

## Understanding Legal Responses to Technological Change of *In Vitro* Fertilization

Lyria Bennett Moses\*

Introduction .....	506
I. The Arrival of a New Technology .....	508
A. <i>In Vitro</i> Fertilization and Other Reproductive Technologies.....	508
B. The Nature of Technological Change .....	512
C. <i>In Vitro</i> Fertilization as an Example of Technological Change.....	514
II. New Technologies and Criticism of Law .....	515
A. The Nature of Criticism .....	515
B. Limiting Legal Responses.....	518
1. International Law.....	518
2. European Law.....	519
3. United States Constitution .....	519
C. Reasons to Ban IVF or Related Technologies .....	522
D. Reasons to Regulate IVF and Related Technologies ...	526
E. Reasons to Enhance Certainty .....	528
F. Reasons to Reject Existing Rules .....	531
G. Reasons to Expand or Contract Existing Rules.....	532
H. Differing Dilemmas .....	534
III. Different Paths – Responses to IVF.....	536
A. United States.....	536
B. United Kingdom .....	545
C. New South Wales, Australia.....	549
D. Victoria, Australia.....	555
E. Types of Responses.....	558
IV. Comparative Institutional Analysis.....	559
A. Participation and Interest Group Conflict.....	560
B. Goal-oriented Comparison .....	563
V. New Regulatory Measures.....	563
A. Types of Regulation.....	563
B. The Regulators .....	567
1. The Market .....	567
2. Existing Rules Enforced by the Courts.....	569
a. Problems with Existing Rules Following	

Technological Change .....	569
b. Problems with the Tort Law Generally .....	573
c. Problems with Courts .....	574
3. Professional Societies .....	575
4. Legislators.....	577
5. Administrative Agencies .....	580
6. Combined Response.....	582
C. An Example: The Problem of Multifetal Pregnancy....	582
1. The Nature of the Problem.....	583
2. Common Law Does Not Create Sufficient Incentives.....	589
a. Contract .....	589
b. Tort.....	590
3. Attempting to Address Market Flaws – United States .....	590
4. Strong Professional Regulation – Australia .....	596
5. State Regulation – United Kingdom.....	599
6. Conclusions .....	604
VI. Resolving Uncertainty .....	605
A. Disadvantages of Legislation – The Limits of Words..	606
B. A Possible Solution – Delegation.....	607
C. Disadvantages of the Common Law –Limited Possibilities and Burdened Litigants .....	608
D. An Example: Control of Embryos.....	608
1. United Kingdom .....	609
2. United States .....	612
3. Observations .....	615
Conclusion.....	617

## INTRODUCTION

This paper explores the nature of legal controversies generated by technological change, using as an example *in vitro* fertilization (IVF), first successfully used to produce the birth of Louise Brown, the world's first "test tube baby,"<sup>1</sup> in 1978. It

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\* Associate in Law, Columbia Law School 2002-2004. B.Sc. (Hons.), LL.B., University of New South Wales, LL.M., J.S.D. Candidate, Columbia Law School. The author would like to thank Professors Harold Edgar, Peter Strauss, and William Sage of Columbia Law School and Amelia Simpson of the Australian National University for their useful insights and helpful comments as well as faculty editors Susan Wolf and Jim Chen for their corrections and excellent suggestions. Of course, the author bears sole responsibility for any

grows out of an earlier essay, which classified the ways in which legal and political institutions are called on to adapt to technological change, and briefly compared the ability of courts and legislatures to do so.<sup>2</sup> By exploring different legal and political responses to IVF and related technologies in the United States, United Kingdom, and Australia and their consequences, this article aims to evaluate the advantages and disadvantages of different means of adapting to technological change.

Parts I and II of this article explore the nature of technological change and the challenges it poses for law. General criticisms of the law's failure to keep up with technological change arise from four classes of problems: (1) there may be a perceived need for new laws to ban a technology or to limit the way in which it is practiced; (2) technological change may reveal latent ambiguities in the law, creating new uncertainties; (3) existing rules may be based on explicit or implicit assumptions about technological feasibility that are no longer reasonable; and (4) existing rules may be over-inclusive or under-inclusive with respect to the new technology and related conduct. This four-way classification facilitates an understanding of the nature and desirability of legal and political responses to technological change.

Part III sets out the legal responses to IVF in three common law countries: the United Kingdom and parts of Australia and the United States. All three countries have become leaders in IVF. However, the birth of Louise Brown, which took place in England after United States government reluctance to fund IVF research, sparked significant controversy in each of these jurisdictions. Initially, there were debates in the media as well as in academia and politics as to whether IVF was a "good thing" or ought to be banned. In all three countries, arguments in favor of a ban failed, but residual concerns remained. Most of those concerns were of the first two types: first, the possible need for new regulatory laws and

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remaining errors.

1. Historically, the term "test tube baby" has sometimes been used to refer to children conceived with the assistance of artificial insemination and other non-IVF techniques. This article uses the term in its narrower sense, to refer to children born following an *ex utero* fertilization procedure, that is, fertilization not *in vivo* (in the body) but *in vitro* (outside the body, literally "in glass").

2. Lyria Bennett Moses, *Adapting the Law to Technological Change: A Comparison of Common Law and Legislation*, 26 U.N.S.W.L.J. 394 (2003).

second, the prevalence of uncertainty in the application of existing laws. The jurisdictions considered exemplify different responses to these problems.

Parts V and VI consider and compare these different responses to arguments for increased regulation and increased certainty. The strengths and weaknesses of each approach are analyzed, from the point of view of both the capacity of that approach to resolve the problem identified and its ability to withstand ongoing technological change. My conclusion is that to a large extent, the desirability of using a particular mechanism not only depends on the circumstances but is also contestable. However, it is possible to devise a general framework for considering the desirability of particular approaches in specific contexts. I apply the general framework to evaluate the advantages and disadvantages of different responses to two specific issues—the problem of multifetal pregnancies resulting from *in vitro* fertilization and related techniques, and uncertainty as to the person entitled to exercise control over frozen embryos.

Our intuition that the law faces problems following the introduction of a new technology is correct, and is reflected in metaphors of law struggling to keep up. However, the reflexive response that legislation is required to facilitate the law's adaptation to technological change may be wrong; legislation is inferior to the alternatives in some circumstances. In some cases, there may be benefits in adopting a "wait and see" approach, observing the performance of other mechanisms prior to implementing a statutory or administrative regime. Awareness of the benefits of these alternatives is important in weighing proposals for reform.

## I. THE ARRIVAL OF A NEW TECHNOLOGY

### A. *IN VITRO* FERTILIZATION AND OTHER REPRODUCTIVE TECHNOLOGIES

Few technologies arrive unannounced and few remain unchanged over time. Technologies are not unaffected by the shift from new invention to widely used phenomenon. The development of techniques to facilitate the fertilization of human eggs or ova is no exception.<sup>3</sup> There is thus no single

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3. See generally JENNIFER GUNNING & VERONICA ENGLISH, HUMAN IN VITRO FERTILIZATION: A CASE STUDY IN THE REGULATION OF MEDICAL

date on which all legal issues associated with IVF blossomed, but there are some significant points along the way, including birth of the first IVF baby in 1978, as well as the use of cryopreserved, or frozen, embryos and donated ova in 1983.<sup>4</sup> As the number of people affected by each of these developments grew and general awareness of them increased over time, political, legal, and professional institutions were urged to respond.

The notion of “test-tube babies” was anticipated in Aldous Huxley’s *Brave New World*,<sup>5</sup> first published in 1932. At around the same time, there were reports of successful fertilization of mammalian eggs *in vitro*.<sup>6</sup> By 1969, the same feat had been accomplished with human eggs.<sup>7</sup> These and similar events raised questions about the moral and legal status of a human embryo outside its mother’s body. In fact, one early case in the United States, *Del Zio v. Presbyterian Hospital*,<sup>8</sup> which commenced before any human child conceived *in vitro* had been born, raised the issue of tort liability for destruction of a human embryo *in vitro*.

Despite these early developments and musings, there was relatively little public awareness of IVF technology or widespread concern about its implications until Louise Brown, the world’s first IVF baby, was born in the United Kingdom on July 25, 1978.<sup>9</sup> Her birth was followed by similar achievements in other countries: Candice Reid was born in Victoria, Australia

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INNOVATION 1-12 (1993).

4. See generally Alan Trounson & Linda Mohr, *Human Pregnancy Following Cryopreservation, Thawing and Transfer of an Eight-Cell Embryo*, 305 NATURE 707 (1983); Peter Lutjen et al., *The Establishment and Maintenance of Pregnancy Using In Vitro Fertilization and Embryo Donation in a Patient with Primary Ovarian Failure*, 307 NATURE 174 (1984); Alan Trounson et al., *Pregnancy Established in an Infertile Patient After Transfer of a Donated Embryo Fertilised In Vitro*, 286 BR. MED. J. 835 (1983).

5. ALDOUS HUXLEY, *BRAVE NEW WORLD* (Harper & Row 1969) (1932).

6. Gregory Pincus & E. V. Enzmann, *The Comparative Behavior of Mammalian Eggs In Vivo and In Vitro*, 62 J. EXP. MED. 665 (1935); Miriam F. Menkin & John Rock, *In Vitro Fertilization and Cleavage of Human Ovarian Eggs*, 55 AM. J. OBSTETRICS & GYNECOLOGY 440 (1948).

7. R.G. Edwards et al., *Early Stages of Fertilization In Vitro of Human Oocytes Matured In Vitro*, 221 NATURE 632 (1969).

8. *Del Zio v. Presbyterian Hosp.*, No. 74 Civ. 3588, 1978 U.S. Dist. LEXIS 18443 (S.D.N.Y. Apr. 13, 1978) (motion to dismiss denied); *Del Zio v. Presbyterian Hosp.*, No. 74 Civ. 3588 (CES), 1978 U.S. Dist. LEXIS 14450 (S.D.N.Y. Nov. 14, 1978) (motion to set aside verdict denied).

9. See generally P.C. Steptoe & R.G. Edwards, *Birth After the Reimplantation of a Human Embryo*, 2 LANCET 366 (1978).

in July 1980,<sup>10</sup> and Elizabeth Carr was born in Virginia in the United States in December 1981.<sup>11</sup>

The IVF technique, in its simplest form, involves hormonal monitoring and stimulation of the woman producing ova, harvesting the ova, mixing them with sperm in a petri dish containing a culture medium, waiting for approximately three days for embryo development, and then transferring one or more embryos,<sup>12</sup> back to the woman. The precise technique has varied over time, as IVF practitioners have learned more about the process of fertilization and have improved their ability to predict which embryos are most likely to lead to a successful pregnancy. One variation, for example, is “blastocyst transfer,” whereby embryos are allowed to develop for a longer period of time (approximately five days) prior to transfer in an effort to increase the chances of successful implantation.<sup>13</sup>

Two other important developments were cryopreservation of embryos and the use of donated ova. Embryo cryopreservation was developed in Australia (with the first live birth in 1985) and quickly moved to the United States.<sup>14</sup> Although the use of donated ova was foreseeable from the first days of IVF, the first reported case did not come until 1983.<sup>15</sup> A more recent variation of ova donation, cytoplasm transfer, has been successfully performed in New Jersey.<sup>16</sup> In that

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10. New South Wales Law Reform Commission, *Artificial Conception: In Vitro Fertilization*, Discussion Paper 15 para. 1.14 (1987), available at <http://www.lawlink.nsw.gov.au/lrc.nsf/pages/dp15chp1> (last visited Apr. 6, 2005).

11. Walter Sullivan, *Test Tube Baby Born in US, Joining Successes Around the World*, N.Y. TIMES, Dec. 29, 1981, at C1.

12. The term “pre-embryos” has been used to distinguish embryos in the first 14 days of development. For convenience, the term “embryo” shall be used throughout to refer to the product of fertilization.

13. See, e.g., Del Marek et al., *Introduction of Blastocyst Culture and Transfer for all Patients in an In Vitro Fertilization Program*, 72 FERTILITY & STERILITY 1035, 1035 (1999).

14. See generally Trounson & Mohr, *supra* note 4; Alan Trounson, *Preservation of Human Eggs and Embryos*, 46 FERTILITY & STERILITY 1 (1986); see also Edward F. Fugger, *Clinical Status of Human Embryo Cryopreservation in the United States of America*, 52 FERTILITY & STERILITY 986 (1989); Richard P. Marrs et al., *Successful Pregnancies from Cryopreserved Human Embryos Produced by In Vitro Fertilization*, 156 AM. J. OBSTETRICS & GYNECOLOGY 1503, 1503 (1987); X.J. Wang et al., *The Contribution of Embryo Cryopreservation to In-Vitro Fertilization/Gamete Intra-Fallopian Transfer: 8 Years Experience*, 9 HUM. REPROD. 103 (1994).

15. See P. Lutjen et al., *supra* note 4, at 174, 175.

16. Jacques Cohen et al., *Birth of Infant After Transfer of Anucleate Donor Cytoplasm into Recipient Eggs*, 350 LANCET 186, 186-87 (1997).

technique, the cytoplasm from a donor's ovum is injected into the ovum of an infertile woman together with the father's sperm.<sup>17</sup> It allows an older woman or a woman whose mitochondria are defective to be the near-genetic mother of her child, the genetic material in the mitochondria being the exception. The technique has raised some ethical concerns, and the Food and Drug Administration has determined that further use of the technique would require an Investigative New Drug (IND) application.<sup>18</sup>

There are also procedures that at some time have served as alternatives to standard IVF. An embryo can be washed out of a woman's uterus before it implants and then transferred to another woman's uterus with "embryo flushing." In Gamete Intra-Fallopian Transfer (GIFT), ova and sperm are injected into a woman's fallopian tube so that fertilization occurs in the usual place.<sup>19</sup> With Zygote Intra-Fallopian Transfer (ZIFT), the ova and sperm might still meet *in vitro* but be transferred into the fallopian tube shortly thereafter.<sup>20</sup> The ova's protective layer might be perforated to enhance prospects of fertilization with "Zona Drilling" or "Partial Zona Dissection."<sup>21</sup> Finally, rather than mixing sperm and ova *in vitro*, one might inject a single sperm into an ovum with "Intra-Cytoplasmic Sperm Injection" (ICSI) or inject a small number of sperm into an ovum with "Sub-Zonal Insemination" (SUZI).<sup>22</sup> Standard IVF and ICSI are the most commonly used techniques in the United States.<sup>23</sup>

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17. Jason A. Barritt et al., *Cytoplasmic Transfer in Assisted Reproduction*, 7 HUM. REPROD. UPDATE 428, 429 (2001).

18. See Denise Grady, *Doctors Using Hybrid Egg to Tackle Infertility in Older Women*, N.Y. TIMES, Oct. 10, 1998, at A16; John A. Robertson, *Oocyte Cytoplasm Transfers and the Ethics of Germ-Line Intervention*, 26 J.L. MED. & ETHICS 211, 213 (1998).

19. See Ricardo H. Asch et al., *Preliminary Experiences with Gamete Intrafallopian Transfer (GIFT)*, 45 FERTILITY & STERILITY 366, 366 (1986).

20. Paul Devroey et al., *Zygote Intrafallopian Transfer as a Successful Treatment for Unexplained Infertility*, 52 FERTILITY & STERILITY 246, 246-47 (1989).

21. Jacques Cohen et al., *Implantation Enhancement by Selective Assisted Hatching Using Zona Drilling of Human Embryos with Poor Prognosis*, 7 HUM. REPROD. 685, 685 (1992).

22. Gianpiero Palermo et al., *Pregnancies After Intracytoplasmic Injection of Single Spermatozoon into an Oocyte*, 340 LANCET 17, 17-18 (1992); see also Christopher J. De Jonge & Jessica Pierce, *Intracytoplasmic Sperm Injection--What Kind of Reproduction Is Being Assisted?*, 10 HUM. REPROD. 2518, 2518 (1995) (discussing risks and ethical concerns).

23. See CENTERS FOR DISEASE CONTROL AND PREVENTION, 2002 ASSISTED

All these techniques aim to facilitate of fertilization of human gametes in order to enable pregnancy. Such techniques will be referred to generally here as “reproductive technologies,” “assisted reproductive technologies,” or “ARTs.” There are other, more controversial, techniques that are often associated with these technologies. For example, embryos may be destroyed in order to create embryonic stem cells, and animals can be cloned, bypassing the need for fertilization of gametes. The current debate revolves largely around the ethics of proceeding to create embryonic stem cells or cloned embryos at all, or with public funding. Although technological change is continuous rather than discrete, so that any line drawn is necessarily arbitrary, this paper focuses on reproductive techniques that are or have been generally practiced in the United States, United Kingdom, and Australia.

#### B. THE NATURE OF TECHNOLOGICAL CHANGE

The introduction of IVF and the development of related techniques are examples of technological change. There is no single accepted definition of technology, and much depends on context. A focus on the consequences of technology might lead one to adopt a definition such as: “Technology consists of those material objects, techniques and knowledge that allow human beings to transform and control the inanimate world.”<sup>24</sup> A broader definition would include control of the *animate* world, such as: “man’s use of devices or systematic patterns of thought and activity to control physical phenomena in order to serve his desires with a minimum of effort and a maximum of efficiency.”<sup>25</sup> Both definitions stress the power of technology to effect human control. On the other hand, an account of the historical development of technology might describe technological change as a process of knowledge change, increasing the ability or potential of a people or society to solve problems.<sup>26</sup>

While these and similar definitions are useful in the contexts in which they are employed, they do not explain why

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REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 1-2 (2004).

24. RON WESTRUM, TECHNOLOGIES AND SOCIETY: THE SHAPING OF PEOPLE AND THINGS 7 (1991).

25. RALPH PARKMAN, THE CYBERNETIC SOCIETY 3 (1972).

26. See GOVINDAN PARAYIL, CONCEPTUALIZING TECHNOLOGICAL CHANGE: THEORETICAL AND EMPIRICAL EXPLORATIONS 9, 146 (1999).



technological change has captivated and troubled legal scholars. When legal scholars discuss legal issues arising out of a new technology, they are rarely concerned with regulation of knowledge or problem-solving *per se*, and only sometimes concerned with technology's effects on the natural world. Rather, they generally wish to describe what legal consequences do and ought to flow from certain conduct, in this case, conduct related to the new technology.

The focus on conduct is not surprising given the models commonly employed for understanding the nature of law. Hans Kelsen described a legal order as a system of norms, where a norm is the meaning of an act by which a certain behavior is commanded, permitted or authorized.<sup>27</sup> For H.L.A. Hart, primary rules require people to do or abstain from doing certain actions.<sup>28</sup> Within these models, technological change increases the range of actions that can practically be carried out by people living at a particular time. *In vitro* fertilization leading to the birth of a child has been *theoretically* possible since the dawn of man. But it was not proved to be a *practical* possibility until 1978, and was probably not even *contemplated* as a possibility before the twentieth century. In other words, before 1978 (or perhaps slightly earlier), laws regulating the practice of IVF would have made as little sense as traffic rules for passenger cars that can move vertically would today. If IVF had remained a single isolated event, as some had initially thought it would,<sup>29</sup> legal reform would have been similarly perceived as unnecessary.<sup>30</sup> However, after the technology became more widely employed, the perceived need for a legal response increased. Thus, for current purposes at least, one can think of technological change as the invention, adoption, and diffusion of a new product or process that makes practicable new forms of conduct.<sup>31</sup>

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27. HANS KELSEN, PURE THEORY OF LAW 4-5 (Max Knight ed., 1967).

28. H.L.A. HART, THE CONCEPT OF LAW 81 (1961).

29. Seth Mydans, N.Y. TIMES ABSTRACTS, Aug. 11, 1978, at 76 (quoting Soviet physician, Dr. Leonid Persianinov).

30. It has often been observed that, unless taken up, invention has little social impact. See, e.g., Knut H. Sørensen, *Social Shaping on the Move? On the Policy Relevance of the Social Shaping of Technology Perspective*, in SHAPING TECHNOLOGY, GUIDING POLICY 19, 23 (Knut H. Sørensen & Robin Williams eds., 2002).

