Thus, as regards a regulatory method moving forward, multi-agency collaboration would achieve a framework built on benchmark standards, enhanced by the input and knowledge of researchers, doctors, embryologists, sociologists, scientists, ethicists and the individuals seeking treatment. This method, which should be undertaken, would place a re-emphasis on reproductive choice and still provide an adequate response to general concerns for the welfare of future children.

8.5 PAPER 2 - DOING MORE HARM THAN GOOD?

Applying the Pre-Conception Welfare Principle and the Harm Threshold: Doing More Harm than Good? – was the second paper in this thesis. It set out to challenge the harm threshold mandated by the PCWP. It consecutively explored the operation and functionality of the familial and genetic harm threshold in practice. Overall, this part of the thesis demonstrates that the regulatory scope of the PCWP extends far beyond section 13(5) of the HFE Act. The PCWP’s reach is crucial to the argument advanced in this work and is of key importance to understanding the impact of the principle in the entire regulatory framework.

Interestingly, the analysis conducted in this paper reveals that the tendency in law to squeeze something complex into one isolated provision is not a feasible regulatory method, especially in the context of PGD regulation. First, as regards the familial harm threshold, even if we were to provide the PCWP with the benefit of doubt on its underpinning, what remains absent is any evidence to suggest that the PCWP assessment of familial harm prevents future child abuse or neglect. Without such evidence, the PCWP framework regulating familial harm in this sphere cannot claim to be fair, proportionate or balanced.

However, this paper argued against the benefit of doubt and rejected the function of the familial harm threshold given its grounding in intuition and scope for unconscious bias. It

argued the methodology for assessing familial harm was inconsistent, illogical and unfair. In addition, that the laws protecting existing children are sufficiently responsive to the risk factors identified in the familial harm assessment. Drawing on the same theme identified in paper one previously discussed, a comparison is drawn with the approach in child law which necessitates a streamlined, collaborative and multi-agency assessment which responds to actual welfare risks and tangible harms.

The second part of the paper shifts focus to the genetic harm threshold and the forecast of medical harm controlled by the PCWP. As was shown in [5.5], section 13 (9) of the HFE Act governing embryo testing and selection mirrored public policy promulgated by the HFEA. The relative lack of attention to detail surrounding reproductive harms in the genetic sense thus required a full exploration of the medicalisation of the genetic harm threshold which is central to PGD regulation and justifies (at least on paper) the state’s restriction on preferential embryo selection. Subjecting the foundation and role of the genetic harm threshold to practical scrutiny revealed significant inconsistencies in the ‘highest possible risk and the worst case scenario’ approach adopted by the HFEA. The bottom line here is what matters: the genetic harm threshold is incoherent. Moreover, it negatively reflects on the regulatory powers conferred on the legislature and the HFEA to progressively erode reproductive choice.

The primary criticism is that there is an excessive commitment to assessing perceived notions of pre-conception familial and genetic harm rather than focusing on individuals’ reproductive choices. With an emphasis on positive obligations and positive choices, tensions arise in the broad PCWP framework regarding the extent to which individuals are restricted from acting freely and even irrationally in their choices. A key part of fair, consistent regulation is ensuring the voices of the individuals seeking treatment are heard.

The aspect of this work which is important to future research is the way in which harm is framed and utilised in regulation. It is of crucial importance that a framed approach does not preclude the possible future uses of reproductive biotechnologies and diagnostic techniques without a very clear sense of the harm is in issue. It is vital that regulation is not built upon assumptions and erroneous universalising about harm avoidance and maximised welfare.

666 HFEA, op. cit Explanatory Note, n.447.
Showing the tangible harm or the real prospect of harm is, therefore, the component missing from the current framework. This neatly leads to the third paper included in this thesis to which I now turn.

8.6 PAPER 3 - THE PARADOX OF THE PRE-CONCEPTION WELFARE PRINCIPLE

The stark binary which is created in law and public policy between the PCWP and the genetic harm threshold is the focus of this third paper titled, *Regulating Future People: The Paradox of the Pre-Conception Welfare Principle*. However, it attempts to flesh out and challenge the nexus from a different angle, one which amalgamates a legal and philosophical approach to the PCWP. It critiques the relationship through the lens of prominent ethical theories on the concept of harm. In that respect, its overarching purpose – in terms of the collective body of work - is to add to the evaluation of the Warnock strategy of principalism noted in [2.2]. By giving attention to the legal construction of pre-conception harm and how this is at odds with contemporary philosophical or theological debates, an alternative theory emerges that relates to the relational process undertaken when outlining clear conceptual lines attributable to the PCWP’s genetic harm threshold. It is an argument that suggests that, broadly speaking, principalism is an ineffective regulatory method.

This argument is a key point: the lack of conceptual clarity and interpretive uncertainty has resulted in the PCWP acquiring incremental value from somewhere. People are sensitised to the notion of child welfare and this has manifested into protecting *future* children from harm. In part, this is owing to a framed social construction of ‘welfare’ and ‘harm’, but is also based on an assumption that the PCWP is underpinned philosophically. What became clear from the analysis between the first and second papers is the futility of any regulatory approach without a full understanding of the underpinning of the PCWP.

However, this paper revealed the common misconception of the PCWP: there is little, if any, conceptual depth underpinning it. It argues that the PCWP is paradoxical and asserts that without a clear sense of why it might be morally wrong to provide less than ideal parents with treatment services or to select a particular embryo to bring to birth, the law should not restrict reproductive choices based on preferences or intuitions held by others. Nonetheless it is de facto impossible to separate law from morality when the PCWP and PGD regulation demand attention to moral concepts, value judgements and unconscious bias in the current framework. It is overwhelmingly difficult to translate this philosophical complexity into a concise legal
doctrine but the overwhelming consequence of the current PCWP approach means that the law works against an industry designed to increase family formation, and against the elevation of reproductive rights in the absence of substantiated justification when some choices might be labelled as contentious.

A non-divisive legal framework attentive to relationality should not seek to intervene into every aspect of ARTs. Understanding the issues and depoliticising the need for a pre-conception version of the welfare principle utilised in child law could recast the way in which notions of harm and welfare are conceptualised. In turn, this would challenge the widespread and long-held assumptions that permeate discourse in this context. Breaking down this boundary and bringing this issue to the centre of future Parliamentary debate, in a legal and political sense, would enable us to question the legitimacy of state intervention in this context.

8.7 PAPER 4 - THE LAWS REGULATING SURROGACY

_Reforming the law regulating surrogacy: extending the family_ - was the fourth and final paper in this thesis. This paper critically analysed the current state of play in the laws regulating surrogacy and it focused on the regulation of child welfare prior to and after surrogacy cases but for different reasons which dominated the other three papers contained in this thesis. It also re-emphasised the need for legislative reform, but it did so in relation to the current laws regulating surrogacy. By re-iterating the need for comprehensive reform there is an emphasis on the need to protect the welfare of children born as a result of surrogacy arrangements. Again, as stated in [7.1] the legal framing of surrogacy debates has created inherent complexities in regulation which calls for a new way of thinking about a model of regulation which balances the relationships between families, extended families, surrogates and children born after surrogacy.

This paper explores and offers an alternative model of regulation inspired by fiduciary relationships and obligations. The concepts of legal guardianship and trusteeship allow for discussion of pre-conception agreements which would address the expectations of the parties involved and observe the welfare of children. In that respect, this paper offers a rare and interesting exploration of a framework for law which engages child welfare considerations in the classic sense, for the born child in surrogacy, and a PCWP version if the route to pre-conception agreements and pre-conception parental orders are considered. This aspect of work also offers an exciting dimension to future research, exploring the state’s obligation to
account for child welfare. There is a pressing need for the state to get the legislation right, in that it is not for the state to determine the ‘right’ family form but, it is to create a regulatory system which is not averse to that and respects the reproductive choices of individuals’ reproductive endeavours.

8.8 FINAL THOUGHTS

The writing of this thesis provided me with the opportunity to revisit old ground and challenge some of the foundational assumptions which complement the retention of the PCWP. My aim, overall, was to subject the PCWP to external scrutiny through the lens of a realist. By that, I mean that the substance of the arguments presented here is built from the premise of transparency. In part, that derives from my quest for some form or other of legal coherence in reproductive regulation in the UK. I have argued that the PCWP should be abolished and more specifically, I have claimed that the regulation of ARTs should be based on an ethic of objectivity, contextual-sensitivity and transparency. There is an overwhelming need for a responsive, inclusive and considered approach to reproductive regulation. For the most part, in the context of reproductive decision making and reproductive autonomy, it seems that we spend a significant amount of time talking about the permitted and prohibited choices in regulation, and not enough time thinking about why those choices are no longer choices at all. We need to depoliticise the terminology surrounding pre-conceived child welfare, detach ourselves from the emotional connection we have with the PCWP and jettison our own moral values when we decide what type of society we want to live in.

It will not suffice to wait and react; and it would be a mistake to ignore the fact that the core of the failings in the current regulatory framework stem from the insertion of the PCWP. We should approach a regulatory model with humility and recognise the appropriate limits of regulatory control. Fortunately, it is entirely possible to transform the current regulatory framework so that it is less harm-intensive, and regulate choice in ways that are equitable.
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Applying the preconception welfare principle and the harm threshold: Doing more harm than good?

Sacha R. Waxman
The University of Manchester, UK

Abstract
This article critically examines the application of the preconception welfare principle (PCWP) and the harm threshold engaged in the regulation of in vitro fertilization and pre-implantation genetic diagnosis (PGD). It separates the harm threshold into two distinct categories of harm-based regulation: familial harm and genetic harm. This article opposes the intuitive aspect upon which the familial harm threshold hinges, and it is argued that the familial aspect of the PCWP assessment should be abolished. It is suggested that current laws protecting the welfare of the existing children are sufficiently responsive to the welfare risk factors included in regulation. The express provisions regulating PGD are also examined and the engagement of the genetic harm threshold is explored. It is argued that the genetic harm threshold is inconsistently applied and engages unfairly in practice. Given the lack of transparency revealed in the current framework and the draconian engagement of both harm thresholds in practice, this article achieves its overarching purpose of challenging the legitimacy of the PCWP.

Keywords
In vitro fertilization, pre-implantation genetic diagnosis, harm threshold, regulation, preconception child welfare principle

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Introduction

In the United Kingdom, access to licensed assisted reproductive technologies (ARTs) is not automatically available on request, but rather depends on the provisions of the overarching statute, the Human Fertilisation and Embryology Act 1990 (as amended) (HFE Act), the supporting Code of Practice (CoP) and the oversight provided by the regulator, the Human Fertilisation and Embryology Authority (HFEA). Prospective parents require approval from a clinic providing licensed ARTs prior to any treatment being offered and central to that process is a preconception consideration of child welfare, as contained in section 13(5) of the HFE Act. This article critically examines the connection between the ‘preconception welfare principle’ (PCWP) and the ‘harm threshold’ currently applied in the regulation of in vitro fertilization (IVF) and pre-implantation genetic diagnosis (PGD). The harm threshold operates under the ambit of the PCWP – the legislative development of which is briefly introduced in the first section – which requires account to be taken of child welfare. But in practice, and for the purposes of this article, the harm threshold contained in the PCWP is separated into two distinct categories of harm-based regulation: familial harm and genetic harm. Both categories apply to a theoretical child and, through distinct regulatory provisions outlined, purport to identify and assess possible harm with the objective of preventing it and maximizing a future child’s welfare. There are a number of concerns about the current framework, including a poorly formed principle in the HFE Act and the CoP, the problematic application of the two harm thresholds in practice and an overall ignorance of the impact the PCWP and the harm thresholds have on prospective parent’s lives. It will be argued that not only is the application of the harm threshold impractical, illogical, inconsistent and unfair, but its nexus to the PCWP demonstrates that the legitimacy of the principle is misconceived in regulation.

This article questions the PCWP’s function as an assessment of harm associated with a theoretical child to be born. It does not seek to reframe the provisions that are critically analysed. First, it offers a critique of the familial harm threshold contained in the CoP. It is argued that the familial category of the PCWP’s harm threshold is in fact an assessment demanding clinical speculation on a prospective family dynamic, in addition to an assessment of parental adequacy broadly based on intuition. This article opposes the intuitive aspect upon which the familial harm threshold hinges, arguing that the laws governing the protection of existing children are already sufficiently reactive to the identified welfare risk factors stated in the preconception familial harm assessment. Thus, the prejudicial familial harm threshold should be abolished.

