

AM I MY BROTHER'S KEEPER? THE USE OF  
PREIMPLANTATION GENETIC DIAGNOSIS TO CREATE  
A DONOR OF TRANSPLANTABLE STEM CELLS FOR AN  
OLDER SIBLING SUFFERING FROM A GENETIC  
DISORDER

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INTRODUCTION

Unprecedented advances in genetic screening, combined with innovations in assisted reproductive technology, have raised complex legal, ethical, and public policy questions both in the United States and abroad. On August 29, 2000, the birth in Colorado of a baby named Adam Nash illuminated the issues raised when these technologies are used in tandem.<sup>1</sup> The unusual fact of Adam's birth was not that he was conceived via in vitro fertilization ("IVF"),<sup>2</sup> a technology that had already been pioneered in England over twenty years before with the 1978 birth of Louise Brown.<sup>3</sup> In-

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<sup>1</sup> See Vida Foubister, *Ethicists Debate New Use of Genetic Testing*, 44 AMER. MED. NEWS 22, 22 (2001).

<sup>2</sup> IVF is a method of assisted reproduction whereby a team of reproductive specialists combines a man's sperm and a woman's eggs (oocytes) in a laboratory dish, thereby producing a fertilized egg. The team typically transfers two to four fertilized eggs, called zygotes, to the uterus a few days later. If any of the zygotes implant successfully and become embryos, the pregnancy progresses as it would naturally. See American Society for Reproductive Medicine, *Fact Sheet: In Vitro Fertilization (IVF)*, <http://www.asrm.org/Patients/FactSheets/invitro.html> (last visited May 11, 2005) [hereinafter *ASRM IVF Fact Sheet*].

<sup>3</sup> See Sozos J. Fasouliotis & Joseph G. Schenker, *Ethics and Assisted Reproduction*, 90 EUR. J. OBSTETRICS & GYNECOLOGY AND REPRODUCTIVE BIOLOGY 171, 176 (2000) (citation omitted). According to the American Society for Reproductive Medicine, IVF was first used successfully in the United States in 1981. *ASRM IVF Fact Sheet*, *supra* note 2. From its inception until mid-2004, IVF had led to the births of over one million people worldwide. Human Fertilisation and Embryology Authority,

stead, Adam Nash's birth represented the first time a couple was known to have used a technique called preimplantation genetic diagnosis ("PGD")<sup>4</sup> not only to screen their IVF embryos for a particular genetic disease before implanting them into the mother's womb, the typical use of PGD,<sup>5</sup> but also to achieve the goal of giving birth to a child who would be a suitable tissue donor for a sibling needing a transplant to fight a disease.<sup>6</sup>

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HFEA RESPONSE TO THE TOFT REPORT, Fact Sheet 3 (June 2004), <http://www.hfea.gov.uk/AboutHFEA/HFEAPolicy/HFEAresponsetotheToftReport2004>.

<sup>4</sup> PGD, a technique in use since 1989, is a method of screening embryos created via IVF for one or more genetic diseases before the embryos are implanted in the uterus. Jamie A. Grifo et al., *Pregnancy After Embryo Biopsy and Coamplification of DNA from X and Y Chromosomes*, 268 J. AM. MED. ASS'N 727 (1992); see generally A. H. Handyside et al., *Pregnancies from Biopsied Human Preimplantation Embryos Sexed by Y-specific DNA Amplification*, 344 NATURE 768 (1990). As Professor Milunsky explained:

Following in vitro fertilization, the fertilized ovum is allowed to reach the eight to sixteen cell stage in a petri dish, at which time a single cell is removed for gene mutation analysis. If the defective gene is present, this 'pre[implantation]-embryo' is discarded, and if the gene is not defective, implantation into the uterus is attempted.

Aubrey Milunsky, *International Symposium on Law and Science at the Crossroads: Biomedical Technology, Ethics, Public Policy, and the Law: The 'New' Genetics: From Research to Reality*, 27 SUFFOLK U. L. REV. 1307, 1315 (1993). Typically, any embryos not implanted are either discarded or donated. John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U. L. REV. 421, 449 (1996).

It is important to keep in mind that the PGD technique cannot guarantee the embryo will be unaffected by any disease or disorder. Additionally, the PGD technique may generate risks of its own. See Judith F. Daar, *The Prospect of Human Cloning: Improving Nature or Dooming the Species?*, 33 SETON HALL L. REV. 511, 528 n. 77 (2003) ("We are in the infancy stage of our knowledge of genes and their relationship to health. The use of cloning or PGD to avoid transmission of certain genes may still produce children who suffer from genetically-based illnesses and syndromes."); AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE AND SOCIETY FOR ASSISTED REPRODUCTIVE TECHNOLOGY, A PRACTICE COMMITTEE REPORT: PREIMPLANTATION GENETIC DIAGNOSIS 3 (June 2001), [http://www.asrm.org/Media/Practice/guideline\\_orderform.pdf](http://www.asrm.org/Media/Practice/guideline_orderform.pdf) [hereinafter ASRM PRACTICE COMMITTEE PGD REPORT] (warning patients of "potential diagnostic errors" and "the possibility of currently unknown long-term consequences on the fetus" associated with the PGD process).

<sup>5</sup> Typically, genetic screening of an embryo for genetic disorders at the preimplantation stage is considered in the best interests of the potential child. PGD permits the parents either to decide not to implant the embryo in the uterus or, alternatively, to prepare for the birth of a special needs child. Because PGD screens out defective embryos before implantation even occurs, it can eliminate the need to terminate a future pregnancy. See Fasouliotis & Schenker, *supra* note 3, at 176. The use of PGD to choose healthy embryos for implantation is not without controversy, however, and faces opposition from some advocates for the disabled as well as certain groups that believe destruction of unimplanted human embryos is tantamount to the destruction of human life. See *infra* notes 45-47, 236 and accompanying text.

<sup>6</sup> See Yury Verlinsky et al., *Preimplantation Diagnosis for Fanconi Anemia Combined with HLA Matching*, 285 J. AM. MED. ASS'N 3130, 3133 (2001) (referring to the "first and only experience" of PGD done with the purpose of testing for donor compatibility); Susan M. Wolf, Jeffrey P. Kahn & John E. Wagner, *Using Preimplantation Genetic Diagnosis to Create a Stem Cell Donor: Issues, Guidelines & Limits*, 31 J.L. MED. & ETHICS 327, 327 (2003) (describing the Nash case as "the first reported case

Adam's parents, Lisa and Jack Nash, gave birth to their first child, Molly Nash, on July 4, 1994, and learned shortly thereafter that she suffered from Fanconi anemia ("FA"),<sup>7</sup> a fatal genetic disorder characterized by failure of bone marrow production.<sup>8</sup> As noted by one commentator, children afflicted with this disease "suffer from anemia, bleeding disorders and severe immune system problems and generally die from leukemia or other complications by age 7."<sup>9</sup> According to Dr. John E. Wagner of the University of Minnesota, Molly Nash's surgeon and an expert in cord blood transfers and Fanconi anemia, for such patients the best hope of treatment is a transfer of stem cells found in the umbilical cord blood of a sibling because the recipient's body is not likely to reject the cells.<sup>10</sup>

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of successful use of PGD for HLA matching followed by hematopoietic stem cell transplant"). See also Rick Weiss, *Test-Tube Baby Born to Save Ill Sister: Genetic Selection by Colorado Parents May Herald an Era*, WASH. POST, Oct. 3, 2000, at A1 ("The case represents the first time a couple is known to have screened their embryos before implanting one in the mother's womb for the purpose of saving the life of a sibling."); CNN.com, *Genetic Selection Gives Girl a Brother and a Second Chance* (Oct. 3, 2000), <http://www.cnn.com/2000/HEALTH/10/03/testtube.brother/> [hereinafter *Genetic Selection Gives Girl a Brother*] ("It's the first time that parents have used genetic testing to select a child who is both free of a disease and is the best tissue match for a sibling who needs a transplant to fight that disease.").

The Nashes were not, however, the first family to conceive a child with the hope of obtaining transplantable tissue. In February 1990, a couple named Abe and Mary Ayala publicly announced their intention to conceive, through natural methods, a child who would be a tissue match for their nineteen-year-old daughter Anissa, who was dying of leukemia. See Gina Kolata, *More Babies Being Born to Be Donors of Tissue*, N.Y. TIMES, June 4, 1991, at A1. Mrs. Ayala gave birth in April 1990 to their daughter Marissa, whose tissue did match Anissa's. Just over a year later surgeons transplanted Marissa's umbilical stem cells and bone marrow to Anissa. *Id.* A 1994 report declared the success of the transplant, stating that "Marissa is now a healthy four year old . . . as loved and cherished as her parents said she would be" and "Anissa is now a married, leukemia-free bank clerk." Robert J. Boyle & Julian Savulescu, *Ethics of Using Preimplantation Genetic Diagnosis to Select a Stem Cell Donor for an Existing Person*, 323 BRIT. MED. J. 1240, 1240 (2001) (citing HASTINGS CENTER REPORT, May/June 1994, at 2).

<sup>7</sup> See Foubister, *supra* note 1, at 22; BBC News, *Baby Created to Save Older Sister* (Oct. 4, 2000), [http://news.bbc.co.uk/1/hi/english/health/newsid\\_954000/954408.stm](http://news.bbc.co.uk/1/hi/english/health/newsid_954000/954408.stm) [hereinafter *Baby Created to Save Older Sister*].

<sup>8</sup> See *Baby Created to Save Older Sister*, *supra* note 7 (describing FA); see also Wolf, Kahn & Wagner, *supra* note 6, at 328 ("FA is a rare fatal disorder that is associated with bone marrow failure, leukemia, and marked cancer predisposition and is inherited in an autosomal recessive fashion."). According to one source, about ninety-eight percent of people with FA have bone marrow failure by age thirty-five, and half have it by age seven. *Genetic Selection Gives Girl a Brother*, *supra* note 6.

<sup>9</sup> Weiss, *supra* note 6.

<sup>10</sup> See *Genetic Selection Gives Girl a Brother*, *supra* note 6. The survival rate for a patient with Fanconi anemia is roughly eighteen to thirty-three percent after a stem cell transplant from an unrelated, tissue-matched donor, but rises to seventy-five to one hundred percent with umbilical cord blood from a sibling. See generally John E. Wagner et al., *Hematopoietic Cell Transplantation in the Treatment of Fanconi Anemia*, in HEMATOPOIETIC CELL TRANSPLANTATION 1204 (E. Donnall Thomas et al., eds., 1999). For a discussion of the medical benefits for patients of receiving a stem cell transplant from a

Because both Lisa and Jack Nash are carriers of the genetic mutation associated with Fanconi anemia, any child conceived by them would have a twenty-five percent chance of developing the disease.<sup>11</sup> In order to avoid such a scenario for the birth of their second child and also to achieve the goal of giving birth to a child who would be a suitable stem cell donor for their daughter Molly, the Nashes used IVF and PGD to give birth to Adam.<sup>12</sup> First, fifteen embryos were created in the lab through IVF.<sup>13</sup> Three days later, the embryos were genetically screened to detect one that was not only free of Fanconi anemia but also able to develop into a child who would be a suitable tissue match, or HLA-matched donor,<sup>14</sup> for Molly. The chosen embryo was then implanted in Lisa Nash, who carried it to term and gave birth to son Adam on August 29, 2000.<sup>15</sup> Thus, what was unique about the Nash case was that the embryo screened for genetic disease was also selected for traits that would benefit another person, in this case an older sibling.<sup>16</sup> The Nash family gave permission for details of their case to be made public.<sup>17</sup>

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relative, and the low statistical probability of finding a closely matched unrelated donor, *see* John A. Robertson, Jeffrey P. Kahn, & John E. Wagner, *Conception to Obtain Hematopoietic Stem Cells*, HASTINGS CTR. REP., May/June 2002, at 34.

Along with umbilical cord blood, bone marrow is also a source of stem cells. *See* HOUSE OF COMMONS SCIENCE AND TECHNOLOGY COMMITTEE, HUMAN REPRODUCTIVE TECHNOLOGIES AND THE LAW, FIFTH REPORT OF SESSION 2004-05, Vol. 1, at 58 (Mar. 24, 2005), <http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/7i.pdf> [hereinafter HUMAN REPRODUCTIVE TECHNOLOGIES AND THE LAW]. Bone marrow donation, however, involves risk and discomfort to the donor, *see infra* note 261 and accompanying text, while donation of stem cells from umbilical cord blood does not. *See infra* note 18 and accompanying text.

<sup>11</sup> *See Genetic Selection Gives Girl a Brother*, *supra* note 6.

<sup>12</sup> *See generally* Verlinsky et al., *supra* note 6 (describing the Nash case). *See also Genetic Selection Gives Girl a Brother*, *supra* note 6; Zosia Kmietowicz, *Couple Asks Permission to Select an Embryo to Save Son's Life*, 323 BRIT. MED. J. 767, 767 (2001).

<sup>13</sup> *See* Kmietowicz, *supra* note 12.

<sup>14</sup> The acronym HLA stands for human leukocyte antigens, which furnish the genetic information that determines whether a tissue recipient's body will accept or reject the transplant. *See* OXFORD DICTIONARY OF BIOLOGY 294 (Elizabeth Martin and Robert S. Hine eds., 4th ed. 2000). This article will refer to the process of human leukocyte antigen typing as HLA typing or tissue typing.

<sup>15</sup> *See* Weiss, *supra* note 6; *see also* Verlinsky et al., *supra* note 6, at 3131-33. The Nashes had actually undergone four unsuccessful attempts to use IVF and PGD to create a healthy and tissue-matched donor child before Adam. *See* Wolf, Kahn & Wagner, *supra* note 6, at 328.

<sup>16</sup> *See Genetic Selection Gives Girl a Brother*, *supra* note 6 ("It's the first time that parents have used genetic testing to select a child who is both free of a disease and is the best tissue match for a sibling who needs a transplant to fight that disease . . ."); Kmietowicz, *supra* note 12, at 767 (describing the Nash family as "the first in the world to use preimplantation diagnostic genetics to benefit a relative").

<sup>17</sup> Wolf, Kahn & Wagner, *supra* note 6, at 328 (citing Lisa Belkin, *The Made-to-Order Savior*, N.Y. TIMES, July 1, 2001, Magazine at 36).

Just after Adam Nash's birth, a team of doctors led by Dr. John Wagner of the University of Minnesota collected cells from Adam's umbilical cord in a painless procedure.<sup>18</sup> On September 26, 2000, they infused these cells into the circulatory system of Adam's sister Molly.<sup>19</sup> Molly showed bone marrow recovery after four weeks, and three years later her hematopoietic and immune systems were normal.<sup>20</sup> According to Molly's transplant surgeon, his team's success in helping her demonstrated that "the work done to combine pre-implantation genetic diagnosis (PGD) and in-vitro fertilization (IVF) to create a healthy cord blood donor holds great promise for those not only with Fanconi anemia, but also leukemia, thalassemia, Hurler syndrome and other diseases that cause the immune system and bone marrow to fail."<sup>21</sup>

Indeed, in a similar case that arose in England around the same time as the Nash case, PGD offered the possibility of treatment for the genetic disorder beta thalassemia.<sup>22</sup> In 2001, Raj and Shahana Hashmi were unable to

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<sup>18</sup> Weiss, *supra* note 6. See also Cord Blood Donor Foundation, *What Is Cord Blood?*, <http://www.cordblooddonor.org/> (last modified Oct. 24, 2003) [hereinafter Cord Blood Donor Foundation] (describing cord blood donation as "painless and safe").

<sup>19</sup> Weiss, *supra* note 6; see also Press Release, Univ. of Minn., Umbilical Cord Blood Transplant Succeeds for Molly Nash (Jan. 4, 2001), [http://www1.umn.edu/urelate/newsservice/newsreleases/1\\_01nash.html](http://www1.umn.edu/urelate/newsservice/newsreleases/1_01nash.html) [hereinafter Umbilical Cord Transplant Succeeds].

Umbilical cord blood, which is the blood that remains in the umbilical cord and placenta following birth, can be collected after a baby is born and the umbilical cord has been clamped and cut. The umbilical cord blood contains stem cells which doctors extract and then use to treat the same diseases that bone marrow treats, including leukemia, other cancers, and blood and immune disorders, but with significantly less risk of rejection than bone marrow. Cord Blood Donor Foundation, *supra* note 18. Typically, cord blood would be discarded if not used in a transplant. Umbilical Cord Transplant Succeeds, *supra*. Physicians have used umbilical cord blood in transplants since 1988, and since that time more than two thousand such transplants have been performed. The International Society for Cellular Therapy, Barcelona 2002 Conference, Eliane Gluckman and Vanderson Rocha, *Current Results of Unrelated Cord Blood Transplant: A Report from Eurocord* (2002), <http://www.celltherapy.org/abstracts2002/Speakers/SA018.htm>.

<sup>20</sup> Wolf, Kahn & Wagner, *supra* note 6, at 328. A May 4, 2004 report on other families who chose to undergo the same procedure as the Nashes described both Molly and Adam Nash as "healthy and thriving." ABC News, [abc7chicago.com](http://abc7chicago.com), *Made-to-Order Babies* (May 4, 2004), <http://abclocal.go.com/wls/story?section=News&id=1548808>.

<sup>21</sup> Umbilical Cord Transplant Succeeds, *supra* note 19 (quoting Dr. John Wagner of the University of Minnesota); see also Wolf, Kahn & Wagner, *supra* note 6, at 329 & Table 1 (listing "the range of diseases and indications for which PGD for HLA matching could be used, suggesting significant potential demand").

<sup>22</sup> Beta thalassemia is a rare genetic blood disorder characterized by the body's failure to produce a certain protein necessary for proper formation of the red blood cells that carry oxygen throughout the body. In its most extreme form, beta thalassemia is "a life-threatening anemia that requires regular blood transfusions and extensive ongoing medical care. These extensive, lifelong blood transfusions lead to iron-overload which must be treated with chelation therapy to prevent early death from organ failure." Cooley's Anemia Foundation, About Thalassemia, <http://www.cooleysanemia.org/>

find a suitable stem cell donor for their then two-year old son Zain, who was afflicted with this condition.<sup>23</sup> Although Zain received a daily cocktail of drugs and blood transfusions to treat his disorder, the amount of iron in his blood would ultimately build to dangerous levels on this regimen and his life expectancy was therefore uncertain.<sup>24</sup> A stem cell transplant from a tissue-matched donor could potentially cure Zain's condition, enabling him to enjoy a relatively normal life.<sup>25</sup> Thus, his parents wished to undergo IVF and then to use PGD to select an embryo that would develop into a sibling who would be a suitable donor of umbilical cord stem cells, just as the Nashes had done.<sup>26</sup>

Unlike the Nashes in United States, however, the British Hashmi family needed first to obtain the permission of a United Kingdom statutory body, the Human Fertilisation and Embryology Authority ("HFEA"), before proceeding with PGD.<sup>27</sup> The primary duties of the HFEA, a government body established in 1991,<sup>28</sup> are to "[l]icense and monitor clinics that carry out *in vitro* fertilisation (IVF) and donor insemination; [l]icense and monitor research centres undertaking human embryo research; [and r]egulate the storage of gametes and embryos."<sup>29</sup> According to its web site, "[u]nderlying all these activities is the HFEA's desire to safeguard the interests of patients, children, the general public, doctors, service providers, the scientific community, and also future generations."<sup>30</sup> The HFEA, which

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sections.php?sec=1 (last visited May 17, 2005). See also Harvard Information Center for Sickle Cell and Thalassemic Disorders, *Thalassemia*, <http://sickle.bwh.harvard.edu/thalover.html> (last revised Oct. 9, 1999) (describing thalassemia).

<sup>23</sup> See Kmietowicz, *supra* note 12, at 767. Neither Zain's parents nor his four siblings had tissue that matched his. Roger Highfield, *Fertility Authority Gives Go-Ahead For "Designer Babies,"* THE DAILY TEL., Dec. 13, 2001, at 9.

<sup>24</sup> See R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2003] 3 W.L.R. 878 ¶ 1 (C.A. 2003). One of the appellate justices deciding the Hashmis' case considered that Zain "may live to his 30s or even early 40s on evolving medication and frequent blood transfusions; he could become allergic to medication, which could itself be life-threatening; and he might at any time develop fairly rapid organ failure." *Id.* ¶ 99.

<sup>25</sup> *Id.* ¶ 99.

<sup>26</sup> Kmietowicz, *supra* note 12, at 767.

<sup>27</sup> The application to the HFEA was actually submitted by Dr. Simon Fishel, director of the Centre for Assisted Reproduction at the Park Hospital in Nottingham, England, who sought permission to select an embryonic sibling to provide stem cells for transplant to Zain Hashmi. See Highfield, *supra* note 23.

<sup>28</sup> The HFEA was established pursuant to the Human Fertilisation and Embryology Act 1990, 1990 c. 37 (Eng.). See *infra* notes 72-79 and accompanying text for further discussion of the HFEA.

<sup>29</sup> Human Fertilisation and Embryology Authority, About the Human Fertilisation and Embryology Auth., <http://www.hfea.gov.uk/AboutHFEA> (last visited May 19, 2005).

<sup>30</sup> *Id.*

is the first statutory body of its type,<sup>31</sup> has no analogue in the United States.<sup>32</sup> Thus, the U.K. regulates much more strictly than the U.S. the use of PGD with tissue typing in order to obtain umbilical cord stem cells for transplant in an older sibling. Interestingly, while the U.K. House of Commons Science and Technology Committee has called for changes in governmental regulation of PGD with tissue typing, including more parental autonomy in making decisions regarding this technology,<sup>33</sup> some commentators in the U.S. legal, medical, and academic communities have advocated for greater oversight of this technology.<sup>34</sup>

Part I of this article will describe both the medical and non-medical uses of PGD, and then contrast the relative paucity of regulation of preimplantation genetic diagnosis in the United States with the highly regulatory environment in the U.K. Part II will examine the effect of the current U.K. regulatory regime on two British families, the Hashmis and the Whitakers, who have sought PGD with tissue typing for the purpose of conceiving a stem cell donor for an older sibling afflicted with a genetic disorder. In order to determine whether such regulation is beneficial, Part III will analyze the ethical arguments for and against the practice of PGD with tissue typing in order to create a donor sibling. Part IV will consider a recent Parliamentary proposal in the U.K. calling for less regulation of PGD with tissue typing, as well as recent scholarship in the U.S. supporting greater regulation. Further, building upon the scholarship of Professors Wolf, Kahn, and Wagner, whose work is informed by their personal involvement in the Nash case, Part IV will also evaluate their proposal for enhanced involvement on the part of hospital institutional review boards ("IRBs") and ethics review committees for the purpose of protecting stem cell donor siblings. Part IV leaves open the possibility of future regulation if the ongoing collection of

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<sup>31</sup> HUMAN FERTILISATION AND EMBRYOLOGY AUTH., ABOUT THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY, INTRODUCTION (May 2003), <http://www.hfea.gov.uk/AboutHFEA/About%20the%20HFEA.pdf>.

<sup>32</sup> See Wolf, Kahn & Wagner, *supra* note 6, at 329 (explaining that the U.S. has no central body regulating reproductive technologies) (citation omitted).

<sup>33</sup> See HUMAN REPRODUCTIVE TECHNOLOGIES AND THE LAW, *supra* note 10, at 60 ("We conclude that there are no compelling reasons for a statutory authority to make judgements on whether or not a family can seek preimplantation tissue typing, provided they fall within parameters set by Parliament.") and at 157 (emphasizing its goal of optimizing "the freedom of patients to make decisions in consultation with their doctors").