31. There are no clear boundaries between technological and other types of change. For example, the discovery that conduct is safer or more pleasant than previously thought increases the probability that people will engage in

C. *IN VITRO* FERTILIZATION AS AN EXAMPLE OF TECHNOLOGICAL CHANGE

In order to understand how a technology makes possible many new forms of conduct, consider the example of IVF. By making possible the fertilization of a human ovum outside the body of the mother, IVF technology led to several new activities:

(i) It allowed some otherwise infertile couples to bear and raise a genetically related child.

(ii) It created a new field of activity, providing IVF services, that could potentially be carried out by people with different ranges of knowledge, skill and experience, exercising different degrees of care.

(iii) By moving an existing entity (the embryo) to a new location, it created the possibility of new tests and manipulations. It also increased the ease with which an embryo may be destroyed. It can also, of course, be transferred to the uterus of a woman.

Taking into account techniques associated with IVF:

(iv) Fertile people may now use IVF, for example to avoid birth of a child affected by a genetic anomaly of concern.

(v) Embryos may be cryopreserved and stored for an arbitrary period of time. A cryopreserved embryo can be tested, manipulated, or destroyed. It can also be thawed and either transferred to the uterus of a woman, allowed to perish, or used in research.

(vi) The woman gestating a child need not be its genetic mother. A woman may undergo ovarian stimulation and have her ova removed so that another woman may become pregnant. Contracts related to this transaction may be entered into (characterizing it as ova donation or surrogacy). Such contracts have the potential to lead to increased commercialization of reproduction.

(vii) Children genetically the product of one generation may be born into a different generation.

(viii) Because a woman's uterus remains receptive to a pregnancy after menopause, post-menopausal women can become gestational mothers using ova provided by a younger woman.

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that conduct. At the extreme, it might be said that the conduct was not really practicable before the discovery (perhaps because people thought it would kill them).

(ix) More than one embryo can be transferred into the uterus of a woman at the same time.

Each of these new activities can be commanded, prohibited, restricted, or authorized by law. They can also be encouraged or discouraged through education, government funding, taxation and the potential for civil suits. As each of these new forms of conduct became possible, and came to the attention of scholars and decision-makers, it made sense to talk about deducing or altering their legal consequences. In addition, because ART services can be advertised as well as covered or denied coverage under health insurance contracts, questions specific to ART might arise in other areas of law as well.<sup>32</sup>

## II. NEW TECHNOLOGIES AND CRITICISM OF LAW

### A. THE NATURE OF CRITICISM

Scholars examining legal issues posed by technological change such as IVF are often critical of the law. The law is frequently accused of containing gaps,<sup>33</sup> of being slow or outpaced<sup>34</sup> and thus lagging behind technology,<sup>35</sup> and of

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32. See, e.g., *Kinzie v. Physician's Liab. Ins. Co.*, 750 P.2d 1140, 1142-43 (Okla. 1987) (insurance); *Egert v. Conn. Gen. Life Ins. Co.*, 900 F.2d 1032, 1036-38 (7th Cir. 1990) (insurance); *Karlin v. IVF Am., Inc.*, 93 N.Y.2d 282, 293 (N.Y. 1999) (advertising).

33. E.g., Laura A. Brill, *When Will the Law Catch Up with Technology? Jaycee B. v. Superior Court of Orange County: An Urgent Cry for Legislation on Gestational Surrogacy*, 39 CATHOLIC L. 241, 268 (1999) ("Paradoxically, absent fully encompassing legislation, and with a body of case law that leaves gaps with respect to key issues, the very methods that can create a family can also destroy it."); Richard F. Storrow, *Parenthood by Pure Intention: Assisted Reproduction and the Functional Approach to Parenthood*, 53 HASTINGS L.J. 597, 601 (2002) ("Moreover, very few contests between genetic, gestational and intending mothers have been resolved in the courts, leaving gaps in the law that render unclear the outcome of potential future disputes.").

34. James E. Bailey, *An Analytical Framework for Resolving the Issues Raised by the Interaction Between Reproductive Technology and the Law of Inheritance*, 47 DEPAUL L. REV. 743, 814 (1998) ("the source of the legal conundrums discussed here is the inherent inability of law to maintain pace with technologically-driven social change."); Kathryn Venturatos Lorio, *Alternative Means of Reproduction: Virgin Territory for Legislation*, 44 LA. L. REV. 1641, 1641 (1984) ("[M]edical advances have outpaced the ability of society to accommodate those advances."); Lynne M. Thomas, Comment, *Abandoned Frozen Embryos and Texas Law of Abandoned Personal Property: Should There Be a Connection*, 29 ST. MARY'S L.J. 255, 259 (1997) ("The law, however, generally develops at a much slower pace than technology."); David M. Vukadinovich, *Assisted Reproductive Technology Law: Obtaining Informed Consent for the Commercial Cryopreservation of Embryos*, 21 J. LEGAL MED. 67, 67 (2000) ("Unlike the leaps that technology has taken, the law and public

needing to respond to new technologies<sup>36</sup> and address new issues.<sup>37</sup> Even when the law is not directly criticized, technology is seen as challenging law.<sup>38</sup> When law is praised, it is for responding speedily.<sup>39</sup> These metaphors conjure images of technology racing ahead of, and perhaps overwhelming, a

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policy have been slower to advance.”).

35. *Mount Isa Mines Ltd. v. Pusey* (1970) 125 C.L.R. 383, 395 (per Windeyer, J.) (“Law, marching with medicine but in the rear and limping a little”); Michael Kirby, *Medical Technology and New Frontiers of Family Law*, 1 AUST. J. FAM. L. 196, 212 (1987) (“The hare of science and technology lurches ahead. The tortoise of the law ambles slowly behind.”); Joseph J. Saltarelli, Note, *Genesis Retold: Legal Issues Raised by the Cryopreservation of Preimplantation Human Embryos*, 36 SYRACUSE L. REV. 1021, 1021 (1985) (“In recent years, dramatic advances have been made in the technology of artificial human reproduction, giving rise to a variety of moral, ethical, and legal issues. The law has, however, constantly lagged far behind science in the formulation of workable responses to such breakthroughs.”). Note also the title of Weldon E. Havins & James J. Dalessio, *The Ever-Widening Gap Between the Science of Artificial Reproductive Technology and the Laws Which Govern That Technology*, 48 DEPAUL L. REV. 825 (1999).

36. Patricia A. Martin & Martin L. Lagod, *The Human Preembryo, the Progenitors, and the State: Toward a Dynamic Theory of Status, Rights and Research Policy*, 5 HIGH TECH. L.J. 257, 261 (1990) (“our legal institutions must respond to the challenge of IVF technology”); see also Sheila A. M. McLean, *Some Legal Aspects of Modern Reproductive Technology*, in TOUGH CHOICES: IN VITRO FERTILIZATION AND THE REPRODUCTIVE TECHNOLOGIES 147, 147 (Patricia Stephenson & Marsden G. Wagner eds., 1993).

37. Sharon M. Steeves, Comment, *Artificial Human Reproduction: Legal Problems Presented by the Test Tube Baby*, 28 EMORY L.J. 1045, 1046-47 (1979) (“Neither common law principles nor statutory enactments in the majority of states address the legal issues presented by artificial reproductive technology.”).

38. Robert S. Summers, *Law, Technology and Values*, in LAW, LIFE AND THE IMAGES OF MAN: MODES OF THOUGHT IN MODERN LEGAL THEORY 65, 66 (Frank Fleerackers et al. eds., 1996) (“Nearly all technological developments pose challenges for law and government.”); Colleen M. Browne & Brian J. Hynes, Note, *The Legal Status of Frozen Embryos: Analysis and Proposed Guidelines for a Uniform Law*, 17 J. LEGIS. 97, 97 (1990) (“These dynamic medical advancements [IVF and cryopreservation] have challenged the legal community to keep reins on practices affecting embryos.”); M. Karen McCartan, *A Survey of the Legal, Ethical, and Public Policy Considerations of In Vitro Fertilization*, 2 NOTRE DAME J.L. ETHICS & PUB. POL’Y 695, 695 (1986) (“A rapidly advancing technological civilization challenges a legal system which historically has responded to existing problems and seldom has anticipated them.”).

39. Michael D.A. Freeman, *Responding to the Reproductive Revolution: Law Reform – Dilemmas and Difficulties*, in LAW REFORM AND HUMAN REPRODUCTION 3, 3 (Sheila A.M. McLean ed., 1992) (“The law, both in its legislative and judicial forms, has, in most relevant countries, responded with some rapidity and vigour to the new territory explored by the exponents of assisted conception.”).

legal system trapped in the past. As technologies move more rapidly from invention to widespread application,<sup>40</sup> so too does the speed with which the law must move.

It is easy to understand the frustration with the law felt by these authors. On occasion, it can seem as if some laws were designed for an older world and now outmoded technology.<sup>41</sup> Several types of criticisms of the law can be found in the literature on IVF, namely, that law is uncertain, normatively undesirable, or nonexistent. Critics argue, at least in certain cases, that technological change creates reasons to change the law. Then authors take the failure to make the sorts of changes suggested by them promptly as a sign that the law is outpaced by or has failed to respond to technological change. The proposals for change can be grouped into the following categories (although a single author may propose more than one):

(i) **New rules.** We need to regulate certain new forms of conduct and new, specially tailored, laws are required to do this. In some cases, it may even be appropriate to ban a particular technology or particular applications of that technology.

(ii) **Uncertainty.** The law is uncertain as it applies to new forms of conduct. In other words, it is not clear whether such conduct is commanded, prohibited, or authorized. Existing rules need to be clarified.

(iii) **Scope of rules.** Existing rules were not formulated with new technologies in mind. Thus, some rules in their current form inappropriately include or exclude new forms of conduct.

(iv) **Justification for rules.** Some existing rules are explicitly or implicitly based on a premise that no longer exists, and are thus no longer justified.

The list does not include criticisms that are not related to technological change. It is possible (and common) to criticize legislatures for enacting a faulty law, a judge for misinterpreting the law or for lacking expertise,<sup>42</sup> or to blame existing rules for contributing to social problems. Such

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40. RICHARD C. DORF, *TECHNOLOGY, SOCIETY AND MAN* 14 (1974).

41. See Monroe E. Price, *The Newness of New Technology*, 22 *CARDOZO L. REV.* 1885, 1888 (2001).

42. On the latter, see generally Mark Mansour et al., *Regulating Biotechnology: Science, Ethics, Law and Governance Meet Head On in the Age of Informed Ignorance*, 21 *TEMP. ENVTL. L. & TECH. J.* 93, 94 (2003).

criticisms are, however, ongoing and are not affected by the introduction or diffusion of a new technology. Technological change is neither a sufficient nor necessary condition for the existence of uncertain, ineffective, and bad laws; yet it is often the occasion for them. In these cases, one might sensibly use concepts such as “catching up,” “responding,” and “adapting” to describe the process by which problems arising as a result of technological change are resolved.

## B. LIMITING LEGAL RESPONSES

Sometimes there will be limits on the nature of legal changes that might otherwise take place in response to technological change. For example, a law that might otherwise be thought beneficial could be unconstitutional. Even unenforceable higher norms, such as those found in international law, can play an important role in political argument and legal discourse. In the context of reproductive technologies, both actual and hypothetical laws have been challenged on the grounds that they restrict procreative liberty, an alleged constitutional or international law right.

### 1. International Law

There is no enforceable principle of international law that would prevent a state from prohibiting or restricting the practice of IVF or related technologies. However, reproductive rights have been recognized internationally since the 1948 Universal Declaration of Human Rights (UDHR).<sup>43</sup> In particular, Article 16 provides for the right to marry and found a family “without any limitation due to race, nationality or religion” and states that the family is the natural and fundamental group unit of society and is entitled to protection by society and the state.<sup>44</sup> These rights and recognitions are repeated in Article 23 of the International Covenant on Civil and Political Rights.<sup>45</sup> It is unclear whether these provisions, even if enforceable, would do more than prevent a state from interfering with a person’s natural coital capacity to

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43. Universal Declaration of Human Rights, G.A. Res. 217A, U.N. GAOR, 3d Sess., Supp. No. 3, U.N. Doc. A/810 (1948).

44. *Id.*

45. International Covenant on Civil and Political Rights, G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (1966) (The United States, the United Kingdom, and Australia are all parties to this Covenant).

reproduce.<sup>46</sup> Certainly, they do not require the government to assist the infertile with ART.<sup>47</sup> Even if these provisions apply to the infertile, they may only apply to infertile people who are married.<sup>48</sup>

## 2. European Law

The European Convention for the Protection of Human Rights and Fundamental Freedoms<sup>49</sup> is, through the Human Rights Act 1998 (U.K.), part of the law of the United Kingdom. Article 12 of the Convention is similar to Article 16 of the UDHR, providing a right to marry and found a family; as such, its scope is subject to similar comments.<sup>50</sup>

Article 8 of the Convention may also be relevant to those advocating for reproductive rights. It provides that “[e]veryone has the right to respect for his private and family life, his home and his correspondence” and that no public authority can interfere with this right except:

such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.<sup>51</sup>

The broad nature of the exception, in particular the reference to protection of morals, may limit the usefulness of this Article for those seeking to promote reproductive liberty.

## 3. United States Constitution

The Due Process Clause of the Fourteenth Amendment of the United States Constitution<sup>52</sup> has been held to protect certain fundamental rights, including rights related to freedom of choice in matters relating to marriage and family life.<sup>53</sup>

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46. See McLean, *supra* note 36, at 147, 151.

47. Bernard M. Dickens, *Reproduction Law and Medical Consent*, 35 U. TORONTO L.J. 255, 256 (1985).

48. See John Murphy, *Public Representation and the Legal Regulation of Assisted Conception in Britain*, in *NATURE RISK AND RESPONSIBILITY* 117, 119 (Patrick O’Mahoney ed., 1999).

49. European Convention for the Protection of Human Rights and Fundamental Freedoms, Nov. 4, 1950, ETS No. 155, 213 U.N.T.S. 221.

50. *Id.* art. 12.

51. *Id.* art. 8.

52. U.S. CONST. amend. XIV, § 1.

53. *Griswold v. Connecticut*, 381 U.S. 479, 485-86 (1965) (freedom to use of contraception within marital relationship); *Eisenstadt v. Baird*, 405 U.S.

Laws that prohibit or otherwise restrict IVF might be unconstitutional if a right to non-coital reproduction were held to be fundamental.<sup>54</sup> No Supreme Court case deals directly with this question, but there are some indications that such a right could be found to exist.

The main case cited to support a right to reproduce, as opposed to a right to avoid reproduction, is *Skinner v. Oklahoma*.<sup>55</sup> In that case, a state statute provided for mandatory sterilization of criminals who had been convicted three or more times for particular crimes.<sup>56</sup> The statute was struck down, but on equal protection grounds.<sup>57</sup> However, advocates of reproductive rights might point to the language of Justice Douglas's opinion, which described the right to marry and procreate as "fundamental to the very existence and survival of the race."<sup>58</sup> Similar statements include the Court's comment in *Meyer v. Nebraska*,<sup>59</sup> that the liberty guaranteed by the Fourteenth Amendment included "the right of an individual . . . to marry, establish a home and bring up children,"<sup>60</sup> and its observation in *Stanley v. Illinois*<sup>61</sup> that "[t]he rights to conceive

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438, 453 (1972) (freedom to use of contraception by unmarried couples); *Carey v. Population Servs. Int'l*, 431 U.S. 678, 685 (1977) (freedom to use contraception); *Roe v. Wade*, 410 U.S. 113, 153 (1973) (woman's freedom to choose to terminate a pregnancy); *Planned Parenthood v. Casey*, 505 U.S. 833, 846 (1992) (woman's freedom to choose to terminate a pregnancy prior to viability); *Loving v. Virginia*, 388 U.S. 1, 12 (1967) (freedom to marry a person of another race); *Pierce v. Soc'y of Sisters*, 268 U.S. 510, 534-35 (freedom to direct the upbringing and education of children); *Lawrence v. Texas*, 539 U.S. 558, 578 (2003) (freedom to engage in consensual adult sodomy); *see also* *Prince v. Massachusetts*, 321 U.S. 158 (1944); *Skinner v. Oklahoma*, 316 U.S. 535 (1942).

54. Professor John Robertson is a leading proponent of this view. *See, e.g.*, JOHN A. ROBERTSON, *CHILDREN OF CHOICE* (1994); John A. Robertson, *Procreative Liberty and the Control of Conception, Pregnancy and Childbirth*, 69 VA. L. REV. 405 (1983) [hereinafter Robertson, *Procreative Liberty*]; John A. Robertson, *Decisional Authority over Embryos and Control of IVF Technology*, 28 JURIMETRICS J. 285 (1988) [hereinafter Robertson, *Decisional Authority*]; John A. Robertson, *Procreative Liberty and Harm to Offspring in Assisted Reproduction*, 30 AM. J. L. & MED. 7, 20 (2004).

55. 316 U.S. 535 (1942).

56. *Id.* at 536-37.

57. *Id.* at 538. Chief Justice Stone concurred in the result, but did not agree that the equal protection clause was the appropriate rationale. *Id.* at 543-44.

58. *Id.* at 541.

59. 262 U.S. 390 (1923) (case concerned right of parents to control the education of their children).

60. *Id.* at 399.

61. 405 U.S. 645 (1972).



and raise one's children have been deemed 'essential,' 'basic civil rights of man,' and 'rights far more precious . . . than property rights.'<sup>62</sup> One can also point to comments in some of the Court's cases involving the right not to reproduce.<sup>63</sup>

Some lower courts have dealt with the issue of a right to use ARTs more directly. Federal district courts have recognized the right to submit to medical procedures that may bring about pregnancy, such as artificial insemination<sup>64</sup> and embryo transfer.<sup>65</sup>

Although there is no Supreme Court precedent precisely on point, it seems likely that the Court would classify the right to use IVF as fundamental. If this is correct, then laws that prohibit or severely restrict the use of IVF would be unconstitutional.

Even if the Constitution protects the right of couples to use technologies such as IVF to have children, that right would not be absolute. It could be overridden by a compelling government interest.<sup>66</sup> The Court has recognized a government interest in preservation of a fetus' potential life and protection of maternal health.<sup>67</sup> In the context of abortion, the Supreme Court has stated that regulation that does not pose an undue burden on the protected right is permitted.<sup>68</sup> Thus a state could probably mandate distribution of literature regarding the risks of IVF

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62. *Id.* at 651 (internal citations omitted) (case concerned right to raise children).

63. See *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972) (referring to "the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."); *Planned Parenthood v. Casey*, 505 U.S. 833, 851 (1992) ("These matters [including the decision whether to bear or beget a child], involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment."); *Carey v. Population Servs. Int'l*, 431 U.S. 678, 685 (1977) (referring to the right of an individual "without unjustified government interference" to make "personal decisions relating to marriage . . . procreation . . . contraception . . . family relationships . . . and child rearing and education" and declared that "the decision whether or not to beget or bear a child is at the very heart of this cluster of constitutionally protected choices.").

64. *Cameron v. Bd. of Educ.*, 795 F. Supp. 228, 237 (S.D. Ohio 1991).

65. *Lifchez v. Hartigan*, 735 F. Supp. 1361, 1376-77 (N.D. Ill. 1990).

66. See, e.g., *Shapiro v. Thompson*, 394 U.S. 618, 634 (1969); *Roe v. Wade*, 410 U.S. 113, 155-56 (1973).

67. *Roe v. Wade*, 410 U.S. 113, 162-63 (1973); *Planned Parenthood v. Casey*, 505 U.S. at 871, 878.