2. HFE Act s. 25 requires the HFEA to provide the Code of Practice. The HFEA is the regulatory body entrusted by the HFE ACT to regulate the ethical and practical problems of assisted human reproduction, s. 5–10.
In the second part of this article, the genetic harm threshold is explored in the context of PGD regulation. PGD is the primary technology used to enable parents to have a child without a particular genetic condition thus avoiding ‘serious medical harm’ noted in both the statute and the CoP. Currently, PGD can be used to test for 390 widely variable genetic conditions included in the HFEA central list, ranging from life-threatening conditions, to chronically debilitating conditions, to late onset conditions and some even indicating an increased susceptibility to cancer. Therefore, understanding the basis on which the genetic harm threshold engages in this context is crucial, especially for prospective parents accessing fertility treatment services, given the potential effect it has on their reproductive path. This article examines the initial engagement of the genetic harm threshold criteria and challenges the centralized approach to regulating PGD. The application of the genetic harm threshold will be explored; including permitted and prohibited uses of PGD that are provided for within the strict legislative provisions and the CoP. This article will show that the genetic harm threshold is manipulated in regulation to justify the permitted and prohibited uses of PGD, as well as justifying the restrictions on permitted uses. Moreover, when the genetic harm threshold is broken down, its engagement is also shown to be inconsistent and unfairly applied. This article argues that this model of regulation is draconian and lacks transparency. The retention of the current genetic harm threshold is thus opposed, and it is suggested here that the multifaceted way in which the harm threshold is applied in regulation, in both the familial and genetic context, renders the retention of the PCWP as indefensible.

A very brief background of the PCWP

Section 13 of the HFE Act 1990 stipulated the conditions of licences for treatment, containing the considerations that clinics must adhere to prior to providing treatment to people who could not conceive naturally. In particular, subsection 5 detailed the PCWP, commonly considered as the most controversial inclusion owing to its ‘inherently (and unashamedly) discriminatory nature’ towards unmarried couples, single

3. It is a criminal offence to perform PGD other than in accordance with the terms of a licence, without a licence, or to sex select an embryo for non-medical reasons. Selecting an embryo on the basis of its sex for non-medical grounds is now punishable by 2 years of imprisonment, a fine and/or both. HFE Act ss. 3 (1) – (1A), 11, 41 (2) and Schedule 2, paras 1ZA-B.
5. PGD can also be used to sex select between embryos to avoid certain genetic conditions which are sex linked. In addition, it can be used for human leucocyte antigen (HLA) tissue typing in order to identify an embryo that would be an exact tissue match for an existing sick sibling in need of stem cell donation. This article will not examine these two uses of PGD in any depth.
6. HFE ACT Schedule 2 3 1ZA s. 1.
parents and same-sex families. When the HFE Act 2008 came into force on 1 October 2009, a modest amendment to the original wording of the PCWP was enacted, eradicating the need for a father and thus liberalizing those constraints on parenthood. Now, in its full form, the amended PCWP reads:

A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.

By deliberately excluding any definition of the PCWP, parliament simultaneously achieved flexibility in regulation while ensuring that child welfare considerations were promoted. It also avoided the complexities of trying to establish a consensus on what the PCWP actually meant in practice. The consequence of such a strategic approach was twofold. First, any moral connotations attached to the PCWP were left to individual supposition, and second, it generated an understanding that the principle had a moral value ascribed to it. Almost two decades later, when the 2008 reforms were debated in the parliament, the basic constitution of the PCWP was similarly never critically explored. The consequence of Parliament avoiding those two opportunities to clarify the constitution of the statutory PCWP, it is argued, is displayed in the development of the principle in regulation. For reasons that will now be revealed, the regulatory approach to the PCWP is problematic.

**Codifying the PCWP**

By virtue of its CoP, the HFEA provides what could be described as the only insight into a code of ethics in the regulation of ARTs in the United Kingdom. It is written and maintained by the HFEA, setting out the rules and criterion for principles-based regulation (PBR), which includes, but is by no means limited to, the regulation of...
the welfare of the child. The CoP (2009) version 7.0, ‘User Guide to the Code’. The principle itself is also stated to be linked to regulatory principles 1, 6, 7 and 10 which are not directly linked to child welfare but rather focus towards how to treat patients, gaining consents, clinical conduct and record keeping. It is stated that the principles inform every part of the code and that they should be read in conjunction with the guidance notes, also supplied by the HFEA.


15. Principle 4 states ‘take account of the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth’.


17. CoP 8.10 states ‘The centre should consider factors that are likely to cause a risk of significant harm or neglect to any child who may be born or to any existing child of the family. These factors include any aspects of the patient’s or (if they have one) their partner’s’.

A mere three and a half pages of material are dedicated to the welfare of the child within the entire 258 page document. In that sense, the content is relatively brief and non-prescriptive on the underpinnings of the principle. Although the material is also lacking an explicit definition of the PCWP, its constitution is implied via the child welfare assessment material included within section 8.0. The factors a clinic must take into account when conducting a welfare assessment are as follows:

(a) Past or current circumstances that may lead to any child mentioned above experiencing serious physical or psychological harm or neglect, for example,
   (i) previous convictions relating to harming children;
   (ii) child protection measures taken regarding existing children; or
   (iii) violence or serious discord in the family environment.

(b) Past or current circumstances that are likely to lead to an inability to care throughout childhood for any child who may be born or that are already seriously impairing the care of any existing child of the family, for example,
   (i) mental or physical conditions;
   (ii) drug or alcohol abuse;
(iii) medical history, where the medical history indicates that any child who may be born is likely to suffer from a serious medical condition; or

(iv) circumstances that the centre considers likely to cause serious harm to any child mentioned above.

It is evident from the criteria that the application of the PCWP pivots between two distinct categories of harm assessment; those being, familial harm considerations, noted between (a) (i to iii) and (b) (i and ii) – which relate to the environment into which a child would be born – and then the medical and genetic harm considerations, related to the health of a child noted between (b) (iii and iv). Both avenues of the welfare assessment incorporate their own distinct threshold of harm, but importantly both thresholds are devolved to the doctors’ clinical discretion via the assessment.18

The patient history assessment is by no means difficult to navigate or complex in nature. In order to gain familial information, the first section of the form is completed by the prospective parents and submitted to the clinic. The process then demands a familial harm assessment conducted by clinic staff who are guided by the questions speculating on both direct and peripheral harms within a future family environment. Every child welfare assessment necessitates an interview between clinic staff and prospective parents before treatment can be offered. It requires an exercise of subjective judgment by the staff conducting it – as opposed to more objective- or evidence-based reasoning that is used to judge the severity of genetic conditions in the genetic harm threshold discussed below – to determine a risk level of familial harms according to the HFEA set criteria. The specific welfare considerations based on historic events within 8.10 (a) and (b) are particularly problematic, as they mandate an assessment of not only the category of risk but also the task of judging the seriousness of any prior risk which may allude to the possibility of a future risk. The difficulty with this is that such welfare factors are widely variable and based on unpredictable human behavioural patterns, thus creating more doubt as to the predictive accuracy of the assessment criteria. In addition, assessing the stated welfare factors is likely to be largely outside of the range of expertise of the clinic staff conducting the assessment, as they plainly involve other sociological and criminological disciplines if strictly assessed. Given that the assessment necessitates intuitively balancing historic events against current family dynamics, which are then set against projected future family environments, it quickly becomes a convoluted and illogical process. Moreover, despite a clinic being able to confirm that a PCWP assessment has been conducted by clinic staff, it cannot be said that every assessment of familial harm is properly judged or conducted fairly.

In contrast, the criteria in (b) (iii and iv) link to the medical history and provide the genetic harm threshold. Given that clinics are reliant on HFEA approval regarding the mandatory level of seriousness for each genetic condition in order to meet the assessment criteria specific to PGD,19 the preliminary assessment of genetic harm is more objective

19. HFE Act, 2008 Schedule 2 IZA (1) and (2).
than the familial harm threshold. Thereafter, the genetic harm threshold connects the application of the PCWP assessment to separate guidance on embryo testing within the CoP.\textsuperscript{20} Notwithstanding a failure by the HFEA to explicitly reference the connection between the PCWP assessment and the guidance on embryo testing, identifying the link between them is simple. Both aspects of regulation utilize a harm threshold contained in the CoP at 8.10 to justify the imposition of permissive or prohibitive regulation. PGD is used to detect embryos affected by genetic conditions or abnormalities. It allows parents the option of avoiding implanting affected embryos. In a simplistic sense, given that deselection of affected embryos circumvents serious medical or genetic harm (in that the birth of a child affected by a genetic condition is avoided), the genetic harm threshold central to the regulation of PGD appears grounded in the principle of non-maleficence.\textsuperscript{21} The message this generates is that by deselecting embryos affected by serious genetic conditions, a future child’s welfare is maximized by regulation, as opposed to diminished welfare if a child was born with a serious genetic condition. If this rationale is accepted, it justifies – in theory – the imposition of points 8.10 (b) (iii) and (iv) in the PCWP criteria assessing medical harm. Once that genetic harm threshold engages, the additional embryo testing provisions contained in the CoP apply. Upon reading those additional provisions, which are detailed and critiqued in section ‘Applying the genetic harm threshold in PGD regulation’, it is evident that a combination of objective and subjective reasoning is required when determining the acceptable parameters in which PGD is authorized. Sarah Elliston rightly observes the issue at this stage:

The idea that the state would involve itself through legal regulation about the genetic makeup of children and intrude on reproductive choices of potential parents in this way raises troubling questions, despite the apparently beneficent motive of preventing children being born with potentially devastating genetic conditions.\textsuperscript{22}

\textsuperscript{20} CoP 2009, 10 Embryo Testing.


Although the familial and genetic harm thresholds operate under the one PCWP, the two harm thresholds have distinct roles and engage at different times in the process of seeking access to IVF and PGD. The familial harm threshold is considered in every case before any treatment can be offered to prospective parents, whereas the full extent of the genetic harm threshold engages separately when PGD is sought, though it is possible that both thresholds could be considered together in the preliminary stages of seeking treatment. In the sections that follow the two categories of the harm threshold will be consecutively explored. This will provide clarity as to how the two harm thresholds engage and how they are practically applied in regulation. The criticisms of each harm threshold will then be easier to identify in terms of inconsistency, illogicality and unfairness.

### Applying the familial harm threshold

The majority of the familial harm threshold factors contained in the CoP assessment criteria connect it to the statutory demand of supportive parenting.\(^{23}\) Strictly speaking, this entails a prolonged prediction of the family dynamic up to an 18-year period until that child attains adulthood.\(^{24}\)

In the main, the factors listed between 8.10 (a) and (b) assessing both past and current circumstances are broadly familial aspects of welfare determined by the social environment a child is born into. But by virtue of being included within the child welfare assessment by the HFEA, the individual factors can be interpreted as those which are deemed to denote a preferred level of parental adequacy, thus indicative of a preferred family environment in tune with the HFEA structure of supportive parenting. In this context, the concept of regulation imposes a state of influence on what are considered appropriate and inappropriate behaviours of prospective parents. It also implies that the familial harm considerations are the correct considerations to undertake in all preconception cases assessing child welfare. Take, for example, the assumption at 8.10 (a) that a lack of previous convictions indicates no risk or a minimized risk of harm to a future child. If accepted, it follows that child welfare would be increased via parental adequacy if parents are of good character. Yet there is nothing to support such an assertion or anything to suggest that the absence of previous convictions denotes a lack of identified risk to child welfare, those explicitly being a ‘commitment to the health, well-being and development of the child’.\(^{25}\) While initially an assessment of family specific welfare risks may seem intuitively appealing and represent a justified intrusion into prospective

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23. CoP 2009 8.11 ‘Supportive parenting is a commitment to the health, well-being and development of the child. It is presumed that all prospective parents will be supportive parents, in the absence of any reasonable cause for concern that any child who may be born, or any other child, may be at risk of significant harm or neglect. Where centres have concern as to whether this commitment exists, they may wish to take account of wider family and social networks within which the child will be raised’.


parent’s procreative liberty – on the basis that it prevents high risk parents bringing a child into existence in a harmful environment – the familial harm threshold demands a speculative use of potentially discriminatory intuitions. In a recent study conducted by Lee et al., it was shown that although the refusals to offer treatment based on child welfare grounds are low, concerns regarding familial harm were still raised by some clinics.26 Ten of the 20 clinics interviewed indicated welfare concerns in cases where violence had previously been an issue, and 11 clinics raised concerns over criminal convictions.27 One ‘hard case’ details a young male – and thus his partner – being refused treatment on welfare grounds due to one previous conviction for violence recorded against him. Albeit not committed in a domestic setting or upon a child, the existence of a violent conviction was relied upon to deny access to treatment on child welfare grounds.28 Thus, the scope and strength of intuition exercised at the clinical level is equally broad and strong, especially given that no additional guidance is provided and the option of adopting a multi-agency approach to ‘hard cases’ is not included in the CoP.