<sup>34</sup> See, e.g., Wolf, Kahn & Wagner, *supra* note 6, at 330-36 (offering specific criteria families seeking PGD with tissue typing must meet and recommending review by an ethics committee or ethics consultant, in addition to oversight by a hospital institutional review board ("IRB")). See also Lisa Belkin, *The Made-to-Order Savior*, N.Y. TIMES, July 1, 2001, Magazine at 36 (quoting Dr. John Wagner, Molly Nash's transplant surgeon, as stating that PGD with tissue typing for the purpose of conceiving a stem cell donor "has been forced into the private sector where there are no controls" and "that there should be limits" decided upon through social consensus).

data about this technology suggests such regulation is necessary. This article concludes that oversight by private medical professionals, coupled with enhancement of this system, is preferable absent more data supporting the need for governmental regulation of this relatively new technology.

I. THE PRACTICE AND REGULATION OF PREIMPLANTATION GENETIC DIAGNOSIS IN THE UNITED STATES AND THE UNITED KINGDOM

A. *The Practice and Governmental Regulation of Preimplantation Genetic Diagnosis in the United States*

PGD is not widely practiced in the United States, due to its high cost and the limited number of reproductive centers offering this technique. PGD adds costs of approximately \$2,500 per fertility cycle<sup>35</sup> and can be implemented only in tandem with IVF, which alone costs approximately \$12,400 per cycle.<sup>36</sup>

While the number of centers offering PGD and the number of babies born using this technique are difficult to ascertain, one recent source indicates PGD is available at about only 50 institutions worldwide and approximately 2,000 babies have been born throughout the world using PGD.<sup>37</sup> Nonetheless, shortly after he performed Molly Nash's surgeon, Dr. Wagner stated that he had witnessed "a tremendous outpouring of requests for the ability to have a child that is free of a disease but also one that is HLA-matched with a child that needs a transplant within the family," and that he personally had received hundreds of inquiries about PGD from families around the world.<sup>38</sup> In a May 5, 2004 article in the *Journal of the American Medical Association*, researchers demonstrated the feasibility of

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<sup>35</sup> ASRM PRACTICE COMMITTEE PGD REPORT, *supra* note 4, at 3.

<sup>36</sup> ASRM IVF Fact Sheet, *supra* note 2.

<sup>37</sup> See Tania Simoncelli, *Pre-Implantation Genetic Diagnosis and Selection: From Disease Prevention to Customized Conception*, DIFFERENTAKES NO. 24 (POPULATION AND DEV. PROGRAM AT HAMPSHIRE COLLEGE) at 1 (2003), [http://www.genetics-and-society.org/resources/cgs/200303\\_difftakes\\_simoncelli.pdf](http://www.genetics-and-society.org/resources/cgs/200303_difftakes_simoncelli.pdf) (citation omitted). Another source has estimated the number of births using PGD as over 1,000, and states that while more than forty centers worldwide offer the procedure, including institutions in the U.S., Europe, the eastern Mediterranean, Southeast Asia, and Australia, nearly all the reported cases originate from four centers in Chicago, Livingston, NJ, Bologna, and Brussels. See John A. Robertson, *Extending Preimplantation Genetic Diagnosis: The Ethical Debate*, 18 HUMAN REPRODUCTION 465, 465 (2003) (citing International Working Group on Preimplantation Genetics, *Conference Report of the 11th Annual Meeting: Preimplantation Genetic Diagnosis: Experience of 3000 Clinical Cycles*, 3 REPRODUCTIVE BIOMED. ONLINE 49 (2001)).

<sup>38</sup> Foubister, *supra* note 1, at 22. See also Wolf, Kahn & Wagner, *supra* note 6, at 329 (describing increasing demand worldwide for PGD with tissue typing in order to conceive donor siblings).

conducting PGD with tissue typing in order to conceive stem cell donors for older siblings affected by a range of genetic disorders involving bone marrow failure.<sup>39</sup> What is more, according to survey results announced by the Genetics and Public Policy Center of Johns Hopkins University in May 2004, sixty-one percent of Americans approve of using PGD to select an embryo that could benefit a sick brother or sister, while only thirty-three percent disapprove of this practice.<sup>40</sup> Thus, it is likely that the demand for PGD, including PGD with tissue typing, will increase both in the United States and in other nations.<sup>41</sup>

Present technology does not permit reproductive specialists to employ PGD to select embryos for physical characteristics, behavioral traits, or intelligence, though it is expected that ultimately such selection will be possible, thereby permitting parents to “customize conception.”<sup>42</sup> There are some concerns that such non-medical use of PGD will lead to several negative consequences, such as eugenic procreative practices; an excessively consumer-driven attitude toward bearing children; improper expenditure of limited medical resources; and increasing disparities between the affluent, who will be able to afford healthier children, and economically disadvantaged families, who will not. On the other hand, proponents of a *laissez-faire* approach toward PGD contend that parents are entitled to procreative autonomy.<sup>43</sup> Another non-medical use of PGD, gender selection, is indeed practicable. Those opposed to PGD contend this practice not only raises all of the ethical problems posed by other non-medical uses of PGD, but also perpetuates discrimination on the basis of gender and may even lead to population imbalances between males and females in certain nations.<sup>44</sup> All

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<sup>39</sup> See Yury Verlinsky et al., *Preimplantation HLA Testing*, 291 J. AM. MED. ASS'N 2079 (2004).

<sup>40</sup> *Most Americans Find Genetic Testing of Embryos Acceptable in Conceiving a Child Who Will Donate Tissue to Save an Older Sibling*, ASRM BULLETIN, Vol. 6, No. 27 (May 6, 2004), <http://www.asrm.org/Washington/Bulletins/vol6no27.html> [hereinafter *Most Americans Find Genetic Testing of Embryos Acceptable*].

<sup>41</sup> According to the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology, while at present PGD “requires specialized equipment, methodology, and experience,” it “should be regarded as an established technique with specific and expanding applications for standard clinical practice.” ASRM PRACTICE COMMITTEE PGD REPORT, *supra* note 4.

<sup>42</sup> See Jason Christopher Roberts, *Customizing Conception: A Survey of Preimplantation Genetic Diagnosis and the Resulting Social, Ethical, and Legal Dilemmas*, 2002 DUKE L. & TECH. REV. 12 (2002).

<sup>43</sup> *See id.*

<sup>44</sup> The Ethics Committee of the American Society for Reproductive Medicine, *Sex Selection and Preimplantation Genetic Diagnosis*, 72 FERTILITY AND STERILITY 595, 596 (1999) [hereinafter *1999 ASRM Report on PGD*]. In China and India, for example, strong parental preference for male heirs and the consequent use of ultrasound screening and abortion for gender selection purposes has led to great disparities in the sex ratio of the population. See J.A. Robertson, *Extending Preimplantation Genetic Diagnosis: Medical and Non-Medical Uses*, 29 J. MED. ETHICS 213, 214 (2003).

of these non-medical uses of PGD are likely to generate even more controversy as the technique becomes more affordable and commonplace.

Even the use of PGD to screen embryos for genetic disorders is not entirely free from controversy. As one commentator noted, the argument most often cited against medical use of PGD relates to the moral status of the embryo. Specifically, pro-life activists argue that life begins at fertilization, not conception, and that embryos created via IVF therefore merit the same legal protections as individuals who have been born.<sup>45</sup> Another argument against medical use of PGD is that it reinforces societal beliefs that individuals with disabilities are somehow inferior or less deserving of life.<sup>46</sup> The utility of PGD screening for genetic disorders arguably grows even more questionable in two situations: first, where the full extent of the diagnosed disability is not truly known, since improved treatment or even complete cures for the condition may be available in the future; and second, where the onset of the disease is expected so late in life that the embryo, if carried to term, could expect to live many healthy years.<sup>47</sup> On the other hand, those supporting the availability of PGD for medical uses maintain that families ought to be able to decide for themselves whether to bear the emotional, physical, and financial costs imposed by caring for a person afflicted with a significant genetic disorder.<sup>48</sup>

For the most part, U.S. families exercise great autonomy in choosing whether to use PGD. Like most other assisted reproductive technologies, PGD remains largely unregulated in the United States. As Professor Daar explained, “the U.S. is a virtually regulatory-free environment when it comes to reproductive technologies, with only a few states codifying behavior” surrounding assisted reproductive technologies.<sup>49</sup> Four states

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<sup>45</sup> See Roberts, *supra* note 42.

<sup>46</sup> See *id.*

<sup>47</sup> See *id.* See also Wolf, Kahn & Wagner, *supra* note 6, at 327 n.4 (gathering cites that discuss the legal and ethical implications of PGD for late-onset disorders).

<sup>48</sup> See Roberts, *supra* note 42.

<sup>49</sup> Judith F. Daar, *Assisted Reproductive Technologies and the Pregnancy Process: Developing an Equality Model to Protect Reproductive Liberties*, 25 AM. J.L. & MED. 455, 464 n.93 (1999). The federal government likewise has promulgated little legislation relating to assisted reproductive technology, leaving such regulation to the states. While state malpractice and tort laws apply, these do not address the ethical questions raised by new procedures. See Robertson, *supra* note 37, at 470.

The single piece of federal legislation governing assisted reproduction centers, The Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. §§ 263a-1 to -7 (2000), requires fertility centers to report pregnancy success rates to the Centers for Disease Control and also calls for states voluntarily to implement a certification procedure for such centers in order to maintain quality control. Implementation of the Fertility Clinic Success Rate and Certification Act of 1992—A Model Program for the Certification of Embryo Laboratories, 64 Fed. Reg. 39,374 (July 21, 1999). This Act primarily prohibits fraudulent advertisements or misleading claims of pregnancy success rates, however, rather than regulating medical procedures at fertility clinics. See 138 Cong. Rec. H5350 (daily ed. June 29,

forbid therapeutic PGD unless it can be shown that it causes no harm to the embryos and is beneficial,<sup>50</sup> and no state or federal laws directly control the nontherapeutic use of PGD.<sup>51</sup> Congress has elected not to fund research concerning the use of PGD, including PGD with tissue typing, but has also declined to regulate the use of PGD in the private sector.<sup>52</sup> Therefore, as Professor Robertson noted: “How PGD is used and for what indications is thus left largely to the discretion of providers offering those services and the patients who seek it.”<sup>53</sup>

One U.S. group promulgating *voluntary* industry standards relating to PGD is the American Society for Reproductive Medicine (“ASRM”), a membership-driven nonprofit organization for professionals in the fields of

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1992) (statement of Rep. Waxman) (describing the act as a form of consumer protection); 138 Cong. Rec. H5351 (daily ed. June 19, 1992) (statement of Rep. Wyden) (same).

While the reporting provision of The Fertility Clinic Success Rate and Certification Act of 1992 is now operative, *see* 65 Fed. Reg. 53,310 (Sept. 1, 2000), the CDC is not aware of any state presently implementing the model certification program. E-mail from Public Inquiries Group, Division of Reproductive Health, Centers for Disease Control and Prevention, to Donna M. Gitter, Assistant Professor of Legal and Ethical Studies, Fordham University Schools of Business (Dec. 9, 2003, 09:28:00 EST) (on file with author). Moreover, according to the CDC, since the cost of federal and state oversight of embryo laboratories would fall upon the participating laboratories, for which participation in the program is entirely voluntary, “to date, embryo laboratories have not indicated they would opt into such a voluntary program.” *Id.* It should be noted, however, that two hundred sixty-four U.S. labs are participating voluntarily in an accreditation program maintained by the College of American Pathologists, a nonprofit professional organization. E-mail from Justin Chambers, Operations Specialist, College of American Pathologists, to Donna M. Gitter, Assistant Professor of Legal and Ethical Studies, Fordham University Schools of Business (Apr. 19, 2003, 12:51:00 EST) (on file with author).

Professor Daar has explained that among the possible reasons for the lack of legislative activity surrounding assisted reproduction is that “the issue of assisted human reproduction is highly politically charged because of its perceived affiliation with the abortion debate” as well as “our nation’s emphasis on autonomy and liberty in medical and procreative decision-making,” particularly where conception and procreation are involved. Judith F. Daar, *Regulating Reproductive Technologies: Panacea or Paper Tiger?*, 34 HOUS. L. REV. 609, 639-40 (1997).

<sup>50</sup> *See* June Coleman, *Playing God or Playing Scientist: A Constitutional Analysis of State Laws Banning Embryological Procedures*, 27 PAC. L.J. 1331, 1354 & n.153 (1996). *See also* LA. REV. STAT. ANN. §§ 9:122, 9:129 (1991); ME. REV. STAT. ANN. tit. 22, § 1593 (1992); MINN. STAT. ANN. § 45.421 subd. 1, 2 (West 1998); 18 PA. CONS. STAT. ANN. § 3216(a) (2000).

<sup>51</sup> *See* Robertson, Kahn & Wagner, *supra* note 10, at 39 (noting that “there are few legal barriers preventing parents and physicians from using prenatal testing and PGD to produce HLA-matched stem cells for transplant”); Roberts, *supra* note 42 (citing Rachel Remaley, “The Original Sexist Sin”: *Regulating Preconception Sex Technology*, 10 HEALTH MATRIX: J. LAW-MED. 249, 282 & n.166 (2000)). The only restriction the federal government has imposed, albeit indirectly, on families seeking PGD with tissue typing in order to conceive a tissue donor is federal legislation criminalizing abortion of a fetus for the purpose of obtaining fetal tissue, designating it a felony punishable by up to ten years in prison. *See* National Institutes of Health Revitalization Act of 1993, 42 U.S.C. § 289g-2 (1994).

<sup>52</sup> *See* Robertson, Kahn & Wagner, *supra* note 10, at 39.

<sup>53</sup> Robertson, *supra* note 37, at 470.

infertility, reproductive medicine, and biology.<sup>54</sup> The ASRM supports the use of PGD to detect genetic disorders<sup>55</sup> but has not declared any policy regarding the use of PGD with tissue typing to create a stem cell donor.<sup>56</sup>

B. *The Practice and Governmental Regulation of Preimplantation Genetic Diagnosis in the United Kingdom*

According to a report published in 2004 by the United Kingdom Human Fertilisation and Embryology Authority (“HFEA”),<sup>57</sup> preimplantation genetic diagnosis is available at nine licensed centers in the United Kingdom.<sup>58</sup> These centers use PGD to detect a variety of single gene defects and chromosome disorders, as well as fetal gender.<sup>59</sup> In the U.K., IVF at one

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<sup>54</sup> American Society for Reproductive Medicine, Welcome to the ASRM Web Site, <http://www.asrm.org/index.html> (last visited Nov. 10, 2005). Commentators have described the ASRM as “the lead professional society issuing guidelines for reproductive medicine.” Wolf, Kahn & Wagner, *supra* note 6, at 329. The Society for Assisted Reproductive Technology (“SART”), an affiliate of the ASRM and another voluntary membership organization, describes itself on its web site as the “governmental watchdog for ART [assisted reproductive technology]-prospectively preventing governmental intrusion.” Society for Assisted Reproductive Technology, What Does SART Do Anyway?, <http://www.sart.org/whatis.html> (Winter 2000).

<sup>55</sup> See *Enhanced Preimplantation Genetic Diagnosis Method Allows Full Identification of Chromosomal Abnormalities and Greater Opportunity to Test Single Gene Defects*, [http://www.obgyn.net/infertility/infertility.asp?page=/infertility/news/asm\\_genetics](http://www.obgyn.net/infertility/infertility.asp?page=/infertility/news/asm_genetics) (last visited Nov. 10, 2005) (“To increase the chances of having a successful pregnancy, patients undergoing IVF may choose to have preimplantation genetic diagnosis (PGD) done on their embryos, so that normal ones can be transferred, and abnormal ones, without the potential to develop into healthy children, can be discarded.”); see also ASRM PRACTICE COMMITTEE PGD REPORT, *supra* note 4, at 1 (“The opportunity to exclude in-vitro derived embryos with documented genetic abnormalities before the initiation of pregnancy is an attractive means of preventing heritable genetic disease.”).

<sup>56</sup> See *Most Americans Find Genetic Testing of Embryos Acceptable*, *supra* note 40 (stating that “ASRM’s Practice Committee has developed guidelines on Preimplantation Genetic Diagnosis and its Ethics Committee has released reports on Pre-conception Gender Selection for Non-Medical Reasons and Sex Selection and Pre-Implantation Genetic Diagnosis,” but not mentioning any report on PGD with HLA typing). See also e-mail from Eleanor Nicoll, Public Affairs Manager, American Society for Reproductive Medicine, to Donna M. Gitter, Assistant Professor of Legal and Ethical Studies, Fordham University Schools of Business (May 24, 2005, 05:45:00 PM) (on file with author) (“At this point, the Society has not chosen to take a position on the issue.”).

<sup>57</sup> See *infra* notes 72-79 and accompanying text for a discussion of the HFEA.

<sup>58</sup> HUMAN FERTILITY AND EMBRYOLOGY AUTH., *FACING UP TO THE CHALLENGE: HFEA ANNUAL REPORT 2003/04*, at 8 (2004), <http://www.hfea.gov.uk/HFEAPublications/AnnualReport>. As explained *infra*, see notes 72-76 and accompanying text, only licensed centers may perform IVF and PGD in the United Kingdom.

<sup>59</sup> See HUMAN FERTILISATION AND EMBRYOLOGY AUTH. AND ADVISORY COMMITTEE ON GENETIC TESTING, *CONSULTATION DOCUMENT ON PREIMPLANTATION GENETIC DIAGNOSIS 4-5* (1999), <http://www.hfea.gov.uk/AboutHFEA/Consultations/PGD%20document.pdf> (last visited Nov. 10,

representative clinic costs approximately £ 2,250 per cycle (equivalent to about \$ 4,100),<sup>60</sup> on top of the £ 2,650 (about \$ 4,800) for IVF.<sup>61</sup>

Both IVF and PGD are highly regulated in the U.K. According to Professor Stenger, public discussion in the United Kingdom concerning assisted reproductive technology arose following the 1978 birth of Louise Brown in Lancashire, England.<sup>62</sup> By 1982, the United Kingdom's Secretary of State for Social Services announced the establishment of a sixteen member committee composed of theologians, social workers, attorneys, and scientists, led by the philosopher Dame (and later Lady) Mary Warnock, charged with examining the legal and ethical issues surrounding assisted reproductive technology.<sup>63</sup> In 1984, this committee produced the Warnock Report,<sup>64</sup> which made specific recommendations to Parliament about different reproductive technologies.<sup>65</sup> As Professor Stenger noted, "[t]he Warnock Report's recommendations proved to be quite influential when subsequent discussions and legislation incorporated them," especially with respect to the creation of "a licensing authority to authorize and regulate personnel and clinics offering assisted reproduction."<sup>66</sup>

In 1990, the U.K. Parliament, heeding the Warnock Report's call for legislation,<sup>67</sup> enacted the Human Fertilisation and Embryology Act 1990 ("the HFE Act").<sup>68</sup> One aim the U.K. Parliament had in drafting the HFE Act was to "make provision in connection with human embryos and any subsequent development of such embryos; [and] to prohibit certain practices in connection with embryos and gametes."<sup>69</sup> The HFE Act defines an

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2005) [hereinafter CONSULTATION DOCUMENT ON PGD] (describing the uses of PGD in the U.K.). See *infra* note 131 and accompanying text describing the U.K.'s regulation of PGD with gender selection.

<sup>60</sup> For currency conversions, see xe.com, Currency Calculator, <http://www.xe.com> (last visited Nov. 10, 2005).

<sup>61</sup> See The Bridge Center, Treatment and Prices, <http://www.thebridgecentre.co.uk/treatment1.htm> (last visited Nov. 10, 2005).

<sup>62</sup> Robert L. Stenger, *The Law and Assisted Reproduction in the United Kingdom and United States*, 9 J.L. & HEALTH 135, 139 (1994-95). See *supra* text accompanying note 3 regarding the birth of Louise Brown, the first child born using IVF.

<sup>63</sup> See Stenger, *supra* note 62, at 140-41.

<sup>64</sup> DEPARTMENT OF HEALTH AND SOCIAL SECURITY, REPORT OF THE COMMITTEE OF INQUIRY INTO HUMAN FERTILISATION AND EMBRYOLOGY (1984) [hereinafter WARNOCK REPORT].

<sup>65</sup> See Stenger, *supra* note 62, at 142.

<sup>66</sup> *Id.*

<sup>67</sup> See *id.* at 145.

<sup>68</sup> Human Fertilisation and Embryology Act, 1990, c. 37 (Eng.) [hereinafter HFE Act].

<sup>69</sup> *Id.* The long title of the HFE Act discusses the purposes of the HFE Act and provides for additional purposes other than those discussed above. See *id.*

embryo as either “a live human embryo where fertilization is complete”<sup>70</sup> or “an egg in the process of fertilization.”<sup>71</sup>

The HFE Act also created a statutory licensing body, the Human Fertilisation and Embryology Authority,<sup>72</sup> which authorizes and regulates clinics that offer assisted reproductive procedures.<sup>73</sup> The HFEA may grant licenses for providing treatment services, for storage of gametes and embryos, and for research.<sup>74</sup> It conducts inspections before a license is granted and also requires annual reinspections.<sup>75</sup> The HFEA also may refuse or revoke licenses.<sup>76</sup>

In addition to licensing and monitoring clinics that perform assisted reproduction procedures, the HFEA maintains a Code of Practice that sets forth guidelines to clinics about the proper conduct of licensed activities.<sup>77</sup> The HFEA also has a statutory duty to collect information about licensed treatments and their outcomes and to maintain a register of information from data provided by licensed clinics.<sup>78</sup> As explained in an HFEA annual report, the purpose of collecting this information is “to provide information to children born as a result of such treatments; to monitor the provision of treatments; and to assist in the provision of information to the Government, patients, clinics and the general public.”<sup>79</sup>

In 2001, the HFEA, together with the Human Genetics Commission,<sup>80</sup> reviewed both the issue of using PGD and the additional step of tissue typ-

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<sup>70</sup> *Id.* § 1(1)(a).

<sup>71</sup> *Id.* § 1(1)(b).

<sup>72</sup> *Id.* § 5.

<sup>73</sup> *Id.* § 11 & sched. 2. The HFE Act ensures public representation on the HFEA, as no more than half the members may fall within the following categories: medical practitioners; persons “concerned with keeping or using gametes or embryos outside the body;” or persons directly “concerned with commissioning or funding any research” involving keeping or using gametes or embryos outside the body. *Id.* sched. 1 § 4(3)-(4). These categories of people are also disqualified from being appointed chair or deputy chair of the HFEA. *Id.* sched. 1 § 4(3). The HFE Act also seeks to achieve adequate representation of both men and women. *Id.* sched. 1 § 4(2).

<sup>74</sup> HFE Act, *supra* note 68, at § 11.

<sup>75</sup> *Id.* § 9(7)-(11).

<sup>76</sup> *See id.* § 18-19.

<sup>77</sup> *See id.* § 25. The Sixth Edition of the HFEA Code of Practice, published in 2004, is available to the public at <http://www.hfea.gov.uk/HFEAPublications/CodeofPractice/Code%20of%20Practice%20Sixth%20Edition%20-%20final.pdf>.

<sup>78</sup> HFE Act, §§ 8, 31 (1990).

<sup>79</sup> HUMAN FERTILISATION AND EMBRYOLOGY AUTH., ELEVENTH ANNUAL REPORT AND ACCOUNTS 4 (2002), available at <http://www.hfea.gov.uk/HFEAPublications/AnnualReport/2002%20HFEA%20Annual%20Report.pdf> [hereinafter HFEA ELEVENTH ANNUAL REPORT].