68. See, e.g., *Planned Parenthood v. Casey*, 505 U.S. at 874-79.

generally or particular practices such as the transfer of high numbers of embryos, discussed *infra* in Part V.C. Further, while the government might be compelled to allow ARTs, it would not be *required* to provide funding for such artificial reproductive technologies.<sup>69</sup>

### C. REASONS TO BAN IVF OR RELATED TECHNOLOGIES

One reason why the law might be accused of falling behind technology is that bans are either not being imposed, or are not being imposed quickly enough. For example, one author, in the course of criticizing state governments for failing to restrict certain ART practices, writes, “[W]ith the ever-changing and quick development of new technology, the states, unlike our foreign counterparts, are *outpaced* by science and medicine.”<sup>70</sup> Although few continue to argue that IVF ought to be banned, some did argue for a ban when IVF was first introduced.

By containing new intrinsic possibilities, even in its most basic form, IVF also advances certain values. As artificial insemination enabled procreation without resort to sexual intercourse, IVF moved the act of fertilization as well as human embryos from women’s bodies to the laboratory. Especially in the 1970s and 1980s, this conflicted with many prevailing conceptions of the sanctity of human life and the role of women in procreation. The conflict between the values embedded in the technology and prevailing or sectoral social values affected the willingness of some to accept the technology, and led to calls for a ban from various quarters.<sup>71</sup> Although many of these arguments are now only of historic interest, one can see how they gave rise to possible reasons for banning or restricting the use of IVF.

One strand of arguments against IVF comes from organized religions. Although many religions find particular aspects of the technology problematic (such as donated gametes or surrogacy), Catholic doctrine condemns the entire

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69. *See id.*; *see also* Maher v. Roe, 432 U.S. 464, 480 (1977); Harris v. McRae, 448 U.S. 297, 311 (1980); Webster v. Reprod. Health Services, 492 U.S. 490, 507-11 (1989); Rust v. Sullivan, 500 U.S. 173, 193 (1991).

70. Sherri A. Jayson, Comment, “*Loving Infertile Couple Seeks Woman Age 18-31 to Help Have Baby. \$6,500 plus Expenses and a Gift*”: *Should We Regulate the Use of Assisted Reproductive Technologies by Older Women?*, 11 ALB. L.J. SCI. & TECH. 287, 299-300 (2001) (emphasis added).

71. A similar observation was made with respect to artificial insemination in Gaia Bernstein, *The Socio-Legal Acceptance of New Technologies: A Close Look at Artificial Insemination*, 77 WASH. L. REV. 1035, 1041-42 (2002).

enterprise.<sup>72</sup> As well as disapproving of the destruction of embryos, the Church opposes the separation of procreation from the act of conjugal union, and finds it contrary to notions of dignity and equality that the technology places human life within the power of technologists.<sup>73</sup>

A broader religious complaint, made more commonly against techniques such as genetic manipulation than against IVF, is that they constitute an illicit attempt to “play God.” A secular version of the same criticism might point to the fact that biotechnology gives us power to alter nature without endowing us with a sufficient (God-like) understanding of the possible consequences.<sup>74</sup> In a similar vein, many commentators sought to condemn technological interference with reproduction on the ground of its unnaturalness.<sup>75</sup> For example, Reverend William B. Smith, spokesperson for the Archdiocese of New York, likened IVF to “switching the marital bed into a chemistry set.”<sup>76</sup>

There are also concerns about the health of children conceived through IVF. In the early days of IVF, some commentators considered it unethical experimentation because insufficient data existed about the possible negative effects on the resulting child.<sup>77</sup> There is now more data available on the nature of risks to IVF children. Studies now show only minor deviations in birth weight and age, at least where multiple births are ignored; furthermore, such deviations may also be explained by other factors such as maternal age and

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72. Congregation for the Doctrine of the Faith, *Instruction on Respect for Human Life in Its Origin and on the Dignity of Procreation – Replies to Certain Questions of the Day* (February 22, 1987), available at [http://www.vatican.va/roman\\_curia/congregations/cfaith/documents/rc\\_con\\_cfaith\\_doc\\_19870222\\_respect-for-human-life\\_en.html](http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html) (last visited Apr. 6, 2005).

73. *Id.*

74. PRESIDENT’S COUNCIL ON BIOETHICS, *BEYOND THERAPY: BIOTECHNOLOGY AND THE PURSUIT OF HAPPINESS* 287 (2003), available at <http://www.bioethics.gov/reports/beyondtherapy/> (last visited Apr. 6, 2005).

75. See, e.g., Leon Kass, *Making Babies – The New Biology and the ‘Old’ Morality*, 26 PUB. INT. 18, 48-50 (1972) (“the laboratory production of human beings is no longer *human* procreation”).

76. *The First Test Tube Baby*, TIME, July 31, 1978, at 58, 69.

77. See, e.g., Hans O. Tiefel, *Human In Vitro Fertilization: A Conservative View*, 247 JAMA 3235, 3237-38 (1982); Paul Ramsey, *Shall We “Reproduce?” I. The Medical Ethics of In Vitro Fertilization*, 220 JAMA 1346, 1347 (1972); Leon R. Kass, *Babies By Means of In Vitro Fertilization: Unethical Experiments On the Unborn?*, 285 NEW ENG. J. MED. 1174, 1175-76 (1971).

primogeniture.<sup>78</sup> While some studies have also suggested that IVF children are more likely to suffer from birth defects,<sup>79</sup> the defects are more likely related to maternal characteristics<sup>80</sup> and the prevalence of multiple births than to IVF itself.<sup>81</sup> While possible links between IVF and specific conditions have been identified, additional investigation is required before informed conclusions can be drawn.<sup>82</sup>

In the 1980s, some feminists and feminist groups such as the Feminist International Network of Resistance to Reproductive and Genetic Engineering (FINRRAGE) advocated a different set of objections to IVF.<sup>83</sup> They raised a variety of concerns, including that IVF transfers power away from women<sup>84</sup> and distracts from efforts to prevent infertility or deal with more important health issues.<sup>85</sup> Other concerns raised

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78. ALASTAIR G. SUTCLIFFE, IVF CHILDREN: THE FIRST GENERATION 30 (2002); Med. Research Council Working Party on Children Conceived by In Vitro Fertilisation, *Births in Great Britain Resulting from Assisted Conception, 1978-87*, 300 BRIT. MED. J. 1229, 1232 (1990).

79. See, e.g., Michèle Hanson et al., *The Risk of Major Birth Defects After Intracytoplasmic Sperm Injection and In Vitro Fertilization*, 346 NEW ENG. J. MED. 725, 729-30 (2002).

80. SUTCLIFFE, *supra* note 78, at 30-31; T. Bergh et al., *Deliveries and Children Born After In-Vitro Fertilization in Sweden 1982-95: A Retrospective Cohort Study*, 354 LANCET 1579, 1583-84 (1999).

81. Bergh, *supra* note 80, at 1583-84; see also Press Release, ASRM Media Advisory, ASRM Comments on Release of Report on Outcomes Study of ART Children (Oct. 19, 2004), available at [http://www.asrm.org/Media/Press/ART\\_child\\_study.html](http://www.asrm.org/Media/Press/ART_child_study.html) (last visited Apr. 6, 2005).

82. See, e.g., A.C. Moll et al., *Incidence of Retinoblastoma in Children Born After In-Vitro Fertilisation*, 361 LANCET 309, 309-10 (2003); Rosie Mestel, *Some Studies See Ills for In Vitro Children: Evidence of Increases in Eye Cancer and Mental Retardation Needs to be Verified*, L.A. TIMES, Jan. 24, 2003, at A1; see also SUTCLIFFE, *supra* note 78, at 36 (discussing a study that showed a possible link between IVF and increased cancer rates). See generally MED. RESEARCH COUNCIL, ASSISTED REPRODUCTION: A SAFE, SOUND FUTURE (2004) (discussing need for and design of future research), available at [http://www.mrc.ac.uk/index/publications/publications-research\\_reviews/public-assisted\\_reproduction\\_report.htm](http://www.mrc.ac.uk/index/publications/publications-research_reviews/public-assisted_reproduction_report.htm) (last visited Mar. 29, 2005).

83. See generally Resolution from the FINRRAGE Conference, July 3-8, 1985, Vällinge, Sweden, in MADE TO ORDER: THE MYTH OF REPRODUCTIVE AND GENETIC PROGRESS 211-12 (Patricia Spallone & Deborah Lynn Steinberg eds., 1987).

84. See, e.g., Robyn Rowland, *Of Women Born, But for How Long? The Relationship of Women to the New Reproductive Technologies and the Issue of Choice*, in MADE TO ORDER: THE MYTH OF REPRODUCTIVE AND GENETIC PROGRESS 67, 77, 80 (Patricia Spallone & Deborah Lynn Steinberg eds., 1987).

85. See, e.g., Lori B. Andrews, *Alternative Modes of Reproduction*, in REPRODUCTIVE LAWS FOR THE 1990S 361, 262-63 (Sherill Cohen & Nadine

were that IVF was experimental, onerous, usually unsuccessful and possibly dangerous, and that women were coerced or misled into bearing the risks and the costs.<sup>86</sup>

Some objections to the practice of IVF might, with hindsight, be characterized as Luddite objections to the new. Overly simplistic analogies fall in this category.<sup>87</sup> For example, Leo Abse, a British MP, stated that “[t]he issue is how far we play God, how far we are going to treat mankind as we would animal husbandry.”<sup>88</sup> One can always compare a technology such as human IVF to its past associations, but the argument is meaningless unless the similarities and differences between human and non-human reproductive technologies are explored. Some objections to a new technology are based on “fear, ignorance, prejudice, or raw emotion”<sup>89</sup> or are an example of a pessimistic attitude towards new things.<sup>90</sup>

Both negative reflex reactions and more sophisticated objections to new technology generally soften over time.<sup>91</sup> For example, between 1978 and 1994, acceptance of IVF in the United States increased from 60% to 75%,<sup>92</sup> and between 1981

Taub eds., 1989); Gena Corea et al., *Prologue, in* MADE TO ORDER: THE MYTH OF REPRODUCTIVE AND GENETIC PROGRESS 8 (Patricia Spallone & Deborah Lynn Steinberg eds., 1987).

86. GENA COREA, *THE MOTHER MACHINE: REPRODUCTIVE TECHNOLOGIES FROM ARTIFICIAL INSEMINATION TO ARTIFICIAL WOMBS* 166-85 (1985); see also Gena Corea & Susan Ince, *Report of a Survey of IVF Clinics in the United States, in* MADE TO ORDER: THE MYTH OF REPRODUCTIVE AND GENETIC PROGRESS 133-39 (Patricia Spallone & Deborah Lynn Steinberg eds., 1987).

87. See generally Michael H. Shapiro, *Illicit Reasons and Means for Reproduction: On Excessive Choice and Categorical and Technological Imperatives*, 47 HASTINGS L.J. 1081 (1996) (discussing the misuse of analogy in the context of the debate on reproductive technologies).

88. *The First Test Tube Baby*, TIME, July 31, 1978, at 58, 69.

89. Arthur Caplan, *Introduction, in* BEYOND BABY M: ETHICAL ISSUES IN NEW REPRODUCTIVE TECHNIQUES 5-6 (Dianne M. Bartels et al. eds, 1990).

90. See E. Donald Elliott, *Against Ludditism: An Essay On the Perils of the (Mis)Use of Historical Analogies in Technology Assessment*, 65 S. Cal. L. Rev. 279, 281-82 (1991).

91. See Tabitha Rowledge, *Reproductive Technologies and the Bottom Line, in* EMBRYOS, ETHICS AND WOMEN'S RIGHTS: EXPLORING THE NEW REPRODUCTIVE TECHNOLOGIES 203, 203 (Elaine Hoffman Baruch et al. eds., 1988); ALLAN MAZUR, *THE DYNAMICS OF TECHNICAL CONTROVERSY* 97-98 (1981); see also ANDREA L. BONNICKSEN, *IN VITRO FERTILIZATION: BUILDING POLICY FROM LABORATORIES TO LEGISLATURES* 45 (1989). See generally Bernstein, *supra* note 71, at 1060-71 (analyzing how artificial insemination gained social and legal acceptance).

92. Keith Alan Byers, *Infertility and In Vitro Fertilization: A Growing Need for Consumer-Oriented Regulation of the In Vitro Fertilization Industry*, 18 J. LEGAL MED. 265, 283-84 (1997) (reporting the results of an attitudinal

and 2000, the proportion of Australians who approved of IVF for married couples rose from 77% to 85%.<sup>93</sup> Eventually, public attention turns from thoughts of *whether* a new technology ought to be used to *how* it ought to be used and what consequences ought to flow from its use. Of course, a disastrous event may turn the public's mind back to the initial question. Even where negative reactions merely delay, rather than prevent the introduction of a new technology, the controversy itself can prove to be beneficial because it may lead to greater public awareness and, in some cases, increased regulation or oversight.<sup>94</sup>

#### D. REASONS TO REGULATE IVF AND RELATED TECHNOLOGIES

If no decision is made to ban a new technology, a more modest desire might be to control its use.<sup>95</sup> Failure of political institutions to impose such limits may be described as a "legal vacuum."<sup>96</sup>

There are various reasons why it might be thought desirable to subject a new technology to regulation. Sometimes, the mere exercise of centralized control can allay public fears as to the direction the technology might otherwise take.<sup>97</sup> For example, the Warnock Report,<sup>98</sup> commissioned in the United Kingdom to examine the implications of developments in ART, frequently referred to the need to allay

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survey by Princeton Survey Research Associates).

93. The Roy Morgan Research Centre Finding No. 3359, *Vast Majority of Australian's Support Medicare-Funded IVF, But Most Oppose Sperm Bank Use By Single Women or Lesbian Couples*, THE BULLETIN, Jan. 9, 2001, available at <http://www.roymorgan.com/news/polls/2001/3359/> (last visited Apr. 6, 2005).

94. See generally ALLAN MAZUR, *supra* note 91, at 126-27.

95. See, e.g., Alexander Morgan Capron, *The New Reproductive Possibilities: Seeking a Moral Basis for Concerted Action in a Pluralistic Society*, 12 L. MED. & HEALTH CARE 192, 192-93 (1984).

96. See, e.g., Nicholas P. Terry, "Alas! Poor Yorick," *I Knew Him Ex Utero: The Regulation of Embryo and Fetal Experimentation and Disposal in England and the United States*, 39 VAND. L. REV. 419, 456 (1986) (emphasizing the "legal vacuum" that has allowed embryo research to take place outside a regulatory regime).

97. See Margaret Brazier, *Regulating the Reproduction Business?*, 7 MED. L. REV. 166, 168 (1999) (referring to the common plea that "something must be done" about the reproduction business and that "something" usually takes the form of external regulation).

98. REPORT OF THE COMMITTEE OF INQUIRY INTO HUMAN FERTILISATION AND EMBRYOLOGY, July 1984, Cmnd. 9314 [hereinafter Warnock Report].

public fears.<sup>99</sup> The Foreword to the Warnock Report refers to the fact that people want “*some principles or other*” to govern the development and use of the new techniques,<sup>100</sup> including “*some barriers*”<sup>101</sup> and “*some limits.*”<sup>102</sup> The Conclusion makes a similar point, indicating a desire to protect society “from its real and very proper fear of a rudderless voyage into unknown and threatening seas.”<sup>103</sup> Regulation can thus serve a symbolic function; the mere existence of limits reassures people that the technology is under control.<sup>104</sup>

The usual purpose of regulation, however, is to protect those affected by the use of a technology. “Technology assessment” refers to the process used to determine the effectiveness, safety, and appropriate use of a new technology.<sup>105</sup> Technology assessment is primarily concerned with predicting the future consequences (economic, social, or environmental) of technological development.<sup>106</sup> Typically, harmful consequences are avoided by prescribing the manner in which a technology is designed or employed or by discouraging its use.<sup>107</sup> Such regulation can increase efficacy, as well as protect the health and safety of technologists, those seeking to benefit from the technology, others in society, and even the environment. Of course, not all technologies will pose

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99. Janet Gallagher, *Embryos, Eggs and Fetuses: Anxiety and the Law*, in *REPRODUCTIVE TECHNOLOGIES: GENDER, MOTHERHOOD AND MEDICINE* 139, 147 (Michelle Stanworth ed., 1987).

100. MARY WARNOCK, *A QUESTION OF LIFE: THE WARNOCK REPORT ON HUMAN FERTILIZATION AND EMBRYOLOGY*, WITH TWO NEW CHAPTERS BY MARY WARNOCK 2 (1985) (emphasis in original).

101. *Id.* (emphasis in original).

102. *Id.* (emphasis in original).

103. *Id.* at 100.

104. See McCartan, *supra* note 38, at 713 (“The goals of policy in the IVF arena should emphasize control and containment of present applications and procedures.”).

105. See, e.g., H. David Banta, *Technology Assessment and Infertility Care*, in *TOUGH CHOICES: IN VITRO FERTILIZATION AND THE REPRODUCTIVE TECHNOLOGIES* 53, 60 (Patricia Stephenson & Marsden G. Wagner eds., 1993). See generally DORF, *supra* note 40, at 289; NAT’L ACAD. OF SCIENCES PANEL ON TECH. ASSESSMENT, *TECHNOLOGY: PROCESSES OF ASSESSMENT AND CHOICE* 1-19 (1969).

106. See NAT’L ACAD. OF SCIENCES PANEL ON TECH. ASSESSMENT, *supra* note 105, at 1-19.

107. See Richard B. Stewart, *Regulation, Innovation, and Administrative Law: A Conceptual Framework* 69 Cal. L. Rev. 1256, 1263-73 (1981). See generally Laurence H. Tribe, *Legal Frameworks for the Assessment and Control of Technology*, 9 MINERVA 243 (1971).

the same threats; in the case of IVF, the focus of regulation tends to be on the effectiveness of the procedure, the health of the woman seeking access to IVF, the proper treatment of the embryo, and the health of the child born as a result of the procedure.

Not all regulation need be aimed at ensuring health and safety; it may be economic in character or may relate to the preservation of other interests and values that are less easily subjected to utilitarian calculation.<sup>108</sup> There is often vigorous social disagreement on what values are implicated by biotechnologies and their relative importance. In the case of IVF, one frequently hears reference to values such as family, community, privacy, and human dignity. In Louisiana, for example, restrictive legislation regulating IVF serves the symbolic function of classifying an embryo as the moral equivalent of a person.<sup>109</sup> The perceived need to preserve social values or place limits on a technology, as well as the desire to maximize its benefits and minimize its harms, are all reasons why regulation might be seen as a necessary response to technological change.

#### E. REASONS TO ENHANCE CERTAINTY

The problem of uncertainty in law is pervasive; it will never be possible to determine the precise meaning of all legal rules so as to be able to answer all legal questions unequivocally. H.L.A. Hart described legal rules as having a penumbra of uncertainty, created in part by the open texture of language.<sup>110</sup> Technological change thus enters onto a stage occupied by an already uncertain law. While it does not create the problem of uncertainty, it may exacerbate it by revealing latent ambiguities in the law and raising new legal questions for which there are no clear answers. References to technology outpacing law can portray the slow pace at which such new

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108. See Derek Morgan & Robert Lee, *Assisted Conception in Common Law Jurisdictions*, in *BIOMEDICINE, THE FAMILY AND HUMAN RIGHTS* 479, 484-92 (Marie-Thérèse Meulders-Klein et al. eds., 2002) (exploring society's interest in the ethical concerns surrounding assisted conception); Cynthia B. Cohen, *Unmanaged Care: The Need to Regulate New Reproductive Technologies in the United States*, 11 *BIOETHICS* 348, 350 (1997) (arguing the validity of social and moral concerns associated with the nature of family and value of children).