**Inconsistency**

The familial harm threshold and the demand for supportive parenting can be criticized further in terms of inconsistency.29 Emily Jackson, a staunch opponent of the PCWP, has previously observed that no such assessment of parental adequacy is conducted for people fortunate enough to conceive naturally or for couples seeking assistance to conceive via unlicensed medical intervention (such as receiving prescription medication to improve ovulation). Prospective parents travelling abroad for treatment also fall outside of this regulatory framework, in the same way as those who facilitate their own private ‘do-it-yourself’30 arrangements for sperm donation and artificial insemination. Though there might be a prescribed presumption in favour of supportive parenting and a

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27. Lee et al., *Assessing Child Welfare*, Table 2, p. 5.
presumption to treat,\textsuperscript{31} the very essence of the welfare assessment of familial harm subjects those seeking access to ARTs to a level of external scrutiny which is unparalleled in any other area of healthcare regulation. Even parents who have had a child or multiple children permanently removed from their care due to inadequate parenting or willful neglect – which would engage 8.10 (a) (i to iii) – are not prevented from conceiving a further child.\textsuperscript{32}

The second difficulty which manifests from a discussion on inconsistency is whether individuals have a right to reproduce and the notion of positive and negative rights.\textsuperscript{33} The European Court of Human Rights acknowledged in Dickson v. United Kingdom\textsuperscript{34} that Article 8 rights to private life were engaged in laws regulating ARTs. Wall J noted in Evans v. United Kingdom\textsuperscript{35} that the right to found a family ‘through IVF can only, put at its highest, amount to a right to have IVF treatment\textsuperscript{36} but that this did not extend to a right to be treated with success. Those patients who seek access to treatment require the positive right to be treated in order to fulfil their reproductive choices, contrasted with individuals who conceive naturally and enjoy the negative right of non-interference with bodily integrity. These two categories of rights play a central role in reproductive ethics and, it is argued, respect for the different interpretations of moral rights–based arguments is lost in the current regulatory framework. Consequently, a troubling conflict arises in respect of the PCWP assessment of familial harm and the rights of individuals to gain access to fertility treatment services.

\textbf{Unfair and unnecessary}

A further point here is this; an assessment of familial harm in order to determine a future child’s lifetime aggregate welfare is unfairly speculative. It is reliant on a broad exercise of clinical discretion assessing the current suitability of prospective parents. Previously, it has been described as a crude system of prospective parental filtering which is ‘in simple and crude terms, none of the laws business’,\textsuperscript{37} and on reflection has little to do with child welfare but more to do with who are ideal candidates for receiving treatment. In order to function, it also unfairly burdens clinic staff conducting the assessment calling on their own moral value judgments. In this context, the

\textsuperscript{31} CoP 2009, 8.11.
\textsuperscript{32} The Children Act 1989, s. 20, provides provisions for the accommodation of children, ss 4 states a local authority may provide accommodation for any child within their area (even though a person who has parental responsibility for him is able to provide him with accommodation) if they consider that to do so would safeguard or promote the child’s welfare (the paramount consideration in accordance with s. 1 CA 1989).
\textsuperscript{34} Dickson v. United Kingdom 920080 46 EHRR 41, para. 71.
\textsuperscript{35} Evans v. United Kingdom 920070 46 EHRR 34.
\textsuperscript{36} [2003] EWHC 2161 (Fam), para. 263.
\textsuperscript{37} Jackson, ‘Conception and the Irrelevance’, p. 203.
PCWP represents an indeterminate assessment of potential harm to a child who might exist in the future.

To reinforce this argument, NHS funding eligibility for ARTs has been reported to have a negative effect on the process of assessing the potential nature and presence of familial harm within a family. In particular, ‘consideration of funding eligibility reintroduces some elements of scrutiny that are no longer carried out in the name of child welfare’ but are still intrinsically linked to PCWP considerations surrounding who is a deserving parent when funding is scarce. It has been documented that a patient’s honest disclosure of smoking, or a mere clinical suspicion of smoking, was sufficient information to preclude even a full child welfare assessment being conducted, thus barring the option of NHS-funded treatment to prospective parents who honestly disclosed information during a preliminary assessment. The issue of resource allocation then emerges, a full discussion of which is outside of the scope of this article. But, for the purposes of examining the legitimacy of the PCWP being used in decisions about who gains access to treatment, it is argued that the principle is being utilized in practice beyond the scope for which it was intended. Regardless of any call to the moral responsibility of a reasonable mother-to-be to give up smoking during her pregnancy, it remains her autonomous decision to legally smoke. When we consider that a woman, as an autonomous human being, is exempt from any liability to her child in respect of damage caused before birth from smoking, drinking or otherwise, a refusal to offer treatment on smoking grounds signifies a troubling way in which the familial harm threshold could be unfairly manipulated in practice. A pregnant woman who smokes excessively, or who is addicted to heroin, or who drinks to such excess during pregnancy that her child is born with foetal alcohol syndrome cannot be sued by her born child. A mother is immune from such claims under the Congenital Disabilities (Civil Liability) 1976 Act, and no criminal offence is recognized for a child harmed in utero, given that the foetus is not recognized as a person in law. It is argued then, that by virtue of the familial harm threshold, the law imposes an unfair and inequitably higher standard of parental adequacy on prospective parents seeking fertility treatment services than parents who naturally conceive. An

39. Ibid, 479.
42. Congenital Disabilities (Civil Liability) Act 1976 provides a code of liability for disabled children, s. 2 a mother is only liable for injuries caused through negligent driving of a vehicle on a road.
expectant mother is able to smoke 20 cigarettes a day, while a woman seeking access to IVF could be criticized on PCWP grounds for simply being espoused to a smoking man. In effect, it demands that at all times a woman should morally behave as if she were already pregnant in order to prevent the engagement of the familial harm threshold.

When we consider the multi-agency streamlined approach taken in child law for assessing an existing child’s welfare, governed by the Children Act 1989 or the Adoption and Children Act 2002 for example, the contrast to the subjective approach in pre-conception cases assessing familial harms could hardly be starker. When applying the child welfare principle in regulatory frameworks relating to existing children, the process demands a unique evaluation of each particular case. Each assessment of an existing child’s welfare is then determined by an individualistic view of parental responsibility, combined with an idealistic view of a preferred family dynamic and home environment to raise that child in.

In the context of gaining access to IVF, the familial harm assessment is not based on any reliable or well-reasoned assessment tool. In acknowledging the complexity of the PCWP demand for supportive parenting, Sheldon et al. articulated:

... it is important to remember that regulation does not operate in a vacuum. Professional practice is rather determined by a broad range of influences including the ‘residue’ of earlier legal provisions, institutional pressures, professional cultures, the individual’s own moral views and emotional reactions, and economic constraints.

Noting these competing values strengthens further the argument against the application of the familial harm threshold. Given that in reality there is no objective criterion for assessing an ideal parent or an ideal family, it begs the question of why prospective parents seeking assistance to conceive are forced to endure such external scrutiny.

47. This argument can be further explored in the context of families who seek to conceive a matching sibling donor for an existing sick sibling. The argument that the harm principle is the underlying feature in legislation in western society is thoroughly explored by M. Smith, Savour Siblings and the Regulation of Assisted Reproductive Technology: Harm, Ethics and Law (London: Routledge, 2015).
A further crucial point is that any harm caused to an existing child after birth is adequately redressed by both criminal and family law. Of particular relevance, the Children and Young Persons Act 1933 (CYP Act 1933) states that if any person who has attained the age of 16 and is responsible for a child or person under that age:

\[\ldots\] wilfully assaults, ill-treats, neglects, abandons, or exposes him, or causes or procures him to be assaulted, ill-treated, neglected, abandoned, or exposed, in a manner likely to cause him unnecessary suffering or injury to health (including whether the suffering or injury is of a physical or a psychological nature) he is guilty of an offence.\[50\]

The recent enactment of what has become known as the ‘Cinderella Law’\[51\] extends the criminalization of causing harm to a child to include suffering or injury which is physical or psychological.\[52\] This is in addition to the powers of the Court to remove a child from a harmful family environment,\[53\] and in addition to the requirements imposed by the Sexual Offences Act 2003\[54\] protecting the general public or any particular member of the public from serious sexual harm by a person who has been convicted of a sexual offence.\[55\] Given that the law is sufficiently responsive to the familial harm threshold criteria in the event of criminality, and that it provides sufficient safeguards for an existing child’s welfare as the paramount consideration,\[56\] it can be argued that those avenues of legal redress adequately rebut the need to retain the familial harm threshold as contained in the PCWP assessment. After all, if the law is sufficiently responsive, it ought not to be prejudicially pre-emptive.

\textit{Illogical}

Another very significant point has also been consistently missed here, which offers a brief introduction of the role of philosophical thinking in the regulation of the familial harm threshold. Even though the application of the familial harm assessment is largely intuitive and necessitates discretionary decision-making, it demands the impossible. The

\[50\] Children and Young Persons Act 1933, s. 1.
\[52\] The Serious Crime 2015, s. 66 (1) and (3) amends the Children And Young Persons Act 1933 to reflect child cruelty cases and causing psychological harm to a child under 16 years of age.
\[53\] The Children Act 1989, s. 20.
\[54\] Sexual Offences Act 2003 Part 2 replaced the Sex Offenders Act 1997, for the Sex Offender Register s. 80 and Sexual Offences Prevention Order s. 104.
\[55\] Including but not limited to sexual offences involving children. Refer to Schedule 3 Sexual Offences for the purposes of Part 2 of the Sexual Offences Act 2003.
\[56\] The Children Act 1989, s. 1.
comparative task underlying a moral assessment of welfare implies that a child’s welfare is maximized if it is born in ideal circumstances. It has previously been advocated by Emily Jackson that this aspect of regulation suggests that if a child is not born in the ideal sense, then it might be better for it to not to been born at all. But strictly speaking, that is an impossible comparison to undertake, for the same child could not be born in alternative settings, to alternative parents and at an alternative time. Very basic human biology supports this philosophical argument, as only one child could be born from the gametes that she originated from, at the time she was born and in the family that she was born into. This serves to strengthen a rejection of the familial harm threshold, on the basis that an assessment of projected aggregate welfare is both practically impossible and a philosophically illogical task. It crucially lacks an appreciation of a very complex philosophical aspect of preconception harm and what is familiarly known as Parfit’s time dependency claim. This argument asserts if any person had not been conceived at that exact time, then she never would have existed. The argument assumes that each gamete entails a different person, and ‘if any particular person had not been conceived when he was in fact conceived, it is in fact true that he would never have existed’. Stephen Wilkinson then rightly claimed a ‘different gamete entails ‘different person’. It follows, therefore, that theoretical child welfare cannot be assessed. Although it is theoretically possible to discuss different children who may exist in the future, it is nothing higher than theoretical possibility. To then attempt to predict a future child’s welfare is illogical when an individual person’s existence is so largely variable in itself. The illogicality goes further when we consider the impossible task of guessing how sensitive a future child might be to potential welfare affecting factors. While this identified philosophical confusion does not preclude conducting comparative assessments of the quality of life that born children enjoy – especially given that the application of a welfare assessment for an existing child is comparatively more contextual in child law – in a preconception context, the lack of logic supports the argument against the familial harm threshold.

61. The Children Act 1989, s. 1 and 7 allow the court to order the preparation of child welfare reports for assessing an existing child’s welfare.
62. For an anti-natalist argument on the harm of coming into existence, see the work of David Benatar, where he argues that every person is harmed by existing and by bringing a person into existence you are impermissibly harming that person. D. Benatar, Better to Never Have Been: The Harm of Coming into Existence (Oxford: Oxford University Press, 2006).
But the criticism here of the HFEA is not in failing to consider philosophical concepts of harm, but rather its reluctance to recognize that the comparative task of assessing the familial welfare of existing children is distinct from its own *preconception* harm assessment model. In the latter, clinics are tasked to conduct nothing more than a subjective guess. In addition, the HFEA has failed to recognize the harm caused by these regulatory provisions to wishful parents embarking on their endeavour to start family who are denied access to ARTs. Despite the familial harm threshold seeming intuitively attractive, this model of regulation cannot be reconciled with the reproductive freedoms of prospective parents given the unjustified barriers it erects in their path.