<sup>80</sup> The U.K. government established the Human Genetics Commission in 1999 as a regulatory and advisory body in the area of biotechnology. Human Genetics Commission, About HGC: Origin and Role, [http://www.hgc.gov.uk/Client/Content\\_wide.asp?ContentId=6](http://www.hgc.gov.uk/Client/Content_wide.asp?ContentId=6) (last visited Nov. 17, 2005). On its web site, HGC describes itself as an “independent source of advice” for the U.K. government. *Id.*

ing to determine if an embryo has tissue compatible with an existing sibling.<sup>81</sup> The HFEA incorporated in its findings the results of a public consultation process assessing public attitudes toward this technology.<sup>82</sup> In its November 2001 report on the use of PGD, the HFEA recommended that PGD with tissue typing should “only be available when there is a significant risk of a serious genetic condition being present in the embryo” itself, based on the genetic makeup of its parents.<sup>83</sup> At its meeting on November 29, 2001, the HFEA also agreed, in principle, to permit PGD with tissue typing subject to the following criteria:

(1) the condition of the affected child should be severe or life-threatening, of a sufficient seriousness to justify the use of PGD;<sup>84</sup>

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<sup>81</sup> HFEA ELEVENTH ANNUAL REPORT, *supra* note 79, at 16.

<sup>82</sup> *Id.*

<sup>83</sup> HUMAN GENETICS COMM'N AND HUMAN FERTILISATION AND EMBRYOLOGY AUTH., OUTCOME OF THE PUBLIC CONSULTATION ON PREIMPLANTATION GENETIC DIAGNOSIS 6 (2001), *available at* <http://www.hgc.gov.uk/UploadDocs/DocPub/Document/pgdoutcome.pdf> [hereinafter PUBLIC CONSULTATION ON PGD].

<sup>84</sup> This first condition might be difficult to interpret in a case where a family wishes to use PGD with tissue typing prospectively. Dr. Simon Fishel, the doctor treating the Hashmis, *see infra* Part II.A, stated in 2002 that he consulted with such a family, who had approached him to discuss conceiving a baby and freezing its stem cells for future use in the event that their existing child, who was in remission from leukemia, suffered a relapse. *See* Clare Dyer, *Watchdog Approves Embryo Selection to Treat 3 Year Old Child*, 324 BRIT. MED. J. 503, 503 (2002). This circumstance presents particular difficulties for the affected family because, as Dr. Fishel explains: “No paediatric oncologist is going to search donor banks for a child in remission. But when the child goes into relapse, if they don’t find a donor match, there would not be time [to create a tissue-matched sibling] to save the life of the child.” *Id.* When contacted about this case, the HFEA explained that it could not share information because it is required by law to protect the privacy of those involved. E-mail from Dr. Richard Martin, FOI Records Manager, Human Fertilisation and Embryology Authority, to Donna M. Gitter, Assistant Professor of Legal and Ethical Studies, Fordham University Schools of Business (Mar. 3, 2005, 3:48 PM) (on file with author). The HFEA reiterated that it evaluates each application for PGD with tissue typing on a case-by-case basis. E-mail from Dr. Katy Berry, Policy Manager, Human Fertilisation and Embryology Authority, to Donna M. Gitter, Assistant Professor of Legal and Ethical Studies, Fordham University Schools of Business (Mar. 31, 2005, 9:57 AM) (on file with author).

The HFEA recently indicated its intent to approve licenses for PGD with tissue typing in these prospective cases, declaring that “some have stated that the argument that the child is instrumentalised is diminished since in this case the use of the child as a donor is merely conditional” and expressing the HFEA position that “there was no objection in principle to applications being considered in the same way as for cases in which the affected child was symptomatic at the time of the application.” *See* HUMAN FERTILISATION AND EMBRYOLOGY AUTH., HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY REPORT: PREIMPLANTATION TISSUE TYPING 9 (2004), *available at* <http://www.hfea.gov.uk/AboutHFEA/HFEAPolicy/Preimplantationtissuetyping/PreimplantationReport.pdf> [hereinafter PREIMPLANTATION TISSUE TYPING REPORT].

(2) the embryos conceived in the course of this treatment should themselves be at risk from the condition by which the existing child is affected;<sup>85</sup>

(3) all other possibilities of treatment and sources of tissue for the affected child should have been explored;

(4) the techniques should not be available where the intended recipient is a parent;<sup>86</sup>

(5) the intention should be to take only cord blood for the purposes of treatment, and not other tissues or organs;<sup>87</sup>

(6) appropriate implications counseling should be a requirement for couples undergoing this type of treatment;

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<sup>85</sup> In July 2004, the HFEA eliminated criterion (2) from the list above. This change in policy made PGD with tissue typing available to families facing non-inheritable genetic disorders. *See* Press Release, Human Fertilisation and Embryology Authority, HFEA Agrees to Extend Policy on Tissue Typing (July 21, 2004), <http://www.hfea.gov.uk/PressOffice/Archive/1090427358>; *see also* THE BRITISH MEDICAL ASSOCIATION, MEDICAL ETHICS TODAY (2d ed.) update, Chap. 8 (2004), *available at*, [http://www.bma.org.uk/ap.nsf/Content/METUPDATES/\\$FILE/Chap8\\_2.pdf](http://www.bma.org.uk/ap.nsf/Content/METUPDATES/$FILE/Chap8_2.pdf).

The Ethics Committee of the HFEA, a sub-group of the authority, initially advised in November 2001 against the HFEA's inclusion of criterion (2) among the requirements that must be met in order to qualify for a license to perform PGD with tissue typing. According to the Ethics Committee, while "in the majority of cases there will be indications for PGD to select an embryo free from a heritable genetic condition, there are some cases in which an affected sibling requires tissue from a putative child who would not themselves be at risk." ETHICS COMMITTEE OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTH., ETHICAL ISSUES IN THE CREATION AND SELECTION OF PREIMPLANTATION EMBRYOS TO PRODUCE TISSUE DONORS 12 (2001), *available at* <http://www.hfea.gov.uk/PressOffice/PressReleasesbysubject/PGDandtissuetyping/Ethics%20cttee%20PGD%20November%202001.pdf> [hereinafter ETHICAL ISSUES IN THE CREATION AND SELECTION OF PREIMPLANTATION EMBRYOS]. Therefore "the Committee recommend[ed] that *the technique should also be available where there is an existing sibling with a life-threatening but non-inherited condition*". *Id.* The HFEA declined to follow this suggestion, however, until after the Whitaker case. *See infra* Part II.B for a discussion of the Whitaker case and the HFEA's policy change in response to it.

<sup>86</sup> The HFEA believes this criterion is no longer applicable. According to the HFEA, "[t]he expectation is that the recipient will be a sibling, however there is no prohibition on the recipient being a parent." E-mail from Stephanie Croker, Policy Officer, Human Fertilisation and Embryology Authority, to Donna M. Gitter, Assistant Professor of Legal and Ethical Studies, Fordham University Schools of Business (June 8, 2005, 10:34 AM) (on file with author). Nonetheless, "[t]he incidences in which a parent may benefit are likely to be very rare, and to date the HFEA has not received a request for this use of the technique." *Id.*

<sup>87</sup> The HFEA also eliminated this criterion in July 2004, since it "does not have the power to impose a condition on a license that would prohibit any future attempt to obtain bone marrow, should a cord blood donation fail." PREIMPLANTATION TISSUE TYPING REPORT, *supra* note 84, at 7. *See also* R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2005] UKHL 28 ¶ 37 (House of Lords 2005) (stating that this condition "was in practice unenforceable because once the embryo had been implanted and the child conceived, the case passed out of the jurisdiction of the [HFEA]").

(7) families should be encouraged to participate in follow-up studies and, as with PGD, clinics should provide detailed information about treatment cycles and their outcomes; and

(8) embryos should not be genetically modified to provide a tissue match.<sup>88</sup>

In a press release dated December 13, 2001, the HFEA announced the use of these criteria to evaluate all applications for PGD with HLA tissue typing on a case-by-case basis.<sup>89</sup> Contemporaneously, requests for licenses to use PGD with HLA tissue typing to treat genetic diseases affecting two different families, the Hashmis and the Whitakers, demonstrated how the HFEA would apply the criteria it had developed, as well as how the judiciary would review the HFEA's decision-making process.

## II. THE HASHMI AND WHITAKER CASES DEMONSTRATE THE HFEA'S INTENTION TO LICENSE PGD WITH TISSUE TYPING AND THE JUDICIARY'S APPROVAL OF THIS APPROACH

### A. *The Hashmi Case*

Unlike the Nash family in the United States, who, in order to proceed with PGD with HLA-matching for the purpose of conceiving a donor of umbilical cord blood stem cells for an older sibling, needed only to secure the approval of each of the IRBs at the three medical centers involved in the transplant,<sup>90</sup> the Hashmi family in the United Kingdom had to meet the

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<sup>88</sup> HFEA ELEVENTH ANNUAL REPORT, *supra* note 79, at 16 (listing the criteria the HFEA applies when considering applications for PGD with tissue typing); *see also* Press Release, Human Fertilisation and Embryology Authority, HFEA Confirms that HLA Tissue Typing May Only Take Place when Preimplantation Genetic Diagnosis Is Required to Avoid a Serious Genetic Disorder (Aug 1, 2002), <http://hfea.gov.uk/PressOffice/Archive/43573563> (same).

<sup>89</sup> *See* Press Release, Human Fertilisation and Embryology Authority, HFEA to Allow Tissue Typing in Conjunction with Preimplantation Genetic Diagnosis (Dec. 13, 2001), <http://www.hfea.gov.uk/PressOffice/Archive/HFEAtoallowtissuetypinginconjunctionwithpreimplantationgeneticdiagnosis>. Ruth Deech, who was then chair of the HFEA, emphasized that the HFEA would grant a license for PGD with HLA tissue typing "only in very rare circumstances and under strict controls." *Id.*

<sup>90</sup> The Colorado Center for Reproductive Medicine in Denver performed the Nashes' IVF treatment; the Reproductive Genetics Institute in Chicago conducted the PGD screening and tissue typing; and Dr. John E. Wagner of the University of Minnesota led the transplant team. *See* Wolf, Kahn, & Wagner, *supra* note 6, at 327 (citation omitted). As experts with personal knowledge of the Nash case explained, "[t]he HealthONE Institutional Review Board (IRB) in Denver approved the IVF and PGD protocols, the Illinois Masonic Medical Center IRB in Chicago approved the PGD protocol as well, and the University of Minnesota IRB approved the transplant protocol." *Id.* at 328. While each procedure

HFEA's requirements for using PGD to create a stem cell donor.<sup>91</sup> The Hashmis wanted to use this technology because they had been unable to locate a genetically matched bone marrow donor for their son Zain, who suffered from thalassaemia.<sup>92</sup>

Before they ever sought to use IVF and PGD to give birth to a tissue donor for Zain, Raj and Shahana Hashmi attempted to conceive such a child without these technologies. When prenatal testing showed that the first child the couple conceived naturally after Zain would have beta thalassaemia major, Mrs. Hashmi underwent an abortion. She conceived another child naturally and a healthy son was born after Zain, but his tissue did not match Zain's.<sup>93</sup> At this point, the Hashmis contacted Dr. Simon Fishel, the managing and scientific director of Centers for Assisted Reproduction Ltd. ("CARE"), the U.K.'s largest single provider of IVF services.<sup>94</sup>

Dr. Fishel described to the Hashmis an innovative procedure developed in the United States which permitted physicians not only to screen embryos for beta thalassaemia prior to implantation but also to screen them for compatibility with Zain's tissue.<sup>95</sup> This procedure involved the following steps:

- (i) The fertilisation "in vitro" ("IVF") of a number of eggs taken from Mrs Hashmi with sperm taken from her husband to form embryos. (ii) The removal from the developing embryo of a single cell by a biopsy. (iii) The examination of that cell using molecular genetics to see whether the embryo carried the beta thalassaemia disease. This process is commonly described as "Pre-implantation Genetic Diagnosis" ["PGD"]. (iv) Use simultaneously of the same process to identify whether the embryo had the same tissue type as Zain. . . . [t]his form of PGD is described as "HLA typing". . . . (v) Jettison of embryos found by this analy-

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received a separate IRB review, no IRB reviewed the use of the three technologies together, even though, arguably, combining IVF, PGD, and stem cell transplantation constitutes "a novel research use" of these technologies as a treatment for Fanconi Anemia. See e-mail from Dr. Jeffrey Kahn, Maas Family Chair in Bioethics, Director, Center for Bioethics, University of Minnesota, to Donna M. Gitter, Assistant Professor of Legal and Ethical Studies, Fordham University Schools of Business (May 17, 2005, 4:20 PM) (on file with author).

<sup>91</sup> See *supra* notes 27-29 and accompanying text regarding the licensing requirement in the U.K. Research has revealed no jurisdiction other than the United Kingdom and the state of Victoria in Australia that has issued guidelines on using IVF and PGD together in order to create a tissue donor. See Wolf, Kahn & Wagner, *supra* note 6, at 329 & n.28.

<sup>92</sup> See *supra* notes 22-26 and accompanying text regarding the Hashmi family's situation. When Mrs. Hashmi was pregnant with Zain, a prenatal test had failed to disclose that he would be affected by beta thalassaemia. R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2003] 3 W.L.R. 878 ¶ 1 (C.A. 2003).

<sup>93</sup> R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2003] 3 W.L.R. 878 ¶ 3 (C.A. 2003).

<sup>94</sup> *Id.* ¶ 4. CARE provides IVF services to both National Health Service and private patients. *Id.*

<sup>95</sup> See *id.*

sis to be either disease bearing or of a different HLA type to Zain and implantation in the womb of Mrs H of an embryo shown to be disease free and of the same HLA as Zain.<sup>96</sup>

Because the HFEA had never before issued a license for PGD combined with tissue typing (though it had issued licenses for the use of PGD to screen for genetic disease), CARE applied to the HFEA on September 27, 2001 for a ruling as to whether an IVF clinic could properly apply for a license to conduct tissue typing.<sup>97</sup> It was in response to this request that the HFEA issued its November 2001 decision in principle to grant a license to permit PGD with tissue typing if certain conditions were met.<sup>98</sup>

In keeping with its November 2001 decision in principle, on February 22, 2002, the HFEA granted a license to Park Hospital operated by CARE in Nottingham to carry out an IVF treatment that included PGD for “beta thalassaemia in conjunction with HLA typing for patients known as Mr and Mrs H.”<sup>99</sup> After the HFEA had granted this license, Ruth Deech, who was then chair of the HFEA, emphasized that the license granted to the hospital did not “set a precedent” and that the HFEA “will approve applications only after rigorous examination of the ethical and medical implications of the treatment and the welfare of the children.”<sup>100</sup>

Pro-life groups in the U.K. decried the HFEA action. Although he expressed sympathy for the Hashmi family, Paul Danon, of the Society for the Protection of Unborn Children, criticized the treatment as “profoundly discriminatory” and tantamount to “playing God.” Peter Garrett, director of research for LIFE, insisted society should not “allow a child to be manufactured in order to serve the medical needs of an older brother.”<sup>101</sup> Ultimately, the U.K. public advocacy group Comment on Reproductive Ethics (“CORE”), acting through its founder Josephine Quintavalle, requested judicial review of the HFEA’s grant of a license to the hospital treating the Hashmi family.<sup>102</sup> CORE, which Ms. Quintavalle established in 1994, describes itself on its web site as “a public interest group focusing on ethical

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<sup>96</sup> *Id.*

<sup>97</sup> *See id.* ¶¶ 5, 101.

<sup>98</sup> *See supra* notes 84-88 and accompanying text (discussing the HFEA’s November 2001 decision in principle).

<sup>99</sup> *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 ¶ 7 (C.A. 2003).

<sup>100</sup> *See* Michael Leventhal, *Couple Given Go-Ahead for Designer Baby*, DAILY EXPRESS, Feb. 23, 2002, at 6 (quoting HFEA Chair Ruth Deech). *See also supra* note 89 and accompanying text (explaining that the HFEA has declared that it will examine all applications for PGD with tissue typing on a case-by-case basis).

<sup>101</sup> Leventhal, *supra* note 100, at 6.

<sup>102</sup> *See R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 2 All ER 105 ¶ 5 (Q.B. 2003).

dilemmas surrounding human reproduction, particularly the new technologies of assisted conception.”<sup>103</sup> CORE challenged the HFEA’s statutory power to license PGD with tissue typing.<sup>104</sup>

On December 20, 2002, the High Court of Justice held in CORE’s favor in its review of the HFEA decision in the Hashmi case, ruling that the HFEA had acted outside of its statutory authority in granting the license.<sup>105</sup> This ruling forced the Hashmi family to cease its reproductive treatments,<sup>106</sup> which in two attempts had failed to result in a pregnancy with an embryo both free of beta thalassaemia and also a tissue match for Zain.<sup>107</sup> On April 8, 2003, however, the Appeal Court overturned the High Court’s ruling, holding that the HFEA was indeed able to grant a license for PGD with HLA tissue typing.<sup>108</sup> The Appeal Court set forth the reasons for its holding in a judgment dated May 16, 2003.<sup>109</sup> This ruling permitted the Hashmi family to proceed with their treatment.<sup>110</sup>

After the Appeal Court’s decision in the *Quintavalle* action, CORE petitioned the House of Lords to overturn the appellate court’s 2003 ruling permitting the Hashmis to proceed.<sup>111</sup> On April 28, 2005, five Law Lords ruled unanimously that the HFEA had the authority to issue a license for PGD with tissue typing.<sup>112</sup> Tragically, the judgments of the Appeal Court and House of Lords have not assisted Zain Hashmi, who, according to recent media reports, continues to have monthly blood transfusions and drugs

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<sup>103</sup> Comment on Reproductive Ethics, About, About Core, <http://www.coreethics.org/about/about.asp> (last visited May 12, 2006).

<sup>104</sup> See *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2005] UKHL 28 ¶ 42 (House of Lords 2005) (“This case is all about the scope of power, not about its exercise. The important, but limited, question it raises is whether the Human Fertilisation and Embryology Authority . . . , created by the Human Fertilisation and Embryology Act 1990 . . . is empowered by the 1990 Act to license tissue typing . . .”).

<sup>105</sup> See *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 2 All ER 105 ¶¶ 17-20 (Q.B. 2003).

<sup>106</sup> See *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 ¶ 8 (C.A. 2003).

<sup>107</sup> See *id.*

<sup>108</sup> Human Fertilisation and Embryology Authority, *Preimplantation Tissue Typing*, available at <http://www.hfea.gov.uk/PressOffice/Backgroundpapers/PreimplantationTissueTyping> (last visited Oct. 24, 2005).

<sup>109</sup> *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 (C.A. 2003).

<sup>110</sup> BBC News, “*Designer Baby*” Ban Quashed (Apr. 8, 2003), <http://news.bbc.co.uk/1/hi/health/2928655.stm> (quoting HFEA Chair Suzi Leather as stating: “This means that the Hashmi family can continue with their treatment.”).

<sup>111</sup> See PREIMPLANTATION TISSUE TYPING REPORT, *supra* note 84, at 7.

<sup>112</sup> See generally *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2005] UKHL 28 (House of Lords 2005).

fed by a drop twelve hours each day.<sup>113</sup> Since the Appeal Court's ruling in their favor, his parents have undergone six unsuccessful attempts at IVF, in each instance either failing to produce an embryo of the right tissue type or suffering a miscarriage.<sup>114</sup>

The legal judgments in the Quintavalle action concern the somewhat narrow legal issue of the HFEA's statutory authority under the HFE Act to authorize PGD with tissue typing for the purpose of creating a stem cell donor sibling,<sup>115</sup> rather than addressing the broader ethical and legal questions regarding the propriety of using PGD with HLA tissue typing for this purpose and the optimal means of regulating this technology. Nevertheless, analysis of these legal judgments reveals that consideration of the broader ethical issues did inform the judgments of the Appeal Court and House of Lords, which ruled in favor of the HFEA based upon their understanding of the ethical basis for PGD with tissue typing and of the importance of a family's right to procreative autonomy. These judgments will be analyzed in terms of their discussion of these larger ethical and regulatory issues.

#### 1. The December 20, 2002 Decision of the High Court of Justice Halts the Hashmis' Treatment

In her challenge to the HFEA's grant of a license for PGD with tissue typing to the hospital assisting the Hashmi family, plaintiff Quintavalle, on behalf of CORE, emphasized that Section 3 of the Human Fertilisation and Embryology Act (HFE Act) provides, in pertinent part, that "No person shall . . . (b) keep or use an embryo, except in pursuance of a licence."<sup>116</sup> According to CORE, although the HFE Act authorizes the HFEA to grant licenses to medical facilities providing treatment services to assist in conceiving children,<sup>117</sup> the Act does not permit the HFEA to grant licenses for

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<sup>113</sup> BBC News, *Lords Back "Designer Baby" Choice* (Apr. 28, 2005), <http://newswww.bbc.net.uk/2/hi/health/4492345.stm>.

<sup>114</sup> Clare Dyer, *Law Lords Give the Go Ahead for Creation of "Saviour Siblings,"* 330 BRIT. MED. J. 1041, 1041 (2005).

<sup>115</sup> See *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2005] UKHL 28 ¶ 42 ("This case is all about the scope of a power, not about its exercise. The important, but limited, question it raises is whether the Human Fertilisation and Embryology Authority . . . , created by the Human Fertilisation and Embryology Act 1990 . . . is empowered by the 1990 Act to license tissue typing . . .").

<sup>116</sup> Human Fertilisation and Embryology Act, 1990, c. 37, § 3(1)(b) (Eng.).

<sup>117</sup> See *id.* § 11(1)(a) ("[t]he Authority may grant . . . licences under paragraph 1 of Schedule 2 to this Act authorising activities in the course of providing treatment services"). The HFE Act also permits the HFEA to grant licenses for "the storage of gametes and embryos," *id.* § 11(1)(b), and "for the purposes of a research project," *id.* § 11(1)(c), two practices not at issue in the instant action. See *supra*

PGD with tissue typing for the purpose of creating a stem cell donor.<sup>118</sup> Under CORE's interpretation, the HFE Act defines "treatment services" as "medical, surgical or obstetric services" intended "for the purpose of assisting women to carry children."<sup>119</sup> PGD with tissue typing, however, does not assist a woman to carry a child, but rather has the goal of providing transplantable cells for a child who is already born.<sup>120</sup>

The HFEA advanced two arguments in response to CORE's claims. First, the HFEA maintained that tissue typing does not require a license because it does not fall within Section 3(1)(b) of the HFE Act,<sup>121</sup> since it does not involve "use of an embryo," but rather the study of one or two cells already removed from the embryo for the PGD process (for which a license must already have been granted).<sup>122</sup> According to the HFEA, these further tests on cells already removed from an embryo do not amount to "use of an embryo."<sup>123</sup> Justice Maurice Kay, writing for the High Court, rejected this argument based on both interpretation of the statutory language<sup>124</sup> and also on public policy. Sensibly, the Court concluded that the legislature, in enacting the HFE Act, intended to govern controversial mat-

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notes 72-76 and the accompanying text (describing the HFEA's licensing authority with respect to clinics that offer assisted reproductive procedures).

<sup>118</sup> See R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2002] 2 All ER 105 ¶ 6 (Q.B.) ("In a nutshell, the case for CORE is that (1) tissue typing is prohibited by s[ection] 3(1)(b) of the 1990 Act as it involves the use of an embryo but (2) it cannot be licensed under Sch[edule] 2 because it cannot be said to arise in the course of providing 'treatment services' or to be necessary or desirable for the purpose of providing 'treatment services.'").

<sup>119</sup> HFE Act § 2(1).