109. LA. REV. STAT. ANN. § 9:123 (West 2003). See generally *id.* §§ 9.121-133.

110. See HART, *supra* note 28, ch. 7; H.L.A. Hart, *Positivism and the Separation of Law and Morals*, 71 *HARV. L. REV.* 593, 607-08 (1958).



questions are answered.<sup>111</sup> In describing the gap between technology and the law caused by uncertainty, the terms “legal vacuum” and “legal void” are sometimes used.<sup>112</sup>

Generally speaking, uncertainties arise when new entities, relationships, or activities do not fit easily into existing conceptual and legal categories. Our rules assume the existence of “property” (which can be traded or transmitted via will) and “persons” (who can own and inherit), and it can be difficult to classify new entities such as cryopreserved embryos for the purposes of these rules. Although notions of property and persons are inherently contestable, even previously clear concepts can acquire more than one meaning. Prior to the use of reproductive technologies, the woman who gave birth to a child, necessarily a genetic parent, was its mother (subject to rules on adoption). Yet the notion of motherhood harbored latent ambiguity, which was revealed once it became possible to separate genetic from gestational motherhood.<sup>113</sup>

Consider the Tennessee custody dispute addressed in *Davis v. Davis*.<sup>114</sup> Following a divorce, Mary Sue Davis wanted to attempt pregnancy with cryopreserved embryos created with her eggs and her husband’s sperm; the husband, Junior Davis,

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111. See, e.g., Vukadinovich, *supra* note 34, at 67; Wendy Dullea Bowie, Comment, *Multiplication and Division – New Math for the Courts: New Reproductive Technologies Create Potential Legal Time Bombs*, 95 DICK. L. REV. 155, 156, 163 (1990); Michael Booth, *Fate of Frozen Embryos Brings NJ Again to Bioethics Fore*, N.J.L.J., Mar. 9, 1998, at 1; NEW SOUTH WALES HEALTH DEPARTMENT, REVIEW OF THE HUMAN TISSUE ACT 1983 (1997) (discussion paper), available at <http://www.health.nsw.gov.au/csd/lisb/legislation/humantiss.html> (last visited Apr. 6, 2005).

112. See, e.g., Lee M. Silver & Susan Remis Silver, *Confused Heritage and the Absurdity of Genetic Ownership*, 11 HARV. J.L. & TECH. 593, 610 (1998); Laura D. Heard, Comment, *A Time to be Born, a Time to Die: Alternative Reproduction and Texas Probate Law*, 17 ST. MARY’S L.J. 927, 928 (1986); Kelly L. Frey, Comment, *New Reproductive Technologies: The Legal Problem and a Solution*, 49 TENN. L. REV. 303, 318-19 (1982).

113. See, e.g., *In re Marriage of Buzzanca*, 72 Cal. Rptr. 2d 280 (Cal. Ct. App. 1998) (involving parentage of child born because a couple agreed to have an embryo genetically unrelated to either of them transferred to a surrogate); Parm Belluck & Adam Liptak, *Split Gay Couples Face Custody Hurdles: Judges Lack Road Maps for Laws Unintended for Same-Sex Unions*, N.Y. TIMES, Mar. 24, 2004, at A18 (concerning a dispute following the breakup of a lesbian relationship in which one partner had served as the gestational mother and the other as the genetic mother).

114. *Davis v. Davis*, No. E-14496, 1989 WL 140495 (Tenn. Cir. Ct. Sept. 21, 1989).

wanted to avoid involuntary parenthood.<sup>115</sup> The trial court could have potentially treated the cryopreserved embryos as “children,” whose custody would be determined in the best interests of the child or as “property,” in which case they would be jointly owned by the parties.<sup>116</sup> Trial court Judge W. Dale Young found that “human life begins at the moment of conception” and that the best interests of the child would be served by granting custody of the embryos to Mary Sue.<sup>117</sup>

The *Davis* case was appealed to the Court of Appeals of Tennessee, by which time Mary Sue wanted to donate the embryos to another couple.<sup>118</sup> The appellate court held that the trial court’s decision violated Junior’s reproductive rights, and ordered that the parties be given joint control over the embryos.<sup>119</sup> On appeal from that decision, the Tennessee Supreme Court struck a middle ground between the two positions.<sup>120</sup> Embryos were neither persons nor property, but were entitled to special respect because of their potential for human life.<sup>121</sup> Ultimately, therefore, neither analogy was considered appropriate, the court instead resolving the dispute by balancing the parties’ interests.<sup>122</sup> Prior to *Davis v. Davis*, there was real uncertainty as to how disputes over cryopreserved embryos would be viewed.

Another potential source of uncertainty, peculiar to the common law, arises out of the reliance on *stare decisis* in determining the content of common law rules. Where technological change makes possible new forms of conduct, there will automatically be a difference between the first case involving that conduct and *all* previous cases. Determining whether the new conduct in question is “like” existing forms of conduct may be difficult. Seeking to rely on a precedent will often prove futile—a particular judge’s conception of the appropriate legal rule is unlikely to clarify the status of conduct that was not possible, and possibly not even foreseen, at the time.

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115. *Id.* at \*18-20.

116. *Id.* at \*9.

117. *Id.* at \*9, \*11.

118. *Davis v. Davis*, No. 180, 1990 WL 130807, at \*2, \*3 n.1 (Tenn. Ct. App. Sept. 13, 1990).

119. *Id.* at \*2-3.

120. *Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1992).

121. *Id.* at 597.

122. *Id.* at 603-04.

This does not mean that the outcome in every case involving the application of a common law rule to new conduct will be uncertain. At one extreme, the immateriality of some facts is obvious. At the opposite extreme, there might be a perception (whether later proved true or false) that no existing rules apply to new forms of conduct merely because they are new. This tendency was evident in some of the earlier literature on law and the Internet.<sup>123</sup> More common is the view that the applicability of at least some old rules to new forms of conduct is uncertain.

#### F. REASONS TO REJECT EXISTING RULES

Law reform may be urged where new technologies alter the facts that had justified existing common law and statutory rules.<sup>124</sup> An example of reform can be found in early cases addressing the question of whether artificial insemination of a woman with sperm originating from a man other than her husband constituted adultery. The first hurdle the law needed to address was uncertainty: it was unclear whether artificial insemination constituted adultery, that is, whether adultery was sexual intercourse outside of marriage or sharing reproductive capacity outside marriage.<sup>125</sup> A Canadian court initially held that adultery was sharing reproductive capacity outside of marriage,<sup>126</sup> but subsequent cases decided that it was sexual intercourse outside of marriage.<sup>127</sup> Once that uncertainty was resolved, the rationale for the evidentiary rule relating conception of another man's child to adultery was undermined. The rule was therefore abandoned.<sup>128</sup>

Because rules may become obsolete, unenforceable, or too expensive, the law may be criticized for dealing with new technologies "in terms of existing statutes or cases which were written at a time when these new modes of reproduction were

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123. See, e.g., David R. Johnson & David Post, *Law and Borders -- The Rise of Law in Cyberspace*, 48 STAN. L.R. 1367, 1367, 1400-02 (1996).

124. See generally David Friedman, *Does Technology Require New Law?*, 25 HARV. J.L. & PUB. POL'Y 71 (2001-02) (arguing technological change can alter facts used to justify existing law, and in such situations the legal system may alter existing law).

125. *Orford v. Orford*, 58 D.L.R. 251, 258 (Ont. 1921).

126. *Id.*

127. See Bernstein, *supra* note 71, at 1067; see also MacLennan v. MacLennan 1958 Sess. Cas. 105, 113-15 (Scot.).

128. See Bernstein, *supra* note 71, at 1067.

not envisioned.”<sup>129</sup> As Justice Felix Frankfurter stated, when factual assumptions on which a law is premised change, “law cannot be static . . . for facts are stubborn and will not yield.”<sup>130</sup> If laws that have lost their reason for being continue in force, the law might well be accused of responding too slowly in a changing world.

#### G. REASONS TO EXPAND OR CONTRACT EXISTING RULES

Where a rule is created prior to some technological change, it will rarely be drafted with that change in mind. Such a rule may either include within its scope conduct that its creators would have (had they thought of it) excluded or exclude conduct that would have been included. Most rules are over-inclusive and under-inclusive, even in the absence of technological change. A person drafting a rule will need to balance the problems of over-inclusiveness and under-inclusiveness against other considerations, such as whether the rule as drafted is clear and easy to apply.<sup>131</sup> We might assume that a competent drafter would reach an acceptable (if controversial) balance. But the rule may also apply (or fail to apply) to conduct that could not have been foreseen at the time of its creation. A better balance might be reached by deliberately excluding (or including) that new conduct. In these cases, technological change might argue in favor of amending the rule.

In the IVF context, consider the following Virginia law, enacted in 1984:

With the exception of hair, blood and other self-replicating body fluids, it shall be unlawful for any person to sell, to offer to sell, to buy, to offer to buy, or to procure through purchase any natural body part for any reason including, but not limited to, medical and scientific uses such as transplantation, implantation, infusion or injection.<sup>132</sup>

At the time that law was enacted, ovum donation was a very new technique. Ova are not self-replicating, and their sale therefore fell within the prohibition. Yet selling ova is not necessarily equivalent to selling a kidney because a donor has

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129. Lorio, *supra* note 34, at 1642.

130. Felix Frankfurter, *The Zeitgeist and the Judiciary*, in LAW AND POLITICS: OCCASIONAL PAPERS OF FELIX FRANKFURTER, 1913-1938, at 6 (1939).

131. See Colin S. Diver, *The Optimal Precision of Administrative Rules*, 93 YALE L.J. 65, 67 (1983) (discussing the importance of balancing a rule's transparency, accessibility, and congruency).

132. VA. CODE ANN. §§ 32.1-289.1 (Michie 1991).

many more spare ova than kidneys. In fact, the Virginia law was amended in 1991 to exclude transactions in ova.<sup>133</sup>

Conversely, rules may fail to include conduct that falls within the rule's rationale. Many states have laws regulating sperm donation and artificial insemination. For example, in 2001, forty-two states had laws regulating sperm donation.<sup>134</sup> These often include safety regulations requiring testing for communicable or genetic diseases, mandatory record keeping to avoid sperm switching and create a genetic data resource for future children, and special consent requirements.<sup>135</sup> Such laws should be equally applicable to the practice of ovum donation. Yet, without further amendment, the legislation only covers the use of male gametes.

There are other examples of rules that were criticized for being over-inclusive or under-inclusive in light of the use of IVF. Some have argued that stealing embryos ought to constitute "theft" despite the limitation in some laws that theft only applies to property.<sup>136</sup> Many states require insurers to cover or offer coverage for particular medical services; and many amended their statutes to include IVF.<sup>137</sup>

The problem of over-inclusiveness and under-inclusiveness is greater with statutes than with common law rules. This is because common law rules are read with greater reference to their underlying justifications.<sup>138</sup> Consider, by way of example, an imaginary rule providing: "Any person driving a carriage led by one or more horses who collides with a pedestrian shall be liable for the damages so caused irrespective of negligence." If the source of this rule were a statute, the rule would create a

133. 1991 Va. Acts ch. 600.

134. NAT'L CONF. OF STATE LEGISLATURES, GENETICS POLICY REPORT: REPRODUCTIVE TECHNOLOGIES 9-10 (Alissa Johnson & Cheye Calvo eds., 2001).

135. *Id.*

136. *See generally infra* Part V.B.2.a.iii.

137. *See, e.g.*, ARK. CODE ANN. §§ 23-85-137, 23-86-118 (Michie 2005); CONN. GEN. STAT. § 38a-536 (2003); HAW. REV. STAT. ANN. §§ 431:10A-116.5, 432:1-604 (Michie 2003); 215 ILL. COMP. STAT. 5/356m (2003); MD. CODE ANN., INS. § 15-810 (2002); MASS. GEN. LAWS ANN. § 47H, ch. 176A, § 8K, ch. 176B, § 4J (West 2003); MONT. CODE ANN. § 33-31-102 (2003); N.J. STAT. ANN. §§ 17:48-6x, 17B:27-46.1x, 26:2J-4.23 (West 2001 & Supp. 2003); OHIO REV. CODE ANN. § 1751.01 (Anderson 2003); R.I. GEN. LAWS §§ 27-18-30, 27-19-23, 27-20-20, 27-41-33 (2003); TEX. INS. CODE ANN. §§ 1366.001-007 (Vernon 2004).

138. *See* FREDERICK SCHAUER, PLAYING BY THE RULES: A PHILOSOPHICAL EXAMINATION OF RULE-BASED DECISION-MAKING IN LAW AND IN LIFE 174-81 (1991).

regime of strict liability in the circumstances contemplated. Even if the purpose of the rule were a concern for pedestrian welfare in light of the faster and heavier horse-drawn carriages, it would not extend to injury caused by an automobile.<sup>139</sup> Although the purpose of the statute is important in deducing meaning, it cannot extend the meaning beyond the limits that words will bear.

Common law rules are not bound to their words in the same way. There is no single authoritative text for common law rules. Even when a rule is stated in canonical form, the rule will not necessarily bind courts according to its terms. It is always open to a later court to create a new exception to the rule or extend it by analogy. If the horse-drawn carriage rule were found in the common law, it would likely be extended by analogy to new situations when justified by the rule's underlying rationale. The fact that common law rules can be extended or retracted in light of their underlying justifications is a crucial advantage when making laws intended to apply in the context of rapidly changing technologies. This is discussed further in Parts V.B.4 and VI.A.

#### H. DIFFERING DILEMMAS

Following technological change, law may confront the range of challenges described here. However, the particular challenges that arise will vary by technological change and jurisdiction. In fact, many new technologies pose no challenges for law—one does not find lawmakers struggling with the implications of the electric can-opener, for example.

Consider the separation of genetic and gestational motherhood introduced by the use of IVF with surrogate gestation in two hypothetical jurisdictions. The first has laws expressly stating that the woman who gives birth to a child is to be registered as its mother. In the second, the law contains no such explicit statement, presumably because it seemed obvious. The difference was almost an accident since the practice in all jurisdictions prior to the use of IVF is identical; the woman giving birth to a child is registered as its mother (*mater est quam gestatio demonstrat*).<sup>140</sup>

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139. There has been some commentary on the question of whether statutes might be extended to situations not contemplated at the time of their enactment by use of analogy. See, e.g., Roscoe Pound, *Common Law and Legislation*, 21 HARV. L. REV. 383, 385 (1908).

140. J.K. MASON & R.A. MCCALL SMITH, LAW AND MEDICAL ETHICS 57 (2d

Yet, once genetic and gestational motherhood are separated, each jurisdiction is in a different dilemma. In the first jurisdiction, the laws treating the birth mother as mother were accidental and were not the result of any balancing of interests of a gestational mother and a separate genetic mother. After IVF becomes possible using gestational surrogacy, controversy results. Some may believe that the original rule is right and that the gestational mother should be registered as the child's parent, despite the absence of a genetic link. Others may argue that the legal position ought to be changed as a result of new technology and that, until the law is changed, it is stuck in the past. Whatever position is taken, all groups would agree that the original rule was formulated in the context of factual assumptions that are no longer correct. The question of whether a genetic or gestational mother has a right to be recognized as the child's legal parent ought to be resolved on its own merits. In the second jurisdiction, the question is one of pure uncertainty, rather than one of existing rules being arguably out of date.

Not only may different dilemmas exist in different jurisdictions, but different dilemmas may be perceived in the same jurisdiction. While people may agree that the factual assumptions on which a law was formulated have changed or that existing rules were drafted without contemplation of new technologies, they may disagree as to whether the law should be changed. Those arguing for the law to remain static may feel that existing rules are nevertheless justified or that the application of an existing rule to new conduct is desirable, even if fortuitous. Others, perhaps rhetorically pointing to the law's inability to keep up with technology, may argue for legal change. Thus, pressure for law reform might be felt more strongly in some jurisdictions than in others. Nevertheless, it is difficult to deny that technological change has generated a reason to change or clarify the law; what is really in dispute is the extent to which this reason is sufficient.

Where technology does provide a reason to change or clarify the law, that reason may fit in more than one of the categories set out above. For example, uncertainty in relation to family relationships may itself be a reason to ban or restrict the use of certain ARTs. Alternatively, the fact that an existing rule is over-inclusive with respect to new forms of conduct

might lead some to conclude that it ought to be repealed entirely.

### III. DIFFERENT PATHS – RESPONSES TO IVF

Although it would be surprising if all common law countries subjected IVF to the same laws, it is interesting that different jurisdictions have taken widely divergent routes. The three countries discussed here—the United States, the United Kingdom, and Australia—are subject to different constitutional and regional norms, and differ in their political and legal cultures.<sup>141</sup> Because of these differences, approaches taken in one jurisdiction may be impossible or ineffective in another.<sup>142</sup>

But it would be going too far to assume that comparisons between these jurisdictions are meaningless. As will be evident from Parts V and VI, these countries also share common problems and common goals. They all have a common law system, and state control is exercised in legislative and administrative fora. Despite cultural and political differences, each country can still learn from the experience of others—the outcomes of differing choices. The result of the comparison may be to question assumptions about the optimum legal and political response to technological change.

This Part briefly describes the legal responses to IVF in most of the United States, the United Kingdom, and two states in Australia. Because the discussions in Parts V and VI below focus on particular aspects of each regime, only an outline is included here.

#### A. UNITED STATES

American law on IVF is complicated by the fact that it is largely state-based. For example, Louisiana places tight reins on the practice of IVF, based on the principle that an *in vitro*

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141. See Kathryn Venturatos Lorio, *The Process of Regulating Assisted Reproductive Technologies: What We Can Learn from Our Neighbors – What Translates and What Does Not*, 45 LOY. L. REV. 247, 249 (1999). See generally P.S. ATIYAH & ROBERT S. SUMMERS, *FORM AND SUBSTANCE IN ANGLO-AMERICAN LAW* (1987).

142. See, e.g., PRESIDENT'S COUNCIL ON BIOETHICS, *REPRODUCTION & RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES* 12 (2004) [hereinafter *REPRODUCTION & RESPONSIBILITY*], available at <http://www.bioethics.gov/reports/reproductionandresponsibility/index.html> (last visited Apr. 6, 2005).



embryo has the same legal status as a person.<sup>143</sup> New Hampshire also has detailed laws regarding liability, the length of time that embryos can be stored *in vitro*, and patient selection.<sup>144</sup> Florida prohibits the sale of embryos, mandates agreements to provide for disposition of embryos and gametes in the event of death or divorce, and states that a child conceived after the death of a parent does not inherit.<sup>145</sup> Virginia requires HIV testing for gamete donors, requires physicians to provide certain disclosures to patients, and states that an ART child born after a decedent's death may inherit.<sup>146</sup> In addition, many states have laws determining parentage of ART children.<sup>147</sup>

States have also tended to deal with particular issues surrounding ART and IVF. For example, California requires consent for embryo and gamete donation;<sup>148</sup> Kansas permits destruction of embryos;<sup>149</sup> Kentucky prohibits the use of public facilities for research purposes if embryonic destruction may result;<sup>150</sup> New Mexico requires that embryos be transferred to a woman to avoid clinical experimentation restrictions;<sup>151</sup> New Jersey deals with questions of inheritance, requiring that an heir be in gestation at the time of the decedent's death;<sup>152</sup> Oklahoma prescribes conditions for egg and embryo

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143. LA. REV. STAT. ANN. §§ 9:121-133 (West 2000).

144. N.H. REV. STAT. ANN. §§ 168-B:12-B:15, B:29-B:31 (2001).

145. FLA. STAT. ANN. ch. 742.17 (West 1997); FLA. STAT. ANN. ch. 873.05 (2000).

146. VA. CODE ANN. §§ 32.1-45.3, 64.1-68.1 (Michie 2004); VA. CODE ANN. § 54.1-2971.1 (Michie 2002).

147. North Dakota and Virginia have laws based on the UNIFORM STATUS OF CHILDREN ASSISTED CONCEPTION ACT, 9B U.L.A. 191 (West Supp. 1999). N.D. CENT. CODE § 14-18-01 to 07 (2003); VA. CODE ANN. § 20-158 (Michie 2004). Colorado, Delaware, Texas, Washington, and Wyoming have laws based on the UNIFORM PARENTAGE ACT (2000). COLO. REV. STAT. §§ 19-4-101, -106 (2003); DEL. CODE ANN. tit. 13, §§ 8-101 to -102, 8-701 to -707 (Supp. 2004); TEX. FAM. CODE ANN. §§ 160.101-102, 160.701-763 (Vernon 2002 & Supp. 2004); WASH. REV. CODE ANN. §§ 26.26.010-011, 26.26.700-740 (Supp. 2004); WYO. STAT. ANN. §§ 14-2-401 to -402, 14-2-901 to -907 (Michie 2003). Florida and Illinois make provision for gestational surrogacy agreements. FLA. STAT. ANN. ch. 742.11-17 (West 1997 & Supp. 2004); 750 ILL. COMP. STAT. §§ 47/1-47/75 (West 2004). Many more states have laws dealing with pre-IVF issues such as sperm donation. *See infra* note 559.