The genetic harm threshold to which I now turn is still a relatively new area of regulation insofar as the law regulating PGD is concerned, and the basis in which it applies is important, given the significant expansion of the permitted uses of PGD in recent years. In order to understand the regulation of PGD, a combined reading of the HFE Act and the CoP is required. The genetic harm threshold is contained in both, and it will now be demonstrated that the same genetic harm threshold has been manipulated in the statutory and regulatory provisions. In doing so, the genetic harm threshold can be criticized, in that it is ill-defined, applied inconsistently and the motivation behind it lacks regulatory transparency. Moreover, it further erodes prospective parent’s capacity to exercise reproductive choice, a shortcoming of the overarching PCWP.

**Applying the genetic harm threshold in PGD regulation**

Prior to the 2008 reforms, the HFEA, as the sole architect of the CoP, exercised carte blanche in deciding the appropriate uses of PGD. The HFEA decided in what circumstances PGD could be used and whether a clinic should be granted a licence to use it. It devised the entire licensing framework for PGD in successive editions of its CoP. Such criteria evolved from PGD being available only where there was a ‘significant risk of a serious genetic condition’ to a ‘substantial risk’, and in the current CoP ‘only where there is a significant risk of a serious genetic condition being present in the embryo’. When the 2008 Act amendments came into force, the codified system regulating PGD was simply placed on a statutory footing. The only real practical difference to take effect from 1 October 2009 was that PGD was no longer regulated on

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63. It should be noted that prior to the enactment of the HFE Act 2008, the HFEA had received unanimous support by the House of Lords in licensing embryo testing. See, *Quintavalle (Comment of Reproductive Ethics) v. Human Fertilisation and Embryology Authority* [2005] UKHL 28.

64. The criteria was initially established in line with prenatal diagnosis and the ground of foetal abnormality as contained in Abortion Act 1967 (AA 1967), s. 1 (1) (d). It was first included in the sixth edition of the Code of Practice published in 2003.


66. CoP 2008, s. 3.3.2.

67. CoP 2009, s. 10.6.

68. Op cit, s. 10.6.
a case specific basis, but rather a condition-by-condition basis for genetic conditions approved by the HFEA and included in a formalized central list of genetics conditions.69

**Ill-defined**

A clear objective of the HFE Act 2008 was to establish parliamentary authority over the use of PGD. Although the HFEA retained discretion to approve a genetic condition as sufficiently serious to warrant the use of PGD, it does so now according to the following statutory criteria:

Schedule 2 IZA (1) and (2) read:

1. A licence under paragraph 1 cannot authorize the testing of an embryo, except for one or more of the following purposes:
   
   a. establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth;
   
   b. in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality;
   
   c. in a case where there is a particular risk that any resulting child will have or develop:
      
      i. a gender-related serious physical or mental disability,
      
      ii. a gender-related serious illness70 or
      
      iii. any other gender-related serious medical condition, establishing the sex of the embryo;
   
   d. in a case where a person (‘the sibling’) who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of those persons) suffers from a serious medical condition which could be treated by umbilical cord blood stem cells, bone marrow or other tissues of any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling; and
   
   e. in a case where uncertainty has arisen as to whether the embryo is one of those whose creation was brought about by using the gametes of particular persons, establishing whether it is.

2. A licence under paragraph 1 cannot authorize the testing of embryos for the purpose mentioned in subparagraph (1) (b) unless the authority is satisfied:


(a) in relation to the abnormality of which there is a particular risk and
(b) in relation to any other abnormality for which testing is to be authorized
under subparagraph (1)(b), that there is a significant risk that a person with
the abnormality will have or develop a serious physical or mental disabil-
ity, a serious illness or any other serious medical condition.

The HFE Act does not include a definition of a significant risk of serious harm. When
the House of Lords debated the use of terminology in the statute, Baroness Royall made
it clear that a definition of ‘serious’ was deliberately excluded from the statute with a
view to ensuring that the HFEA was able to exercise appropriate flexibility to make
licensing decisions.\(^71\) Consequently, the HFEA provided additional guidance in the form
of explanatory notes for its Licence Committee (the Committee) specifying whether a
risk exists as per the criteria set out in paragraph IZA (1)(b).\(^72\) That guidance provides
the entire framework for how a Committee should determine both the ‘significance’ of
the risk and the level of ‘seriousness’ for any genetic condition, and on closer examina-
tion it provides a surprisingly lower harm threshold than that which is contained in the
statutory provisions and the CoP. The guidance specifically covers issues of penetrance
levels in various genetic mutations,\(^73\) and although the potential variability in symptoms
is noted, the document is clear in its recommendation that in making a decision on the
harm threshold, a Committee should assess penetrance according to the highest possible
risk on the penetrance figure,\(^74\) while presuming the worst symptoms and the ‘worst case
scenario’ in each case.\(^75\) A ‘significant risk of serious harm’ is thus a misleading use of
terminology.

**Inconsistency**

Many genetic conditions self-evidently meet the serious harm threshold.\(^76\) It is reason-
ably safe to assume that there would be scant moral criticism of a decision made by
prospective parents to avoid the birth of a child who would endure intolerable suffering
by being born with a serious genetic condition. Tay-Sachs disease and spinal muscular
atrophy, for example, are both undeniably serious genetic conditions which involve
significant suffering and often result in infantile death. But they are relatively

\(^{71}\) Baroness Royall’s comments from the debates, Hansard 21 January 2008: Column 30.
\(^{72}\) HFEA ‘Preimplantation genetic Diagnosis testing (PGD) Explanatory Note for Licence
\(^{73}\) HFEA ‘PGD 2010’, s. 4.
\(^{74}\) Op cit., s. 5.4.
\(^{75}\) Op cit., s. 5.5.
\(^{76}\) Note the work of Isabel Karpin in the context of preconception harm and reproductive
choice. See I. Karpin, Taking Care of the ‘Health’ of Preconceived Human
Embryos or Constructing Legal Hrms’, in J. Nisker, F. Baylis, I. Karpin, C. McLeod, and
R. Myktitiuk, eds., *The Healthy Embryo: Social, Biomedical, Legal and Philosophical
Perspectives* (Cambridge: Cambridge University Press, 2010), pp. 136–150; I. Karpin and
B. Bennett, ‘Freedom to Choose?: Embryo Selection, Reproductive Decision-making
uncontentious examples. There are currently 390 genetic conditions included in the central list and of course not all of them are as easily categorized. More controversy surrounds the detection of perhaps less serious conditions included in the HFEA central list such as cystic fibrosis (CF), a life-limiting condition where the potential degree of suffering is so widely variable given the different classifications of the CF mutation. While there are six classifications of the CF-transmembrane conductance regulator (CFTR) gene, there are more than 1800 mutations; some are common and others are rare and found only in a few patients. Each one of the varying CF mutations is independently classified depending on the level and functions of the CFTR gene. This means that the Committee’s genetic harm threshold mandating the highest possible risk in the worst-case scenario is not entirely coherent when applied to CF. The ‘worst case scenario’ approach cannot be accurately applied to a genetic condition where the symptoms and prognosis are so widely variable and unpredictable in each patient. In addition, such an approach in assessing genetic harm takes no account of several significant exterior non-genetic factors affecting the level of harm and suffering of a CF patient, such as air quality, the level of care received, nutritional status of the individual and the patient’s age on diagnosis.

A further problematic example of inconsistency in regulating a genetic harm threshold is evident when you consider its implications for ‘carrier status’ embryos. Those embryos detected as carrying a single copy of the CF protein gene, indicating an unaffected carrier of CF if brought to birth, also strictly fall within the statutory genetic harm threshold criteria set out in IZA (1)(b) ‘where there is a particular risk that the embryo may have any gene’ permitting the use of PGD to test for CF. Yet the only circumstance where being a CF carrier has any potential physical effect is if two carriers of the gene were to procreate. Only then would there be 25% chance that their child would be born with CF or a 50% chance of their child being another carrier of the CF mutation. Prior to the act of procreation, both CF carriers would live their lives unharmed by the gene. Given that one person in 25 is said to be a carrier of CF in the United Kingdom, the possibility of CF-affected children being born remains a point of consideration. PGD presents the possibility of eradicating that possibility by virtue of deselection justified on the basis of the genetic harm threshold. But strictly speaking, there is nothing to suggest that the aggregate lifetime welfare of a CF carrier is diminished due to their carrier status. There is no plausible argument corroborating the Committee’s endorsement of a ‘worst-case scenario’ when an embryo carrying the single CF gene is identified in a cohort of

77. An authorised genetic condition remains on the central list and is subject to review every 5 years. Available at: www.hfea.gov.uk/‘embryo testing’ (accessed 25 April 2016).
embryos. Despite paragraph IZA (2) stating that a licence for the purpose of paragraph IZA (1)(b) cannot be issued for embryo testing unless the HFEA is satisfied that ‘there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition’, the difficulties in interpretation are self-evident. It follows that, given the inclusion of CF in the central list, a decision could then be legitimately made by a clinic to detect a CF carrier embryo by PGD and deselect it because of the genetic harm threshold.

While it is not explicitly stated within the HFE Act or the CoP that the genetic harm threshold is linked to PCWP considerations, it is clear that the rationale underpinning the provisions use child welfare as a means of justifying the testing. The approach to harm prevention insofar as deselecting embryos affected by a genetic condition demonstrates the regulatory position: prevention of genetic harm equates to maximized child welfare. But this example of detecting CF serves to highlight two salient points countering the use of a genetic harm threshold in the regulation of PGD. First, that although licensing PGD to identify CF is perhaps not contentious per se – as the condition is one with life-affecting symptoms of variable severity – its inclusion in the HFEA central list demonstrates that the genetic harm threshold is open to exceptionally wide interpretation that has been deliberately manipulated beyond the basic parameters of harm prevention. It is not a consistent or transparent model of harm-based regulation. Second, when the statutory restrictions preventing preference selection of affected embryos contained in section 13 (9) and (10) of the HFE Act are considered, the genetic harm threshold model has extremely problematic overtones. It is perhaps less to do with the prevention of serious genetic harm and more to do with eradication of genetic disease. With a strict application of the genetic harm threshold what transpires is the force of regulation; it triumphs in the face of reason, the need for transparency and a respect for reproductive autonomy, in equal measure.

The inclusion of the BRCA 1 and BRCA 2 gene mutations in the HFEA central list invites similar concerns regarding the appropriateness of the genetic harm threshold criterion as a guide for the moral use of PGD. Criticism surrounds issues of necessity, given that serious genetic harm is not absolute, but rather a very high possibility. But if the rationale of serious harm prevention underlying this approach is accepted, then the potential expansion of the genetic harm threshold is on the horizon. Recent research has discovered 93 genes that, if mutated, can cause normal tissue to become cancerous and increase the risk of susceptibility to aggressive cancers. It was stated by the NHS that this ‘landmark research paves the way for new and better treatments . . . as well as ways of preventing the disease ever occurring’. If such discoveries follow suit insofar as susceptibility to serious harm are concerned, thus engaging the genetic harm threshold, then

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82. Schedule 2, para. IZA (2).
83. These provisions are discussed in detail below.
84. BRCA 1 and 2 mutations indicate an increased risk of developing a cancer.
we are crucially forced to question whether the current genetic harm threshold is an appropriate means to regulate PGD. It fails to measure the variable severity of genetic conditions, given the uncertain development of some genetic mutations, the variability of prognosis in different people, the effect that age can have on diagnosis and, of course, the increasing prospects of successful therapeutic treatments.