<sup>120</sup> See R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2003] 2 All ER 105 ¶ 6 (Q.B. 2003). Used alone, the process of PGD can determine whether an embryo created via IVF is free of certain genetic disorders before fertility specialists implant that embryo in a woman. See *supra* notes 4-5 and accompanying text. In contrast, the additional step of HLA tissue typing has as its only goal the identification of an embryo that will provide a suitable tissue match for an existing child. See *supra* notes 11-16 and accompanying text.

<sup>121</sup> See *supra* note 116 and accompanying text.

<sup>122</sup> See R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2003] 2 All ER 105 ¶ 11 (Q.B. 2003).

<sup>123</sup> *Id.* (explaining the HFEA's argument that once cells "have been removed from an embryo pursuant to a licence for the purpose of PGD, the carrying out of further tests on them does not amount to the use of an embryo").

<sup>124</sup> See *id.* ¶ 12. The Court interpreted broadly the heading of HFEA § 3, "Prohibitions in connection with embryos," and considered analysis of one or two cells from an embryo to be "in connection with embryos." *Id.* Furthermore, the Court noted that the HFEA press release giving rise to these proceedings itself described tissue typing as "an additional step whereby *the embryo* is simultaneously tested for its tissue-compatibility with an affected sibling." *Id.* (emphasis supplied). See *supra* note 89 and accompanying text regarding this HFEA press release.

ters such as genetic testing of embryos, even if such testing were conducted upon cells already removed from the embryos.<sup>125</sup>

For its second argument in support of its decision, the HFEA argued it could lawfully authorize tissue typing pursuant to the HFE Act.<sup>126</sup> Section 11(1)(a) of the Act permits the HFEA to grant licenses for “treatment services,”<sup>127</sup> which are defined by the Act as procedures “for the purpose of assisting women to carry children.”<sup>128</sup> The HFEA interpreted the phrase “treatment services” as “broadly synonymous with ‘fertility treatment’”<sup>129</sup> and, therefore, understood it to include a procedure such as tissue typing that permits a woman “to carry a child *with a particular characteristic*—whether it be freedom from genetic disorder or tissue compatibility with an affected sibling.”<sup>130</sup> While acknowledging that such a broad view could eventually give rise to “social selection,” meaning the selection of embryos for non-medical traits preferred by their parents (such as gender),<sup>131</sup> the

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<sup>125</sup> See R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2003] 2 All ER 105 ¶ 12 (Q.B. 2003).

<sup>126</sup> See *id.* ¶ 15.

<sup>127</sup> Human Fertilisation and Embryology Act, 1990, c. 37, § 11(1)(a) (Eng).

<sup>128</sup> HFE Act § 2(1).

<sup>129</sup> See R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2003] 2 All ER 105 ¶ 16 (Q.B. 2003) (paraphrasing the argument of the HFEA’s legal counsel).

<sup>130</sup> *Id.*

<sup>131</sup> The HFEA permits the use of PGD with gender selection for medical purposes. For example, clinics in the U.K. may obtain a license to use PGD in order to avoid implantation of male embryos in cases where the family is affected by an X-linked disorder, which arises from a mutation on the X chromosome and typically affects only males. See CONSULTATION DOCUMENT ON PGD, *supra* note 59, at 4, 27 (defining X-linked disorders and describing the use in the U.K. of PGD to detect such disorders); Deborah Orr, *The Yuk Factor is Not a Good Enough Reason to Deplore James Whitaker’s Birth*, INDEPENDENT (London), June 20, 2003, at 16 (stating that in the U.K. “a couple of clinics . . . are now licensed to offer sex selection for medical reasons”).

One example of an X-linked disorder is hemophilia, Robertson, *supra* note 4, at 434 n. 51, which is not necessarily detectable through genetic screening for the disorder itself. See F. Shenfield et al., *Taskforce 5: Preimplantation Genetic Diagnosis*, 18 HUM. REPROD. 649 (2003), available at <http://humrep.oupjournals.org/cgi/content/full/18/3/649> (“In the case of sex-linked diseases, looking for specific mutations might be impossible, technically difficult or not accessible to all potential patients.”). PGD permits accurate determination of the gender of the preimplantation embryo, so that only those embryos of the nonaffected gender will be implanted. See John Jain, *The Future of Assisted Reproductive Technologies*, 21 WHITTIER L. REV. 435, 437 (1999).

Individuals in the U.K. have not yet used PGD with gender selection in order to “balance” the mixture of children’s genders within a family. See HUMAN REPRODUCTIVE TECHNOLOGIES AND THE LAW, *supra* note 10, at 63 (describing the case of a couple named the Mastertons, the parents of four boys, who sought a license for PGD with sex selection in order to conceive a girl after losing their only daughter in a domestic accident, but were unable to find a U.K. clinic willing to apply to the HFEA for a license on their behalf).

Unlike in the U.K., U.S. families are able to use PGD for the purpose of gender selection, notwithstanding the fact that the Ethics Committee of the American Society for Reproductive Medicine

HFEA emphasized that its members, “as a mixed body of clinicians, religious leaders, ethicists and others, can be trusted to grapple with the difficult questions that will arise.”<sup>132</sup> According to the HFEA, CORE’s arguments, if taken to their logical conclusion, would militate as well against PGD, a procedure that is not actually necessary to assist a woman to carry a child.<sup>133</sup>

The High Court rejected both of the HFEA’s arguments, holding that the hospital treating the Hashmis could not continue analyzing their embryos for tissue compatibility with their son Zain.<sup>134</sup> Viewing its task as one of statutory construction,<sup>135</sup> the Court declined to interpret the phrase

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discourages this practice. *See* Press Release, The Center for Human Reproduction, Large Fertility Center Follows Most Recent Ethics Opinion on the Use of IVF/PGD for Gender Selection, <http://www.centerforhumanreprod.com/docs/021402.doc> (Feb. 14, 2002) (quoting a letter signed by the Chairman of the ASRM Ethics Committee as stating that “initiating IVF and PGD solely for non-medical gender selection, e.g., for the first child, should be discouraged” and that “initiating IVF and PGD solely to create gender variety in a family should at this time also be discouraged”). One source mentions several U.S. fertility centers that perform PGD for non-medical gender selection, including centers in Los Angeles and Las Vegas. Simoncelli, *supra* note 37, at 2. One such clinic even advertised that “[u]nlike many programs offering sex selection only to very limited couples with known genetic disorders in the family we make sex selection available to all patients seeking to balance their families or assure themselves that a pregnancy will result in ONLY the gender outcome they desire.” The Fertility Institutes, Fertility Evaluation and Procedures: Sex (Gender) Selection Employing PGD and Sperm Selection, [http://www.fertility-docs.com/fertility\\_gender.phtml](http://www.fertility-docs.com/fertility_gender.phtml) (last visited Oct. 25, 2005). *See also* Genetics and IVF Institute, Preimplantation Genetic Diagnosis for Family Balancing, [http://www.givf.com/pgt\\_sepvcfm](http://www.givf.com/pgt_sepvcfm) (last visited Nov. 7, 2005) (“Genetics & IVF uses Microsort® sperm separation (currently in a clinical trial) to increase the likelihood of achieving a pregnancy of the desired gender.”).

In terms of public attitudes in the U.S. toward PGD for the purpose of gender selection, one survey reported that thirty-four percent of U.S. geneticists declared they would perform gender selection for families seeking to have a son, and another twenty-eight percent said they would refer the couple to another person who would do so. LORI B. ANDREWS, *THE CLONE AGE* 143 (1999). According to a more recent survey, among women undergoing infertility treatment, forty-one percent indicated that they would use preimplantation sex selection if it were offered to them at no cost, and half of those would still elect to use it even if they had to bear the cost. *See Choosing Sex of Child Popular Among Infertile Women*, BIOTECH. L. WKLY., Apr. 1, 2005 (reporting on the results of a survey conducted by a University of Chicago researcher). This suggests that the specter of gender imbalances, even in the U.S. where gender equality is practiced much more often than in other nations, is not nearly as remote as the ASRM has suggested in the past. *See 1999 ASRM Report on PGD*, *supra* note 44, at 597 (dismissing potential gender imbalances as a “remote” possibility and “too speculative to place seriously in the balance of ethical assessments of the techniques”).

<sup>132</sup> *See* R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2003] 2 All ER 105 ¶ 16 (Q.B. 2003) (paraphrasing the argument of the HFEA’s legal counsel).

<sup>133</sup> *See id.* The High Court stated that the issue of PGD screening for genetic abnormality before implantation was not at issue in the case before it. *Id.*

<sup>134</sup> *See id.* ¶¶ 17-20.

<sup>135</sup> *See id.* ¶ 7.

“treatment services” as generally synonymous with fertility treatments of any sort, particularly because the HFE Act sets forth a specific definition of “treatment services”<sup>136</sup> as those procedures that assist women “to carry children.”<sup>137</sup> The Court expressed sympathy for the Hashmi family, but noted that when the HFEA and Human Genetics Commission conducted an analysis of the public’s attitudes toward tissue typing in 2000-2001, these bodies felt that the ethical issues raised by this technology necessitated further discussion before tissue typing could become a procedure eligible for licensure by the HFEA.<sup>138</sup> Recognizing the importance of the issue before it, the Court gave the HFEA permission to appeal its judgment to the Appeal Court.<sup>139</sup>

## 2. The Appeal Court Permits the Hashmis’ Treatment to Proceed in April 2003 and Sets Forth Its Reasons in a May 16, 2003, Decision

On April 8, 2003, the Appeal Court issued an early announcement of its judgment to overturn the High Court’s ruling in the *Quintavalle* case, thereby giving the HFEA permission to grant a license for PGD with HLA

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<sup>136</sup> See *id.* ¶ 17.

<sup>137</sup> See *id.* Though Justice Kay interpreted the terms “treatment services” that assist women “to carry children” as permitting PGD only insofar as it screened for defects that would affect the viability of the fetus, not for any other genetic disorders, see *id.* ¶ 17, later courts rejected this holding on the basis of Parliament’s clear intent to permit PGD in order to screen for genetic disorders affecting an embryo’s future health but not necessarily its viability. See *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2005] UKHL 28 ¶¶ 49-50 (House of Lords 2005) (explaining that “no one now is contending” the interpretation adopted by Justice Kay).

<sup>138</sup> See *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 2 All ER 105 ¶ 20 (Q.B. 2003). The High Court was referring to the November 2001 report published by a committee of the HFEA and the Human Genetics Commission, which examined the public’s attitudes toward PGD. See generally PUBLIC CONSULTATION ON PGD, *supra* note 83. This committee had agreed that “there were sufficient ethical difficulties” with tissue typing “that it should be subject to further discussion before its use was considered.” *Id.* at 6. Nevertheless, as the Appeal Court noted, an HFEA Ethics Committee did indeed recommend that the HFEA grant a license to the hospital treating the Hashmis, and the HFEA issued a December 13, 2001 press release permitting PGD with tissue typing “only in very rare circumstances and under strict controls.” See *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 ¶ 101 (C.A. 2003); see also *supra* note 89 and accompanying text regarding this press release.

<sup>139</sup> See *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 ¶ 11 (C.A. 2003) (“Maurice Kay J. gave permission to appeal against his judgment to this court because of the importance of the issue of whether tissue typing can lawfully be licensed by the HFEA.”).

tissue typing.<sup>140</sup> This judgment allowed the Hashmis to continue with their treatment.<sup>141</sup> The Appeal Court set forth its reasons in a unanimous May 16, 2003, decision in which each of the three justices, Lord Phillips of Worth Matravers, Master of the Rolls (Lord Phillips); Justice Schiemann; and Justice Mance, authored separate concurring opinions.<sup>142</sup>

In its judgment interpreting the HFE Act as authorizing the HFEA to issue a license for PGD with tissue typing, the Appeal Court pointed to the HFEA's decision not to raise on appeal its argument that the process of tissue typing does not involve "use of an embryo" under Section 3(1)(b) of the HFE Act.<sup>143</sup> Instead, the Court focused on the "vital question" of whether tissue typing was "for the purpose of assisting a woman to carry a child," as envisaged by Parliament when it enacted the HFE Act.<sup>144</sup> In order to determine the answer to this query, the Court considered it necessary to analyze whether the Warnock Report<sup>145</sup> and the legislative history of the HFE Act indicated approval of PGD screening for hereditary disease,<sup>146</sup> a question the High Court had felt was not relevant.<sup>147</sup>

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<sup>140</sup> Human Fertilisation and Embryology Authority, *Preimplantation Tissue Typing*, available at <http://www.hfea.gov.uk/PressOffice/Backgroundpapers/PreimplantationTissueTyping> (last visited June 1, 2005); Public Health Genetics Unit, Appeal Court Decides to Allow Hashmi Family to Use PGD with Tissue Typing (Apr. 10, 2003), <http://www.wellcome.ac.uk/en/genome/geneticsandsociety/hg15n006.html>.

<sup>141</sup> Public Health Genetics Unit, Appeal Court Decides to Allow Hashmi Family to Use PGD with Tissue Typing (Apr. 10, 2003), <http://www.wellcome.ac.uk/en/genome/geneticsandsociety/hg15n006.html> ("The couple, Raj and Shahana Hashmi, now plan to resume treatment as soon as possible, in the hope of having a healthy child whose cord blood would be a source of stem cells to treat their four-year-old son Zain.").

<sup>142</sup> See generally *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 (C.A. 2003).

<sup>143</sup> See *id.* ¶ 26 ("Neither party now suggests that tissue typing is an activity that is left unregulated by the Act."). See *supra* notes 121-25 and accompanying text regarding Ms. Quintavalle's successful argument to the High Court on this issue. In his separate appellate opinion, Justice Mance concluded that tissue typing did not involve "use of an embryo" so as to require licensure, see *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 ¶ 111 (C.A. 2003) (Mance, J.), an opinion not expressed by either of the other appellate judges considering this action.

<sup>144</sup> *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 ¶ 20 (C.A. 2003). Taken together, Sections 11(1)(a) and 2(1) of the HFEA Act permit the HFEA to grant licenses for "treatment services," which are defined by the Act as procedures "for the purpose of assisting women to carry children." See *supra* notes 127-28.

<sup>145</sup> See *supra* notes 64-68 and accompanying text regarding the Warnock Report.

<sup>146</sup> See *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 ¶¶ 27-45, 117-28 (C.A. 2003).

<sup>147</sup> See *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 ¶ 37 (C.A. 2003) ("Maurice Kay J did not find it appropriate to consider whether the Act permits PGD screening for hereditary diseases."); see also *supra* note 133 and accompanying text

In his opinion, Lord Phillips found PGD screening to be “an important feature of the context in which the [HFE] Act was passed.”<sup>148</sup> Indeed, Schedule 2 of the HFE Act gives the HFEA authority, in the *research* context, to license activity with the purpose of “developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.”<sup>149</sup> As Lord Phillips noted, “[t]he clear inference of permitting such research was that Parliament approved of PGD to avoid implantation of embryos carrying genetic defects” in the treatment context, for it is not logical for Parliament to permit research into PGD techniques and simultaneously ban the use of such techniques for treating patients.<sup>150</sup>

Once it had determined that the HFE Act permits PGD screening of embryos for genetic abnormality in the treatment context, the Court then considered the Act’s definition of treatment services, which the Act defines as services “for the purpose of assisting women to carry children.”<sup>151</sup> The Court considered whether IVF treatment “which is designed not to assist the processes of fertilisation and gestation, but to ensure that the child which is produced by those processes is healthy,”<sup>152</sup> satisfies the condition that it be “for the purpose of assisting women to carry children.”<sup>153</sup> The Court concluded in the affirmative. In the words of Lord Phillips,

if the impediment to bearing a child is concern that it may be born with a hereditary defect, treatment which enables women to become pregnant and to bear children in the confidence that they will not be suffering from such defects can properly be described as “for the purpose of assisting women to carry children.”<sup>154</sup>

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(explaining that the High Court stated that the issue of PGD screening for genetic abnormality before implantation was not at issue in the case before it).

<sup>148</sup> R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2003] 3 W.L.R. 878 ¶ 37 (C.A. 2003).

<sup>149</sup> Human Fertilisation and Embryology Act, Schedule 2 § 3(2)(e) (1990).

<sup>150</sup> See R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2003] 3 W.L.R. 878 ¶¶ 38, 40 (C.A. 2003). Justice Mance concurred in this view, noting with respect to PGD that “[w]hile it is theoretically possible that Parliament intended to permit research into methods of detecting abnormalities, or into applications of knowledge acquired about disease, which it would be impermissible to license for practical use unless the Act was amended, it seems improbable that it was contemplated that research, a particularly contentious matter, should be permissible into methods and applications the use of which in practice Parliament had decided to exclude.” *Id.* ¶ 120.

<sup>151</sup> HFE Act § 2(1) (1990).

<sup>152</sup> R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2003] 3 W.L.R. 878 ¶ 42 (C.A. 2003).

<sup>153</sup> See *supra* note 144 and accompanying text.

<sup>154</sup> R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2003] 3 W.L.R. 878 ¶ 43 (C.A. 2003).

The Court based this interpretation not only on the HFE Act's clear permission for PGD research, but also on legislative history supporting this conclusion.<sup>155</sup> What is more, according to Lord Phillips, a narrow interpretation of the phrase "for the purpose of assisting women to have children" would "render unlawful a practice [PGD screening for genetic abnormality] which has been carried on for over a decade and which is patently beneficial."<sup>156</sup>

As the Court noted, PGD combined with tissue typing was not possible at the time of the HFE Act's enactment.<sup>157</sup> Lord Phillips analogized this new technology, PGD with tissue typing, to PGD for screening for genetic abnormality, noting that in both cases a family seeks to select the characteristics of the embryos.<sup>158</sup> Parliament plainly granted to the HFEA the power to decide which characteristics families could select<sup>159</sup> and the HFEA therefore "was right to decide that the Act authorised it to licence IVF treatment with PGD for the purpose of tissue typing subject to such conditions as it considered appropriate."<sup>160</sup>

Justice Schiemann concurred with Lord Phillips's broad interpretation of Section 1(1)(d) of Schedule 2 of the HFE Act, which provides that the HFEA may license "practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose."<sup>161</sup> This provision of the Act was, according to Justice Schiemann, "wide enough to embrace ensuring that the embryo does not suffer from a genetic defect and tissue incompatibility,"<sup>162</sup> thereby defining tissue incompatibility as a situation which the HFEA might lawfully permit a family to avoid.

Justice Mance also considered the wishes of the family paramount in reaching the conclusion that the HFEA possesses the authority to license PGD with tissue typing. Section 13(5) of the HFE Act requires a treatment clinic "to take account of the welfare of every child who may be born as a result of the treatment and of any other child who may be affected by the

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<sup>155</sup> See *id.* ¶¶ 37-43, 116-28.

<sup>156</sup> *Id.* ¶ 43.

<sup>157</sup> See *id.* ¶ 109 (speaking of "the difficulty that arises in deciding whether a modern invention or activity falls within statutory language used at a time when it did not exist"). See also *id.* ¶ 25 ("It is not often that Parliament has to frame legislation apt to apply to developments at the advanced cutting edge of science") (citing *House of Lords in R (Quintavalle) v. Secretary of State for Health*, [2003] 2 W.L.R. 692 ¶ 12 (2003)).

<sup>158</sup> See *id.* ¶ 48.

<sup>159</sup> See *id.* ¶ 50.

<sup>160</sup> *Id.* ¶ 49.

<sup>161</sup> Human Fertilisation and Embryology Act, Schedule 2 § 1(1)(d) (1990).

<sup>162</sup> *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 ¶ 96 (C.A. 2003).

birth.”<sup>163</sup> In addition, the legislative history clearly established that “the concept of ‘services . . . for the purpose of assisting women to carry children’ extends beyond the purely physical problems affecting the viability of the embryo during pregnancy and birth, and allows the screening of embryos for genetic abnormalities.”<sup>164</sup> Taken together, this legislative language and history made it clear to Justice Mance “that such services may have regard to prospective parents’ and society’s concern for others and for the future.”<sup>165</sup> Thus, when considering whether an embryo is “suitable” to be placed in a woman,<sup>166</sup> “[t]he compatibility of the particular embryo with the particular mother must, at least, be a fundamental consideration.”<sup>167</sup> In Justice Mance’s view, tissue typing can help to achieve this goal by “providing assistance matching the felt and perceived needs of the family as a whole and the parents and siblings in particular.”<sup>168</sup> Justice Mance placed particular emphasis on the reason why the Hashmis sought PGD with tissue typing: not for “purely social reasons” or “personal indulgence,” but rather to relieve the suffering of a family member.<sup>169</sup>

The HFEA decision to grant a license to the Hashmis would not, in the Court’s view, lead inexorably to licenses for social selection<sup>170</sup> as the HFE Act does not “impose upon the [HFEA] the express obligation to sanction the grant of licences even if what was proposed was indubitably necessary for the purpose of assisting a woman to carry a child.”<sup>171</sup> Ethical concerns about the proper use of tissue typing “fall appropriately to be addressed by the HFEA and the care clinic in the exercise of their respective functions.”<sup>172</sup>

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<sup>163</sup> *Id.* ¶ 122 (referring to HFE Act § 13(5)). Section 13(5) of the HFE Act proscribes 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.” HFE Act § 13(5). Justice Mance noted that while “that subsection probably had primarily in mind consideration of any adverse effects on the welfare of the future or any existing child, the language does not exclude positive effects.” *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 ¶ 133 (C.A. 2003).

<sup>164</sup> *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 ¶ 142 (C.A. 2003).

<sup>165</sup> *Id.*

<sup>166</sup> *See* HFE Act, Schedule 2 § 1(1)(d).

<sup>167</sup> *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 ¶ 127 (C.A. 2003).

<sup>168</sup> *Id.* ¶ 145.

<sup>169</sup> *Id.* ¶¶ 134-35.

<sup>170</sup> *See supra* note 131 and accompanying text for a discussion of the use of PGD for social selection.

<sup>171</sup> *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 ¶ 98 (C.A. 2003).

<sup>172</sup> *Id.* ¶ 134.

After the Appeal Court's decision in the *Quintavalle* action, CORE petitioned the House of Lords to hear the case.<sup>173</sup> The House of Lords heard the case in March 2005<sup>174</sup> and upheld the judgment of the Appeal Court on April 28, 2005.<sup>175</sup>

### 3. The House of Lords Upholds the Appellate Decision Permitting the Hashmis to Proceed with Treatment

Central to the unanimous judgment of the House of Lords in *Quintavalle* upholding the ruling of the Appeal Court was the notion that determining the "suitability" of an embryo for implantation in a woman<sup>176</sup> "includes taking into account the particular wishes and needs of the mother."<sup>177</sup> According to the Lords, the HFE Act clearly gave the HFEA the authority to honor a family's request for PGD with tissue typing if the HFEA found it proper, as well as to decline such a license on ethical or other grounds.<sup>178</sup>

In his detailed opinion in the matter, Lord Hoffman based his holding on his analysis of the Warnock Report and the legislative history of the HFE Act. The Warnock Report did in fact consider the possibility of using PGD for the purpose of gender selection, recommending that "the whole question of acceptability of sex selection should be kept under review (See chapter 13)."<sup>179</sup> Chapter 13 of the Warnock Report expressly advised that "[t]he authority should be specifically charged with the responsibility to regulate and monitor practice in relation to those sensitive areas which raise fundamental ethical questions."<sup>180</sup> From this, Lord Hoffman drew the conclusion that the Warnock Committee "contemplated that the [HFEA] would decide the circumstances, if any, in which sex selection on social grounds should be authorized," and since gender selection on social grounds "is the most obvious case of selecting an embryo on grounds other than its health, I would infer that the Warnock Committee did not intend that selection of

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<sup>173</sup> PREIMPLANTATION TISSUE TYPING REPORT, *supra* note 84, at 7.