148. CAL. PENAL CODE § 367g (West 1999); CAL. BUS. & PROF. CODE § 2260 (West 2003 & Supp. 2005).

149. KAN. STAT. ANN. § 65-6702 (2002).

150. KY. REV. STAT. ANN. § 311.715 (Michie 2002).

151. N.M. STAT. ANN. §§ 24-9A-1 to -7 (Michie 2003).

152. N.J. STAT. ANN. § 3B:5-8 (West 2004).

donation;<sup>153</sup> and Pennsylvania requires that certain IVF statistics be reported.<sup>154</sup> Many states have laws, often tied in with laws regulating abortion, that restrict what can be done with *in vitro* embryos.<sup>155</sup> Further, some states have laws requiring certain insurers to provide or offer coverage for IVF.<sup>156</sup>

There are various theories that attempt to explain the lack of federal legislation on IVF, including constitutional restrictions on government action, deference to medical practitioners, anti-regulation and free market ideology, and entanglement with the contentious abortion debate.<sup>157</sup> Yet, despite knowledge of these factors, many had predicted that legislation would be passed,<sup>158</sup> and there has been some public demand for regulation.<sup>159</sup>

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153. OKLA. STAT. ANN. tit. 10, § 554-556 (West Supp. 2004).

154. 18 PA. CONS. STAT. ANN. § 3213(e) (West 2000).

155. See 720 ILL. COMP. STAT. 5/9-1.2 (West 2002) (prohibiting killing any unborn child, defined as an “individual of the human species from fertilization until birth”); ME. REV. STAT. ANN. tit. 22, § 1593 (West 2004) (prohibiting the use, transfer, or distribution of *in utero* and *ex utero* fetuses for experimentation); MASS ANN. LAWS ch. 112, § 12J (Law. Co-op. 2004) (prohibiting research on a fetus, defined to include embryos); MICH. COMP. LAWS ANN. § 333.2685 (West 2004) (prohibiting non-therapeutic research on embryos); MINN. STAT. ANN. §§ 609.266–.2691 (West 2003) (providing for various offenses against unborn children, defined to be “the unborn offspring of a human conceived, but not yet born”), MINN. STAT. ANN. §§ 145.421, 422 (West 1998 & Supp. 2004) (prohibiting research on a living human conceptus, defined to include human organism from fertilization through the first 265 days thereafter); N.M. STAT. ANN. §§ 24-9A-1, -3, -5 (Michie 2003) (prohibiting research on a fetus, defined as the product of conception); N.D. CENT. CODE 14-02.2-01 (2004) (prohibiting research on a fetus “before or after expulsion from its mother’s womb”); 18 PA. CONS. STAT. ANN. §§ 3203, 3216 (West 2000) (prohibiting non-therapeutic research on an unborn child, defined as a human from fertilization until live birth); R.I. GEN. LAWS § 11-54-1 (2002) (prohibiting research on a live fetus, defined to include an embryo); S.D. CODIFIED LAWS §§ 34-14-16 to -20 (Michie 2004) (prohibiting research on an embryo, defined to include *in vitro* embryos from the single-celled stage); UTAH CODE ANN. § 76-7-310 (2003) (prohibiting research on live unborn children; held unconstitutionally vague in *Jane L. v. Bangerter*, 61 F.3d 1493, 1502 (10th Cir. 1995)); WIS. STAT. ANN. § 940.04 (West 1996 & Supp. 2004) (prohibiting destruction of an unborn child, defined as a human being from conception until live birth).

156. See *supra* note 137.

157. See George J. Annas, *The Shadowlands: The Regulation of Human Reproduction in the United States*, in CROSS CURRENTS: FAMILY LAW AND POLICY IN THE UNITED STATES AND ENGLAND 143, 143 (Sanford N. Katz et al. eds., 2000); REPRODUCTION & RESPONSIBILITY, *supra* note 142, at 8-12.

158. See, e.g., Robertson, *Procreative Liberty*, *supra* note 54, at 427.

159. See, e.g., *Guidelines Sought on Fertilization*, N.Y. TIMES, Aug. 9, 1984,

The history of IVF provides another explanation for the lack of federal government involvement. In the late 1970s, the Carter administration appointed an Ethics Advisory Board to consider issues of research involving human IVF. Federally funded embryo research had to be reviewed by the Board before it could proceed.<sup>160</sup> The Board issued a report on May 4, 1979, concluding that it was acceptable from an ethical standpoint to undertake and fund research involving human IVF and embryo transfer subject to various qualifications.<sup>161</sup> On the moral status of the embryo, the Board concluded that “the human embryo is entitled to profound respect; but this respect does not necessarily encompass the full legal and moral rights attributed to persons.”<sup>162</sup> The Board recommended that a model or uniform law be drafted dealing with the legal status of children born as a result of IVF.<sup>163</sup>

However, the Board’s funding was denied under the Carter, Reagan, and first Bush administrations. Because federally funded research in this area had to be approved by the Board, the lack of Board funding created a *de facto* ban on such research. This Board approval requirement was removed in 1993.<sup>164</sup>

In 1994, the Human Embryo Research Panel, an advisory panel within the National Institutes for Health, endorsed funding for embryo research as well as embryonic stem cell research.<sup>165</sup> While President Clinton approved the Panel’s overall recommendation on human embryo research, he prohibited the use of federal funding for the creation of embryos to be used in research.<sup>166</sup> However, in 1995 and subsequent years, Congress has attached a rider to its appropriations bill, effectively precluding *all* funding for

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at D23; *Pressure to Regulate In Vitro Fertilization Grows as Demand Rises*, N.Y. TIMES, July 28, 1988, at B7.

160. 45 C.F.R. § 46.204(d) (1993).

161. Report and Conclusions: HEW Support of Research Involving Human In Vitro Fertilization and Embryo Transfer, 44 Fed. Reg. 35,033, 35,056 (June 18, 1979).

162. *Id.*

163. *Id.* at 35,058.

164. National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, § 121, 107 Stat. 122, 133 (1993).

165. 1 NAT’L INSTITUTES OF HEALTH, REPORT OF THE HUMAN EMBRYO RESEARCH PANEL xvi – xviii (1994).

166. See John Schwartz & Ann Devroy, *Clinton to Ban U.S. Funds For Some Embryo Studies*, WASH. POST, Dec. 3, 1994, at A1.

embryo research by the NIH.<sup>167</sup> The debate has since moved on to questions involving embryonic stem cell research.<sup>168</sup>

It is both the lack of legislative intervention and private nature of IVF practice and research that gives the area a “Wild West” image.<sup>169</sup> The National Conference of State Legislatures, for example, complains, “[A] substantial portion of research and innovative therapy in reproductive medicine need not be subject to peer review, may not conform to current standards for informed consent, and may be offering services that have never been fully evaluated for safety and efficiency.”<sup>170</sup> Jonathan Von Blerkom, co-director of the Reproductive Genetics In Vitro, a Denver clinic, similarly commented that “[t]hings are done in this field that would never, ever be done in any other field of medicine without review or without big studies that look at efficacy or safety.”<sup>171</sup>

The only direct federal regulation of IVF is found in the Fertility Clinic Success Rate and Certification Act of 1992,<sup>172</sup> which effectively came into operation in 1996, when the Department of Health and Human Services began to fund its implementation.<sup>173</sup> There are two parts to this Act—reporting and certification. The reporting requirement, which is now in operation, institutes a system of centralized annual reporting on pregnancy success rates.<sup>174</sup> The success rates are published along with a list of clinics that fail to disclose their pregnancy success rates in accordance with the regulations.<sup>175</sup> Not all

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167. See, e.g., Consolidated Appropriations Act, 2004, Pub. L. No. 108-199, § 510 (2004).

168. See Dep’t of Health and Hum. Services, Fact Sheet (July 14, 2004), at <http://www.hhs.gov/news/press/2004pres/20040714b.html> (last visited Feb. 16, 2005).

169. See Alexander N. Hecht, *The Wild Wild West: Inadequate Regulation of Assisted Reproductive Technology*, 1 HOUS. J. HEALTH L. & POL’Y 227, 228 (2001).

170. NAT’L CONF. OF STATE LEGISLATURES, *supra* note 134, at 28.

171. Tracy Weber & Julie Marquis, *In Quest for Miracles, Did Fertility Clinic Go Too Far?*, L.A. TIMES, June 4, 1995, at A1.

172. 42 U.S.C. §§ 263a-1 to -7 (2000).

173. Weldon E. Havins & James J. Dalessio, *The Ever-Widening Gap Between the Science of Artificial Reproductive Technology and the Laws Which Govern that Technology*, 48 DEPAUL L. REV. 825, 844 (1999).

174. 42 U.S.C. § 263a-1; see also Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs, 65 Fed. Reg. 53,310 (Sept. 1, 2000).

175. *Id.* § 263a-5.

clinics comply with the reporting requirement,<sup>176</sup> and the President's Council on Bioethics<sup>177</sup> has suggested stronger penalties for noncompliance.<sup>178</sup> The Act also directs the Secretary of Health and Human Services to develop a model program for the certification of embryo laboratories to be carried out by the states,<sup>179</sup> which was done in 1999.<sup>180</sup> To date, the model program has not been adopted in any state.<sup>181</sup>

IVF clinics are also affected by more general regulations. For example, the Clinical Laboratory Improvement Amendments of 1988 amended the Public Health Service Act<sup>182</sup> to require the certification of "laboratories," which includes facilities that examine "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings."<sup>183</sup> ART facilities are not covered by this definition, but the Act does apply to andrology and endocrinology tests performed at these facilities.<sup>184</sup> Requirements under the Act are confined to issues of quality control, and states may obtain an exemption from the Act if they adopt more stringent laboratory certification requirements.<sup>185</sup> The Food and Drug Administration also exercises jurisdiction over facilities donating, processing, or storing of sperm, ova, and embryos through its power to

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176. In the report for 2002, 391 clinics reported data in compliance with the Act, and 37 clinics were listed as non-reporting (meaning that their data were not reported or that verification was not provided by the clinic medical director). See CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 23, at 5-6, 509-10.

177. The President's Council on Bioethics is a Presidential advisory committee established by Pres. George W. Bush under the Federal Advisory Committee Act "to advise the President on bioethical issues that may emerge as a consequence of advances in biomedical science and technology." Exec. Order No. 13,237, 66 Fed. Reg. 59,851 (Nov. 28, 2001).

178. REPRODUCTION & RESPONSIBILITY, *supra* note 142, at 210-14.

179. 42 U.S.C. § 263a-2.

180. 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, 39,382 (July 21, 1999).

181. REPRODUCTION & RESPONSIBILITY, *supra* note 142, at 50.

182. Pub L. No. 100-578, 102 Stat. 2903 (codified as amended at 42 U.S.C. § 263a (2000)).

183. 42 U.S.C. § 263a(a).

184. REPRODUCTION & RESPONSIBILITY, *supra* note 142, at 63. However, these tests are not covered by the Act when undertaken as an adjunct to the performance of ART services. *Id.*

185. 42 U.S.C. § 263a(p)(2).

prevent the spread of communicable disease and its power to regulate drugs, devices and biological products.<sup>186</sup> In addition, the manufacture of certain devices related to the practice of IVF is regulated.<sup>187</sup>

Various bodies have considered legislative responses to issues raised by IVF and other reproductive technologies. The now defunct Office of Technology Assessment published *Infertility: Medical and Social Choices* in 1988, setting out issues raised by the technology.<sup>188</sup> More recent official analyses of the issues related to reproductive technologies can be found in the work of the President's Council on Bioethics. Although all of the reports issued by the President's Council touch on issues related to the practice of IVF,<sup>189</sup> the most relevant is the recent report entitled *Reproduction & Responsibility: The Regulation of New Biotechnologies*.<sup>190</sup> The New York State Task Force on Life and the Law has also issued an influential report.<sup>191</sup>

The absence of formal government regulation does not mean that IVF is necessarily the Wild West of medicine. Various professional groups have imposed extra-legal standards relating to professional qualifications and the manner in which procedures ought to be carried out, as well as opinions on what is and is not acceptable. The bodies that currently articulate standards for the practice of IVF in the United States are:

**-American Medical Association (AMA).** The AMA's House of Delegates maintains a code of conduct consisting in part of nine Principles of medical ethics.<sup>192</sup> In addition, the

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186. See Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. 5447, 5452-53 (Jan. 19, 2001).

187. 21 C.F.R. §§ 884.6100-.6190 (2004).

188. See Princeton Office of Technology Assessment Website, at <http://www.wws.princeton.edu/~ota/> (last visited Mar. 21, 2005), [http://www.wws.princeton.edu/~ota/ns20/alpha\\_f.html](http://www.wws.princeton.edu/~ota/ns20/alpha_f.html) (last visited Mar. 21, 2005) (describing the legacy of the OTA and providing the text of the report).

189. See, e.g., PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY (2002); PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH (2004); PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 74.

190. REPRODUCTION & RESPONSIBILITY, *supra* note 142.

191. N.Y. STATE TASK FORCE ON LIFE AND THE LAW, ASSISTED REPRODUCTIVE TECHNOLOGIES: ANALYSIS AND RECOMMENDATIONS FOR PUBLIC POLICY 170 (1998).

192. AM. MED. ASSOC., PRINCIPLES OF MEDICAL ETHICS, *available at*

AMA's Council on Ethical and Judicial Affairs publishes its current opinions on how the code applies to specific issues in medicine.<sup>193</sup> These include opinions relevant to the field of reproductive medicine.<sup>194</sup>

**-American Society for Reproductive Medicine (ASRM), formerly the American Fertility Society.** ASRM describes itself as a voluntary, non-profit organization established "for the advancement of the art, science, and practice of reproductive medicine."<sup>195</sup> The Practice Committee and Ethics Committee of the ASRM issue guidelines on particular topics.<sup>196</sup> None of these are mandatory, although they are very influential. The ASRM has also adopted a Reproductive Laboratory Accreditation Program in conjunction with the College of American Pathologists.<sup>197</sup>

**-Society for Assisted Reproductive Technology (SART).** SART describes itself as "the premiere organization of professionals dedicated to the practice of ARTs in the United States."<sup>198</sup> SART has 370 members, representing over 95% of clinics practicing ART.<sup>199</sup> SART members must report their success rates annually in accordance with federal law (in fact, they have been required to report their success rates since 1987),<sup>200</sup> allow inspections, and run or use accredited

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<http://www.ama-assn.org/ama/pub/category/2512.html> (last visited Mar. 20, 2005).

193. See Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions*, at <http://www.ama-assn.org/ama/pub/category/4325.html> (last visited Feb. 4, 2005).

194. See E-2.055: Ethical Conduct in Assisted Reproductive Technology, at <http://www.ama-assn.org/ama/pub/category/4325.html> (last visited Jan. 20, 2005).

195. ASRM Website, at <http://www.asrm.org/mission.html> (last visited Feb. 3, 2005).

196. See *id.*, at <http://www.asrm.org/Media/Practice/practice.html> (last visited Feb. 4, 2005), <http://www.asrm.org/Media/Ethics/ethicsmain.html> (last visited Feb. 4, 2005).

197. See College of American Pathologists Website, at [http://www.cap.org/apps/docs/laboratory\\_accreditation/lap\\_info/specialty.html](http://www.cap.org/apps/docs/laboratory_accreditation/lap_info/specialty.html) (last visited Mar. 29, 2005).

198. SART Website, at <http://www.sart.org/whatis.html> (last visited Jan. 20, 2005).

199. *Id.*

200. See Med. Research Int'l et al., *In Vitro Fertilization / Embryo Transfer in the United States: 1987 Results from the National IVF-ET Registry*, 51 FERTILITY & STERILITY 13 (1989). There are also retrospective reports for 1985 and 1986. Med. Research Int'l & Am. Fertility Soc'y Special Interest Group, *In Vitro Fertilization / Embryo Transfer in the United States: 1985 and 1986 Results from the National IVF/ET Registry*, 49 FERTILITY & STERILITY 212

embryology laboratories. Members of SART are also obliged to comply with ASRM and SART guidelines, with loss of membership as the penalty for non-compliance. As of 2001, this penalty had never been imposed.<sup>201</sup> SART also organizes the National Coalition for Oversight of Assisted Reproductive Technology, which brings together representatives from various government agencies and professional, legal, and consumer groups to discuss mutual issues.<sup>202</sup>

**-American College of Obstetricians and Gynecologists (ACOG).** Although IVF practitioners need not join ACOG, many choose to join both ACOG and the Society for Reproductive Endocrinology and Infertility, an organization comprised of practitioners certified by the American Board of Gynecologists in Obstetrics and Gynecology and the subspecialty of Reproductive Endocrinology.<sup>203</sup> Membership in these organizations is limited to those satisfying certain professional requirements.<sup>204</sup> Those who do join ACOG may be expelled for failure to comply with ACOG's rules and ethical guidelines.<sup>205</sup>

Although compliance with ASRM, SART, and ACOG standards is not generally compulsory, it may be required in particular circumstances. Some health insurance contracts that cover the cost of IVF for patients, for example, limit coverage to IVF performed by members of organizations such as SART or to procedures complying with guidelines issued by ACOG or ASRM. The reason for this limitation can often be found in state insurance requirements.<sup>206</sup> However, a person with resources and the willingness to travel can obtain treatment deemed unethical by the relevant professional societies. Also, many of the guidelines are themselves worded

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(1988).

201. Howard W. Jones, Jr. & Jean Cohen, *IFFS Surveillance* 01, 76 FERTILITY & STERILITY S5, S10 (2001).

202. SART Website, at <http://www.sart.org/whatis.html> (last visited Jan. 20, 2005).

203. See SREI Website, at <http://www.socrei.org/> (last visited Feb. 17, 2005).

204. See *id.*; ACOG Website, at [http://www.acog.org/departments/dept\\_notice.cfm?recno=22&bulletin=2635](http://www.acog.org/departments/dept_notice.cfm?recno=22&bulletin=2635) (last visited Feb. 17, 2005).

205. See ACOG Website, at [http://www.acog.org/from\\_home/acogcode.pdf](http://www.acog.org/from_home/acogcode.pdf) (last visited Feb. 17, 2005).

206. Hawaii, Illinois, Maryland, New Jersey, and Texas all limit their insurance requirements to services provided at clinics complying with professional codes of practice. See *supra* note 137.



as advice rather than mandatory requirements.<sup>207</sup> The President's Council on Bioethics has recommended strengthening the enforcement of such professional requirements.<sup>208</sup>

#### B. UNITED KINGDOM

The United Kingdom was where the first IVF child was born, and it was among the first countries to consider the ethical and legal implications of IVF. Policies were devised by the Medical Research Council as early as March 1979.<sup>209</sup> In July of 1982, the Committee of Inquiry into Human Fertilisation and Embryology was commissioned.<sup>210</sup> Its charge was to consider recent and potential developments in medicine and science related to human fertilization and embryology; to consider what policies and safeguards should be applied, including consideration of the social, ethical, and legal implications of these developments; and to make recommendations.<sup>211</sup> Dame Mary Warnock was appointed chair of the Committee and its final report, published in July 1984, became known as the Warnock Report.<sup>212</sup> While the Report was being prepared, other organizations offered guidelines.<sup>213</sup> The Warnock Report concluded that IVF was an acceptable technique that had passed the research stage and become an "established form of treatment for infertility."<sup>214</sup> It recommended the establishment of a statutory licensing scheme for IVF practitioners, to be administered by a statutory authority.<sup>215</sup> As an interim measure, in 1985 the Medical Research Council and the Royal College of Obstetricians and Gynecologists formed a Voluntary Licensing Authority (from

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207. REPRODUCTION & RESPONSIBILITY, *supra* note 142, at 186.