Huntington’s disease (HD) is also included in the central list and is categorized as a late-onset genetic condition. It is dissimilar in nature to CF or BRCA 1 and 2, notably because it is an autosomal dominant disorder, meaning that a person needs only one copy of the defective gene to definitely develop HD in their lifetime. It commonly takes effect in later years and most significantly it is incurable. In an objective assessment of genetic harm, it qualifies as a serious genetic condition with a wide spectrum of aggressive symptoms usually causing movement, cognitive and psychiatric effects. But the issue in contention is not with HD itself as a serious genetic condition, more so with the application of the genetic harm threshold primarily contained in the PCWP assessment 8.10 (b) (iii). First, the genetic harm threshold is nothing to do with child welfare considerations when a genetic disease is late onset. Second, the legislative restrictions prohibiting the selection and implantation of an embryo detected as carrying a late-onset condition disregard the intervening years a person lives for prior to being symptomatic and diagnosed. While objectively a late-onset condition can be categorized as sufficiently serious to satisfy a genetic harm threshold, the application of the genetic harm threshold in this context is problematic. Given that late-onset genetic conditions provide a time frame for life before diagnosis, the worst-case scenario licensing threshold becomes as nonsensical as child welfare considerations are in this context.

When prospective parents seek PGD, the embryo testing provisions contained in the CoP take practical effect alongside section 13 (9) and (10). The guidance notes on embryo testing contain additional welfare-based factors for clinics to consider prior to agreeing to provide PGD to prospective parents, such as the likely degree of suffering associated with the condition, set against the availability of fast-growing effective therapies and the views of the people seeking treatment including their previous reproductive experience. Given that the range of factors can be judged objectively, for example, the speed of degenerative progressive disorders, compared to individual family experiences which are subjectively judged, such as the personal views from parents who are at risk of having maybe another child with a serious genetic condition, this regulatory approach has been labelled as ‘a mixed objective – subjective “seriousness” test’ for applying the genetic harm threshold in practice.

It is worth noting, however, that due to the HFE Act 2008 amendments to the standard conditions placed on licences, the codified mixed objective–subjective test contained in

87. HFE Act, s. 13 (9) and (10).
88. CoP 2009, s. 10.7 (b).
89. Op cit, s. 10.7 (c).
90. Op cit, s. 10.7 (a).
the CoP becomes obsolete. In some scenarios, the personal views of the prospective parents are simply irrelevant when the statutory restrictions are properly considered. The very clear overriding objective for introducing section 13 (9) and (10) into the HFE Act was to prevent PGD being deliberately used to positively select for genetically disabling traits or conditions. In general, section 13 specifies the licence conditions authorized by the HFEA, and subsection (9) is specific to PGD. It provides the following:

(9) Persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality, involving a significant risk that a person with the abnormality will have or develop:

(a) a serious physical or mental disability,
(b) a serious illness or
(c) any other serious medical condition, must not be preferred to those that are not known to have such an abnormality.

Once subsection (9) came into force, the HFEA was stripped of its discretionary power to respond to a request to positively select an embryo with a genetic condition. This statutory restriction extends to the positive selection of donors and donor gametes to prevent an attempt to increase the possibility of having a child with a disability. Though there may be tactical avenues to circumvent these legislative amendments, on the face of the HFE Act, prospective parents are now prohibited from deliberately selecting an embryo affected by a genetic condition based on the statutory version of the genetic harm threshold. Even if prospective parents articulated a case that the PCWP was not violated, and supported their case by either their own reproductive experiences of having a child with a particular genetic disease or based on their own experience of living with a genetic disease, they would be unsuccessful, provided at least one unaffected embryo offered an alternative option. The interesting aspect of these provisions is that they are not discretionary provisions but they are not completely prohibitive either, for only preferential selection is prevented for positively selecting for disability. The position is further qualified in the CoP where a blanket prohibition on transferring affected embryos is precluded.

On that basis, the genetic harm threshold quickly loses coherence and, of more practical importance, it becomes difficult to reconcile a pragmatic ethical solution within the basic parameters of the current statutory provisions. The provisions prohibit the deliberate selection of an embryo affected by factors listed in section 13 (9) (a)–(c) and

94. CoP 2009 states of s. 13 (9) and (10) that “where there is no other embryo suitable for transfer, an embryo with these characteristics may be transferred”, 10C.
95. Op cit., s. 10C.
that prohibition extends to a chance selection between a combination of affected and unaffected embryos. However, in the event that only affected embryos are available for selection, the genetic harm threshold then ceases to apply. In that scenario, prospective parents are allowed to exercise their reproductive liberty and select an embryo regardless of the genetic condition affecting it. There are no additional prohibitive caveats contained within the HFE Act or the CoP restricting such a choice in those specific circumstances. In this context, regulation institutes a rather unpalatable hierarchy of embryo selection based on the genetic information from the cohort of embryos. Insofar as the scope of choice is concerned, the application of the genetic harm threshold divides in three separate categories, each demanding or relinquishing a level of regulatory engagement depending on the circumstances. First, where only unaffected ‘healthy’ embryos are available for selection, prospective parents can select any embryo. Second, where a combination of affected and unaffected embryos are available for selection, the scope for choice is then limited. Third, where only affected embryos are available for selection, the hierarchical system of embryo selection evolves. The first scenario is unproblematic insofar as that particular autonomous choice is concerned. The second scenario empowers the genetic harm threshold and simultaneously minimizes autonomy on prohibiting preferential or chance selection. In contrast, the third scenario empowers prospective parents with reproductive autonomy just as the genetic harm threshold disengages. This represents a significant concession in the regulation of a genetic harm threshold endorsed by the PCWP. It demonstrates that the genetic harm threshold which is central to the promotion of the health-related concerns of the PCWP is not solely focused on projected child welfare or health. Notwithstanding the lack of transparency in the restrictive provisions, it is easy to discern a hidden agenda contained in regulation that is justified on a loose harm prevention model.

The fact that genetic harm of any magnitude could affect an embryo and that embryo could be selected for implantation when no other embryos were available for selection demonstrates the inconsistent utilization and application of the genetic harm threshold. In turn that amplifies the inherent problems in the PCWP. Similar to the way in which a familial harm threshold imposes a state of influence on appropriate behaviours, the genetic harm threshold problematically endorses a form of parental reproductive responsibility insofar as the scope for reproductive choice is concerned. The underlying rationale is that if regulation restricts that particular reproductive choice, then by implication it is not the right reproductive choice to make. In regulating PGD in this way, the parliament and the HFEA have effectively empowered themselves to act in loco parentis by assuming the fundamental rights of prospective parents embarking on what should be their private reproductive path.

**Conclusion**

This article sought to address two main questions. First, how does the PCWP’s harm threshold apply in the regulation of IVF and PGD? Second, how does its engagement reflect on the overall legitimacy of the PCWP? These two questions are intrinsically linked because the harm threshold operates under the ambit of the PCWP as contained in the HFE Act and as divulged in the CoP. However, this article has shown that this hybrid
regulatory approach is unsatisfactory and that the current framework regulating a harm threshold in accordance with the PCWP is problematic for a variety of reasons.

It is argued that the way in which the statutory PCWP found its place in the regulation of ARTs has contributed to the unsatisfactory state the principle remains in today. The absence of a statutory definition of the PCWP has resulted in inevitable confusion regarding the constitution of the principle. The task of developing the principle has always fallen to the HFEA and the harm threshold is an integral part of the assessment. In order to answer the first question posed by this article, the function of the harm threshold was divided into two distinct categories of harm-based regulation: familial harm and genetic harm. The intention was to demonstrate not only the process of applying each threshold in practice but also, crucially, to emphasize the impact each harm threshold has on prospective parents seeking access to fertility treatments, such as IVF and PGD.

An argument for deregulation of the familial harm threshold was advanced in this article. Given that this aspect of the PCWP assessment occupies such a pivotal role in the assessment process – in that it is the gatekeeper to accessing fertility treatment services – the dangers of subjectivity on the part of clinic staff unravelling the criteria and conducting the assessment lend significant doubt as to the appropriateness of its retention. This article represents an attempt to oppose the intuitive appeal of the familial harm threshold. I have argued that the value of such intuition is significantly outweighed by the discriminatory dangers outlined in terms of inconsistency, unfairness and illogicality. The notion that regulating a PCWP offers justification for vetting prospective parents is rejected because of those three combined arguments. My contention is that the current codified approach to regulating the PCWP’s familial harm threshold, despite an apparent presumption to offer treatment, lacks parity with the unregulated world of natural conception and places prospective parents seeking assistance to conceive in an unfair position.

This article has demonstrated that the genetic harm threshold engages in practice on multiple levels. In 2007, when Lord Darzi introduced the HFE Bill to the House of Lords, he stated that the Bill was to ‘make explicit the basic parameters for screening and selecting embryos’. What followed was the adoption of the existing codified system of public policy promulgated by the HFEA in the preceding years. By way of examples, I have shown that the use of ‘basic parameters’ regulating a genetic harm threshold is problematic on grounds of inconsistent application, incoherence and a lack of clarity in the express provisions regulating PGD. My purpose has been to identify the reasons why continued regulation of the current genetic harm threshold is open to challenge. I suggest that perhaps it is time to achieve regulatory transparency, seek greater clarity on the restrictive provisions and revisit the legitimacy of regulatory powers of Parliament and the HFEA which systematically erode reproductive choice for prospective parents. By outlining the problems in applying the genetic harm and familial harm thresholds, an answer to the second question posed by this article is revealed, that is an argument declaring that the continued retention of the current PCWP is indefensible in law.

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Reforming the law regulating surrogacy: extending the family
Margaret Brazier

The University of Manchester, Law School

Sacha Waxman*

The University of Manchester, Law School

Abstract

This paper considers the current law relating to surrogacy and re-emphasises the need for urgent reform. It starts by reflecting on how we got where we are and notes that the legal framing of surrogacy debates has forced us into the legislative and regulatory position we are now in. We argue that a review of the law regulating surrogacy should be comprehensive and we look at a potential model of regulation in the future. We suggest surrogacy regulation should be inspired by a fiduciary model recognising relationships between families, extended families and surrogates. The model we suggest is one of mutual fiduciary obligations owed by intended parents to surrogates and vice versa, supported by pre-conception agreements reflecting such mutual duties while recognising the overriding concern for the welfare of a child born as a result of a surrogacy arrangement. We lack space in this paper to argue for the law to give full status to legally enforceable fiduciary obligations in surrogacy. We simply contend that the concept offers a helpful model in thinking about the future for regulating surrogacy.

Introduction

This paper was first delivered by Margaret Brazier as the keynote address at the seminar which forms the basis of this special issue. As Kirsty Horsey notes in her Introduction,¹ one of the objectives of the seminar was to press for reform of the law regulating surrogacy. Much has changed since that sunny day in May. The Law Commission’s consultation on its Thirteenth Programme for law reform asks whether the Law Commission should include in

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¹ K. Horsey, this issue, at pp. 153-154.
that programme a review of the law relating to surrogacy. The answer in our view is 'yes' and the review must be comprehensive. After decades of inaction, despite calls for law reform, it seems that the chaotic state of UK law relating to surrogacy may at last be addressed. Thus the original title of this paper ‘Jam Tomorrow Will Not Do’ is (we hope) no longer apt. ‘Jam’, that is to say proposals for reform with a reasonable chance of success, may be on its way.

Other papers in this collection address many aspects of surrogacy and set out the authors' proposals for law reform. In our paper, we first re-iterate why comprehensive reform of the law relating to surrogacy is so urgently needed to protect the well-being of children born as a result of surrogacy arrangements, and reflect about how and why we reached this current impasse on surrogacy. We then note how the legal framing of surrogacy debates has created problems of its own and suggest ways of thinking about surrogacy inspired by a fiduciary model representing a relationship between families, new ways of creating and recognising extended families, rather than a commercial model of babies for sale grown in carriers who happen to be women. Intended parents, couples and individuals seek surrogacy arrangements because they passionately wish to found a family. Most women who choose to become surrogates do so because they have a strong desire to help others found their own family.

The need for reform now

One objection to embarking on what will be a complex and costly review of surrogacy laws might be that even at the most expansive estimate of the number of surrogacy arrangements, that number, and thus the number of children born of surrogacy, is relatively small. The bald number of children at risk should not matter when the potential consequences for children (and

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3 In the wake of evidence of changing attitudes to surrogacy and a highly publicised case where an arrangement broke down in a blaze of media publicity, the government commissioned a review of payments and regulation of surrogacy arrangements. The review team reported in 1998 but none of the recommendations for reform were implemented: see Surrogacy: Review for Health Ministers of Current Arrangements for Payments and Regulation Cm 4068 (1998) hereafter ‘Surrogacy Review’.
5 See Lewis Carroll, Alice in Wonderland. The White Queen declared ‘The rule is, jam tomorrow and jam yesterday - but never jam today’.
6 See the paper by N. Smith, this issue, especially at pp. 247-250.
8 Ibid. Another factor to consider is the cost in terms of legal fees and court time of the sheer number of cases now heard in the Family Division.
their parents, genetic, gestational, social or psychological) may be dire. A response to calls for law reform that simply asserted that only a few children faced risk of harm would be swiftly attacked.