<sup>174</sup> HUMAN REPRODUCTIVE TECHNOLOGIES AND THE LAW, *supra* note 10, at 10.

<sup>175</sup> R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2005] UKHL 28 (House of Lords 2005) (dismissing Quintavalle's appeal).

<sup>176</sup> See *supra* note 161 and accompanying text regarding the concept of "suitability" of an embryo pursuant to the HFE Act.

<sup>177</sup> R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth., [2005] UKHL 28 ¶ 14 (House of Lords 2005) (Lord Hoffman).

<sup>178</sup> *Id.* ¶ 35 (holding "that both PGD and HLA typing could lawfully be authorized by the authority as activities to determine the suitability of the embryo for implantation") (Lord Hoffman), ¶ 62 (holding that "suitability is for the woman, the limits of permissible embryo selection are for the authority") (Lord Brown).

<sup>179</sup> *Id.* ¶ 16 (quoting the Warnock Report).

<sup>180</sup> *Id.* ¶ 17 (quoting the Warnock Report).

IVF embryos on grounds which went beyond genetic abnormality should be altogether banned.”<sup>181</sup>

Lord Hoffman further noted that Parliament followed the suggestions set forth in the Warnock Report,<sup>182</sup> so that aside from certain enumerated prohibitions,<sup>183</sup> the 1990 HFE Act grants the HFEA broad authority to grant licenses for PGD.<sup>184</sup> Since both the Warnock Report and the Parliament considering the HFE Act contemplated the issue of gender selection on social grounds, but the HFE Act did not expressly prohibit this practice, “the only reasonable inference is that Parliament intended to leave the matter to the authority to decide.”<sup>185</sup> According to Lord Hoffman,

[O]nce one says that the concept of suitability can include gender selection on social grounds, it is impossible to say that selection on the grounds of any other characteristics which the mother might desire was positively excluded from the discretion of the authority, however unlikely it might be that the authority would actually allow selection on that ground.<sup>186</sup>

Lord Hoffman also declared that the diverse membership of the HFEA demonstrates that this body was intended to grapple with complex ethical issues.<sup>187</sup> Should Parliament find that the HFEA has failed in its task of making ethical distinctions, Parliament reserves regulatory powers under Section 3(3)(c) of the HFE Act.<sup>188</sup>

Lord Brown agreed with Lord Hoffman that if the HFEA were to grant an improper license, Parliament could invoke its regulatory power under Section 3(3)(c), adding that “in an extreme case the court’s supervisory jurisdiction could be invoked.”<sup>189</sup> In his view, “once the concession is made (as necessarily it had to be) that PGD itself is licensable to produce not just

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<sup>181</sup> *Id.* ¶ 19.

<sup>182</sup> *Id.* ¶ 20 (stating that a government White Paper “suggests acceptance of the views of the Warnock Committee” that the HFEA might permit PGD for purposes other than detecting genetic abnormality).

<sup>183</sup> *See id.* ¶ 23 (listing activities expressly prohibited by the HFE Act).

<sup>184</sup> *See id.* ¶ 24 (noting that, subject to certain enumerated prohibitions, “the licensing power of the authority is defined in broad terms”).

<sup>185</sup> *Id.* ¶ 29.

<sup>186</sup> *Id.*

<sup>187</sup> *Id.* ¶ 26. *See also id.* ¶ 7 (noting that the HFEA has a lay chair and deputy chair and a majority of lay members, and that members provide “a broad range of experience: social, legal, managerial, religious and philosophical, as well as medical and scientific”).

<sup>188</sup> *Id.* ¶ 28. Section 3(3)(c) of the HFE Act provides that the HFEA cannot issue a license for “keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use.”

<sup>189</sup> *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2005] UKHL 28 ¶ 62 (House of Lords 2005).

a viable foetus but a genetically healthy child, there can be no logical basis for construing the authority's power to end at that point.<sup>190</sup>

Notwithstanding the judiciary's upholding of the HFEA's grant to the Hashmis of a license for PGD with tissue typing to conceive a stem cell donor, the Hashmis have been unable to conceive a donor.<sup>191</sup> For another U.K. family, however, PGD with tissue typing provided a cure for their son. This family, the Whitakers, was forced to seek treatment in the U.S. because the HFEA denied a license to the clinic treating the family, only to change its policy subsequently.<sup>192</sup>

B. *The Whitaker Case Leads the HFEA to Broaden the Availability of PGD with Tissue Typing to Families with Non-Inheritable Genetic Disorders*

Shortly after it granted a license to the clinic treating the Hashmis, the HFEA demonstrated its intention to issue licenses for PGD with tissue typing only in very narrow circumstances. In August 2002, the HFEA rejected an application from a clinic treating a couple named Michelle and Jayson Whitaker, who wished to use PGD with tissue typing to conceive a child who would be a genetic match for their son Charlie.<sup>193</sup> Charlie, three years old at that time, suffered from a rare blood disorder, Diamond-Blackfan Anemia ("DBA"), which required him to undergo daylong blood transfusions and daily injections. Like beta thalassemia, DBA can often be cured with stem cells from the umbilical cord blood of a sibling with genetically matched tissue.<sup>194</sup> Unlike beta thalassemia, however, DBA generally arises as a result of sporadic genetic mutation, rather than a genetically inherited one.<sup>195</sup> The HFEA initially denied the clinic treating the Whitakers a license for PGD with tissue typing because DBA is not a heritable condition while

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<sup>190</sup> *Id.*

<sup>191</sup> See *supra* note 114 and accompanying text.

<sup>192</sup> See *infra* Part II.B for a discussion of the Whitakers' situation.

<sup>193</sup> Josie Appleton, *Life and Death Decisions*, SPIKED (Aug. 20, 2002), <http://www.spiked-online.com/Articles/00000006D9E1.htm>; Press Release, Human Fertilisation and Embryology Authority, HFEA Confirms that HLA Tissue Typing May Only Take Place when Preimplantation Genetic Diagnosis Is Required to Avoid a Serious Genetic Disorder (Aug. 1, 2002), <http://hfea.gov.uk/PressOffice/Archive/43573563>.

<sup>194</sup> See Appleton, *supra* note 193. The Whitakers' second child, conceived naturally, was not a tissue match for Charlie. See HUMAN REPRODUCTIVE TECHNOLOGIES AND THE LAW, *supra* note 10, at 60.

<sup>195</sup> Press Release, Human Fertilisation and Embryology Authority, HFEA Confirms that HLA Tissue Typing May Only Take Place when Preimplantation Genetic Diagnosis Is Required to Avoid a Serious Genetic Disorder (Aug. 1, 2002), <http://hfea.gov.uk/PressOffice/Archive/43573563>.

beta thalassaemia, the condition for which the HFEA had approved the Hashmis' treatment, is a heritable condition.

In 2002 when the HFEA first considered the Whitakers' application for PGD with tissue typing, the HFEA imposed, among others, the criterion that "the embryos conceived in the course of this treatment should themselves be at risk from the condition by which the existing child is affected."<sup>196</sup> Because neither Mr. nor Mrs. Whitaker appeared to be a carrier of DBA and the genetic mutation present in their son Charlie arose sporadically, the HFEA concluded that any embryos conceived in the future by these parents faced little risk of DBA. Therefore, the Whitakers' case did not satisfy the criterion.<sup>197</sup> The biopsy procedure necessary for PGD involves some risk to the developing embryo.<sup>198</sup> The HFEA was willing to accept such risk to the embryo only if the embryo itself stood to benefit from the procedure, through a potential diagnosis of a genetic defect.<sup>199</sup> What is more, the HFEA evidently believed public opinion would oppose PGD for the purpose of avoiding non-inheritable genetic disorders.<sup>200</sup>

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<sup>196</sup> *Id.* See *supra* notes 83 and 85 and accompanying text for a discussion of this criterion that an applicant must satisfy before receiving a license for PGD with tissue typing.

<sup>197</sup> Press Release, Human Fertilisation and Embryology Authority, HFEA Confirms that HLA Tissue Typing May Only Take Place when Preimplantation Genetic Diagnosis Is Required to Avoid a Serious Genetic Disorder (Aug. 1, 2002), <http://www.hfea.gov.uk/PressOffice/Archive/43573563>.

<sup>198</sup> See Press Release, Human Fertilisation and Embryology Authority, HFEA Agrees to Extend Policy on Tissue Typing (July 21, 2004), <http://www.hfea.gov.uk/PressOffice/Archive/1090427358> (explaining that "[i]n 2001 the HFEA adopted a precautionary approach when considering this procedure and decided that it should only be permitted when it was combined with tests to enable parents to select embryos which are free from a serious genetic disorder" because "the technique is invasive and there was a concern about a potential risk of damaging the embryo, so tissue typing was only allowed on cells which had already been taken from the embryo for genetic diagnosis"). *But see infra* note 213 and accompanying text (regarding the HFEA's current view regarding the absence of risks relating to the embryo biopsy procedure).

<sup>199</sup> Professors Sheldon and Wilkinson effectively critiqued the logic underlying this argument, by viewing each individual embryo as a separate entity with its own interest in being born. They explain that, with PGD alone, the biopsy procedure does not benefit a particular embryo by *preventing* or *curing* genetic disorder, but rather can be said to benefit an already healthy embryo only insofar as the biopsy procedure causes that particular embryo to be implanted and therefore to be born. That same benefit accrues to the embryo implanted through PGD with tissue typing, meaning that this principle of benefit "fails to justify drawing a moral distinction between screening for genetic disorders and saviour sibling selection." See Sally Sheldon & Stephen Wilkinson, *Should Selecting Saviour Siblings Be Banned*, 30 J. MED. ETHICS 533, 535 (2004). Like other commentators, Sheldon and Wilkinson employ the term "saviour sibling" to refer to a child conceived as a tissue donor for an older sibling affected by a genetic disorder.

<sup>200</sup> See Press Release, Human Fertilisation and Embryology Authority, HFEA Confirms that HLA Tissue Typing May Only Take Place when Preimplantation Genetic Diagnosis Is Required to Avoid a Serious Genetic Disorder (Aug. 1, 2002), <http://www.hfea.gov.uk/PressOffice/Archive/43573563> (basing its policy position in part on "the results of a public consultation on the acceptability of PGD").

The HFEA's decision in the Whitakers' case occasioned much criticism. The British Medical Association supported the Whitakers' position, declaring through its ethics chair that "where technology exists that could help a dying or seriously ill child, without involving major risk for others, then it can only be right that it is used for this purpose."<sup>201</sup> Dr. Mohammed Taranissi from the Assisted Reproduction and Gynaecology Centre in London criticized the HFEA's differing decisions in the Hashmi and Whitaker cases, stating: "They have made two decisions that are exactly the opposite of each other. This reflects the fact that they don't really know what to do. They are sitting on the fence, picking and choosing."<sup>202</sup> With respect to public opinion, one commentator attacked the HFEA's rationale: while the HFEA had suggested that its decision to deny a license in the Whitakers' situation was based upon public consultation, that consultation "did not explicitly ask respondents what they thought about using PGD for tissue typing—and it certainly didn't illustrate this question by using a case like the Whitakers', which would have helped bring the issue to life."<sup>203</sup>

Most importantly, supporters of the Whitakers' position noted that the Whitakers were actually more likely than the Hashmis to succeed in con-

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<sup>201</sup> Sarah Boseley, *As Age of the Saviour Sibling Dawns, Pressure Mounts Inexorably to Change Embryo Rules*, GUARDIAN, June 20, 2003, at 3 (explaining that the BMA's support for the Whitakers encouraged the HFEA to reexamine its stance on this issue); see also PREIMPLANTATION TISSUE TYPING REPORT, *supra* note 84, at 8 ("[T]he Medical Ethics Committee of the BMA [British Medical Association] suggests that there is no morally significant distinction between tissue typing as an adjunct to PGD and tissue typing alone and concludes that both should be available.").

<sup>202</sup> Appleton, *supra* note 193 (quoting Dr. Taranissi).

<sup>203</sup> *Id.* A 1999-2000 HFEA survey of public opinion regarding PGD asked respondents whether they agreed with the current practice of licensing PGD "for a limited number of specific serious inherited conditions" and offered three choices of answers: "Yes," "No—greater restriction needed," or "No—less restriction needed." Seventy-four percent replied "yes," twenty percent opted for greater restriction, and eight percent for less restriction. PUBLIC CONSULTATION ON PGD, *supra* note 83, at 12-13.

However, when the firm Opinion Leader Research conducted a survey in May and June 2004 to understand public attitudes toward embryo selection to produce tissue donors, the firm found that "[p]articipants believe embryo selection for tissue donation provides an opportunity for science to provide beneficial and cost-efficient treatment to improve the quality of life of individual children and their families." Human Fertilisation and Embryology Authority, PGD/HLA IN CONTEXT, Annex G, at 127 (June 2004), available at <http://www.hfea.gov.uk/AboutHFEA/Committees/EthicsandLawCommittee/2004June> [hereinafter PGD/HLA IN CONTEXT]. While the participants believed that embryo selection for tissue donation was acceptable only where the recipient child suffers from a life-threatening disorder, the donor child does not experience physical pain in the donation process, and there is a reasonable chance the technique will succeed, the participants felt it was less important whether the donor child was himself at risk of the disorder. PGD/HLA IN CONTEXT, *supra*, Annex G, at 127-28. See *supra* note 40 and accompanying text regarding survey results indicating approval in the United States for PGD with tissue typing to conceive a stem cell donor.

ceiving a healthy, tissue-matched sibling for their child, since they were not known to be carriers of any genetic disorder. According to estimates, the Hashmis had only a two to three percent chance of conceiving a child that was both free of beta thalassaemia and a tissue match for Zain, while the Whitakers had only a two to three percent chance of conceiving a child suffering from DBA.<sup>204</sup>

After the HFEA refused to grant a license for PGD with tissue typing to the clinic treating the Whitakers, the family sought treatment in the United States at the Reproductive Genetics Institute in Chicago,<sup>205</sup> the same center where the Nashes had undergone PGD.<sup>206</sup> Mrs. Whitaker gave birth in June 2003 to a son they named Jamie,<sup>207</sup> who was genetically matched to their older son Charlie.<sup>208</sup> According to an October, 2004 newsletter issued by the Public Health Genetics Unit, which is part of the U.K. National Health Service,<sup>209</sup> Charlie Whitaker was “‘effectively cured’ of Diamond Blackfan Anaemia (DBA) as a result of a bone marrow transplant from his genetically selected brother,”<sup>210</sup> performed using umbilical cord blood stem cells collected at Jamie’s birth.<sup>211</sup>

Meanwhile, just over a year after Jamie Whitaker’s birth, in July 2004, the HFEA announced its decision, upon reexamination of the issue, to make PGD with tissue typing available to families such as the Whitakers who wish to use PGD with tissue typing to select a tissue-matched embryo for an existing child suffering from a non-inheritable condition.<sup>212</sup> The HFEA explained in a 2004 report that PGD with tissue typing involves little risk of physical harm in terms of the effect of the biopsy procedure on the developing fetus.<sup>213</sup> The HFEA also found no evidence that children conceived as

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<sup>204</sup> See Orr, *supra* note 131.

<sup>205</sup> M. Spriggs, *Is Conceiving a Child to Benefit Another Against the Interests of the New Child?*, 31 J. MED. ETHICS 341, 341 (2005).

<sup>206</sup> See *supra* note 90. See also “‘Designer Baby’ Born to UK Couple”, BBC NEWS (June 19, 2003), <http://news.bbc.co.uk/1/hi/health/3002610.stm> (stating the Reproductive Genetics Institute was involved in the births of Adam Nash and Jamie Whitaker).

<sup>207</sup> See “‘Designer Baby’ Born to UK Couple”, BBC NEWS (June 19, 2003), <http://news.bbc.co.uk/1/hi/health/3002610.stm>.

<sup>208</sup> See Spriggs, *supra* note 205, at 341.

<sup>209</sup> Public Health Genetics Unit, About the Public Health Genetics Unit (PHGU), [http://www.phgu.org.uk/about\\_phgu/index.html](http://www.phgu.org.uk/about_phgu/index.html) (last visited June 7, 2005).

<sup>210</sup> Public Health Genetics Unit, Newsletter, No. 75, *Genetically Selected Boy “Cures” Older Brother*, [http://www.phgu.org.uk/newsletter/past\\_issues/2004/oct04.shtml](http://www.phgu.org.uk/newsletter/past_issues/2004/oct04.shtml) (Oct. 2004).

<sup>211</sup> See *id.*

<sup>212</sup> See PREIMPLANTATION TISSUE TYPING REPORT, *supra* note 84, at 10; see also Press Release, Human Fertilisation and Embryology Authority, HFEA Agrees to Extend Policy on Tissue Typing (July 21, 2004), <http://www.hfea.gov.uk/PressOffice/Archive/1090427358>.

<sup>213</sup> See PREIMPLANTATION TISSUE TYPING REPORT, *supra* note 84, at 5 (“[T]he HFEA took the view that the risk to the resulting child associated with embryo biopsy is not enough to warrant a policy

tissue donors would suffer psychological harm as a result, though it nonetheless recommended counseling and follow-up studies of involved families.<sup>214</sup> However, the clinical team treating the afflicted child must demonstrate in their application that “they have considered every other treatment possible first before applying to the HFEA and that every step has been taken to find an existing match using world wide tissue banks and cord blood banks.”<sup>215</sup> The HFEA characterized preimplantation tissue typing as a method of last resort.<sup>216</sup> Pursuant to its policy change, the HFEA granted a license in September 2004 to the Fletcher family. The Fetters sought to conceive a baby who would be a tissue match for their son Joshua, who suffers from Diamond Blackfan Anemia.<sup>217</sup> Jodie Fletcher was born in July 2005. Her family must wait six months in order to be certain that she is not

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which distinguishes between cases in which preimplantation tissue typing is used in combination with PGD for serious disease and where discovering tissue type is the sole treatment objective”). The HFEA has estimated the risk of harm to the fetus from the biopsy procedure as less than five percent, and noted that such damage typically would render the embryo non-viable. *Id.* at 4.

<sup>214</sup> *Id.* at 5. (“[T]he Authority found no evidence that was transferable or relevant to the issue of preimplantation tissue typing that adverse psychological effects would result from the procedure. However, the Authority wished to recommend that these issues be carefully and sensitively addressed, with counseling being available from appropriately qualified counselors, and that follow-up studies of children and their families be strongly encouraged.”). The children born through this relatively new procedure are still too young for such follow-up studies to be definitive.

The HFEA reached the conclusion that PGD with tissue typing would not cause psychological problems for donor children by studying families where one sibling had donated bone marrow to another. *See id.* at 4-5. In particular, a 2004 report of the HFEA Ethics and Law Committee stated that, according to expert opinion, child donors in sibling-to-sibling bone marrow transplants “are not necessarily a population at risk of psychological adversity.” PGD/HLA IN CONTEXT, *supra* note 203, Annex C, at 5. *Cf.* Wendy Packman et al., *Psychosocial Adjustment of Adolescent Siblings of Hematopoietic Stem Cell Transplant Patients*, 21 J. PEDIATRIC ONCOLOGY NURSING 233, 234 (2004) (stating that according to their study of adolescents who did and did not donate bone marrow to their ill siblings, while donor siblings self reported “significantly more anxiety and lower self-esteem than nondonor siblings,” both donor and nondonor siblings reported similar levels of post-traumatic stress, and teachers reported that donor children demonstrated “significantly more adaptive skills in school” and fewer school problems).

However, the 2004 HFEA report did emphasize that the newborn donor’s child “secure attachment” to the parents might be impeded “if during the early stages of her or his life, parents are spending much time in hospital with the recipient sibling rather than with the new baby.” PGD/HLA IN CONTEXT, *supra* note 203, Annex C, at 6. The 2004 HFEA report also suggested that the older child’s cord blood transplant “should be postponed until the donor child had some time to bond with his or her parents.” *See id.* at 7. This concern regarding secure attachment, while important, certainly is not unique to donor children conceived through PGD with tissue typing. Indeed, obstacles to attachment can arise anytime a newborn’s older sibling is affected with a serious medical problem.

<sup>215</sup> Press Release, Human Fertilisation and Embryology Authority, HFEA Agrees to Extend Policy on Tissue Typing (July 21, 2004), <http://www.hfea.gov.uk/PressOffice/Archive/1090427358>.

<sup>216</sup> PREIMPLANTATION TISSUE TYPING REPORT, *supra* note 84, at 7.

<sup>217</sup> *Designer Baby Gets Go-Ahead*, DAILY MAIL (London), Sept. 7, 2004, at 16.

affected by DBA. Only then can the stem cells collected at her birth be transferred to her older brother Joshua.<sup>218</sup>

Notwithstanding its recent relaxation of some of the criteria facing families seeking PGD with tissue typing for the purpose of conceiving donor siblings, the U.K. still regulates this technology strictly, subjecting each party requesting a license to individual review.<sup>219</sup> In contrast, the U.S. government minimally regulates this technology.<sup>220</sup> These stances could change, however, as the U.K. House of Commons Science and Technology Committee has called for changes in governmental regulation of PGD with tissue typing, including more parental autonomy in making decisions regarding this technology,<sup>221</sup> while some commentators in the U.S. legal, medical, and academic communities have advocated for greater oversight of this technology.<sup>222</sup> In order to analyze the merits of governmental regulation of PGD with tissue typing and the importance of procreative autonomy in this particular context, it is necessary to examine the arguments raised by both advocates and opponents of PGD with tissue typing.

### III. ARGUMENTS ADVANCED IN SUPPORT OF AND AGAINST PGD WITH TISSUE TYPING FOR THE PURPOSE OF CONCEIVING DONOR SIBLINGS

#### A. *Arguments Militating in Favor of PGD with Tissue Typing for the Purpose of Conceiving Donor Siblings*

Supporters of PGD with tissue typing for the purpose of conceiving a stem cell donor sibling point to the several benefits this process affords the

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<sup>218</sup> Bill Moulard, *Designed for Life*, DAILY MAIL (London), July 16, 2005, at 3.

<sup>219</sup> See *supra* note 89 and accompanying text. See also e-mail from Stephanie Croker, Policy Officer, Human Fertilisation and Embryology Authority, to Donna M. Gitter, Assistant Professor of Legal and Ethical Studies, Fordham University Schools of Business (June 8, 2005, 10:34 AM) (on file with author) (“Preimplantation tissue typing is regulated on a case by case basis and applicants should demonstrate that the treatment is the last resort and all other possibilities have been explored.”).

<sup>220</sup> See *supra* Part I.A.

<sup>221</sup> See HUMAN REPRODUCTIVE TECHNOLOGIES AND THE LAW, *supra* note 10, at 60 (“We conclude that there are no compelling reasons for a statutory authority to make judgements on whether or not a family can seek preimplantation tissue typing, provided they fall within parameters set by Parliament.”) and 157 (emphasizing its goal of optimizing “the freedom of patients to make decisions in consultation with their doctors”).