208. *Id.* at 192.

209. See GUNNING & ENGLISH, *supra* note 3, at 15.

210. Warnock Report, *supra* note 98, at 1.2.

211. *Id.*

212. See *id.*

213. See Med. Research Council (UK), *Research Related to Human Fertilisation and Embryology*, 285 BRIT. MED. J. 1480 (1982); British Med. Ass'n, Working Group on In Vitro Fertilization and Embryo Replacement and Transfer, *Interim Report on Human In Vitro Fertilisation and Embryo Replacement and Transfer*, 286 BRIT. MED. J. 1594 (1983); Royal Coll. of Obstetricians and Gynaecologists, *Report of the RCOG Ethics Committee on In Vitro Fertilization and Embryo Replacement or Transfer* (1983), discussed in GUNNING & ENGLISH, *supra* note 3, at 27-31.

214. Warnock Report, *supra* note 98, at 5.15.

215. *Id.* at 13.3.

1989, renamed the Interim Licensing Authority) to regulate the practice of IVF, including licensing IVF centers.<sup>216</sup> The Warnock Report was debated in the House of Commons and House of Lords soon after its release,<sup>217</sup> but it was not until December 1986 that the government published a Consultative Paper,<sup>218</sup> followed by a White Paper in November 1987.<sup>219</sup>

The Human Fertilisation and Embryology Act 1990 ("UK Act"),<sup>220</sup> which largely implemented the recommendations in the Warnock Report, was introduced in 1989, passed by a free vote, and received Royal Assent a year later. The UK Act creates three levels of control over IVF and other reproductive technologies.<sup>221</sup> The first level, the Act itself, directly prohibits certain procedures, namely keeping or using an embryo after the appearance of the primitive streak,<sup>222</sup> placing a human embryo in an animal, and replacing the nucleus of the cell of an embryo.<sup>223</sup> It also instructs practitioners to take account of the interests of the child to be born, including its need for a father, and to offer counseling.<sup>224</sup> The second level consists of regulations promulgated by the Secretary of State for Health which, depending on the subject area, either must be placed before Parliament and subjected to the possibility of annulment, or else must receive positive parliamentary approval.<sup>225</sup> The third level covers the responsibilities of the

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216. Frances Price, *Establishing Guidelines: Regulation and the Clinical Management of Infertility*, in BIRTHRIGHTS: LAW AND ETHICS AT THE BEGINNING OF LIFE 37, 38-39 (Robert Lee & Derek Morgan eds., 1989).

217. See Douglas Cusine, NEW REPRODUCTIVE TECHNOLOGIES: A LEGAL PERSPECTIVE 193-96 (1988).

218. See LEGISLATION ON HUMAN INFERTILITY SERVICES AND EMBRYO RESEARCH: A CONSULTATION PAPER, 1986, Cm. 46. This paper suggested three alternatives for the control of IVF and related research: (1) a statutory authority as recommended in the Warnock Report; (2) licenses issued by the Secretary of State for Health, as suggested by some pro-life groups; and (3) self-regulation, along the lines of the Voluntary Licensing Authority. See *id.* at 9-13.

219. See DEP'T OF HEALTH AND SOC. SEC., HUMAN FERTILISATION AND EMBRYOLOGY: A FRAMEWORK FOR LEGISLATION, 1987, Cm. 259.

220. Human Fertilisation & Embryology Act (UK Act), 1990 (U.K.).

221. See *R (Quintavalle) v. Secretary of State for Health*, [2003] 2 W.L.R. 692 at [4].

222. Deemed to have occurred before the "end of the period of 14 days beginning with the day the gametes are mixed, not counting any time during which the embryo is stored." UK Act § 3(4).

223. See *id.* §§ 3(3)(b), (d).

224. See *id.* §§ 13(5), (6).

225. See *id.* § 45.

Human Fertilisation and Embryology Authority (HFEA), a non-departmental public body<sup>226</sup> reporting to the Secretary of State for Health. The members of HFEA are appointed in accordance with the requirements set out in Schedule One of the UK Act.<sup>227</sup> These provisions are designed to ensure that HFEA includes, but is not controlled by, medical practitioners and those involved in the infertility industry.<sup>228</sup> HFEA's role is to license clinics and research centers, including imposing license conditions, to advise the Secretary of State if called upon, to issue directions on certain matters, and to prepare and update a Code of Practice.<sup>229</sup> The Secretary of State and Parliament have some opportunity to monitor HFEA's activities: the Secretary and Parliament are presented with an annual report<sup>230</sup> as well as an auditor's report,<sup>231</sup> and the Code of Practice must be approved by the Secretary of State and laid before Parliament.<sup>232</sup>

The UK Act regulates IVF by limiting what activities may be licensed and controlling the behavior of licensees. It provides for three categories of licenses—treatment, research, and storage.<sup>233</sup> An application for a license is handled by a licensing committee, which is a subcommittee of HFEA.<sup>234</sup> An application for a license is followed by an inspection of the premises.<sup>235</sup> Interim inspections continue to take place annually with additional spot checks, and the license must be renewed every three years.<sup>236</sup> It is possible to appeal to HFEA from the decision of a licensing committee on the merits,<sup>237</sup> and there is also the possibility of judicial review to correct an error of law.<sup>238</sup>

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226. HFEA is nominally independent of the public service but relies upon government funding.

227. *See id.* § 5; *see also id.* sch. 1, para. 4.

228. *See id.* sch. 1, para. 4.

229. *See* UK Act, §§ 8, 9, 11, 23, 25.

230. *See id.* § 7(1).

231. *See id.* § 6(3).

232. *See id.* § 26(4).

233. *See id.* § 11.

234. *See id.* § 9.

235. *See* UK Act § 9(7).

236. *See* HUMAN FERTILISATION AND EMBRYOLOGY AUTH., THIRTEENTH ANNUAL REPORT AND ACCOUNTS 2003/04, at 7 (2004), *available at* <http://www.hfea.gov.uk/HFEAPublications/AnnualReport/> (last visited Mar. 28, 2005).

237. *See* UK Act § 20.

238. *See id.* § 21.

The first Code of Practice was published in 1991, with subsequent editions in 1993, 1995, 1998, 2001, and 2003 (the sixth edition came into effect in March 2004). These revisions were necessary to address practical problems, new procedures, new information, and changing legal requirements.<sup>239</sup> Section 25(6) of the UK Act provides that, although a failure to observe a provision of the Code of Practice does not create liability, it may be taken into account by a licensing committee considering whether there has been a failure to comply with the conditions of a license or whether a license ought to be varied or revoked.

The current edition of the Code includes both requirements and statements of proper conduct.<sup>240</sup> Breaches of the Code must be promptly reported to HFEA.<sup>241</sup> The Code of Practice is significantly more detailed than the Voluntary Licensing Authority guidelines it replaced.<sup>242</sup> According to a survey published in 1994, clinics are generally satisfied with the system of licensing and the Code of Practice.<sup>243</sup>

The Public Health Minister announced in January 2004 that the Department of Health will begin to review the UK Act, followed by full public consultation in 2005.<sup>244</sup> The reasons given for the review included the need to ensure that “the Act remains effective in the 21st century,” and was said to be in response to, *inter alia*, new procedures and technologies as well as changing public perceptions of assisted reproduction.<sup>245</sup> It is likely that HFEA will eventually be merged with the Human Tissue Authority, as established under the Human Tissue Act

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239. Lynn Hagger, *The Role of the Human Fertilisation and Embryology Authority*, 3 MED. L. INT'L 1, 5-6 (1997).

240. See HUMAN FERTILISATION AND EMBRYOLOGY AUTH., CODE OF PRACTICE 12 (6th ed. 2003).

241. See *id.* para. 2.25.

242. The first Code of Practice was forty pages, compared with four pages of guidelines. See GUNNING & ENGLISH, *supra* note 3, at 116.

243. See B.A. Lieberman et al., *The UK Human Fertilisation and Embryology Act 1990 – How Well is it Functioning?*, 9 HUM. REPROD. 1779, 1779 (1994) (73% of clinics reported that they were satisfied with the system of licensing and 78% felt that the Code of Practice was working well).

244. DEP'T OF HEALTH, REVIEW OF THE HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990 (2004), available at [http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/AssistedConception/AssistedConceptionGeneralInformation/AssistedConceptionGeneralArticle/fs/en?CONTENT\\_ID=4069149&chk=MSMizC](http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/AssistedConception/AssistedConceptionGeneralInformation/AssistedConceptionGeneralArticle/fs/en?CONTENT_ID=4069149&chk=MSMizC) (last visited Jan. 31, 2005).

245. *Id.*

2004.<sup>246</sup>

Professional organizations in the United Kingdom also have a role in monitoring the practice of IVF and related technologies. For example, the Association of Clinical Embryologists, representing over 90% of embryologists in the UK,<sup>247</sup> maintains a Code of Conduct, and members are required to sign a form stating their willingness to comply.<sup>248</sup> The Code contains laudable, but general, goals such as safeguarding patient interests and exercising due care.<sup>249</sup> Non-compliance with the code may constitute professional misconduct and entail loss of registration as a clinical embryologist. The Royal College of Obstetricians and Gynaecologists also publishes clinical guidelines on the assessment and treatment of infertility problems.<sup>250</sup> This offers advice on what are best practices, but does not constitute a mandatory code.<sup>251</sup> Presumably because of extensive government regulation, professional bodies have been less involved in the oversight of IVF in the United Kingdom than in the United States and Australia.<sup>252</sup>

### C. NEW SOUTH WALES, AUSTRALIA

Like the United States, Australia has a federal system in which the regulation of medical practice is generally left to the states. Jurisdiction over the determination of parental rights is split, with the federal government having power to determine such rights only in the context of divorce or matrimonial causes.<sup>253</sup> Determination of parental rights for all purposes

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246. Human Tissue Act, 2004 (U.K.); HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY, *supra* note 236, at 12.

247. Press Release, Association of Clinical Embryologists, *available at* <http://ace.ivf.net/ace/press.php> (last visited Jan. 31, 2005).

248. ASS'N OF CLINICAL EMBRYOLOGISTS, CODE OF PROFESSIONAL CONDUCT FOR CLINICAL EMBRYOLOGISTS (2d ed. 2003), *available at* <http://www.ace.ivf.net/ace/coc2004.doc> (last visited Jan. 31, 2005).

249. *See id.*

250. NAT'L COLLABORATING CTR. FOR WOMEN'S AND CHILDREN'S HEALTH, CLINICAL GUIDELINE, FERTILITY – ASSESSMENT AND TREATMENT FOR PEOPLE WITH FERTILITY PROBLEMS (Feb. 2004), *available at* [http://www.rcog.org.uk/resources/Public/Fertility\\_full.pdf](http://www.rcog.org.uk/resources/Public/Fertility_full.pdf) (last visited Jan. 31, 2005).

251. *See id.* at 1.

252. *See* Martin H. Johnson, *Should the Use of Assisted Reproduction Techniques be Deregulated?: The UK Experience: Options for Change*, 13 HUM. REPROD. 1769, 1774-75 (1998).

253. *See* AUSTL. CONST. ch. 1, pt. V, § 51(xxii).

therefore requires both state and federal legislation. The federal Family Law Act includes a section regarding parentage of children born as a result of artificial conception procedures.<sup>254</sup> The provisions of that section only apply if in accord with state law. In New South Wales, the Status of Children Act 1996 is the relevant law.<sup>255</sup> Reading the two acts together, a child born to a married woman as a result of fertilization procedures such as IVF carried out with the consent<sup>256</sup> of both spouses is presumed to be a child of the woman and her husband.<sup>257</sup> The same applies for co-habiting unmarried heterosexual couples.<sup>258</sup>

There is no comprehensive state regulation of IVF in New South Wales. This is not for lack of consideration. In October 1983, the Attorney General of New South Wales asked the New South Wales Law Reform Commission to inquire into and report on the need to make laws with respect to ART.<sup>259</sup> The Commission issued a Discussion Paper in 1987 and its final report in 1988.<sup>260</sup> Compared to the Warnock Committee in the United Kingdom, the Commission expressed greater confidence in the possibility of professional self-regulation and greater doubt about the benefits of legislative schemes, in part because of their tendency to become “almost immediately obsolete.”<sup>261</sup> The recommended approach was to deal with matters of “fundamental importance” in legislation and to establish an

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254. See Family Law Act, 1975, § 60H (Austl.) (as amended by the Family Law (Amendment) Act, 1987, § 24 (Austl.) inserting § 60H, titled “Children Born as a Result of Artificial Conception Procedures,” into the Family Law Act).

255. See Status of Children Act, 1996 (N.S.W.).

256. Consent is presumed. See *id.* § 14(5); Family Law Act, 1975, § 60H (Austl.).

257. See Status of Children Act, 1996, § 14(1) (N.S.W.); Family Law Act, 1975, § 60H (Austl.).

258. See Status of Children Act, 1996, § 14(6) (N.S.W.); Family Law Act, 1975, § 60H(4) (Austl.).

259. See NEW SOUTH WALES LAW REFORM COMM’N, REP. NO. 58, ARTIFICIAL CONCEPTION: IN VITRO FERTILIZATION xv-xvi (1988), available at <http://www.lawlink.nsw.gov.au/lrc.nsf/pages/R58toc> (last visited Feb. 21, 2005).

260. See *id.*

261. *Id.* at 2.17, 4.1. Similar sentiments were expressed by the then-Law Reform Commissioner. Russell Scott, *Experimenting and the New Biology: A Consummation Devoutly to be Wished*, in 1ST INTERNATIONAL CONFERENCE ON HEALTH LAW AND ETHICS (Sydney 1986), cited in Helen Szoke, *The Nanny State or Responsible Government?*, 9 J.L. & MED. 470, 476 (2002).

independent body that would operate similarly to HFEA.<sup>262</sup> However, no legislation along the lines recommended by the Commission was enacted.

A national approach to regulation was suggested by the Family Law Council of Australia in 1985.<sup>263</sup> The Council suggested establishing a national body to advise federal and state governments as well as the community on the implications of reproductive technologies and develop ethical and practice guidelines.<sup>264</sup> No such body was established, although a National Bioethics Consultative Committee was set up and it produced a number of reports on bioethical issues.<sup>265</sup> Eventually, the Australian Health and Welfare Ministers decided at a joint meeting to transfer responsibility for advising on bioethical issues to the National Health and Medical Research Council (NHMRC), a statutory authority<sup>266</sup> operating as the major funding body for medical research in Australia.<sup>267</sup>

The regulation of IVF is thus left to non-mandatory guidelines. The Fertility Society of Australia began issuing standards for the practice of reproductive medicine in 1986, with the publication of the Code of Practice for Centers using Assisted Reproductive Technology. In 1987, it established the Reproductive Technology Accreditation Committee (RTAC), allocating to it the responsibility for recommending changes in the Code as required, reviewing applications for accreditation, monitoring compliance with the Code, encouraging good practice among clinics, and publishing lists of accredited clinics.<sup>268</sup> Some practices, such as transferring a human

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262. See NEW SOUTH WALES LAW REFORM COMM'N, REP. NO. 58, *supra* note 259, at 4.2-4.10 (1988).

263. See FAMILY LAW COUNCIL OF AUSTRALIA, CREATING CHILDREN: A UNIFORM APPROACH TO THE LAW AND PRACTICE OF REPRODUCTIVE TECHNOLOGY IN AUSTRALIA (1993). The Family Law Council's role is to advise the Attorney-General of Australia on matters related to family law. See Family Law Act, 1975, § 115 (Austl.).

264. See FAMILY LAW COUNCIL OF AUSTRALIA, CREATING CHILDREN: A UNIFORM APPROACH TO THE LAW AND PRACTICE OF REPRODUCTIVE TECHNOLOGY IN AUSTRALIA 107 (1993).

265. H.W. Gordon Baker, *Problems with the Regulation of Assisted Reproductive Technology: A Clinician's Perspective*, 9 J.L. & MED. 457, 468 (2002).

266. See National Health and Medical Research Council Act, 1992 (Austl.).

267. Helen Szoke, *Regulation of Assisted Reproductive Technology: The State of Play in Australia*, in *CONTROVERSIES IN HEALTH LAW* 240, 243 (Ian Freckelton & Kerry Petersen eds., 1999).

268. FERTILITY SOC'Y OF AUSTRALIA, REPRODUCTIVE TECHNOLOGY

embryo to an animal uterus, are described as “not acceptable” in the RTAC Guidelines.<sup>269</sup> RTAC conducts regular audits to monitor compliance with the Guidelines and reviews accreditation periodically (clinics are normally accredited for three years).<sup>270</sup> RTAC also requires that accredited clinics comply with guidelines issued by the NHMRC.<sup>271</sup>

The NHMRC guidelines, like the RTAC guidelines, are not mandatory. The first NHMRC statement on IVF was published in 1982.<sup>272</sup> Following public consultation, the NHMRC published Ethical Guidelines on Assisted Reproductive Technology in 1996.<sup>273</sup> Although focused primarily on research, the Guidelines also addressed innovations in clinical practice, as well as ordinary clinical issues such as consent, counseling, and record-keeping.<sup>274</sup> As in the RTAC guidelines, some practices were described as “ethically unacceptable” and “prohibited.”<sup>275</sup> The NHMRC required that those offering reproductive technology services also obtain accreditation from RTAC and comply with RTAC guidelines. A revised set of guidelines, with greater emphasis on clinical issues, was released in 2004.<sup>276</sup>

In 2002, two federal statutes, the Research Involving Human Embryos Act, 2002 (Austl.) and the Prohibition of Human Cloning Act, 2002 (Austl.), were enacted. They have been either adopted or mirrored in state law. The former Act regulates the use of “excess ART embryos,”<sup>277</sup> and in particular

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ACCREDITATION COMMITTEE, CODE OF PRACTICE FOR CENTRES USING ASSISTED REPRODUCTIVE TECHNOLOGY 4 (2002).

269. *See id.* at 11.

270. *See id.* at 12.

271. *See id.* at 11.

272. NAT'L HEALTH AND MED. COUNCIL, STATEMENT ON HUMAN EXPERIMENTATION, SUPPLEMENTARY NOTE 4: STATEMENT ON IN VITRO FERTILIZATION AND EMBRYO TRANSFER (Sept. 3, 1982).

273. NAT'L HEALTH AND MED. RESEARCH COUNCIL, ETHICAL GUIDELINES ON ASSISTED REPRODUCTIVE TECHNOLOGY (1996), *available at* <http://www.nhmrc.gov.au/rescinded/pdf/e28.pdf> (last visited Apr. 7, 2005).

274. *Id.* at iv.

275. *Id.* at 15.

276. AUSTRALIAN HEALTH ETHICS COMM., NAT'L HEALTH AND MED. RESEARCH COUNCIL, ETHICAL GUIDELINES ON THE USE OF ASSISTED REPRODUCTIVE TECHNOLOGY IN CLINICAL PRACTICE AND RESEARCH, DRAFT FOR PUBLIC CONSULTATION (2004), *available at* <http://www.nhmrc.gov.au/publications/synopses/e56syn.htm> (last visited Apr. 7, 2005).

277. Research Involving Human Embryos Act, No. 145, 2002, § 9 (Austl.), *available at* <http://www.health.gov.au/nhmrc/embryo/pdf/embryact.pdf> (last



research on such embryos.<sup>278</sup> Such use must be licensed unless it is one of a number of specified uses ordinarily carried out in the course of clinical practice.<sup>279</sup> The latter Act prohibits the creation of a human embryo clone for any purpose as well as various other activities, some of which had already been banned.<sup>280</sup>

The cooperation between state and federal governments on legislation relating to cloning and research on embryos was the result of agreement reached by the Council of Australian Governments.<sup>281</sup> This Council also considered the possibility of a uniform approach to the regulation of ARTs.<sup>282</sup> On April 5, 2002, it agreed that national consistency could be achieved largely through the existing reliance on professional self-regulation through RTAC.<sup>283</sup>

Although RTAC accreditation and compliance with RTAC and NHMRC guidelines are not mandatory, there are strong incentives for compliance. For example, only clinics accredited by RTAC can access drugs through the government-funded program<sup>284</sup> and only clinics complying with NHMRC guidelines

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visited Apr. 7, 2005). This term is defined to refer to those embryos created in the course of treatment that beyond the reproductive needs of the woman or couple for whom they were created.