Imagine this scenario:

Twins are born in the UK to an unmarried couple, Ana and Ben. Ana is from the Ukraine and a student in the UK. Ben is a refugee from Somalia. Ana dies in a road accident on the way home from hospital. Ben is unable to cope with grief and two new born babies. The infants look dirty and malnourished. Neighbours become concerned. Social services tell them they should contact the Ukrainian and Somali embassies. ‘Foreign babies’ are not their concern. The Ukrainian embassy replies that unmarried women do not transmit Ukrainian nationality to their children. The Somalian embassy says that Ben has forfeited his citizenship and bars Ben’s sister from coming over to the UK to help Ben care for the twins. Ana’s brother is also refused a visa to come to help.

The twins’ fate is raised in Parliament. Ministers express regret, pointing out this is an unusual case involving only two babies. The case will be carefully examined in due time.

Of course no local authority social services department would simply leave two infants physically in their jurisdiction to starve to death. Something will be done about the immediate risks to the babies whatever their nationality. The media would have a field day if a Minister responded ‘only two babies’ were abandoned by the state – the fact that it was only two babies at risk would cut little ice.

The risks to children arising from the inadequacy of UK law in relation to surrogacy arrangements are not as stark as the risks to our hypothetical twins. There are nonetheless significant risks to the well-being of children when surrogacy arrangements go awry, often but not always arrangements with a foreign aspect. The complex and inadequate state of the law (or a toxic mix of UK and foreign laws) may mean that a baby (or babies) risks to quote Hedley J, being ‘marooned stateless and parentless’ and, were the letter of the law to be applied, babies could not be united with the parent or parents who sought their birth. In rare cases wholly unsuitable arrangements create chaos on breakdown and may involve outright fraud.

In relation to overseas surrogacy arrangements, judges are regularly asked to approve a parental order in cases involving the exchange of sums of money which are hard to see as even generous expenses. While UK law makes it a condition of the grant of a parental order that only reasonable expenses may be

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9 Lady Hale in *Re G (children)* [2006] UKHL 629 [32-37].

10 *In re X and Y (Children) (Parental Order: Foreign Surrogacy)* [2008] EWHC 3030 (Fam) [10].

11 *R v. Pollard*, Bristol Crown Court (June 2014); See also *Re A v. X* [2016] EWFC 34 for an illustration of the problems encountered with Facebook and social-media.
paid to the surrogate, many foreign jurisdictions allow surrogates to be paid for their services and to make a profit on the arrangement. Time and again judges are asked to approve payments already made to the foreign surrogate of the equivalent of £15,000 and more. The payment may well be in addition to a payment to a foreign agency and the agreement to make the payment may be framed in such a way that if interpreted literally, it cannot be seen as other than straight deal to pay the surrogate for handing over the child. If the letter of UK law were followed, the intended parents would be denied a parental order and might be unable to acquire the status of the child’s legal parents.

Different laws governing legal parenthood at birth often mean that while UK law regards the birth mother and her husband as the legal parents at birth whose consent is needed for the parental order, the foreign law confers parental status on the intended parents. When the child is born abroad to a Ukrainian mother and her husband, that child will not have UK nationality nor any right to enter this sceptre’d isle. With some help from the Borders Agency judges find ways of settling the infant with the parents who sought his existence. In many of these cases, absent judicial creativity, children might languish in orphanages overseas. It is unsurprising that the judges have for many years called for Parliament to intervene. Nearly a decade ago in *In re X and Y (Children) (Parental Order: Surrogacy)*, a married couple domiciled in England entered into a surrogacy arrangement with a married Ukrainian woman. She had been implanted with embryos derived from donor eggs fertilised by the husband’s sperm and gave birth to twins. Under Ukrainian law once the twins had been handed over to the intended parents, the woman had no parental rights or duties to the children and the children had no right to Ukrainian nationality or rights of residence in Ukraine. As far as Ukrainian law was concerned the intended parents were for all purposes the legal parents of the twins. Under UK law, the surrogate and her husband were the legal parents and the twins had no claim to British nationality. The children were at the time of the application for a parental order ‘effectively legal orphans’ and stateless. As was to happen many times in later cases, Hedley J exercised judicial ingenuity to enable him to secure the welfare of the children in granting a parental order to the British couple. He commented fairly mildly that the government had ‘indicated that it was minded to review the law and regulation of surrogacy. It is no part of the court’s

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12 See s. 54 Human Fertilisation and Embryology Act 2008 (formerly s. 30 Human Fertilisation and Embryology Act).
13 See *In re X and Y* (n 10, at [16]).
14 Note that the payment may also in theory preclude the couple from adopting the child; see s. 95 Adoption Act 2002; see *C v. S* 1996 SLT 1387.
15 See *Re K (Minors)* [2010] EWHC 1180 Fam.
16 [2008] EWHC 3030 Fam.
function to express views on that save perhaps to observe that some of the issues
thrown up in this case may highlight the wisdom of holding such a review’. Moylan J was more forthright in 2014:

There is in my view a compelling need for a uniform system of regulation
to be created by an international instrument in order to make available an ap-
propriate structure in respect of what can only be described as the surrogacy
market.19

Problems with surrogacy posing risks to the well-being of the child are not
limited to overseas surrogacy arrangements. Consider Re N (a Child).20 P agreed
to carry a child for a married couple, SJ and TR. She underwent artificial inse-
mination with the husband’s sperm. She became pregnant but later told the
couple untruthfully that she had miscarried. She gave birth to and kept the
child, N. The couple later discovered the fraud and when N was eighteen months
old the Court of Appeal upheld the decision by Coleridge J that N’s biological
father, SJ should be granted a residence order. It further emerged that some
years earlier P had practiced a similar deceit on another couple. It was agreed
that the child C, now nearly six, should remain with P and her husband but at
some later time should be told about her genetic paternity. To put it at its lowest,
C experienced the loss of her sibling and at some stage must come to terms
with her mother’s extraordinary behaviour.

Data on surrogacy is thin.21 A number of arrangements take place ‘beneath
the radar’ - with no formal legal process at all. The dangers of such informality
are illustrated by JP v. LP and others.22 A married couple agreed with a friend
that she would act as a surrogate. She became pregnant after self-insemination
with the husband’s sperm. No attempt was made by the couple to apply for a
parental order and some months after the birth the marriage broke down and
the wife JP left the couple’s home. JP absent a parental order had no claim to
legal parenthood although she was the child’s primary carer. The surrogate was
the legal mother and the husband the legal father. After years of legal wrangling
Eleanor King J made the child a ward of court and granted the former couple
a joint residence order. This order gave JP parental responsibility. The surrogate
remained the legal mother also enjoying parental responsibility though forbidden

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18 Ibid. [29].
19 Re D (a child) [2014] EWHC 2121 Fam [1].
20 [2007] EWCA Civ 1053.
21 See M. Crawshaw/E. Blyth/O. Akker, ‘The changing profile of surrogacy in the UK – Implica-
tions for national and international policy and practice’, Journal of Social Welfare and Family
Law 34 (2012), 265; and K. Horsey, ‘Surrogacy in the UK: Myth busting and reform’ Report of
the Surrogacy UK Working Group on Surrogacy Law Reform (Surrogacy UK, November 2015).
22 [2014] EWHC 595 (Fam); Re A v. X [2016] EWFC 34.
by court order from any attempt to exercise parental responsibility without the leave of the court. Eleanor King J warned of:

[T]he real dangers that can arise as a consequence of private ‘partial’ surrogacy arrangements where assistance is not sought at a licensed fertility clinic (or indeed of full surrogacy arrangements where the child is born abroad). At a licensed clinic consideration will be given to the welfare of a child born as a result of a surrogacy arrangement and counselling services will be provided to the parties which will include the provision of information about the likely repercussions of a surrogacy arrangement and the importance of obtaining a parental order.23

Agreeing ‘something must be done’ is easy. Determining what can and should be done is harder and the difficulty of formulating sensible proposals for law reform helps explain why successive governments have turned a deaf ear to judicial and other calls for reform of the law24 and left the mess for judges to sort out case by case.

The challenge for those working to change the law is to create a framework that will incentivise better practice and reduce the hard cases which now beset the courts ensuring the best possible outcome for the children of surrogacy and their families. No framework will be perfect. Even if within the UK we create a system of regulation that makes home-grown surrogacy the most attractive option to most intended parents potential surrogates, some will still resort to access abroad or informal ‘under the radar’ arrangements. Regulation may be off-putting to some people seeking surrogacy and an incentive to avoid domestic regulation. That is why ideally a solution to the problems of surrogacy law should be international.25

Back to basics

We need to start by going back to the beginning. In 1984, the Warnock Committee noted that surrogacy presented them with ‘some of the most difficult questions we encountered’.26 Public opinion was sharply divided on many of the other issues addressed by the Committee. In relation to surrogacy the Committee found that that there were ‘strongly held objections to the concept of surrogacy, and it seems from the weight of evidence submitted to

24 See Surrogacy Review.
25 See Jackson, this issue, at p. 197, and Rogerson, this issue, at p. 275.
us that public opinion is against the practice.\textsuperscript{27} The Committee proposed measures designed to discourage surrogacy. At the time the Chair of the Committee, then Dame Mary Warnock, joined the majority of the Committee in rejecting the minority view that surrogacy should be regulated by an official agency which would oversee and approve surrogacy arrangements and facilitate the handover of the child. Baroness Warnock later changed her mind.\textsuperscript{28} In 1984, however, when the Warnock Committee published its Report, opposition to laws facilitating surrogacy was, as the Committee found, fairly widespread. In 1978 in \textit{A v. C}, the first surrogacy case to come before a British court, the Lord Justices of Appeal declared surrogacy arrangements to be ‘irresponsible, bizarre and unnatural’.\textsuperscript{29}

After \textit{Warnock} and before the Human Fertilisation and Embryology Act 1990 became law, Kim Cotton gave birth to a child for an overseas couple receiving a payment of £6500 with a further £6500 paid to the agency that arranged the surrogacy. Mrs Cotton was content to hand over the child as agreed.\textsuperscript{30} Social services intervened and Latey J was entrusted with the task of determining if the couple could take custody of the baby. In a highly pragmatic judgment which was to set the precedent for later judicial interventions focusing on the welfare of the child, Latey J granted custody to the intended parents.\textsuperscript{31} The Kim Cotton case however highlighted the role of agencies and dubious practices in the USA. A picture emerged in the media of surrogacy as a crude commercial transaction. Women were seen as being lured into selling their babies. The women themselves might be vulnerable and ripe for exploitation. At the end of the process they might be forced to hand over the child against their will. Stories of variable authenticity circulated about women who were able to carry a child choosing to opt for surrogacy to avoid ruining their figures or damaging their careers. The emergence of aggressive US surrogacy agents (salesmen) re-enforced a dystopian vision of a commercial baby market. The Warnock Committee suggested that it would be degrading for a child to be ‘bought for money’.\textsuperscript{32}

In this climate, the Surrogacy Arrangements Act 1985 was rushed though Parliament. Payments to any third party for arranging surrogacy were banned and ‘contracts’ for surrogacy made unenforceable. More general disapproval of the practice also led the Committee to rule out any non-profit making state service. Fear of a child being born ‘tainted with criminality’ meant that while

\textsuperscript{27} \textit{Ibid}. para 8.10.
\textsuperscript{28} Mary Warnock, \textit{Making Babies: Is there a right to have Children?} (OUP, 2002), 87-93; also see Mary Warnock’s Foreword to this issue, at p. 155.
\textsuperscript{29} \textit{A v. C} [1985] FLR 445 (decided in 1978 but not reported until 1985).
\textsuperscript{30} See Kim Cotton’s own account, in this issue, especially at p. 230.
\textsuperscript{32} \textit{Warnock}, at para 8.11.
much of the Surrogacy Arrangements Act was re-enforced by criminal sanctions, if an ‘illegal’ payment was made directly from the couple to the surrogate no crime was committed but the original provision in section 30 of the 1990 Act relating to parental orders set the condition that no order should be granted if the surrogate received more than reasonable expenses. Surrogacy in the UK became a kind of ‘hold your nose’ practice – not to be encouraged, but not to be banned, as it was in France.