<sup>222</sup> See, e.g., Wolf, Kahn & Wagner, *supra* note 6, at 330-35 (offering specific criterion that families seeking PGD with tissue typing must meet and recommending review by an ethics committee or ethics consultant, in addition to IRB oversight). See also Belkin, *supra* note 34, at 62 (quoting Dr. John Wagner, Molly Nash’s transplant surgeon, as stating that PGD with tissue typing for the purpose of conceiving a stem cell donor “has been forced into the private sector where there are no controls” and that “[t]here should be limits” decided upon through social consensus).

child afflicted with a genetic disorder; the family of the affected child, including any children conceived through the use of this technology; and society as a whole. Most importantly, PGD with tissue typing has the potential to save the life of the affected child by facilitating the extraction of transplantable stem cells from the umbilical cord blood of a donor child through a painless procedure at the time of the donor child's birth.<sup>223</sup> As explained in an opinion of the Ethics Committee of the Human Fertilisation and Embryology Authority, "there is a strong argument that if safe scientific techniques exist and can be used benevolently, then they should be so used."<sup>224</sup>

Naturally, when a stem cell transplant is successful, the family of the affected child is a much happier one, spared the loss of a child. Thus, the ability to act as a donor may also be considered in the best interests of any subsequent child born through PGD with tissue typing.<sup>225</sup> Through the circumstances of his birth, this child could contribute to the happiness of his family by saving a sibling's life. Moreover, such a child would preserve a companion sibling for himself.<sup>226</sup>

Without access to PGD with tissue typing, it is possible families would attempt to conceive a tissue match on their own<sup>227</sup> and then selec-

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<sup>223</sup> See *supra* note 18 and accompanying text regarding the process of collecting transplantable stem cells from the donor child.

<sup>224</sup> ETHICAL ISSUES IN THE CREATION AND SELECTION OF PREIMPLANTATION EMBRYOS, *supra* note 85, at 10.

<sup>225</sup> Such a focus on the welfare of the child born through PGD with tissue typing is critical under both U.K. and U.S. law. In the U.K., Section 13(5) of the HFE Act provides: "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 . . . , and of any other child who may be affected by the birth." See Human Fertilisation and Embryology Act, 1990, c. 37, § 13(5) (Eng.). In the U.S., federal rules governing research involving children preclude federal funding for such research if it poses greater than minimal risk to the child but offers in return no prospect of direct benefit to the child. See 45 C.F.R. § 46.405 (2005); 21 C.F.R. § 50.52 (2005).

<sup>226</sup> See ETHICAL ISSUES IN THE CREATION AND SELECTION OF PREIMPLANTATION EMBRYOS, *supra* note 85, at 10 (noting that "it is certainly possible that it is in the interest of the putative child to be able to save the life of its sibling" thereby "saving its family from the turmoil of bereavement, preserving companion siblings, etc."). See also Guido Pennings et al., *Ethical Considerations on Preimplantation Genetic Diagnosis for HLA Typing to Match a Future Child as a Donor of Haematopoietic Stem Cells to a Sibling*, 17 HUM. REPROD. 534, 536 (2002).

The child that cannot donate will see its sibling die and will grow up in a family that is marked by the death of a family member. However vague, the underlying idea is that the social, emotional and psychological interests of a person depend on the happiness in the family in which he grows up.

*Id.* (citation omitted).

<sup>227</sup> Even without the use of IVF and PGD with tissue typing, families can attempt to conceive a tissue donor. In 1990, in the U.S., the Ayala family, see *supra* note 6, was the first to admit publicly their intention to conceive a tissue donor for their daughter Anissa, who was dying of leukemia. They did conceive a tissue match through natural methods, and after successful transplant surgery both chil-

tively abort those fetuses that did not conform to their wishes.<sup>228</sup> Such an approach not only harms the sick child, whose treatment is delayed, but

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dren enjoyed good health. *See* Kolata, *supra* note 6; *see also supra* note 6 and accompanying text regarding the Ayala family. Around the time of the highly publicized Ayala case, at least one survey of the nation's bone marrow transplant centers indicated that it was not unusual for parents to conceive donor siblings. *See* Kolata, *supra* note 6 (citing the survey results as indicating that at least forty donor siblings had been conceived in the five preceding years). However, the Ayala case differs significantly from the Nash, Hashmi, Whitaker, and Fletcher cases in that Marissa Ayala donated to her sister more than just fetal stem cells, but also bone marrow, which necessitates discomfort on the donor's part. *See id.*

<sup>228</sup> *See* ETHICAL ISSUES IN THE CREATION AND SELECTION OF PREIMPLANTATION EMBRYOS, *supra* note 85, at 8 ("An alternative to selecting preimplantation embryos is the selection of fetuses by natural conception combined with the selective abortion of those which are shown by prenatal diagnosis to be either affected or not an appropriate tissue match."); *see also* Wolf, Kahn & Wagner, *supra* note 6, at 328.

Conception without PGD in an effort to create a donor was most prevalent after the mid-1980s once prenatal diagnosis of FA and HLA-type became available. Despite the risk of having a fetus affected with FA (25 percent), a number of couples attempted to conceive a donor, knowing they might face a difficult decision about terminating the pregnancy if the fetus was not HLA-matched.

Wolf, Kahn & Wagner, *supra* note 6, at 328 (citations omitted).

One survey indicated that in several cases parents have conceived a fetus specifically to serve as a tissue donor and were prepared to abort the fetus if it was not a tissue match. Pennings et al., *supra* note 226, at 535. Another researcher, however, studied thirty-two couples who underwent prenatal testing after conception of a child they had hoped would serve as a tissue donor to an older sibling affected with Fanconi anemia. The study showed that only two of the twenty-six healthy fetuses that were not tissue matches were aborted. Arleen D. Auerbach, *Umbilical Cord Blood Transplants for Genetic Disease: Diagnostic and Ethical Issues in Fetal Studies*, 20 BLOOD CELLS 303, 307 (1994).

One commentator noted that, in rare cases, a family might even decide to put up for adoption a subsequent child who is not a tissue match. *See* Robertson, *supra* note 37, at 468 (stating that families seeking to conceive a tissue-matched child as a stem cell donor for an older sibling might "carry the fetus to term and give up the child for adoption") (citing Auerbach, *supra*). In every reported instance where a family has requested PGD with tissue typing, however, it has been understood that the embryo conceived to be a suitable tissue donor for a sibling would itself be carried to term and be raised by its genetic parents. Thus, while the issue of creating an embryo for "spare parts" theoretically is raised by PGD with tissue typing, such a situation remains purely hypothetical. *But see* Highfield, *supra* note 23 (citing Lord Winston, the fertility expert who helped to develop the PGD technique, as criticizing the use of PGD to assist an older sibling, and expressing the "fear that it is treating the offspring to be born as a commodity").

Of course, in the event that PGD with tissue typing is available in another jurisdiction, families might seek treatment there. *See, e.g.,* Dyer, *supra* note 84, at 503 (noting that several British couples have traveled to the U.S. to seek PGD with tissue typing); *see also* Camillo Fracassini, *Couple Abandon Battle for Baby of Their Choice*, SUNDAY TIMES ONLINE (Scotland) (Jan. 23, 2005), <http://www.timesonline.co.uk/article/0,,2090-1452901,00.html> (stating that the Mastertons of the U.K., who were denied PGD with tissue typing in order to achieve gender balance in their family, *see supra* note 131, ultimately sought treatment in Italy). The mere fact that families will seek PGD with tissue typing abroad, however, does not establish that this technology is ethical and that other jurisdictions should permit it. Rather, it proves that, as a practical matter, jurisdictions that are more permissive

also causes great physical and psychological harm to the pregnant woman and the entire family.<sup>229</sup> Moreover, many societies agree that selective abortion should be avoided as a matter of public policy. As stated in an opinion of the Ethics Committee of the HFEA, “whilst tissue donation from a suitable *living* donor (unrelated or other family member) is morally preferable” to PGD with tissue typing, “the approach of natural conception combined with selective abortion until a suitable pregnancy was identified through (post-implantation) prenatal diagnosis is much less acceptable.”<sup>230</sup> Even in cases where the family carries to term a pregnancy with a non-HLA matched child, the birth of another child would surely tax the resources of a family not only dealing with a sick child, but also devastated by its inability to obtain transplantable stem cells.<sup>231</sup>

Further, because PGD with tissue matching is possible only in conjunction with IVF, which itself involves the process of choosing certain embryos for implantation,<sup>232</sup> our society has already accepted the idea of families selecting which embryos they will implant and discarding the

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toward PGD with tissue typing stand to benefit financially by treating foreign patients who cannot gain permission for treatment in their own nations.

<sup>229</sup> See ETHICAL ISSUES IN THE CREATION AND SELECTION OF PREIMPLANTATION EMBRYOS, *supra* note 85, at 8 (stating that, with respect to selective abortion of fetuses that are not healthy tissue matches for an older sibling, “[t]he cost in terms of the abortion of otherwise viable fetuses, the physical and psychological harm to the woman and family, and the delay to treatment of the suffering sibling, is likely to be significant, but it is known that some families are prepared to follow this route”).

<sup>230</sup> *Id.* at 11 (emphasis added). Professor Botkin has pointed out, however, that for those who are fundamentally opposed to abortion, PGD “will be seen as *more* ethically problematic than traditional prenatal diagnosis” because “PGD requires the creation [and ultimate destruction] of numerous embryos for each live birth produced.” Jeffrey R. Botkin, *Ethical Issues and Practical Problems in Preimplantation Genetic Diagnosis*, 26 J. L. MED. & ETHICS 17, 21 (1998). He cited a study involving twelve couples who used PGD to screen for cystic fibrosis. The couples produced among them 137 embryos of which twenty-six were transferred to a woman’s uterus, resulting in five live births. *Id.* (citing Asangla Ao et al., *Clinical Experience with Preimplantation Genetic Diagnosis of Cystic Fibrosis ([DELTA] F508)*, 16 PRENATAL DIAGNOSIS 137 (1996)). Professor Botkin noted that, from the perspective of those opposed to abortion, “[t]he loss of prenatal life was substantially greater through PGD than would have resulted had the twelve at-risk couples pursued traditional prenatal diagnosis and selective termination.” *Id.*

<sup>231</sup> Research has not revealed any studies specifically examining the psychological effects upon subsequent non-HLA matched children born in a family unable to procure transplantable stem cells to treat the illness of an older child suffering from a genetic disorder. One study of adolescent donor and non-donor siblings, however, has indicated that non-donor siblings often demonstrate more problems in school than donor siblings, and report moderate to severe levels of post-traumatic stress just as often as donor siblings do. Packman et al., *supra* note 214, at 234.

<sup>232</sup> See *supra* note 2 for a brief description of the IVF process.

rest.<sup>233</sup> Since not all embryos will be implanted anyway, there is an argument that families might as well choose an embryo for “rational or humanitarian” reasons, such as its ability to provide transplantable stem cells to a sick sibling upon its birth.<sup>234</sup> John Harris, professor of bioethics at the University of Manchester in the U.K. explains:

In IVF, mothers have more embryos than they may implant legally, or indeed ethically. A woman has 6, 10 or 12 embryos; but they only implant three. Surely it is better to choose on the basis of rational or humanitarian reasons, rather than for non-rational reasons? No embryo has an *entitlement* to be implanted.<sup>235</sup>

While Dr. Harris’s argument certainly explains why it could be considered moral to select among embryos for implantation, it likely would not appease those who believe that embryos deserve “special respect as the first stage toward a new person”<sup>236</sup> and therefore wish to limit the number of embryos discarded. Because some families seek IVF coupled with PGD with tissue matching simply in order to conceive a donor child, not because of infertility, the availability of PGD with tissue matching may increase the overall incidence of IVF, and therefore the total number of healthy embryos discarded.<sup>237</sup> Even those who accept IVF and PGD as tools to help infertile couples to conceive and to avoid genetic disease in their offspring might oppose discarding healthy embryos in order to find a tissue donor.<sup>238</sup>

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<sup>233</sup> See *Most US IVF Clinics Discard Unused Embryos*, MED. NEWS TODAY, Sept. 2, 2004 (stating that a survey of U.S. fertility clinics revealed that most clinics discard unused embryos created for in vitro fertilization).

<sup>234</sup> Appleton, *supra* note 193.

<sup>235</sup> *Id.* (quoting Dr. John Harris).

<sup>236</sup> See Robertson, *supra* note 37, at 466 (citation omitted) (describing the views of those who accord a special status to embryos and therefore feel that PGD is “ethically acceptable when done for good reasons, such as preventing offspring with serious genetic defects,” but who do not necessarily accept PGD under all circumstances). What is more, some individuals who believe that an embryo is a person oppose entirely any destruction of embryos, and on these grounds may object to IVF and PGD. See Robertson, *supra* note 44, at 213 (observing that “persons holding right to life views will probably object to PGD for any reason”). While such views are legitimate personal beliefs, they run counter to the legal systems of both the U.S. and U.K., which do indeed permit these technologies, not to mention abortion.

<sup>237</sup> See Boyle & Savulescu, *supra* note 6, at 1242 (describing objections to the use of PGD to conceive a tissue donor on the grounds that “it results in the unnecessary destruction of embryos that are non-compatible tissue donors but likely to be healthy”).

<sup>238</sup> See Robertson, *supra* note 44, at 213 (explaining that those who accept PGD “may disagree, however, over whether particular reasons for PGD show sufficient respect for embryos and potential offspring to justify intentional creation and selection of embryos.”). In his argument before the Court of Appeal in the *Quintavalle* case, counsel for Mrs. Quintavalle unsuccessfully argued a related point. He maintained that, in enacting the HFE Act, Parliament authorized screening out genetic defects in order to assist families in overcoming infertility problems, but did not permit families to use PGD screening

Another concern about curtailing the availability of PGD with tissue typing in order to conceive a stem cell donor is that such a limitation infringes individuals' civil liberties. Many commentators contend that the choice to use such technology belongs to each family, which should be free to act unencumbered by state intervention.<sup>239</sup> As stated in an opinion of the HFEA Ethics Committee, "[t]here is a presumption in law that people should be free to exercise their rights in areas of activity that most closely affect themselves and their families."<sup>240</sup> According to this view, the onus should be on the state to prove its moral right to deny families access to PGD with tissue typing, rather than on the family to prove its moral right to this choice.<sup>241</sup> Another problem with the state's wielding this power is that, in an opinion of the HFEA Ethics Committee, "[i]t may be impossible . . . to discover the parent's motivation by empirical interrogation."<sup>242</sup> While the desire to save the life of a sick child would clearly motivate parents to choose PGD with tissue typing, "it would not, however, be possible to know with certainty whether this were either a primary or sufficient motivation for seeking treatment."<sup>243</sup> What is more, the Ethics Committee noted that the desire to save a sick sibling "clearly does not rule out [the parents'] benevolent intention to love and care for the child [conceived through PGD with tissue typing]."<sup>244</sup>

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to reject healthy embryos because they were not tissue matches for an ill child. *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Auth.*, [2003] 3 W.L.R. 878 ¶ 24 (C.A. 2003).

<sup>239</sup> See JOHN A. ROBERTSON, *CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES* 24, 32 (1994) (arguing, in the context of assisted reproduction generally, for a strong presumption in favor of procreative liberty); Boyle & Savulescu, *supra* note 6, at 1242 ("[U]nless our private reproductive decisions cause harm to others, they should remain immune to legislation even if some people morally disapprove of them.").

<sup>240</sup> ETHICAL ISSUES IN THE CREATION AND SELECTION OF PREIMPLANTATION EMBRYOS, *supra* note 85, at 4.

<sup>241</sup> See Appleton, *supra* note 193.

<sup>242</sup> ETHICAL ISSUES IN THE CREATION AND SELECTION OF PREIMPLANTATION EMBRYOS, *supra* note 85, at 6. See also Boyle & Savulescu, *supra* note 6, at 1241-42 ("Blanket predictions about how parents will treat their children, and defining a set of conditions under which it is appropriate to allow people to parent, are dangerous and liable to be mistaken.").

<sup>243</sup> ETHICAL ISSUES IN THE CREATION AND SELECTION OF PREIMPLANTATION EMBRYOS, *supra* note 85, at 9.

<sup>244</sup> *Id.* See also *infra* notes 254-55 and accompanying text regarding Jayson Whitaker's simultaneous concern for both of his children.

The HFEA Ethics Committee further noted that conceiving a child as a tissue donor "is certainly no worse than other common reasons" for having a child. ETHICAL ISSUES IN THE CREATION AND SELECTION OF PREIMPLANTATION EMBRYOS, *supra* note 85, at 9. Commentators have observed that "[d]ecisions to have children have long been entwined with narcissistic or utilitarian purposes, from continuing one's lineage to seeking companionship, replacing a dead or dying child, adding additional workers to a household, and providing a 'defence 'gainst time's scythe.'" Robertson, Kahn & Wagner, *supra* note 10, at 36. However, as an HFEA Ethics Committee report noted, "it is a fallacy to argue that

B. *Arguments Against PGD with Tissue Typing for the Purpose of Conceiving Donor Siblings*

The arguments against PGD with tissue typing for the purpose of conceiving donor siblings generally fall into three categories. First, some commentators fear children conceived via PGD through tissue typing will be treated, primarily by their parents but also by the medical establishment, as commodities rather than as ends in themselves. A related concern is the psychological effect the knowledge of the circumstances surrounding their birth would have on these children. Finally, some commentators fear that the use of such technology to select embryos for specific characteristics represents the first step down the slippery slope toward eugenics.

The primary critique of the use of PGD with tissue typing to create transplantable stem cells for an older sibling is that this process treats the donor child as a commodity rather than a human being and creates pressure on the child to donate in the future if necessary.<sup>245</sup> Lord Robert Winston, the fertility expert who helped to develop PGD,<sup>246</sup> criticizes the use of PGD with tissue typing for the purpose of conceiving donor siblings because “it is treating the offspring to be born as a commodity” and might unfairly subject the child to a lifetime of donating cells to a sibling.<sup>247</sup> For this rea-

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because there are bad reasons for having children the HFEA should sanction a further bad reason.” ETHICAL ISSUES IN THE CREATION AND SELECTION OF PREIMPLANTATION EMBRYOS, *supra* note 85, at 10.

<sup>245</sup> See Simoncelli, *supra* note 37, at 2 (expressing concerns about “the potential instrumentalization of the ‘sibling saver,’ and the pressure the children might face to donate tissues or organs on a continuous basis, should the initial transplant fail to correct for the disease”); see also Wolf, Kahn & Wagner, *supra* note 6, at 327 (noting that an HLA-matched child “may be considered and asked for tissues and organs throughout his or her life”).

<sup>246</sup> Lord Winston is Professor of Fertility Studies at the Imperial College School of Medicine at London University in England. He is also Director of NHS Research and Development for Hammer-smith Hospital, one of the UK’s leading infertility research centers, and is well known for his highly acclaimed BBC Television series on scientific topics. See 2001 Honorary Graduates of Oxford Brookes University, [https://www.brookes.ac.uk/hon\\_grads/2001/graduates/winston](https://www.brookes.ac.uk/hon_grads/2001/graduates/winston) (last updated Oct. 20, 2005); Press Release, Queen’s University Belfast, Fertility Expert Lord Winston Honoured by Queen’s (Dec. 16, 2004), <http://www.qub.ie/home/TheUniversity/GeneralServices/News/ArchivesPressReleases-CampusNews/2004PressReleases/12-2004PressReleases/#d.en.11620>.

<sup>247</sup> Highfield, *supra* note 23 (quoting Lord Winston). See also Boseley, *supra* note 201 (quoting Lord Winston as criticizing PGD with tissue typing to create a donor sibling as the only medical treatment “which you would expect anybody to undergo without informed consent for somebody’s else’s benefit” and expressing concern that a donor sibling faces “the spectre of being born for somebody else’s benefit throughout his whole life”).

In response to Lord Winston’s statement regarding lack of informed consent, it should be noted that, as a general principal, parents and guardians have the right to make medical decisions on behalf of their minor children. Additionally, courts can exercise judicial oversight in order to protect such chil-

son, Lord Winston advocates investing additional effort into finding alternatives, such as recruiting more tissue donors.<sup>248</sup>

In response to the concern that a child conceived through PGD with tissue typing would be considered a commodity, it should be noted that both the Hashmis and the Whitakers avowed that they wanted another child in any case.<sup>249</sup> Furthermore, a parent's desire to save the life of a child affected by a genetic disorder is not necessarily incompatible with the ability to love and care for a second child.<sup>250</sup> Indeed, "the fact that the parents are willing to conceive another child to protect the first suggests that they are highly committed to the well-being of their children, and that they will value the second child for its own sake as well."<sup>251</sup>

Professors Sheldon and Wilkinson believe that fear of instrumentalization of the donor child results from what they term a "misreading" of Kant's famous dictum, "[n]ever use people as a means but always treat them as an end."<sup>252</sup> In their view, while it clearly would be wrong to create

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dren when the medical procedure is intended to help someone other than the child on which it is performed. See PREIMPLANTATION TISSUE TYPING REPORT, *supra* note 84, at 7 (explaining that while "[y]oung children are not usually old enough to be legally competent to consent to their own medical treatment," "a holder of parental responsibility" may consent if to do so would "be in the best interests of the child," and noting that disagreements between the doctors and parents "can be referred to the court").

<sup>248</sup> See Highfield, *supra* note 23. This alternative, which involves the implementation of properly recruited and resourced public cord blood banks, could avoid the need for PGD with tissue typing to create donor siblings. See ETHICAL ISSUES IN THE CREATION AND SELECTION OF PREIMPLANTATION EMBRYOS, *supra* note 85, at 11 (noting that "prudential storing of cord blood from healthy births is likely to provide a useful resource in the treatment of disease in general"). The HFEA has also expressed hope that biotechnological advances in related areas "such as the management of disease, the use of combined cord or mismatched transplant tissue, the use of peripheral blood stem cells or therapeutic cloning to derive stem cells for treatments, may provide viable alternatives to the use of tissue from matched siblings in the future." PREIMPLANTATION TISSUE TYPING REPORT, *supra* note 84, at 9. For a discussion of the use of embryonic stem cells to produce hematopoietic stem cells, thereby avoiding the need for the birth of a child in order to obtain such cells, see Robertson, Kahn & Wagner, *supra* note 10, at 39. These commentators note that "[t]here are as yet no laws banning the creation of embryos for use or destruction in therapy." *Id.*

<sup>249</sup> Sheldon & Wilkinson, *supra* note 199, at 536 n.18.

<sup>250</sup> See *supra* note 242 and accompanying text.

<sup>251</sup> Robertson, Kahn & Wagner, *supra* note 10, at 35. See also Pennings et al., *supra* note 226, at 536 ("Given the psycho-logic of the parental concern demonstrated by their efforts to save the recipient child, it is highly unlikely that they will not treat the intended donor child as an equal to the existing child.") (citation omitted).

<sup>252</sup> Sheldon & Wilkinson, *supra* note 199, at 534. In his GROUNDWORK OF THE METAPHYSICS OF MORALS, Kant stated this imperative as follows: "So act that you always treat humanity, whether in your own person or the person of any other, never simply as a means, but always at the same time as an end." IMMANUEL KANT, GROUNDWORK OF THE METAPHYSICS OF MORALS 4:429 (Mary Gregor ed. & trans., Cambridge Univ. Press 1998).

a child “solely to advance some further end,” then “just to discard him or her once it had ‘served the purpose,’” it is acceptable to create a child to help fulfill some purpose so long as the child “is also viewed and treated as a human being.”<sup>253</sup> One commentator pointed to Jayson Whitaker’s expression of concern upon the birth of his newborn son Jamie as demonstrating the ability of parents to appreciate and honor the complex duality of the second child’s birth.<sup>254</sup> Mr. Whitaker stated that while “blood tests are being carried out now to see if Jamie is a perfect tissue match and we will know in a few days, . . . at the moment we don’t want to think about the stem cell blood.” The night before Jamie was born Mr. Whitaker “didn’t even care about cord blood. [He] just kept thinking, ‘I hope he’s all right.’”<sup>255</sup> In every reported instance where a family has requested PGD with tissue typing, it has been understood that the embryo conceived to be a suitable tissue donor for a sibling would itself be carried to term and be raised by its genetic parents.