278. Research Involving Human Embryos Act, No. 22, 2003, §§ 3, 5 (Austl., N.S.W.), available at <http://scaleplus.law.gov.au/html/pastereg/3/1783/top.htm> (last visited Apr. 7, 2005).

279. Research Involving Human Embryos Act, No. 145, 2002, § 10 (Austl.), available at <http://www.nhmrc.gov.au/embryo/pdf/embryact.pdf> (last visited Apr. 7, 2005). As discussed in the text accompanying notes 288 and 289 *infra*, some of these activities are only exempt if carried out by an infertility center accredited by RTAC.

280. *Id.* at §§ 13-23; Research Involving Human Embryos Act, No. 22, 2003, §§ 8-18 (Austl., N.S.W.), available at <http://scaleplus.law.gov.au/html/pastereg/3/1783/top.htm> (last visited Mar. 30, 2005); Gene Technology Act, No. 169, 2000, §§ 192B-D (Austl.).

281. The Council of Australian Governments comprises the Prime Minister, the Premier of each state, the Chief Minister of each territory, and the President of the Australian Local Government Association.

282. Communique, Council of Australian Governments' Meeting, June 8, 2001, available at <http://www.coag.gov.au/meetings/080601/index.htm#cloning> (last visited Apr. 7, 2005).

283. Communique, Council of Australian Governments' Meeting, Apr. 5, 2002, Attachment: *Arrangements for Nationally-Consistent Bans on Human Cloning and Other Unacceptable Practices, and Use of Excess Assisted Reproductive Technology (ART) Embryos*, paras. 11-13, available at <http://www.coag.gov.au/meetings/050402/cloning.htm> (last visited Apr. 7, 2005).

284. Szoke, *supra* note 267, at 244.

can receive public research funds.<sup>285</sup> Further, failure to comply with guidelines may have consequences in a tort action or an action for breach of employment contract<sup>286</sup>, and may create adverse publicity.<sup>287</sup> More recently, the Research Involving Human Embryos Act, 2002 (Austl.) has created additional incentives for clinics to obtain RTAC accreditation. For example, the use of excess embryos that are not biologically fit for implantation for diagnostic purposes and the reproductive use of donor embryos are only exempt from the licensing requirements in the Act if carried out by an RTAC-accredited clinic.<sup>288</sup> More importantly, it is an offence to intentionally “use” a human embryo that is not an “excess ART embryo” outside the body of a woman except for a purpose relating to the treatment of a woman carried out by an RTAC-accredited clinic.<sup>289</sup> It is unclear what constitutes “use” of an embryo outside the body of a woman, but if preparing an embryo for transfer to a woman were to constitute “use,” the new law would effectively require that all IVF clinics be accredited by RTAC.<sup>290</sup>

In 2003, the New South Wales Health Department released a draft Assisted Reproductive Technology Bill, following public consultation beginning in 1997.<sup>291</sup> The

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285. National Health and Medical Research Council Act, No. 255, 1992, § 51(3) (Austl.). This provides that recipients of government funds must comply with NHMRC guidelines that relate to the ethical conduct of medical research involving humans. Paragraph 11 of the NHMRC NATIONAL STATEMENT ON ETHICAL CONDUCT IN RESEARCH INVOLVING HUMANS (1999) specifically refers to the NHMRC ETHICAL GUIDELINES ON ASSISTED REPRODUCTIVE TECHNOLOGY (1996).

286. At least where the employment contract requires the employee to comply with NHMRC and/or RTAC guidelines.

287. Loane Skene, *An Overview of Assisted Reproductive Technology Regulation in Australia and New Zealand*, 35 TEX. INT'L L.J. 31, 47-48 (2000).

288. Research Involving Human Embryos Act, No. 145, §§ 10(2)(d), (e) (2002) (Austl.), available at <http://www.nhmrc.gov.au/embryo/pdf/embryact.pdf> (last visited Apr. 7, 2005). These provisions came into force on June 19, 2003. They came into force under New South Wales law on Oct. 1, 2003. N.S.W. Government Gazette No. 154, Sept. 26, 2003, at 9522.

289. Research Involving Human Embryos Act, No. 145, 2002, § 11 (Austl.), available at <http://www.nhmrc.gov.au/embryo/pdf/embryact.pdf> (last visited Apr. 7, 2005).

290. *Id.*

291. NEW SOUTH WALES DEP'T OF HEALTH, DISCUSSION PAPER: REVIEW OF THE HUMAN TISSUE ACT, 1983 (1997), available at <http://www.health.nsw.gov.au/csd/lisb/legislation/artqxd.pdf> (last visited Apr. 7, 2005); NEW SOUTH WALES DEP'T OF HEALTH, CONSULTATION DRAFT BILL: ASSISTED REPRODUCTIVE TECHNOLOGY BILL (Dec. 2003), available at

Department concluded that:

a combination of health professional and private health facility regulation with significant self-regulation, has been effective in respect of many of the clinical aspects of ART. However a range of issues relating to the social and ethical aspects of ART were identified as needing to be addressed through specific legislation.<sup>292</sup>

The draft Bill provides for the registration of practitioners and allows the Director General of the Department of Health to prohibit persons from carrying on a business that provides ART services “if there are reasonable grounds to do so” and, in particular, if the person has breached relevant legislation.<sup>293</sup> There is a separate requirement that treatment be provided by, or under the supervision of, a medical practitioner.<sup>294</sup> Other parts of the Bill deal with surrogacy, infection control standards, the requirement that counseling be made available, the provision of information to patients and gamete donors, requirements for the consent of gamete providers, and establishment of a central gamete donor register to allow gamete donors and their offspring to find out select information about each other.<sup>295</sup>

#### D. VICTORIA, AUSTRALIA

At approximately the same time as the Warnock Committee was considering issues related to reproductive technology in the United Kingdom, a similar committee was considering the same issues in Victoria. Known as the Waller committee,<sup>296</sup> this group worked between May 1982 and August 1984. It issued an interim report in 1982, unanimously agreeing that IVF for married couples with their own gametes was ethically acceptable.<sup>297</sup> The report seemed to take for

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<http://www.health.nsw.gov.au/csd/l1sb> (last visited Apr. 7, 2005).

292. NEW SOUTH WALES DEP'T OF HEALTH, INFORMATION GUIDE, CONSULTATION DRAFT: ASSISTED REPRODUCTIVE TECHNOLOGY BILL, § 1.1 (2003) *available at* <http://www.health.nsw.gov.au/csd/l1sb/legislation/Informationguide.pdf> (last visited Apr. 7, 2005).

293. CONSULTATION DRAFT BILL, *supra* note 291, at pt. 2, div. 1, cls. 7, 59.

294. *Id.* at cl. 11.

295. *Id.* at pts. 2-5.

296. Its official title was the “Committee to Consider the Social, Ethical and Legal Issues Arising from In Vitro Fertilization.”

297. VICTORIAN GOV'T COMM. TO CONSIDER THE SOCIAL, ETHICAL AND LEGAL ISSUES ARISING FROM IN VITRO FERTILISATION: INTERIM REPORT para. 5.5 (Sept. 1982), *reprinted in* PETER SINGER AND DEANE WELLS, MAKING BABIES: THE NEW SCIENCE OF CONTRACEPTION 192-93 (1984).

granted the notion that any restrictions on the practice of IVF ought to be contained in legislation, as opposed to administrative or professional requirements.<sup>298</sup> A second report regarding donor gametes was published in 1983.<sup>299</sup> The third and final report was published in 1984, dealing with further procedures, including cryopreservation of embryos, embryo experimentation, and surrogate motherhood.<sup>300</sup>

In 1984, two companion bills were passed by the Victorian Parliament: the Infertility (Medical Procedures) Act<sup>301</sup> and the Status of Children (Amendment) Act.<sup>302</sup> The latter concerns parentage of children, and corresponds roughly to the equivalent New South Wales provisions.<sup>303</sup> The former, later amended by the Infertility (Medical Procedures) (Amendment) Act, 1987, came into force in stages between 1984 and 1988. This Act was the first legislation regulating IVF and related techniques in the world.<sup>304</sup> It largely followed the recommendations of the Waller committee. The Act prohibited cloning and cross-fertilization between human gametes and animal gametes.<sup>305</sup> IVF itself was permitted, but only if carried out by approved hospitals on married couples<sup>306</sup> who were either infertile or at risk of passing on a genetic disease, consented to the procedure, and received counseling.<sup>307</sup>

298. *Id.* at par. 5.10.2; Louis Waller, *Australia: The Law and Infertility – the Victorian Experience*, in LAW REFORM AND HUMAN REPRODUCTION 17, 20 (Sheila A.M. McLean ed., 1992).

299. VICTORIAN GOV'T COMM. TO CONSIDER THE SOCIAL, ETHICAL AND LEGAL ISSUES ARISING FROM IN VITRO FERTILISATION: REPORT ON DONOR GAMETES IN IVF (Aug. 1983), reprinted in PETER SINGER AND DEANE WELLS, MAKING BABIES: THE NEW SCIENCE OF CONTRACEPTION 194-96 (1984).

300. VICTORIAN GOV'T COMM. TO CONSIDER THE SOCIAL, ETHICAL AND LEGAL ISSUES ARISING FROM IN VITRO FERTILISATION: REPORT ON THE DISPOSITION OF EMBRYOS PRODUCED BY IN VITRO FERTILIZATION (Aug. 1984) reprinted in PETER SINGER AND DEANE WELLS, MAKING BABIES: THE NEW SCIENCE OF CONTRACEPTION 196-97 (1984).

301. Infertility (Medical Procedures) Act, No. 10,163, 1984 (Austl., Vic.).

302. Status of Children Act, No. 8602, 1974 (Austl., Vic.).

303. Current Victorian provisions are in the Status of Children Act, No. 8602, 1974, §§. 10A-10F (Austl., Vic.).

304. Price, *supra* note 216, at 38.

305. Infertility (Medical Procedures) Act, No. 10,163, 1984, §§ 6(1), 6(2) (Austl., Vic.).

306. There was an exception for unmarried, cohabitating heterosexual couples who had already commenced treatment. *Id.* § 3(2). This type of limitation has been held to be contrary to federal anti-discrimination law and therefore invalid. *McBain v. State of Victoria* (2000) 1009 FCA 116, 123.

307. Infertility (Medical Procedures) Act, No. 10163, 1984, §§ 10-13 (Austl., Vic.).

In 1995, a replacement Act was passed, the Infertility Treatment Act.<sup>308</sup> The direct prohibitions in that Act are broader than those in the 1984 Act.<sup>309</sup> It also created mandatory requirements in relation to gamete and embryo storage, record keeping, and confidentiality.<sup>310</sup> As in the earlier legislation, access to IVF was restricted,<sup>311</sup> and consent and counseling were made mandatory.<sup>312</sup> Breach of the Act's requirements can lead to criminal penalties.<sup>313</sup> In addition, the 1995 Act established a system of approvals of those carrying out the procedures and licenses of the premises where the procedures are carried out.<sup>314</sup>

The 1995 Act also established the Infertility Treatment Authority (ITA) to administer the licensing and approvals systems under the Act, including formulating license conditions.<sup>315</sup> One licensing condition imposed by ITA is a requirement that licensed centers be accredited by RTAC.<sup>316</sup> The licensing process is undertaken simultaneously with the RTAC accreditation process; RTAC addresses technical, scientific, and clinical matters and the ITA looks at legal compliance.<sup>317</sup>

Compared to the regime in the United Kingdom, however, the Minister of Health and the ITA have relatively little power to keep the legislation up to date. In Victoria, regulations must relate to one of a number of topics itemized in the Act.<sup>318</sup> The regulations power in the United Kingdom is broader; for example, regulations can prohibit or require licenses for conduct not mentioned in the Act.<sup>319</sup>

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308. Infertility Treatment Act, No. 63, 1995 (Austl., Vic.).

309. *Id.* at pt. 5, div. 1.

310. *Id.* at pt. 5, div. 2, and pt. 7.

311. *Id.* at pt. 8.

312. *Id.* at pt. 8, div. 2 and pts. 9, 11. Additional consent requirements exist when donor gametes are used.

313. *Id.* at pt. 8, div. 5 (establishes that violations result in "480 penalty units or 4 years imprisonment or both").

314. Infertility Treatment Act, pt. 8.

315. *Id.* at pt. 9, div. 1.

316. INFERTILITY TREATMENT AUTH., CONDITIONS FOR LICENCE: APPLICATIONS FOR LICENCES BY HOSPITALS AND DAY PROCEDURE CENTRES 2.1 (5th ed. 2004), available at <http://www.ita.org.au> (last visited Apr. 7, 2005) (referring to provisions of section 93 of the Infertility Act (1995)).

317. INFERTILITY TREATMENT AUTH., ANNUAL REPORT 2004, at 9, available at <http://www.ita.org.au> (last visited Apr. 7, 2005).

318. See Infertility Treatment Act, No. 63, 1995, pt. 13, § 165 (Austl., Vic.).

319. Human Fertilisation & Embryology Act (UK Act), 1990, §§ 3(3)(c),

## E. TYPES OF RESPONSES

Each of the jurisdictions discussed here has adopted a different response to the issues raised by IVF. Throughout most of the United States, there is little legislation aimed at controlling the practice of IVF. Federal legislation is primarily used to correct perceived market flaws, for example by centralizing the collection of information and comparing the performance of IVF clinics.<sup>320</sup> A few states, such as Louisiana, New Hampshire, New Mexico, and Virginia have laws prescribing the manner in which IVF procedures must be carried out.<sup>321</sup> More pervasive than legislation are guidelines provided by professional associations. New South Wales is similar, except that there are greater pressures on clinics to comply with RTAC guidelines.

Two jurisdictions, the United Kingdom and Victoria, have introduced legislation with the goal of regulating IVF. A significant difference between the two Acts is the extent to which the legislature intends its instructions to apply directly to private parties, rather than through an administrative body.<sup>322</sup> The UK Act contains a broader regulations power and grants more discretion to HFEA.

The legal uncertainties arising with the introduction of IVF have also been dealt with differently in each jurisdiction. In some parts of the United States, for example, there are laws clarifying who may exercise control over embryos, parentage of an IVF child, and the circumstances in which an IVF child can inherit.<sup>323</sup> The overall result is patchy, with some jurisdictions resolving issues legislatively, and most other jurisdictions relying on the courts to resolve the issues as they arise. In Australia, issues surrounding parentage of IVF children are resolved for some, but not all, situations and many new

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4(2)-(4), sch. 2, para. 1(g) (U.K.).

320. On the use of compulsory reporting as a form of regulation in the health care context, see generally William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701 (1999).

321. See *supra* notes 143, 144, 153 and accompanying text.

322. Edward L. Rubin, *Law and Legislation in the Administrative State*, 89 COLUM. L. REV. 369, 381 (1989) (Rubin explains that “within the category of external statutes [statutes addressing the behavior of private parties], there is an enormous variation in the extent to which the legislation specifies the effects on private parties that it wants the implementation mechanism to produce.”).

323. See *supra* notes 143-155 and accompanying text.

questions remain unanswered. The United Kingdom has sought to resolve uncertainties surrounding parentage, inheritance and control of embryos by legislation.

#### IV. COMPARATIVE INSTITUTIONAL ANALYSIS

As a result of decisions made at the legislative level, the regulation of IVF and the resolution of uncertainties arising in its wake have taken place in different institutions in each of the jurisdictions described in Part III above. Thus legislatures, administrative agencies, professional societies, and courts have had different roles in determining how IVF is practiced and in answering legal questions posed by IVF-related conduct.

Various schools of thought have emerged on the proper role of legislators, administrators, and judges in the development of the law. The "legal process" school attempted to document the function of each institution in the legal system based on its area of competence.<sup>324</sup> Although this movement has fallen out of favor following criticism from law and economics and critical legal studies scholars, the idea of comparing decisional institutions has not.<sup>325</sup>

Nevertheless, in the context of urging the law to adapt to technological change, comparisons between institutions are usually made fleetingly and are overwhelmed by the substantive issue. Thus, the discovery and use of a new product or process is frequently followed by commentary identifying new ambiguities or criticizing the content or scope of existing law.<sup>326</sup> Rarely is there any detailed discussion of the means by which the law ought to be changed, and proposals for reform usually assume that legislation or the establishment of an administrative body provide the best means of resolving the problem identified.

At least one commentator has observed that legislative reform can sometimes cause as much harm as good. In his book, *Limits*,<sup>327</sup> Roger Dworkin undertook a detailed

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324. See generally HENRY M. HART, JR. & ALBERT M. SACKS, *THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATION OF LAW* (William N. Eskridge & Phillip P. Frickey eds., 1994) (tentative edit., 1958).

325. See Edward L. Rubin, *Commentary: The New Legal Process, the Synthesis of Discourse, and the Microanalysis of Institutions*, 109 HARV. L. REV. 1393, 1403-04 (1996). See also Cass R. Sunstein & Adrian Vermeule, *Interpretation and Institutions*, 101 MICH. L. REV. 885, 915 (2003).

326. See *supra* notes 33-39 and accompanying text.

327. ROGER B. DWORKIN, *LIMITS: THE ROLE OF THE LAW IN BIOETHICAL*

comparison of legal responses to bioethical questions in the rapidly advancing fields of biology and medicine.<sup>328</sup> Dworkin explored the dangers of relying on constitutional law or legislation rather than allowing time for common law evolution in response to bioethical issues such as those arising out of sterilization techniques, assisted reproduction, and the availability of genetic information. He concluded that “[g]iven our present legal institutions and any that seem likely to emerge, the soundest response to a social issue posed by biomedical advance is to begin by assuming that no legal response is necessary” and that “[i]f a legal response to a problem is necessary, the common law should be the presumptive first-line response.”<sup>329</sup> The legislature and government should only intervene where “a *real* problem exists that the common law is demonstrably incapable of dealing with.”<sup>330</sup>

Dworkin’s conclusions are expressed broadly, encompassing all the temptations that a government might have to intervene. However, it is not that simple. For a start, legislation, the common law, and the market are “imperfect alternatives”; each has disadvantages that make it unsuitable in some situations.<sup>331</sup> Further, it is not necessarily the case that the same institution provides the best solution for each of the four types of challenge the law faces following technological change. Nevertheless, there are some general factors to consider in evaluating the capacity of different institutions to resolve the sorts of problems brought about by technological change.

#### A. PARTICIPATION AND INTEREST GROUP CONFLICT

Any claim that the law needs to change in a particular way following technological change is contestable. Part II explained how technological change can generate reasons to implement a ban, regulate new practices, resolve uncertainty, repeal existing rules, or alter the scope of existing rules. Whether these reasons will persuade and override arguments that change is unnecessary or counterproductive will depend on the

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DECISION MAKING (1996).

328. *See generally id.*

329. *Id.* at 169-170.

330. *Id.* at 170.

331. *See generally* NEIL KOMESAR, IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY (1994).



specifics. Various scholars are likely to take different positions on whether and how the law ought to adapt. In the real world, interest groups will inevitably take different positions.

For example, the possibility of IVF raises the question of whether it ought to be banned, restricted, discouraged, or encouraged with government funds. At least in the 1970s and 1980s, arguments were made in favor of each of these positions, and these arguments appealed to different social groups. Some religious conservatives supporting a ban on IVF expounded arguments against unnatural reproduction and destruction of embryos; radical feminists generally came down on the same side, but for different reasons; libertarians favored non-interference; and other groups, such as the infertile and infertility specialists had a more personal interest in the debate.

Where a new technology challenges interests or values, some or all groups may seek to bring their arguments to the attention of legislators. Where the issue at stake is within the power of an administrative agency or a court, individuals and groups with a personal or philosophical stake may, to the extent permitted, present their views to that body. It is therefore impossible to compare institutions without considering the manner in which they are likely to be influenced by competing interest groups.