Surrogacy has not ‘withered on the vine’. Some of the dystopian visions of the Warnock Committee and Parliament during the passage of the 1985 Act have proved groundless. There is no evidence that wealthy career women contract out pregnancy to advance their careers or that the rich and beautiful do so to save their figures. In the UK, in successful arrangements with no overseas element, the crude commercial model of surrogacy has not materialised. In many (but by no means all) cases, surrogacy is a relationship between families or enduring friends. It is this model of relationship which we argue should drive reforms of the law.

There are those who would have no objection to a regulated surrogacy (baby) market, based on a controlled commercial model. For those uncomfortable with such a market the irony is that the dystopian vision of a surrogacy market has come to be largely as a result of attempts to ban it. Payments are made that look excessive, children risk being ‘marooned stateless and parentless’. Poor and powerless women may well be being exploited, but not British women. A largely unregulated international market has sprung up. The objectification of surrogates defined primarily as outsourcing a womb to rent has developed in the USA. The term ‘surrogate mother’ often gives way to the notion of a ‘gestational carrier’. In this model, couples (especially but not solely gay couples) will seek woman A as an egg donor chosen for her genetic strengths of intelligence and beauty and a gestational carrier woman B is chosen perhaps for her childbearing hips and successful record in prior pregnancies. Enforceable contracts grant a high level of control to the couple or individual commissioning the pregnancy. As commercial surrogacy was practised until recently in India and Thailand, egg donor and gestational carrier were similarly separate roles. The carrier was subject to intensively monitored terms of service. Measures to minimise the chance of bonding between the surrogate and the child are put in place. In terms that we cannot better, Julie Wallbank warned intended parents ‘to be

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33 Surrogacy Review, para. 3.44.
34 See the papers by N. Smith, this issue, at p. 237, and N. Gamble & H. Prosser, this issue, at p. 257.
35 See E. Jackson, this issue, at p. 197.
aware that they are collaborating with a woman not a womb’.

Those who engage and those who manage gestational carriers on a commercial basis are, we suggest, wanting to contract with a womb rather than engage with a woman.

A dilemma emerges. Banning payments, outlawing contracts and trying to keep the lid on home grown surrogacy has given rise to the very evils we sought to rule out. Is there a way out? Should we join Lady Warnock in seeking to rethink our understanding of surrogacy and acknowledge that intended parents resorting to surrogacy in the ‘Dark Ages’ of the 1980’s got a raw deal? In those early years, the focus of debate on the emerging reproductive technologies was more one of beneficence to those unable by virtue of medical misfortune to have children rather than on autonomy or the expansion of assisted conception to those seeking alternative family structures. Moreover, the focus was principally on infertile women. IVF helped those who like Lesley Brown had blocked tubes, gamete donation helped couples where the man lacked viable sperm, and women who did not ovulate. Surrogacy was the only source of help for women unfortunate to have been born without a womb or lost that womb to disease, women who did not wish or were not able to adopt. In such cases the infertility was absolute; there was no chance of the woman being able to carry a child. The plight of the wombless did not render them less worthy of help especially as clinically the process of DI and partial surrogacy was so simple that medical help was not strictly necessary (with respect to the Court of Appeal in A v. C, partial surrogacy is less ‘unnatural’ than most forms of assisted conception). Even full surrogacy requiring IVF is on the lower level of complexity in the spectrum of fertility treatments. Did the very fact that surrogacy is not an exclusively medicalised procedure contribute to its controversy? Having a child via partial surrogacy was something willing parties could achieve for themselves, unsanctified by the cloak of medical ‘permission’.

In 2016, as a result of developments on the internet, ‘Do-It-Yourself’ private surrogacy arrangements allow intended parents and surrogates to avoid the regulatory regime that arises when treatment is received at a licensed centre. While there may appear to be benefits to strictly private arrangements, such are equally met with risks given the lack of clinical control for simply testing sperm to ascertain it

is suitable for treatment\textsuperscript{40} or conducting a pre-conception assessment of prospective child welfare.

Fears of adverse consequences arising from facilitating surrogacy led the UK to ban payments and make contracts unenforceable. At this point the first named author must make a humble confession. In agreeing with the ban on payments in 1984 when Warnock reported and in 1998 when she chaired the Surrogacy Review, she was wrong and Michael Freeman was right.\textsuperscript{41} She has not changed her mind about the dangers of the commodification of children or in some cases women who agree to act as surrogates. ‘Commercial’ surrogacy, where acquiring a child is legally and socially conceptualised as akin to buying a high performance sports car, is not a model that fits with the value society ought to accord to children.

The welfare of the child

Judges struggling to avoid adverse consequences to children arising from apparent breaches of the law on expenses,\textsuperscript{42} or incompatible laws on parenthood at birth,\textsuperscript{43} or failures to take formal measures to grant parental status to one or both of the intended parents,\textsuperscript{44} emphasise that the court’s highest priority is the ‘welfare of the child’.\textsuperscript{45} The Human Fertilisation and Embryology (Parental Orders) Regulations 2010\textsuperscript{46} now mandate that the welfare of the child is the ‘paramount consideration’, introducing a welfare checklist which a court must take into account on every application for a parental order. As Hedley J stated in \textit{Re X and Y}:

[I]t is almost impossible to imagine a set of circumstances in which by the time the case comes to court, the welfare of the child...would not be gravely compromised at the very least by a refusal to make a [parental] order.\textsuperscript{47}

In the context of many other Assisted Reproductive Technologies (ARTs), section 13(5) of the Human Fertilisation and Embryology Act 1990, which required that before any licensed treatment can begin, the clinics must take ac-
count of the welfare of ‘any child who may be born as a result of the treatment’ has been roundly condemned.48 The modest amendment of the section in the 2008 Act that replaced the requirement to consider ‘the need for a father’ with the need of that child for ‘supportive parenting’ did little more than dilute criticisms that the provision is discriminatory. So is it right that in the context of surrogacy arrangements, the child’s welfare should be centre stage?

Section 13(5) has been attacked on several grounds. First, a principal philosophical criticism is that in most of the decisions about whether or not to offer ARTs to the patient, if treatment is refused because of the perceived risk to the welfare of an as yet hypothetical child, the choice is whether that child be born or never exist.49 For non-existence to be worse than existing, the potential harm to the child to be would need to be ‘serious’ while presenting a ‘significant risk’.50 Secondly, it entrusts decision about potential welfare to clinicians who lack the expertise, training and facilities to make such welfare judgments. Thirdly, clinics asked to address complex medical and moral considerations about a theoretical child’s welfare may well fall into dangerous realms of clinical speculation and intuitive appeal.51 For example, if prospective parents seek pre-implantation genetic diagnosis and tissue typing to bring about the birth of a ‘saviour sibling’, and if the treatment is refused the saviour baby will never be born. Clinicians are asked to judge not just the medical prospects of treatment, but also to speculate whether the parents will be able to love and care for the saviour child rather than seeing her as just the means to an end. What will the effect be on the saviour child maybe ten or more years on if the donation of cord blood or bone marrow later fails and the elder sibling dies? Such child welfare considerations are evidently complex and fraught with ethical wrestling.

Surrogacy is different. The question is not shall this child be born or would he be better never to be born, but how can the law ensure that the child (any child) once born is cared for in the most favourable environment to allow him to flourish, that he is not a ‘legal orphan’, a bargaining factor between warring ‘parents’, at risk of being separated from the social mother he has bonded with. The questions about welfare are practical; surrogacy unlike other ARTs raises few significant medical questions, or fundamental moral questions about the

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nature of the embryo. Decisions about the implications and implementation of arrangements in the light of child welfare considerations will be made not by clinicians but by experienced judges, or in a reformed legal framework perhaps by a dedicated surrogacy approvals authority. In either case the decision makers will have access to skilled advisors. Placing the welfare of the child at the heart of laws relating to surrogacy does not ask that we decide should this child be born at all but rather how can the law make arrangements more likely to work, how risks of break down can be reduced? What steps can the law legitimately take to maximise the aggregate lifetime welfare of the child born into a surrogacy arrangement? How can a new family be founded that reconciles the needs and wishes of the adult parties and the best chances to promote the well-being of the child?

UK law is muddled and contradictory. The 2010 Regulations governing parental orders require that the interests of the child must take priority in regulating surrogacy. The broader legal framework governing surrogacy fails to support the good intentions of the 2010 Regulations. The difficulty in the law as it stands – the 1985 Act outlawing contracts, the conditions for the grant of a parental order banning payments and the rules defining parental status at birth – make it near to impossible for judges hearing applications for parental orders to prioritise welfare without flagrantly flouting other provisions of the law. Judicial creativity has so far found a way to avoid disastrous outcomes for children at the cost of making the law look like an ass, and because any scrutiny of the arrangement is *ex post facto*, sometimes preventing any substantial evaluation of the initial agreements. The historical aversion to encouraging surrogacy means that regulation to attempt to facilitate good practice in surrogacy remains absent.

**Rethinking regulation**

We now make tentative suggestions for a conceptual framework within which reform of the law might be located if surrogacy is recognised as a legitimate means of founding families, but a model of a surrogacy market based on consumer law is rejected. Such a framework would (as argued above) place the welfare of the child at the centre of the law and also protect and honour the interests of other parties to the arrangement. We argue that the law should be based on a fiduciary model, seeking to endorse and protect relationships of trust between the adult parties and enforcing an obligation of trust in relation to the child. Surrogacy would become part and parcel of modern family law.

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52 We are unaware of the data on this aspect but we do note that although the risk of breakdown is small the costs of breakdown are inevitably traumatic.
Such a model would permit (though not mandate) a moderate payment to the surrogate, encourage clear agreements between the adult parties, allow accredited agencies to facilitate surrogacy, and make the transfer of legal parental status much simpler. The law should seek to make surrogacy work based on the models of good practice garnered from evidence of successful surrogacy practice in the UK today. We first look at how the especially thorny problems illustrated in those cases where the judges have had to stretch the letter of the law near to breaking point might be addressed within a framework based on such a fiduciary model. Then we explore a little further the broader implications of such a fiduciary model.

‘Contracts’, agreements and payments

Contracts and payments have been perhaps the most divisive questions besetting debates on surrogacy and hindering consensus on law reform. At first glance endorsing either seems to steer surrogacy firmly into the commercial arena. This does not need to be the case. Legal language and classifications have not helped. The word ‘contract’ invokes a picture of the market, of sale of goods and buying and selling babies with attendant legal rules about ‘satisfactory quality’ and ‘fitness for purpose’. In the international commercial surrogacy market operating in some parts of the world this situation exists. Contracts control the surrogates’ behaviour, for example, specifying that in certain circumstances should ante-natal tests show the fetus suffers from some form of disability the pregnancy should be terminated. The vendor must hand over the ‘goods’ if the terms of the contract are met. The buyers may reject faulty goods.

Are contracts and a trust based model of surrogacy prioritising the welfare of the child thus incompatible? Not necessarily if we reflect on the language and meaning of contract in everyday language. In common law, agreement alone does not create a legal contract. Both parties must provide consideration, something of value in return for the promise of the other party. Legal contracts at common law are bargains so at first glance the language of contract seems

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53 This would include consideration of the appropriate extent to which agencies could advertise surrogacy services.
55 See e.g. Jadva, this issue, at p. 215; Smith, this issue, at p. 197, and Gamble and Prosser, this issue, at p. 257.
57 See Jackson, Regulating Reproduction 2001 (n. 38), 308-315.
to envisage surrogacy as bargaining for a baby. Strip away the bargain element and focus on popular understanding of contracts as agreements (as is the case in most civil law jurisdictions) and there will be few people who would not agree that the surrogate and the intended parents should negotiate a clear agreement setting out mutually agreed expectations, what the Surrogacy Review termed a Memorandum of Understanding.\(^5\) The Surrogacy Review however recommended that a surrogacy agreement should not permit any payment over and above reasonable expenses. Does paying the surrogate tip the agreement over the threshold of an agreed relationship based on trust and into the jaws of the market?