Another critique of PGD with tissue typing is that a child conceived in this way, even if treasured by its parents for its own sake, will nonetheless face pressure to serve as a continuing source of donations to its ill sibling.<sup>256</sup> Experts with personal involvement in the Nash case have explained, for cases involving leukemia, the many circumstances under which donor children might face requests to donate more than umbilical cord blood:

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<sup>253</sup> Sheldon & Wilkinson, *supra* note 199, at 534. See also Boyle & Savulescu, *supra* note 6, at 1241 (stating that “in reality many children are born for a purpose: to care for their parents, as a companion to a sibling” and contending that “[p]rovided that parents love their child, there is little problem with that child benefiting others”); John Harris, *Sex Selection and Regulated Hatred*, 31 J. MED. ETHICS 291, 293 (2005) (arguing, in the context of gender selection, that “it is very difficult to find evidence or even persuasive anecdotes that if people are treated as means they are treated as mere means or exclusively as means”).

Commentators have also observed that if the law bars parents from using PGD with tissue typing in order to conceive a donor sibling, parents might then conceive a later child to fill the void left by the first child should that child die. Arguably, this “replacement” child is just as instrumentalized as one conceived with the goal of tissue donation in mind. See Pennings et al., *supra* note 226, at 536.

<sup>254</sup> See Spriggs, *supra* note 205, at 341 (noting that Jayson Whitaker’s comments “give weight to the . . . view . . . that allowing PGD with tissue typing is not incompatible with the welfare of the child created”). See also Harris, *supra* note 253, at 293 (criticizing the notion that children conceived as tissue donors “would be so unloved and treated so unacceptably badly that it would cause psychological damage” as “a piece of reckless speculation” for which there is no evidence.).

<sup>255</sup> See Spriggs, *supra* note 205, at 341 (citing P. McGowan, *Agonising Wait for Designer Baby Parents*, THIS IS LONDON, June 19, 2003, News and City Section, available at <http://www.thisislondon.co.uk/news/articles/5397764?source=Evening%20Standard>). A commentator has noted that in the case of the Ayala family as well, “grim predictions were made about [the donor child’s] prospects, but these proved to be false.” Boyle & Savulescu, *supra* note 6, at 1241. See *supra* notes 6 & 227 for additional information on the Ayala family.

<sup>256</sup> See *supra* notes 245-47 and accompanying text.

[C]hildren conceived to be HLA-matched face the possibility of donation throughout their lives. The initial cord blood donation could fail for any of several reasons: inadequate cord blood cell dose, graft failure after cord blood transplant, or the recipient child experiencing a recurrence of leukemia after transplant. If cord blood transplant fails, the next step is bone marrow harvest and transplant. This, too, might not engraft or leukemia may recur, requiring yet another bone marrow transplant. Further, once an HLA-matched donor is created, the need for tissues beyond bone marrow may arise. Indeed, after bone marrow transplant, toxicities related to chemotherapy and irradiation or immunosuppressive drugs could produce organ failure involving the kidneys, liver, or other organs. Then the question would arise whether to harvest a solid organ from the donor child. The HLA-matched child created in the Nash case has thus far escaped further need for tissue or organs by his sister. However, he is quite young. He and all children created as donors face the potential of requests for donation throughout their lives.<sup>257</sup>

In light of the general acceptance within the U.S. and U.K. of bone marrow donation by younger siblings, it is likely children conceived via PGD with tissue typing would face requests to serve as bone marrow donors. In the U.K., all children, not just those conceived via PGD, are considered potential donors of bone marrow once they reach one year of age because “obtaining bone marrow for the treatment of siblings from children from the age of one year was a relatively routine treatment strategy where no other matched donor was available.”<sup>258</sup> In the U.S., “bone marrow donations from infants and minors to siblings have been ethically and legally acceptable for many years.”<sup>259</sup> In addition, the UK Childhood Cancer Study Group, Bone Marrow Transplant Section gathered evidence indicating “that matched bone marrow transplants were far more successful (in particular in Thalassaemia cases) than cord blood treatments.”<sup>260</sup> As a result of these factors, children conceived via PGD with tissue typing will almost certainly face requests to serve as bone marrow donors to their ill siblings.

The notion of specially creating donor siblings is ethically troubling because bone marrow donation involves significant risks to the donor child. As explained by experts involved in the Nash case,

Bone marrow harvest in children is invasive, and usually performed under general anaesthesia. It involves risks of infection (albeit low), risks of general anesthesia, pain, and discomfort and may involve the risks of transfusion. Studies also indicate that the psychological

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<sup>257</sup> Wolf, Kahn & Wagner, *supra* note 6, at 328-29.

<sup>258</sup> PREIMPLANTATION TISSUE TYPING REPORT, *supra* note 84, at 7.

<sup>259</sup> Robertson, Kahn & Wagner, *supra* note 10, at 35.

<sup>260</sup> See PGD/HLA IN CONTEXT, *supra* note 203, Annex D, at 53. Indeed, cord blood donation fails in about twenty-five percent of cases involving thalassaemia patients. *Id.* In the opinion of the UK Childhood Cancer Study Group, Bone Marrow Transplant Section, once a child has donated cord blood, “it would be nonsensical to not also use the child as a bone marrow donor if the cord blood donation failed.” *Id.*

burden to minors of donating bone marrow to a sibling can be significant, including guilt and a sense of responsibility for saving the sibling's life.<sup>261</sup>

With respect to organ donation among siblings, as opposed to bone marrow donation, U.S. and U.K. law certainly furnish safeguards to protect putative donor children, while at the same time leaving open the possibility of solid organ donation by minors. Under U.K. common law, "the best interests test applied by the courts when considering the type of medical procedures that may be performed on a child, is very much higher when such treatment gives no health benefit to the child concerned," and, "[a]s such, solid organ donation is extremely unlikely to be held to be in a child's best interest."<sup>262</sup> Nevertheless, the test of the best interests of the child is often "interpreted broadly, to include the child's psychological well-being" and therefore may take into account the psychological loss involved in losing a sibling.<sup>263</sup> In the U.S. as well, courts considering whether to permit solid organ donation by minors and mentally incompetent people sometimes permit such medical procedures on the theory that it is in the donor child's best interests not to lose the recipient sibling.<sup>264</sup>

Along with the ethical problems surrounding bone marrow and solid organ donation from children conceived via PGD with tissue typing, additional moral dilemmas arise as scientists become increasingly able to make use of fetal tissue. One journalist has raised the following questions:

If society gives its blessing to the use of one child to save another, then what would prevent couples from someday going through with the process but aborting when the pregnancy was far enough along that the cord blood could be retrieved? Or what would prevent couples whose child needed a new kidney from waiting until the fetal kidney was large enough, then terminating the pregnancy and salvaging the organs.<sup>265</sup>

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<sup>261</sup> Wolf, Kahn & Wagner, *supra* note 10, at 334 (citations omitted).

<sup>262</sup> PREIMPLANTATION TISSUE TYPING REPORT, *supra* note 84, at 7.

<sup>263</sup> *Id.* ("If a medical procedure, such as a bone marrow transplant, would save the life of a sibling, it is likely to be in the best interests of the child, since to lose a sibling is psychologically damaging.")

<sup>264</sup> Wolf, Kahn & Wagner, *supra* note 10, at 334.

Over time . . . courts and others have tended to ask whether evidence demonstrates that donation is genuinely in the donor's best interests. Thus, courts have looked for evidence of a relationship between the would-be donor and recipient such that the donor would directly suffer if the recipient died and directly benefit if the recipient recovered.

*Id.* (citations omitted).

<sup>265</sup> Belkin, *supra* note 34, at 40. See also Robertson, Kahn & Wagner, *supra* note 10, at 37 ("In theory, parents could even use abortion not only to screen out affected or poorly matched fetuses, but even to obtain matched tissue *after* abortion."). The HFEA has even raised the specter of an industry breeding prospective tissue donors, but suggests that such an enterprise would be "nonsensical" because unrelated individuals are rarely tissue-matched. ETHICAL ISSUES IN THE CREATION AND SELECTION OF PREIMPLANTATION EMBRYOS, *supra* note 85, at 11.

Even in cases where a family had intended to carry to term a second child conceived through PGD with tissue typing, if the older child were close to death, one can imagine that the family might wish to terminate the second pregnancy in order to save the life of the already born child.<sup>266</sup> In actuality, abortion would be barred in all of the hypothetical situations posed in this paragraph under a federal law that criminalizes abortion of a fetus for the purpose of obtaining fetal tissue, designating it a felony punishable by up to ten years in prison.<sup>267</sup> Nevertheless, there is legitimate concern such a law eventually could be amended if PGD with tissue typing for the purpose of conceiving a stem cell donor became more widely practiced, particularly in light of the fact that a woman's motivation for seeking an abortion generally is not subject to scrutiny under U.S. and U.K. abortion law.<sup>268</sup>

Similar issues regarding pressure on siblings to serve as tissue and organ donors could arise even where the potential donor child was not conceived through PGD with tissue typing. Nevertheless, it is fair to say that a child's status as one conceived for the purpose of saving another might compromise the ability of the parents to take the donor child into account, especially the earlier the donor child is in its state of development (e.g. when it is still a fetus).<sup>269</sup> The potential for the donor child's exploitation emerges as the most significant concern relating to PGD with tissue typing.

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<sup>266</sup> See Belkin, *supra* note 34, at 62 (asking "[i]f Molly [Nash] were closer to death, for instance would her parents have terminated the pregnancy and used stem cells from Adam's fetal liver to save her?").

<sup>267</sup> See National Institutes of Health Revitalization Act of 1993, 42 U.S.C. § 289g-2 (2000); see also *supra* note 51.

<sup>268</sup> See Human Fertilisation and Embryology Act, 1990, c. 37, § 37(1) (Eng.) (permitting abortion in the U.K. when "pregnancy has not exceeded the twenty-fourth week" and allowing it even later if necessary to avoid grave danger to the life or the physical or mental health of the pregnant woman, or to the health of the fetus). See also *Roe v. Wade*, 410 U.S. 113, 153 (1973) (basing a woman's right to choose whether to give birth on her right of privacy).

<sup>269</sup> Commentators with personal involvement in the Nash case have also warned that "stacking" IVF, PGD to create a tissue donor, and stem cell transplant raises particular issues regarding the well-being of the child conceived to be a donor, because reproductive specialists might deliberately increase the risk to the donor child in order to benefit the ill older sibling. See Wolf, Kahn & Wagner, *supra* note 6, at 333.

Examples of variations unacceptably increasing the risk are: transferring extra embryos to the woman's uterus, thereby increasing the risk of conceiving multiples with the attendant risks of prematurity and its sequelae; prolonging efforts to achieve vaginal delivery to increase the amount or quality of cord blood available for transplant, when that prolongation increases risks to the donor child; rapid umbilical cord clamping; and raising the newborn above the mother's abdomen to increase the placental blood volume immediately following delivery.

*Id.* (citation omitted).

For this reason, these commentators advocate that hospital IRBs examine the three technologies in tandem, rather than separately. See *id.* at 331 (suggesting that these three technologies "should only

Critics also raise the possibility of negative psychological effects on the donor child. The HFEA has found no evidence, however, that children conceived as tissue donors would suffer psychological harm as a result.<sup>270</sup> Indeed, a donor child might even be considered more special by its parents because of its role in saving the life of an existing sibling.<sup>271</sup> The donor child certainly might be happier than if he were not a tissue match, in that he could spare his family the tragedy of losing a child and also preserve a companion sibling for himself.<sup>272</sup> What is more, commentators have pointed out the risk of psychological harm to a child born into a bereaved family who later discovers “she was a huge disappointment to her parents because of her inability to save” an older sibling’s life, which further suggests that “it is far from obvious that considerations of child welfare should count against, rather than for, the practice of saviour sibling selection.”<sup>273</sup> Finally, “it is important to remember that the alternative for the child who was conceived to provide stem cells is not another life in which he or she was conceived in another way, but non-existence.”<sup>274</sup> Thus, even if a donor child conceived through PGD did suffer some psychological effects, these effects “are unlikely to be so severe that it would be better for that particular child never to have existed.”<sup>275</sup>

Another objection to PGD with tissue typing is that it leads inexorably to eugenic practices and the creation of “designer babies.” According to this view, “increasing the frequency and scope of genetic screening of prospec-

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be combined in a research protocol capable of generating useful data” and that the “protocol should be reviewed by an IRB examining the entire protocol, not just the IVF or PGD or transplant in isolation”).

<sup>270</sup> See *supra* note 214 and accompanying text.

<sup>271</sup> See Pennings et al., *supra* note 226, at 537 (“The [donor] child may feel proud of its role in attempting to save a sibling’s life.”); Robertson, *supra* note 37, at 468 (“Its birth might save the life of an existing sibling, which would only increase its specialness.”).

<sup>272</sup> See *supra* notes 225-26 and accompanying text (describing the psychological benefits often accruing to donor children); see also Sheldon & Wilkinson, *supra* note 199, at 535-36 (explaining that a “specially selected sibling” would benefit from the company of an existing child “and may well derive pleasure from knowing that he has saved” that child’s life) (citation omitted).

<sup>273</sup> Sheldon & Wilkinson, *supra* note 199, at 536. The obverse of this argument, however, is that a child conceived to be a stem cell donor might experience “a fundamental sense of unworthiness and deficiency and a feeling of not being able to live up to expectations” if the transplant failed. Pennings et al., *supra* note 226, at 537.

<sup>274</sup> Boyle & Savulescu, *supra* note 6, at 1242. Of course, this argument does not justify subjecting the donor child to harm once it is born. Cf. Wolf, Kahn & Wagner, *supra* note 6, at 333 (emphasizing the ethical imperative “to determine the limits of what risks and burdens may ethically be imposed on the donor child-to-be”).

<sup>275</sup> Boyle & Savulescu, *supra* note 6, at 1242. For refutation of the argument that this putatively unhappy donor child conceived through PGD could and should be “replaced” with a relatively happier child not conceived through PGD, see Sheldon & Wilkinson, *supra* note 199, at 536-37 (warning of the ramifications of governmental policies limiting procreative autonomy so as to ensure the birth of “happy” rather than “less happy” individuals).

tive children will move us toward a eugenic world . . . eventually ushering in a world of ‘designer’ children in which genetic engineering of offspring becomes routine.”<sup>276</sup> While all of these objections apply equally to PGD unaccompanied by tissue typing, which families use in order to maximize their chances of giving birth to a healthy child,<sup>277</sup> the objections to PGD arguably gain force when tissue typing is performed in order to save a sibling rather than to offer information about the health of the embryo tested.

It is possible, commentators explain, to allay the concern that eugenic practices may arise from PGD with tissue typing “by noting that PGD in these cases is being used both to avoid serious disease in the child-to-be and to treat a severely disabled child already in existence,” thereby “distin-

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<sup>276</sup> Robertson, *supra* note 37, at 466. See also ETHICAL ISSUES IN THE CREATION AND SELECTION OF PREIMPLANTATION EMBRYOS TO PRODUCE TISSUE DONORS, *supra* note 85, at 7 (“It is frequently suggested that the use of PGD to select embryos for particular genetic characteristics is the ‘thin end of the wedge’ and that there is a ‘slippery slope’ from this to eugenic breeding.”). Another related concern is that ultimately families with economic resources will be able to choose children who are healthy, while economically disadvantaged families will not. See John B. Attanasio, *The Constitutionality of Regulating Human Genetic Engineering: Where Procreative Liberty and Equal Opportunity Collide*, 53 U. CHI. L. REV. 1274, 1306-09 (1986).

<sup>277</sup> See *supra* notes 4-5 and accompanying text. Professor Robertson has explained that some who oppose PGD object to the selection process itself, believing that in every case “it is wrong to choose traits of offspring, no matter how well intentioned.” Robertson, *supra* note 37, at 466. Sometimes grounded in religious belief, this view holds that “human reproduction is a ‘gift’ and that any form of selection or manipulation turns the child into a ‘manufacture’ and thus impairs human flourishing.” *Id.* (describing the arguments of Dr. Leon Kass, current chair of the President’s Bioethics Council in the U.S.). This perspective, while held by a sizeable number of individuals in the U.S. and the U.K., is unlikely to become the norm in either nation due to the prevailing acceptance of reproductive technology, including the routine procedures of amniocentesis and chorionic villus sampling (“CVS”), intended to detect genetic abnormality in a developing embryo. See Sherman Elias, *Editorial: Preimplantation Genetic Diagnosis by Comparative Genomic Hybridization*, 345 NEW ENG. J. MED. 1569, 1569 (2001) (describing amniocentesis and chorionic villus sampling as “the most common techniques for prenatal diagnosis”); see also Boyle & Savulescu, *supra* note 6, at 1242 (estimating, in 2001, that 18,000 amniocenteses occurred annually in Britain) (citation omitted).

Others who oppose the PGD selection process itself note that the process suggests that individuals already living with a condition that can be detected before implantation should not have been born. Cf. ETHICAL ISSUES IN THE CREATION AND SELECTION OF PREIMPLANTATION EMBRYOS TO PRODUCE TISSUE DONORS, *supra* note 85, at 11 (mentioning “concern about the effect of the widespread use of PGD on the perception of those individuals affected by conditions” which can be detected via PGD). Once again, this concern arises not just from the use of PGD, but also CVS and amniocentesis, commonly accepted reproductive technologies. In order to protect the rights of people affected by genetic mutations, it seems that anti-discrimination legislation would prove more effective than laws prohibiting families from using technologies that allow them to select their embryo or fetus based upon medical health. Indeed, the Genetic Interest Group, which represents support groups for British families affected by genetic disorders, opposes “any and all attempts to restrict the range of medical conditions for which preimplantation genetic diagnosis can be performed.” Boyle & Savulescu, *supra* note 6 at 1241 (citation omitted).

guish[ing] this use of PGD from uses that do not address serious medical problems.<sup>278</sup> As Sheldon and Wilkinson noted, a slide down the slippery slope “is not inevitable” in light of the HFEA’s ability to allow selection for some purposes and not others. Indeed, such is the present position in the U.K.<sup>279</sup>

Furthermore, for those concerned that PGD with tissue typing, which involves “highly beneficial negative selection”<sup>280</sup> of an embryo, will lead inexorably to positive alteration and manipulation of an embryo, such as germline gene therapy,<sup>281</sup> commentators have explained that, “[g]iven the clear line between negative selection and positive alteration of embryos, it is not necessary to bar cases of highly beneficial negative selection in order to prevent future positive selection.”<sup>282</sup> Moreover, “some cases of genetic alteration might turn out to be medically desirable and ethically acceptable; one example might turn out to be germline gene therapy to remove genes that cause major congenital malformations.”<sup>283</sup>

Nonetheless, HFEA Chair Suzi Leather has cautioned that selection of embryos constitutes “a significant step further down that slippery slope

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<sup>278</sup> Wolf, Kahn & Wagner, *supra* note 6, at 330. *See also* Robertson, Kahn & Wagner, *supra* note 10, at 38 (“Although PGD for HLA-matching targets a trait that does not threaten a child’s health, it does serve an important, life-affirming social purpose—that of saving the life of a child, reassuring parents that compatible stem cells are available, and preventing abortion.”); Sheldon & Wilkinson, *supra* note 199, at 534-35 (emphasizing that it is easy to make a moral distinction between what they call “saviour siblings” and “designer babies” because there is a “very weighty reason” to create the former, namely “saving an existing child’s life,” but only “trivial” reasons for creating the latter, “such as mere fondness for particular hair colour”).

<sup>279</sup> *See* Sheldon & Wilkinson, *supra* note 199, at 534. *See supra* Part II for a discussion of the HFEA’s past decisions to grant and deny licenses for PGD with tissue typing.

Sheldon and Wilkinson also raise the possibility that the “considerable extra cost, discomfort and inconvenience” of eugenic selection theoretically would deter “would-be ‘designer parents,’” Sheldon & Wilkinson, *supra* note 199, at 534, once the technology was available to choose traits such as eye and hair color and height, which is not yet the case. *See supra* note 42 and accompanying text describing the current limits of PGD. However, such an argument is insufficient in light of the fact that this technology will become more available, and ultimately more affordable. *See id.*

<sup>280</sup> Robertson, Kahn & Wagner, *supra* note 10, at 39.

<sup>281</sup> Germline gene therapy, also called gene transfer,

represents a relatively new possibility for the treatment of rare genetic disorders and common multifactorial diseases by changing the expression of a person’s genes. Typically gene transfer involves using a vector such as a virus to deliver a therapeutic gene to the appropriate target cells. The technique, which is still in its infancy and is not yet available outside clinical trials, was originally envisaged as a treatment of monogenic disorders, but the majority of trials now involve the treatment of cancer, infectious diseases and vascular disease.

Genome.gov, National Human Genome Research Institute, National Institutes of Health, Germline Gene Transfer, <http://www.genome.gov/10004764> (last reviewed Mar. 2006).

<sup>282</sup> Robertson, Kahn & Wagner, *supra* note 10, at 39.

<sup>283</sup> *Id.* at 38-39.

towards designer children,” in both scientific and rhetorical terms.<sup>284</sup> She notes that “in plant and animal husbandry, selection preceded manipulation” and “a common argument in favour of GM [genetic modification of crops] is: ‘look we’ve been altering genomes for years with selective breeding. What’s news about genetic engineering?’”<sup>285</sup>

Such concerns about the potential use of PGD to achieve eugenic goals, as well as commodification of the donor child and resulting psychological harm, have led to calls for heightened regulation of PGD in the U.S. At the same time, the U.S. public strongly supports PGD with tissue typing where it is necessary in order to save the life of a sick child.<sup>286</sup>

#### IV. A PROPOSAL FOR IRB AND INDEPENDENT ETHICS COMMITTEE REVIEW OF PGD WITH TISSUE TYPING TO CREATE A STEM CELL DONOR

While the U.S. public clearly supports PGD with tissue typing in order to conceive a stem cell donor, the choices faced by the Nash family have led commentators, including some with personal involvement in the case, to advocate regulation of this technology.<sup>287</sup> Interestingly, the British press as well has suggested the need for enhanced oversight in the U.S. of assisted reproductive technology, with *The Economist* magazine proposing the creation in the U.S. of a federal regulatory body to monitor human infertility, from IVF centers to embryo research. According to *The Economist*, “this would have the salutary effect of reining in fertility clinics plagued by a recent spate of scandals, and setting standards for those in the business of therapeutic cloning.”<sup>288</sup> At the same time, the U.K. House of Commons Science and Technology Committee has called for changes in governmental regulation of PGD with tissue typing, including devolving

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<sup>284</sup> Progress Educational Trust, Debate: *Saviour Siblings, Is It Right to Create a Tissue-Donor Baby?*, Transcript of Suzi Leather, Chair, Human Fertilisation and Embryology Authority (Oct. 16, 2003), <http://www.progress.org.uk/Events/PastEventsSSLLeather.html>.

<sup>285</sup> *Id.*

<sup>286</sup> See *supra* note 40 and accompanying text.

<sup>287</sup> See, e.g., Wolf, Kahn & Wagner, *supra* note 6, at 330-36 (offering specific criterion that families seeking PGD with tissue typing must meet and recommending review by an ethics committee or ethics consultant, in addition to IRB oversight). See also Belkin, *supra* note 34 (quoting Dr. John Wagner, Molly Nash’s transplant surgeon, as stating that PGD with tissue typing for the purpose of conceiving a stem cell donor “has been forced into the private sector where there are no controls” and “that there should be limits” decided upon through social consensus).

<sup>288</sup> *Storm in a Test Tube: Don’t Place Your Order Just Yet; How Significant Is the Creation of the First Cloned Human Embryo?*, THE ECONOMIST, Dec. 1, 2001, at 76. Therapeutic cloning is a technology with the potential to obviate the need for stem cell donor siblings. See Robertson, Kahn & Wagner, *supra* note 10, at 39.

more decision-making power to parents in partnership with their health care providers.<sup>289</sup> As described in Part III above, the most significant concern raised by leaving this decision entirely to parents and their health care providers, as is done in the U.S., is that individual donor siblings will face pressure to serve as continuing sources of tissue donations to their ill siblings.<sup>290</sup> It is therefore important to formulate an approach that permits families to make decisions that will leave them better off while at the same time protecting the individual children conceived at least in part to serve as tissue donors.

In a report about PGD created to stimulate public dialogue, the Genetics and Public Policy Center, part of The Phoebe R. Berman Bioethics Institute at Johns Hopkins University,<sup>291</sup> set forth various policy options as alternatives to the current U.S. system of leaving decisions about PGD to parents and care providers.<sup>292</sup> Included among these alternatives is one akin to the British model, whereby Congress would enact legislation “delegating to a new or existing federal agency the authority to oversee PGD.”<sup>293</sup> Like the HFEA, this agency “could be charged with: [i]ssuing regulations listing acceptable and unacceptable uses; [a]djudicating specific requests for use of PGD tests; [a]pproving new uses of PGD tests and techniques; [and] [l]icensing and inspecting facilities that engage in PGD.”<sup>294</sup>

In its report, the Genetics and Public Policy Center noted several advantages of this model: “[t]he agency would create clearly enforceable standards governing PGD use;” “[t]he process of rulemaking would stimulate a productive public discussion about the rapidly developing world of human reproductive technology;” and “an oversight body could also facilitate research into PGD’s impact on individuals, family and society.”<sup>295</sup> It is

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<sup>289</sup> See HUMAN REPRODUCTIVE TECHNOLOGIES AND THE LAW, *supra* note 10, at 60 (“We conclude that there are no compelling reasons for a statutory authority to make judgements on whether or not a family can seek preimplantation tissue typing, provided they fall within parameters set by Parliament.”) and 157 (emphasizing its goal of optimizing the “the freedom of patients to make decisions in consultation with their doctors”).

<sup>290</sup> See *supra* notes 256-69 and accompanying text.

<sup>291</sup> Genetics and Public Policy Center, Mission, at <http://www.dnapolicy.org/about/mission.jhtml.html> (November 2002) (explaining that the Center, funded by The Pew Charitable Trusts, “has been established to be an independent and objective source of credible information on genetic technologies and genetic policies for the public, media and policymakers”).

<sup>292</sup> See Genetics and Public Policy Center, PGD Preliminary Policy Options, A Discussion of Challenges, Concerns, and Preliminary Policy Options Related to the Genetic Testing of Human Embryos, <http://www.dnapolicy.org/policy/pgdOptions.jhtml.html> (last visited June 28, 2005).

<sup>293</sup> Genetics and Public Policy Center, PGD Preliminary Policy Options, For What Purpose?, <http://www.dnapolicy.org/policy/pgdOptions02.jhtml.html> (last visited July 14, 2005).

<sup>294</sup> *Id.*

<sup>295</sup> *Id.*

instructive to consider the functioning of the HFEA in order to determine whether an analogous U.S. federal agency would achieve these goals.

The HFEA has seen its greatest success in terms of the second and third goals stated above: stimulating debate about human reproductive technology, including PGD with tissue typing; and facilitating research into PGD's impact on individuals, families, and society. In terms of public debate, because the U.K. government regulates PGD with tissue typing, it has taken the steps of assessing public opinion toward and also fostering public dialogue about this technology.<sup>296</sup> Moreover, because the decisions of the HFEA to grant or deny licenses are available to the public (with certain personal information kept confidential), the U.K. citizenry has the opportunity to consider the issues these technologies raise. In contrast, in the U.S., political debate concerning the regulation of reproductive technologies encounters a "chilling effect" due to "its perceived affiliation with the abortion debate."<sup>297</sup>

Creation in the U.S. of a regulatory body to oversee PGD with tissue typing, among other reproductive technologies, would certainly generate public debate over these issues. In terms of taking action upon that public dialogue, however, the Genetics and Public Policy Center found "[i]t would be extremely difficult to find a majority of lawmakers who could agree on the scope and powers of such an entity."<sup>298</sup> Moreover, as a practical matter, it is quite "difficult to create a stable, effective and non-partisan oversight body" in light of the ability of "lawmakers who disagree with the agency's decisions about PGD use [to] effectively halt agency actions by denying the agency funding."<sup>299</sup>

In terms of fostering research into the impact on individuals, families, and society of PGD with tissue typing, the HFEA has also proven effective. Because of the relatively small number of cases worldwide involving PGD with tissue typing, there is a paucity of data on its effects.<sup>300</sup> Nevertheless, according to the U.K. House of Commons Science and Technology Committee, which is generally critical of the HFEA, the HFEA has succeeded in its efforts to survey this empirical evidence.<sup>301</sup>

The area in which the HFEA has not demonstrated success, however, is in creating clearly enforceable standards governing PGD use. While the

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<sup>296</sup> See generally PUBLIC CONSULTATION ON PGD, *supra* note 83.

<sup>297</sup> See Daar, *Regulating Reproductive Technologies: Panacea or Paper Tiger?*, *supra* note 49, at 639-40.

<sup>298</sup> Genetics and Public Policy Center, PGD Preliminary Policy Options, For What Purpose?, <http://www.dnapolicy.org/policy/pgdOptions02.jhtml.html> (last visited July 14, 2005).

<sup>299</sup> *Id.*

<sup>300</sup> *Cf.* HUMAN REPRODUCTIVE TECHNOLOGIES AND THE LAW, *supra* note 10, at 121.

<sup>301</sup> See *id.* (stating that "[i]t could be argued that the amount of data has not changed radically but the efforts of the HFEA in surveying that evidence has done").

HFEA does issue licenses for PGD with tissue typing, thereby clearly indicating which families will and will not be able to use this technology to conceive a donor sibling, the agency's decisions whether to grant or deny these licenses are certainly vulnerable to criticism. For example, in the Whitaker case, the HFEA first required the embryo to itself be at risk for the condition for which it would be tested.<sup>302</sup> The HFEA later relaxed this requirement.<sup>303</sup> While a national agency overseeing human reproductive technologies certainly retains the prerogative to alter its rules in response to changes in circumstances and technology, it appears in the Whitaker case that the HFEA simply failed to remain abreast of technological progress and public opinion, thereby improperly denying the Whitakers access to PGD with tissue typing at home in the U.K. Moreover, in its 2005 report advocating for an end to the HFEA, the House of Commons Science and Technology Committee criticized the deliberative procedure used by the HFEA licensing committees considering applications for PGD with tissue typing, citing several issues: HFEA procedures are not transparent;<sup>304</sup> "HFEA policy decisions are not necessarily informed by legal opinion;"<sup>305</sup> and "licence committees are not bound by HFEA policy."<sup>305</sup>

Another drawback of establishing a U.S. regulatory agency to govern PGD with tissue typing is the "significant, even unprecedented, intrusion into private medical practice" this approach would constitute and the certainty of Constitutional challenge on the grounds of limiting reproductive choice.<sup>306</sup> Because of the present lack of regulation in the U.S. with respect to assisted reproductive technologies, as well as the high priority placed on parental autonomy in the area of procreative decision making, regulation of PGD with tissue typing would likely meet with significant opposition in the U.S., particularly among trade groups of medical professionals. Even in the U.K., which has traditionally regulated assisted reproductive technologies, the House of Commons Science and Technology Committee sharply criticized the HFEA in a March 2005 report, proposing to replace "[t]he current regulatory model, which provides the HFEA with a large amount of policy-making flexibility, . . . with a system which devolves clinical decision-making and technical standards down to patients and professionals while at the same time strengthening Parliamentary and ethical oversight."<sup>307</sup> Few

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<sup>302</sup> See *supra* Part II.B.

<sup>303</sup> See *supra* Part II.B.

<sup>304</sup> See HUMAN REPRODUCTIVE TECHNOLOGIES AND THE LAW, *supra* note 10, at 106-07 (describing the HFEA licensing committee as "insufficiently open").

<sup>305</sup> *Id.* at 111 (stating that the HFEA's policy and licensing decisions "have undermined our confidence in the HFEA's understanding and/or use of the law").

<sup>306</sup> Genetics and Public Policy Center, PGD Preliminary Policy Options, For What Purpose?, <http://www.dnapolicy.org/policy/pgdOptions02.jhtml.html> (last visited July 14, 2005).

<sup>307</sup> HUMAN REPRODUCTIVE TECHNOLOGIES AND THE LAW, *supra* note 10, at 169.

other nations maintain a regulatory model relating to assisted reproductive technologies.<sup>308</sup> The Committee called upon the Government to “conduct a review of regulatory models overseas and their effectiveness in maintaining public confidence, protecting patients and promoting safe and effective treatment.”<sup>309</sup> With respect to PGD with tissue typing in particular, the Committee concluded “that there are no compelling reasons for a statutory authority to make judgements on whether or not a family can seek preimplantation tissue typing, provided they fall within parameters set by Parliament.”<sup>310</sup>

A system permitting individualized decision-making by families and their health care providers assures ease of access, whereas “more scrutiny will mean restricted or delayed availability and increased costs.”<sup>311</sup> Indeed, it is possible the Hashmis’ failure to conceive a stem cell sibling resulted in part from the delays imposed by the judicial proceedings in their case.<sup>312</sup> For their part, the Whitakers chose to engage in what is commonly termed “reproductive tourism,” traveling to the U.S. at great financial and personal cost in order to gain access to PGD with tissue typing,<sup>313</sup> which essentially cured their son’s condition.<sup>314</sup> Such barriers to treatment are tragic for families denied prompt and affordable access to techniques with the potential to save the lives of their loved ones.<sup>315</sup> For this reason the U.K. House of Commons Science and Technology Committee believes “reproductive de-

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<sup>308</sup> *Id.* at 167-68.

<sup>309</sup> *Id.* at 168. The Committee found troubling U.K. government assertions that the U.K. regulatory model relating to assisted reproduction is “highly regarded,” charging that there is “little substance to support this view, which betrays a worrying complacency.” *Id.*

<sup>310</sup> *Id.* at 60. The House of Commons Science and Technology Committee based this critique in part on the HFEA’s past policy of permitting PGD with tissue typing only where the stem cell recipient is a sibling. The Committee declared that “this distinction implies that there is evidence to suggest the psychological impact on the child, and the nature of the family’s relationship, would be different if the recipient of the stem cells were not a sibling,” while no such evidence exists. *Id.* The Committee expressed concern that the HFEA acknowledged this problem “but stated merely that it raised ‘distinct and significant issues’ and should be the subject of further consideration.” *Id.* (citation omitted). The HFEA has since relaxed this policy, suggesting that a child could donate to a parent. *See supra* note 86 and accompanying text.

<sup>311</sup> *See* GENETICS AND PUBLIC POLICY CENTER, PREIMPLANTATION GENETIC DIAGNOSIS: A DISCUSSION OF CHALLENGES, CONCERNS, AND PRELIMINARY POLICY OPTIONS RELATED TO THE GENETIC TESTING OF HUMAN EMBRYOS, at 14 (Jan. 2004), available at [http://www.dnapolicy.org/downloads/pdfs/policy\\_pgd.pdf](http://www.dnapolicy.org/downloads/pdfs/policy_pgd.pdf).

<sup>312</sup> *See supra* notes 106-07 & 114 and accompanying text.

<sup>313</sup> *See supra* notes 205-06 and accompanying text (explaining that the Whitakers sought treatment at the Chicago institute that had assisted the Nashes).

<sup>314</sup> *See supra* notes 209-11 and accompanying text.

<sup>315</sup> *See supra* note 224 and accompanying text (stating the opinion of the Ethics Committee of the Human Fertilisation and Embryology Authority that “there is a strong argument that if safe scientific techniques exist and can be used benevolently, then they should be so used”).

cisions [should] remain primarily in the private domain, governed by professional ethics and the law of consent.”<sup>316</sup> In light of the legitimate need to protect children conceived with the goal of tissue donation in mind from serving as perpetual donors,<sup>317</sup> three University of Minnesota Professors with personal involvement in the Nash case have proposed a system of nine safeguards.<sup>318</sup>

First, Professors Wolf, Kahn and Wagner propose that “[t]he combination of IVF, PGD to create a donor, and stem cell transplant to treat an affected sibling should currently be conducted as research rather than accepted treatment,” so as to render applicable, under certain circumstances, the federal rules on the protection of human research subjects.<sup>319</sup> However, these federal rules apply only “when federal funding is involved, when an institution involved had assured the federal government that all research conducted there will comply with federal rules on human research subjects, or when Food and Drug Administration (FDA) approval is required.”<sup>320</sup> Because PGD with tissue typing can occur at private clinics that receive no federal funding, this provision, while helpful in certain cases, proves insufficient to protect some children who in the future will be conceived in part as tissue donors. Thus, Professors Wolf, Kahn and Wagner suggest an important additional protection: require an IRB to review the combined technologies of IVF, PGD, and transplant, rather than separate institutions reviewing each procedure in isolation.<sup>321</sup> This combined review will help to

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<sup>316</sup> HUMAN REPRODUCTIVE TECHNOLOGIES AND THE LAW, *supra* note 10, at 171.

<sup>317</sup> See *supra* notes 256-69 and accompanying text.

<sup>318</sup> See Wolf, Kahn & Wagner, *supra* note 6, at 331-36. Professor Susan Wolf is the Faegre & Benson Professor of Law and Professor of Law and Medicine at the University of Minnesota Law School; Professor of Medicine at the University of Minnesota Medicine School; and a Faculty Member in the University's Center for Bioethics. See University of Minnesota, Joint Degree Program in Law, Health and the Life Sciences, [http://www.jointdegree.umn.edu/faculty\\_and\\_staff/bio.susan.wolf.php](http://www.jointdegree.umn.edu/faculty_and_staff/bio.susan.wolf.php) (last visited May 5, 2006). Professor Jeffrey Kahn is Director of the University of Minnesota Center for Bioethics, and Maas Family Chair in Bioethics. He is also Professor in the Department of Medicine, School of Medicine; Division of Health Services Research and Policy, School of Public Health; and Department of Philosophy, at the University of Minnesota. See University of Minnesota, Center for Bioethics, [http://www.bioethics.umn.edu/faculty/kahn\\_j.html](http://www.bioethics.umn.edu/faculty/kahn_j.html) (last visited July 1, 2005). Professors Wolf and Kahn serve on the University of Minnesota's Stem Cell Ethics Advisory Board. See Wolf, Kahn & Wagner, *supra* note 6, at 336. Dr. John Wagner, of the University of Minnesota Stem Cell Institute, was Molly Nash's transplant surgeon. See University of Minnesota Stem Cell Institute, <http://www.stemcell.umn.edu/stemcell/faculty/Wagner/home.html> (July 1, 2005); see also *supra* note 10 and accompanying text.

<sup>319</sup> Wolf, Kahn & Wagner, *supra* note 6, at 331.

<sup>320</sup> *Id.* (citing 45 C.F.R. pt. 42 (2005); 21 C.F.R. pts. 50-56 (2005)).

<sup>321</sup> See *id.*

avoid situations where either IVF or transplantation is conducted in a way that poses greater than usual risk to the donor child.<sup>322</sup>

Second, Professors Wolf, Kahn, and Wagner suggest that PGD with tissue typing should not be permitted unless the child's condition is "life-threatening or seriously disabling" and "likely to be significantly ameliorated" by using IVF, PGD, and transplant in tandem.<sup>323</sup> Such circumstances are necessary in order to justify the burdens on the woman or couple undergoing IVF and PGD and the potential burdens on the child-to-be as a life-long donor.<sup>324</sup> These commentators also consider whether it is proper to use PGD with tissue typing where the sibling's disorder is non-heritable, and conclude it quite likely is not, because the child-to-be does not stand to benefit from the PGD.<sup>325</sup> As explained above, however, this position is not grounded in logic, because even PGD *without* tissue typing does not truly benefit an embryo, in the sense that PGD does not cure the embryo of a genetic disorder. Indeed, for an unhealthy embryo, PGD works counter to that embryo's interest in being born, as some potential parents will choose not to implant an embryo afflicted with a genetic disorder.<sup>326</sup> In actuality, PGD benefits *the family* considering the birth of the embryo, rather than the embryo itself, by giving the family choices as to whether the embryo will be born, and thus the real issue is whether families ought to have the sort of choice afforded by PGD with tissue typing.<sup>327</sup>

Third, Professors Wolf, Kahn, and Wagner propose psychological evaluation of the parents before IVF and PGD to ensure that the parents can love the child to be born and make decisions in its best interests. These scholars recommend that independent professionals, who are not members of the transplant team and not involved in treating the affected child, conduct this evaluation.<sup>328</sup>

Fourth, Professors Wolf, Kahn and Wagner caution that the medical team performing the IVF, PGD, and transplant avoid any "variation in IVF,

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<sup>322</sup> See *supra* note 269 regarding procedures that unacceptably increase risk to the donor child.

<sup>323</sup> Wolf, Kahn & Wagner, *supra* note 6, at 332. The HFEA also requires that the condition be severe or life-threatening. See *supra* note 84 and accompanying text.

<sup>324</sup> See Wolf, Kahn & Wagner, *supra* note 6, at 332.

<sup>325</sup> See *id.* (stating that "the HFEA's disapproval of PGD to create a donor in the case of sporadic Diamond-Blackfan anemia [the Whitaker case] made sense, as there was no medical benefit of the proposed PGD to the child-to-be") (citation omitted). As noted above, the HFEA has since reversed its position on this issue. See *supra* notes 212-18 and accompanying text regarding the HFEA's decision, after denying a license for PGD with tissue typing to the Whitakers, to permit PGD with tissue typing even in cases where the genetic disorder is non-heritable.

<sup>326</sup> See *supra* note 199 and accompanying text.

<sup>327</sup> See *supra* Part III, examining the ethical arguments in favor and opposed to PGD with tissue typing.

<sup>328</sup> See Wolf, Kahn & Wagner, *supra* note 6, at 333.

gestation, delivery, or treatment of the donor child that increases risks to that child in order to benefit the affected sibling.”<sup>329</sup> As discussed above, reproductive specialists can opt for alternatives that would decrease the risk to the donor child.<sup>330</sup>

Fifth, Professors Wolf, Kahn, and Wagner recommend that “[e]very harvesting procedure from the donor child that involves bodily invasion such as bone marrow harvest (but obviously not harvesting umbilical cord blood), . . . be preceded by independent psychological evaluation of the parents and donor child (when age appropriate).”<sup>331</sup> The goal of this review is to make certain the parents are not exploiting the child and that the child receives appropriate medical and psychological care. In addition, since children as young as seven can give informed consent to a medical procedure, the scholars call for affirmative assent at approximately this age.<sup>332</sup>

Sixth, Professors Wolf, Kahn and Wagner advocate limiting the risks to the donor child until the child can assent for him- or herself. While recognizing the low physical or psychological risk involved in cord blood donation, they warn that solid organ donation generally should not be acceptable, even if a court approves it.<sup>333</sup> For the intermediate case of bone marrow transplant, they would require adequate evidence of sufficient benefit to the donor child in order to justify the risks of bone marrow transplantation.<sup>334</sup> They define “benefit” as the ability of the donor child to maintain his or her relationship with the affected child; therefore, they would require proof of “a positive emotional relationship between the proposed donor and recipient to ground an expectation of psychological benefit to the donor.”<sup>335</sup>

Seventh, Professors Wolf, Kahn, and Wagner call for a limit upon the number of times a donor child may undergo bone marrow harvesting.<sup>336</sup> While expressing concern that any absolute numerical limit might “appear arbitrary,” they suggest a limit of one or two bone marrow harvesting procedures.<sup>337</sup>

Eighth, Professors Wolf, Kahn and Wagner recommend that the donor child should have an independent physician advocating on the child’s be-

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<sup>329</sup> *Id.*

<sup>330</sup> *See supra* note 269 regarding the ways in which a medical team might vary the risks the donor child faces.

<sup>331</sup> Wolf, Kahn & Wagner, *supra* note 6, at 333.

<sup>332</sup> *See id.* Under their proposal, an IRB may assess each individual child to determine his or her particular capacity to assent. *See id.*

<sup>333</sup> *See id.* at 333-34. Transplant procedures that the professors personally consider ethically questionable have garnered the approval of U.S. courts. *See id.* at 334.

<sup>334</sup> *See id.* at 334.

<sup>335</sup> *Id.*

<sup>336</sup> *See id.* at 334-35.

<sup>337</sup> *See* Wolf, Kahn & Wagner, *supra* note 6, at 334-35.

half, one who is neither a member of the transplant team nor involved in treating the affected sibling.<sup>338</sup> This physician would serve as the only person “committed solely to understanding and advancing that child’s best interests,” since all of the other involved parties, including the parents and the physicians for the affected sibling, will necessarily attach great importance to the interests of the affected sibling.<sup>339</sup>

Finally, Professors Wolf, Kahn, and Wagner call for independent ethics review by an ethics committee or consultant before each invasive harvesting procedure. They note that an IRB that approved the stacking of IVF, PGD, and stem cell transplant might not be the best body to apply these suggested guidelines, both because the IRB may be based at the institution performing the IVF or PGD but not the transplant and because the suggested guidelines “go[] beyond the oversight usually performed by IRBs under the federal regulations.”<sup>340</sup>

All of the guidelines suggested by Professors Wolf, Kahn, and Wagner will assist in protecting donor children from being used as an “insurance policy and tissue source” for an affected sibling.<sup>341</sup> An additional protection, for future children, would be to require medical centers participating in IVF and PGD with tissue typing for the purpose of stem cell donation, as well as stem cell transplantation following PGD with tissue typing, to maintain adequate records of the psychological and medical effects upon the participants in these procedures and to make those records available to the federal government with personal identifiers removed. After significant data is gathered, Congress could then commission the appropriate federal agency to issue a report on the results of PGD with tissue typing to inform future policy. In this way, the door would be open for further regulation, if and only if it proves warranted based on additional information gathered from outcomes of actual cases.

## CONCLUSION

Review of the British experience of stringent regulatory oversight of PGD with tissue typing suggests this approach sometimes leads to inconsistent or unclear results and affords families too little autonomy to make important decisions affecting the health of their children. As a practical matter, the U.S. population on the whole approves of PGD with tissue typing to create a stem cell donor and typically bristles at the notion of government

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<sup>338</sup> *See id.* at 335.

<sup>339</sup> *See id.*

<sup>340</sup> *Id.*

<sup>341</sup> *Id.* at 333.

regulation of procreative decisions. Moreover, while thorough analysis of the arguments in support of and opposed to PGD with tissue typing suggests that the major concern about this technology relates to the possibility of repeated harvesting of bone marrow stem cells from the donor sibling, Professors Wolf, Kahn, and Wagner have proposed guidelines to protect against exploitation of the donor sibling. This article suggests an additional guideline, namely that medical centers participating in IVF and PGD with tissue typing for the purpose of stem cell donation, as well as stem cell transplantation following PGD with tissue typing, be required to maintain adequate records of the psychological and medical effects upon the participants in these procedures and to make those records available to the federal government with personal identifiers removed. After gathering significant data, Congress could then commission the appropriate federal agency to issue a report on the results of PGD with tissue typing to inform future policy. In this way, this lifesaving technology could still be used, but the door would be open for further regulation, if and only if it proves warranted based on additional information gathered from outcomes of actual cases. Such circumspection is essential when the government considers regulating reproduction and parents' choices for the medical treatment of their children.