Opponents of paying surrogates will say, call the contract what you will, if a surrogate is paid a greater sum than the expenses she has incurred, the intended parents are buying a baby. As Michael Freeman\(^5^9\) and many others have argued, the payment can rightly rather to be regarded as payment for the surrogate’s services, akin to paying the doctors at a fertility clinic in the private sector for their services.\(^6^0\) The payment is not for the sale of goods (babies) but for reproductive labour. The surrogate woman is paid for her services as the fertility doctor is paid for hers.\(^6^1\) A lawyer would not draft a contract without expecting an appropriate fee. The professional status of the service provider only alters the essential nature of the assistance rendered, if we regard labour done by the hands and brain of the doctor as different from the work done by the surrogate in permitting the use of her body. Perhaps the question provokes uncomfortable feelings about the intimate use of women’s bodies? Most women who struggle to feed their baby would have few qualms about the baby being fed by bottle or tube from a breast milk bank. Having another woman breast feed your child may feel uncomfortable albeit the same end is attained.\(^6^2\)

One immediate difference between the surrogate who allows her body to be used to gestate the baby and professionals who use brain and hands to create the embryo is obvious. The private patient must pay the clinic whether or not a take home baby is safely delivered. If we conceptualise the surrogate as a ‘human clinic’, payment would be due independently of the transfer of the infant, just as fees must be paid to the clinic for fertility treatment even if treatment was unsuccessful. Intended parents are unlikely to agree to pay the surrogate’s fees if she is free to change her mind and keep the child. Framing the agreement

\(^5^9\) See Freeman, ‘Does Surrogacy Have a Future’ 1999 (n. 4).
\(^6^0\) See Jackson, Regulating Reproduction 2001 (n. 38).
as for services not sale will not remove the reality that what intended parents seek is ‘their’ child. So do we return to the scenario of a dystopian market and a woman having the child she has carried torn from her arms, even when she may have grounds to be concerned about the welfare of the child if she relinquishes her as agreed?

We should note that even traditional contract rules would not necessarily result in the surrogate being obliged to comply with a contract of sale. Contracts for personal services are not subject to specific performance.\(^6^5\) If you engage a nanny and your views on child care prove irreconcilable, or he just does not like you, you cannot get an order that he continues to work for you. There may be liability in damages for breach of contract, so on traditional contract rules the surrogate who refuses to surrender the child might be liable for the cost to the couple of a further surrogacy arrangement. Nor is the analogy with the nanny a complete fit. The nanny walking out causes domestic disruption but does not deprive parents of ‘their’ child.

### Parental status and a fiduciary model

And therein lies the thorny question, whose child is the baby? Current UK law is clear on maternity; at birth the child is the child of the surrogate.\(^6^4\) At least in relation to gestational surrogacy arguments are advanced that the intended parents should be the legal parents of ‘their’ baby from birth.

Practical considerations offer some support for such a change. English law provides for a no more than two-parent model, and the surrogate mother is the legal mother.\(^6^5\) In the most common case where the surrogate is part of a married heterosexual relationship her husband is the legal father. Complex provisions govern legal fatherhood in other cases but it remains the case that no provision is provided in law for anything other than two legal parents.\(^6^6\) Intended parents can acquire parental responsibility only via a parental order, which cannot be applied for until the child is at least six weeks old, or via adoption. In the interim, decisions about for example necessary medical treatment in theory remain with the surrogate even if she has handed over the child. The child and all possible ‘parents’ exist in a legal limbo that does not square with the paramountcy of the welfare of the child in surrogacy arrangements.

\(^6^3\) *De Francescov Barnum* (1890) 45 Ch D 430; and see Jackson, *Regulating Reproduction* 2001, (n. 38), 312.

\(^6^4\) HFEA 2008 Part 2 section 33 (1).

\(^6^5\) *Ibid.*, Part 2 section 35 (1).

We acknowledge that there are sound arguments to consider changing the law on parental status at birth in surrogacy arrangements but not on the basis of whom the child ‘belongs’ to. She ‘belongs’ to no-one in the sense we usually use that word. In another sense she ‘belongs’ to us all as do all children whose welfare in a modern state is not solely the business of parents even when there is no dispute about who those parents are.

How might a fiduciary model of surrogacy approach parental status and parental rights? Parental rights derive from parental responsibility, a responsibility usually but not always derived from biological parenthood. Where parents are dead or incapacitated, guardians act for a child and care for the child in her minority. Guardians undoubtedly owe fiduciary duties to the child. Guardianship offers another way to think about the triangular relationship between the surrogate, the child and intended parents. During her pregnancy the surrogate is de facto the ante-natal guardian of the child she carries, regardless of whose gametes created the child. She is a trustee for the welfare of the child. It will be envisaged by all parties that at birth she will surrender both the child and its guardianship and formal parental responsibility will be conferred on the intended parents. The relationship between surrogate and child cannot be extinguished at the cutting of the umbilical cord. A guardian who had grounds for serious concern about the welfare of the child she carried would have a moral obligation to take some action. A couple who regarded the surrogate as a partner in their reproductive enterprise would take care to ensure her welfare as well as the child’s, and vice versa. Each adult party is a ‘trustee’ for the well-being of the others. We envisage surrogacy as a ‘marriage’ with sometimes three or more people in it. Such a relationship will be complex at times. Different people will want different things from the relationship as do partners in a marriage. Agreement on what this relationship should entail, clarity and trust are essential.

Concepts of guardianship and trusteeship open the door to consideration of pre-conception agreements which, based on sound advice, would address the welfare of the child, the agreed expectations of the adult parties and provide that the intended parents be presumed to obtain parental responsibility at birth. Pre-conception agreements might be likened to the pre-nuptial contracts in *Radmacher (formerly Granatino) v. Granatino*. The analogy is less than perfect and we use it simply to show that agreements can carry weight while allowing for concerns about any suggestion of coercion or limited understanding on the part of any of parties or those affected by the ‘contract’ being given full scrutiny.

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67 See Alghrani/Griffiths/Brazier, ‘From Piecemeal Tweaks’ 2014 (n. 54).
68 [2010] UKSC 42.
Given societal interests in child welfare, to take legal effect the agreement would require prospective scrutiny by a court or a regulatory authority. The parties to the agreement would need to demonstrate that they have addressed the matters of concern to each of them, including the relationship between the surrogate and the child and her family after birth, payments and expenses, health care provision and what might ensue in certain contingencies, for example if intended parents separate or one partner dies. The agreement must be one entered into wholly voluntarily, fully informed, with all parties having had time to reflect. The approving authority must be satisfied that the agreement meets the needs of the child.

Such an agreement would be scrutinised before conception and the intended parents granted a provisional parental order with the caveat that the surrogate has a set time, normally expiring before the birth, to register an objection relating to changed circumstances and/or risks to the child triggering a full re-hearing. In the absence of objection from the surrogate or other concerns being expressed about the welfare of the child once born, the provisional order could be simply confirmed, rather as a decree nisi becomes a decree absolute.

**Fiduciary obligations**

Once the reproductive enterprise is embarked on and pregnancy established, the relationship between surrogate and intended parents should continue to be based on a fiduciary model, one grounded in trust and utmost good faith. English courts have been reluctant to expand the legal categories of fiduciary relationships, notably in refusing to extend fiduciary relationships to the doctor/patient relationship. We lack space here to argue for the law to give full status to legally enforceable fiduciary obligations in surrogacy. We simply contend that the concept offers a helpful model in thinking about surrogacy.

Classical fiduciary relationships such as trustee and beneficiary, solicitor and client, parent and child, or husband and wife require that the fiduciary acts to promote the interests of the vulnerable party in the relationship, the beneficiary, client, or child, usually in relation to the management of the latter’s property. He enjoys a position of trust and must act in utmost good faith.

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70 *Sidaway v. Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1984] 1 All ER 1018 at 1029 (per Dunn LJ) (CA); and [1985] 1 All ER 643 at 651 (per Lord Scarman) (HL).

MacLachlin J, supporting the extension of fiduciary relationships to doctors and patients in the Canadian Supreme Court, made it clear that it is not enough to abide by the letter of the law: in making decisions about the welfare of the other party the fiduciary must act ‘to the highest standard of dealing with their patients which the trust accorded to them requires’.72

The reluctance of English judges to extend the categories of fiduciary relationships to doctors arose in part from what was perceived as dissimilarity between classical fiduciary relationships and doctor/patient relationships. Fears were also expressed that imposing a fiduciary character on doctor/patient relationships would ‘entrench the power balance’ between doctors and patients.73

A model of fiduciary relationships in surrogacy arrangements is less of a departure from the established notions of fiduciary duties than their extension to doctors. Parents already owe fiduciary duties to their minor children, guardians to their wards and spouses to each other. Within surrogacy, we might argue that all candidates for legal parenthood and/or guardianship owe such a duty to the child. That duty requires that they prioritise the interests of the child in hard cases above their own interests.

From such a duty it follows that unless there are overriding concerns about the welfare of the child coming to light after an approved pre-conception agreement, the surrogate will as soon as possible hand over the child and relinquish any claim to retain ‘custody’ of the child, allowing the child to settle with and bond with the intended parents as quickly as possible. Equally, however, should information come to light casting doubt on the capacity of the intended parents to care for the child, the fiduciary duty to the child requires that the surrogate (as guardian of the child) ensures those concerns are addressed. On their part intended parents have an obligation of utmost good faith that, for example, requires them to disclose any information relevant to the welfare of the child. For example if a provisional parental order is made in favour of A and B, and later A becomes aware that B’s violent temper and impatience create a risk to the child, A has a duty to disclose that information. If when the child is born, he is born with significant disabilities the intended parents nonetheless have a duty to honour the arrangement and undertake parental responsibility for him. They cannot simply walk away.

It might further be argued that a fiduciary model that imposes a duty to the child on all the adult parties means that in the above example of the birth of a disabled child, the surrogate too retains an obligation to the child that becomes highly relevant if the intended parents renege on their agreement. Such an obligation does not compel her to raise the child herself but does require that

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she ensure that the child is cared for. The intended parents again cannot be
compelled to accept the child but their fiduciary duty demands that they provide
financial support for the child should the surrogate decide that she will raise
it.

Our concept of a fiduciary model for surrogacy extends beyond the extension
of the established fiduciary category of parent and child to both the surrogate
and the intended parents to suggesting a model of mutual fiduciary obligations
owed by intended parents to surrogates and vice versa. Pre-conception agree-
ments should reflect such mutual duties of care ensuring for example that the
surrogate will be provided with all she needs for a healthy, happy pregnancy,
that the parties agree on such matters as post-birth contact, and that all agree
on the nature of the intended parents’ involvement in the pregnancy. Should
the agreement not cover points of later dispute the mutual notion of fiduciary
obligation can fill the gaps. So, for example, assume A and B enter into an ar-
rangement with C who at the time of the arrangement plans to emigrate with
her husband, and so no provision is made for contact. C’s husband dies suddenly
and she and her children remain in the UK. C now wishes to retain some con-
nection to the child and the parents. Both her welfare and that of the child
should be considered, not simply the terms of the agreement.

Extending a fiduciary model to the adult parties can be supported on at least
two grounds. First, as with any child, the welfare of a child born as a result of
a surrogacy arrangement can in practice never be wholly divorced from the
welfare of the adults on whom she is dependent. The health and well-being of
the surrogate during pregnancy and the parents who will care for her after birth
affect the child.\textsuperscript{74} A constructive relationship between all the adults benefits the
child. Secondly, fiduciary relationships seek to protect a vulnerable party in a
relationship from misuse of power by the fiduciary. In surrogacy arrangements,
both parties are vulnerable to misuse of power by the other. The risks of
exploitation of surrogates are well rehearsed. Surrogates too have power to ‘ex-
plot’ intended parents demanding more money or deceiving the intended
parents about the outcome of a pregnancy.\textsuperscript{75}

\textbf{No easy task}

Reforming UK law on surrogacy will not be easy. It may be
tempting to seek a ‘quick fix’ to obvious problems. The challenge is to create a
framework of laws and regulations that protects the extended family that surro-
gacy creates and reduces the risks of breakdown and legal wrangling. UK law

\textsuperscript{74} See Jadva, this issue, at p. 215.
\textsuperscript{75} R v. Pollard (n. 11); Re N (A Child) [2007] EWCA Civ 1053.
should offer incentives to opt into domestic regulation and reduce the numbers who seek surrogates overseas. A fiduciary model emphasising the centrality of trust may help inform lawmakers. One question, however, we have not even asked. Is surrogacy now regarded as a responsible and legitimate way to found a family? Has evidence of how surrogacy can work dispelled the deep suspicions of the Warnock Committee? Our answer is ‘yes’, but unless there is first a clear articulation that surrogacy is acceptable, half-hearted measures may again result in hazy laws.76

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