The influence of different interest groups is difficult to measure precisely. In general, however, the greater the participation by people with a particular viewpoint in a decision-making process, the more likely it is that viewpoint will prevail.<sup>332</sup> This is because all decision-making processes rely, directly or indirectly, on the involvement of outsiders for their information. The effect of participation on outcomes is perhaps even stronger when the subject matter is technical; in such cases, decision-makers rely heavily on the expertise of others. Scientific and technical explanations can themselves become powerful vehicles for advocacy, the seeming objectivity often disguising the biases of the author.<sup>333</sup> When those with expertise have a particular viewpoint, or only one viewpoint is represented in the technical material submitted to and

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332. *Id.* at 54-56.

333. See, e.g., Dorothy Nelkin, *Science, Technology, and Political Conflict: Analyzing the Issues*, in *CONTROVERSY: THE POLITICS OF TECHNICAL DECISIONS* 9, 17 (Dorothy Nelkin ed., 2d ed. 1984) (explaining that expert opinions in an area of controversy are often related to political values).

considered by the decision-maker, the impact can be substantial.

People are more likely to participate in politics or court proceedings if their interest in the outcome is sufficiently high to make it worth the investment of time. In the case of politics, perspectives are more likely to be presented and considered if represented by a group that is sufficiently active and collectively powerful to attract the interest of politicians. When the members of a large, diverse group each have only a small interest in the outcome, generally only the intervention of a catalytic subgroup will create the momentum needed to facilitate political influence.<sup>334</sup> When a majority becomes actively interested in an issue, however, its sheer size gives it significant political influence.<sup>335</sup> Thus interest group participation can lead to minoritarian or majoritarian bias.<sup>336</sup>

Because courts and legislators rely on different sources for information and ask different types of questions, they may reach different conclusions as to what the law ought to be. Because legislators are less confined in the range of considerations they may take into account, they can be strongly influenced by interest group pressures. Political decisions will be biased towards groups that are organized and politically powerful. Courts, on the other hand, will be strongly influenced by the position of the parties presenting the issue to the court. Those with an interest in the outcome who are *not* parties to the proceedings in which an issue is raised are at a significant disadvantage in presenting information and arguments to the court. Thus an embryo's right to life is more likely to be taken account of in legislation in those jurisdictions where this right has political support than in a courtroom. Louisiana, for example, requires that unwanted embryos be donated to another couple, even if this is contrary to the wishes of the gamete providers.<sup>337</sup> Some other states prohibit the destruction of embryos.<sup>338</sup> Yet, although the courts in several

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334. KOMESAR, *supra* note 331, at 82-84.

335. *Id.* at 74.

336. *Id.* at 97.

337. LA. REV. STAT. ANN. § 9:129-130 (West 2003). The constitutionality of these provisions have not been tested.

338. See 720 ILL. COMP. STAT. § 5/9-1.2 (West 2002) (prohibiting killing any unborn child, defined as an "individual of the human species from fertilization until birth"); MINN. STAT. ANN. §§ 609.266–2691 (West 2003) (providing for various offenses against unborn children, defined to be "the unborn offspring of a human conceived, but not yet born"); N.M. STAT. ANN. §§ 24-9A-1 to -7

jurisdictions have considered the fate of frozen embryos, the rights of the gamete providers (who were parties to the action) have been controlling, not an embryo's right to life.<sup>339</sup> Thus, the existence of interest group conflict will have an effect on the choice of institutional response to technological change and the consequences of that choice.

#### B. GOAL-ORIENTED COMPARISON

The existence of interest group conflict makes it essential that institutional comparisons be made in the context of a particular goal. Otherwise, disagreement about which institution ought to deal with a particular issue can mask disagreement about what the resolution ought to be. Where there is extensive controversy over ends, arguments about means play a justifiably minor role. For this reason, it is best to refrain from comparing potential, different institutional means for achieving contested objectives.

The comparison of institutions is likely to be more fruitful when there is relative consensus on the goals to be achieved; the performance of different institutions can then be measured. Yet complete agreement on goals is impossible. Controversies continue over the extent to which patient autonomy should be sacrificed for the sake of health, safety, and consumer protection.

### V. NEW REGULATORY MEASURES

#### A. TYPES OF REGULATION

As discussed in Part II.D above, technological change can create reasons to enact new laws. In the case of IVF, people may be concerned that the technology involves health and safety risks to practitioners, patients, or children-to-be, or undermines social values considered important, such as human

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(Michie 2003) (requiring that embryos be transferred to a woman to avoid clinical experimentation restrictions); WIS. STAT. ANN.. § 940.04 (West 1996 & Supp. 2004) (prohibiting destruction of an unborn child, defined as a human being from conception until live birth).

339. See *infra* Part VI.D. Although the embryo's right to life was considered relevant by the trial court in *Davis v. Davis*, No. E-14496, 1989 WL 140495, at \*9, \*11 (Tenn. Cir. Ct. Sept. 21, 1989), this approach was rejected on appeal. *Davis v. Davis*, No. 180, 1990 WL 130807, at \*2, \*3 (Tenn. Ct. App. Sept. 13, 1990); *Davis v. Davis*, 842 S.W.2d 588, 597, 603-04 (Tenn. 1992).

dignity, family values, equality, and fairness. While this has not led to a ban, it has led in some jurisdictions to restrictions.

There are various means (often used in combination) by which technology might be controlled:

-**Approval (technology):** requiring that any new product or process in a particular category obtain advance approval or a license from a public or private body;

-**Approval (people):** requiring that manufacturers, technologists, or users be approved or licensed by a public or private body;

-**Criteria<sup>340</sup> (technology):** requiring that a new product meet certain design specifications or a new process only be performed in a specific way;

-**Criteria (people):** requiring that manufacturers, technologists, or users possess certain qualifications or characteristics; and

-**Criteria (performance):** requiring that a new product or process meet certain performance indicators.

Approval regimes can be used to regulate an established class of products or processes by requiring that new members of that class be approved by a designated body, usually an administrative agency. For example, the UK Act requires that each entity performing a new procedure involving *in vitro* fertilization of human gametes or donated gametes for the first time obtain a license to do so from HFEA.<sup>341</sup> However, approval regimes are only useful in regulating new members of a class of established technologies; by the time the UK Act was enacted in 1990, reproductive technologies were an established class. Where new *types* of technology enter the stage, there may be no approvals regime in place. At that point, a decision must be made whether to ban or regulate the new technology and whether to impose a regime to govern future similar technologies. Of course, new technologies might be included within broadly drafted existing approval regimes. In the United States, for example, the Food and Drug Administration invoked its authority over drugs, devices and biologics in order to

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340. The word "standards" is often used in place of the word "criteria." The latter has been chosen here to avoid confusion with the use of the word "standard" as the opposite of "rule."

341. Human Fertilisation & Embryology Act (UK Act), 1990, §§ 16, 17 (U.K.); HUMAN FERTILISATION AND EMBRYOLOGY AUTH., CODE OF PRACTICE 1.5-1.19 (6th ed. 2003).

effectively ban human cloning.<sup>342</sup> In the United Kingdom, HFEA was able to use its existing powers to consider whether to license clinics to perform genetic testing and tissue typing of embryos prior to transfer in order to determine which embryos would be both free of genetic disease and a suitable tissue match for a sick sibling.<sup>343</sup>

Criteria requirements specify characteristics that the technology or persons associated with it must possess. These requirements might be either rule-like, in that the content of the requirement is specified in advance, or standard-like, in that the content of the requirement remains vague until applied in a specific case.<sup>344</sup> Rule-like restrictions on the technology itself offer precise guidelines to technologists, and the deterrence effect is strong. The main drawback is the possibility that technology will become frozen in its current state of development, hindering further improvements in efficacy and safety.<sup>345</sup> The extent of this problem will depend on the nature of the rule adopted; in some cases, benefits of technological advancement may not become available until the rules are amended. Because lobbying for changes in the rule can be expensive, especially if the rule is legislative, the very existence of rule-like criteria creates a disincentive for those who otherwise would seek to advance the technology. Rule-like performance criteria can place fewer constraints on

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342. Letter from Stuart L. Nightingale, M.D., Assoc. Comm'r, FDA, to multiple recipients (Oct. 26, 1998), *available at* <http://www.fda.gov/oc/ohrt/irbs/irbletr.html> (last visited Apr. 7, 2005); *Issues Raised by Human Cloning Research: Hearing Before the House Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, 107th Cong. 79-81 (2001)* (statement of Kathryn C. Zoon, Dir., Ctr. for Biologics Evaluation and Research, FDA), *available at* <http://energycommerce.house.gov/107/Hearings/03282001hearing141/Zoon205.htm> (last visited Apr. 7, 2005). *See generally* Richard A. Merrill, *Human Tissues and Reproductive Cloning: New Technologies Challenge FDA*, 3 *HOUS. J. HEALTH L. & POL'Y* 1, 52-78 (2002).

343. For a history of HFEA's decisions on this issue, see <http://www.hfea.gov.uk/PressOffice/PressReleasesbysubject/PGDandtissuetyping>.

344. On the distinction between rules and standards, see CASS R. SUNSTEIN, *LEGAL REASONING AND POLITICAL CONFLICT* 21-22 (1996); Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 *DUKE L.J.* 557 (1992).

345. STEPHEN BREYER, *REGULATION AND ITS REFORM* 115-16 (1982); Richard B. Stewart, *Regulation, Innovation, and Administrative Law: A Conceptual Framework*, 69 *CAL. L. REV.* 1256, 1262, 1281 (1981); Murray Mackay, *Liability, Safety, and Innovation in the Automotive Industry*, in *THE LIABILITY MAZE* 220 (Peter W. Huber & Robert E. Litan eds., 1991).

technological development than rules restricting the characteristics of a new product or process. Because the control is over outputs, designers are free to choose different technological means of achieving mandated ends.

In the case of standard-like criteria, the distinction between restrictions on the technology, its practitioners, and its performance may be blurred. Compliance with a requirement that a process be carried out with “due regard to safety” might take account of design features of a product or the steps used in a process, the characteristics and qualifications of those making the product or carrying out the process, and the degree of harm ultimately caused. Standards give less direction to technologists than rules as to what is required, but by the same token they allow technologists more flexibility in optimizing a design or procedure.<sup>346</sup>

The relative advantages and disadvantages of rules and standards have been discussed extensively elsewhere.<sup>347</sup> In a context of ongoing technological change, standards offer some additional advantages over rules. Rule-like criteria as to how a new product is to be designed or a new process carried out may cease to be applicable or may constrain beneficial technological development.<sup>348</sup> Standards are particularly efficient when a technology is in an early stage of development, with frequent adjustments and low uptake.<sup>349</sup>

The deterrent effect of regulation is likely to depend on the whether it requires pre-approval or sets out rule-like or standard-like criteria as well as the consequences of non-compliance. Compliance with approval regimes or rule-like criteria is easy to check. The deterrent effect of these mechanisms is therefore stronger than for standard-like criteria, where there may be disagreement or uncertainty as to what constitutes compliance. Although harsher penalties will usually enhance compliance, they may also create an adversarial atmosphere between the regulator and the regulated, where compliance is minimal and forced, rather than

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346. Tech. Assessment Panel of the Nat'l Acad. of Sciences, *Technology: Processes of Assessment and Choice* (1969), in LAURENCE H. TRIBE, CHANNELING TECHNOLOGY THROUGH LAW 596-97 (1973).

347. See, e.g., SUNSTEIN, *supra* note 344; Kaplow, *supra* note 344; Russell B. Korobkin, *Behavioral Analysis and Legal Form: Rules vs. Standards Revisited*, 79 OR. L. REV. 23 (2000).

348. See, e.g., SUNSTEIN, *supra* note 344, at 131-32, 163; Kaplow, *supra* note 344, at 616.

349. See Kaplow, *supra* note 344, at 562-63.

co-operative and willing.<sup>350</sup> Deterrence is rarely absolute; even clear rules with criminal consequences can be breached and no regulatory regime can guarantee the absence of unscrupulous or careless practices.<sup>351</sup> Despite extensive IVF regulation in the United Kingdom, there have been cases of accidental errors<sup>352</sup> and even intentional foul play.<sup>353</sup>

## B. THE REGULATORS

It may be possible to impose at least some of these different types of regulation by alternative means. There are various potential “regulators” of new technologies, the most well-known of which are the market, courts relying on existing law (especially tort, contract, and criminal law), private groups (such as professional organizations), legislatures, and administrative agencies.<sup>354</sup> Some of these will be limited in the types of regulation they can legitimately impose and some are dependent on the existence of others (for example, administrative agencies require empowering legislation). This Part sets out some of the strengths and weaknesses of each regulator in controlling a technology in order to achieve relatively uncontroversial goals such as health, safety, and consumer protection.

### 1. The Market

Markets do not regulate technologies directly. However, they do control health and safety to the extent that, in a perfect market, people will pay more for services that pose less risk. A consumer-oriented patient population with adequate information could use market power to protect itself from harm

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350. Martin H. Johnson, *The Art of Regulation and the Regulation of ART: The Impact of Regulation on Research and Clinical Practice*, 9 J.L. & MED. 399, 411 (2002).

351. See Judith F. Daar, *Regulating Reproductive Technologies: Panacea or Paper Tiger?*, 34 HOUS. L. REV. 609, 664 (1997).

352. See *Leeds Teaching Hospitals NHS Trust v A*, [2003] E.W.H.C. 259 (involving a sperm mix-up).

353. For example, in the United Kingdom, an embryologist was found guilty of assault causing actual bodily harm and false accounting to obtain money by deception after being accused of pretending to transfer embryos that in fact remained in storage. *Embryologist Fooled IVF Patients*, BBC NEWS, Dec. 11, 2002, available at <http://news.bbc.co.uk/1/hi/england/2562779.stm> (last visited Apr. 7, 2005).

354. See *infra* note 428.

associated with IVF and related technologies.<sup>355</sup>

There are, however, imperfections in the market. Consumers may be unaware of the nature and extent of the risks posed. In a perfect market, consumers will spend resources to obtain information in proportion to the perceived benefit of that information (assuming of course that they are aware that useful information might exist and can estimate its value).<sup>356</sup> However, information may have collective importance to consumers without any single consumer or provider being willing to spend the resources necessary to obtain it. Further, consumers may be in a weak bargaining position or may be emotionally involved and therefore less willing to negotiate.<sup>357</sup> Finally, a technology may have an adverse impact on people who are not parties to any transaction involving their use; in the case of IVF, the conceived child is in this position. While hopeful parents will usually take the interests of a future child into account, there may be conflicts between their interests and those of the child-to-be.<sup>358</sup>

Some deficiencies in the market can be reduced without the need for broader regulation. For example, professional organizations or administrative agencies might collect and distribute data to minimize information deficiencies. In the United States, SART and ASRM and, later, the Centers for Disease Control and Prevention, under legislative mandate, have collected information about success rates at different clinics as well as other important statistics.<sup>359</sup>

Identifiable market deficiencies are not the only concern with markets in sensitive areas such as IVF. For some people, the very idea of a market in reproductive services, a market in

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355. Daar, *supra* note 351, at 664.

356. See generally ANTHONY I. OGUS, REGULATION: LEGAL FORM AND ECONOMIC THEORY 38-41 (1994).

357. Meena Lal, Comment, *The Role of the Federal Government in Assisted Reproductive Technologies*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 517, 535 (1997).

358. RESOLVE, a United States advocacy group for people with infertility problems, denies the existence of this conflict. See Letter from Vicki Baldwin, Chair of the Board of Directors of RESOLVE to Leon R. Kass, Chairman, President's Council on Bioethics (Oct. 2, 2003), available at <http://www.resolve.org/main/national/advocacy/letters/Presidents-Council-Letter-20031002.doc> (last visited Mar. 29, 2005).

359. See, e.g., Med. Research Int'l et al., *supra* note 200. Reports issued by the Centers for Disease Control and Prevention are available at <http://www.cdc.gov/reproductivehealth/art.htm> (last visited Apr. 7, 2005).



embryos, or a market in gestational services is abhorrent.<sup>360</sup> To the extent that new technologies create potential new markets that are seen as degrading, legislation can be enacted to prevent the market forming. For example, some jurisdictions prohibit the sale of embryos.<sup>361</sup>

## 2. Existing Rules Enforced by the Courts

### a. Problems with Existing Rules Following Technological Change

Where conduct, including deceptive conduct or conduct threatening health and safety, will violate existing legal norms, the threat of litigation is one means of deterring that conduct. In the context of technological change, there is a risk that application of existing rules will appear uncertain (reducing their deterrent effect) or existing rules will, on their terms, be under-inclusive. In either case, rules designed to address a particular problem may fail to prevent similar problems because they were not crafted in contemplation of future technological changes. A few examples will illustrate both the potential regulatory effect of existing rules and their potential for failure following technological change.

#### i. *Del Zio v. Presbyterian Hospital*<sup>362</sup>

In 1972, the Del Zios decided to undergo an IVF procedure, after having been advised that IVF had not yet been attempted in humans.<sup>363</sup> On September 12, 1973, ova were removed from Mrs. Del Zio and taken to the Presbyterian Hospital, where Dr. Shettles mixed the ova with sperm from Mr. Del Zio in a test tube culture.<sup>364</sup> The result was stored in an incubator at the Presbyterian Hospital, where it was to remain for four days.<sup>365</sup> On September 13, however, Dr. Shettles's supervisor, Dr.

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360. See generally Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849 (1987). But cf. Neil Duxbury, *Do Markets Degrade?*, 59 MOD. L. REV. 331 (1996) (arguing that objections to certain types of markets are in fact better expressed in terms of specific concerns, rather than as an objection to markets *per se*).

361. See, e.g., FLA. STAT. ch. 873.05 (2003).

362. No. 74 Civ. 3588, 1978 U.S. Dist. LEXIS 14450 (S.D.N.Y. Nov. 14, 1978).

363. *Id.* at \*2.

364. *Id.* at \*3.

365. *Id.*

Vande Wiele, with the concurrence of the President of the hospital and the Dean of Columbia University Medical School, had the test tube removed from the incubator, brought to his office, and placed in the deep freeze.<sup>366</sup> These actions destroyed the culture.<sup>367</sup> Following these events, Mrs. Del Zio claimed to have suffered emotional distress.<sup>368</sup> Mr. and Mrs. Del Zio sued the hospital, Dr. Vande Wiele, and Columbia University on theories of intentional infliction of emotional distress and conversion.<sup>369</sup> The jury, accepting the former claim only, awarded Mrs. Del Zio \$50,000 and Mr. Del Zio \$3.<sup>370</sup> A motion to set aside the verdict or grant a new trial was dismissed.<sup>371</sup>

Thus, even in the early days of an experimental new technology (these events took place even prior to the birth of Louise Brown), new forms of conduct were restricted. Although there were no specific laws governing what could or could not be done with an *in vitro* embryo, the elements of the tort of intentional infliction of emotional distress were broad enough to cover the destruction of an embryo in circumstances where the progenitors might be emotionally harmed.

The same tale also reveals some weaknesses in the notion of courts as protectors. Tort law operates retrospectively.<sup>372</sup> Mrs. Del Zio had already suffered emotional distress. The money might offer a measure of vindication, but it did not make the harm go away. Statutes, unlike tort law, can also operate prospectively by setting up a system of statutory requirements and monitoring compliance on a regular basis.

## ii. Between Persons and Property

Both statutory and common law rules are based on categories rooted in the state of the world at some time in the past. When technological change creates entities that fall outside established categories, existing doctrine may be uncertain or ineffective. In such cases, protections traditionally offered by tort, contract, property, or criminal law will not apply. This problem is evident in cases involving conduct that

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366. *Id.* at \*3-4.

367. *Del Zio v. Presbyterian Hosp.*, No. 74 Civ. 3588, 1978 U.S. Dist. LEXIS 14450, \*3 (S.D.N.Y. Nov. 14, 1978).

368. *Id.* at \*4.

369. *Id.* at \*5, \*10.

370. *Id.* at \*11.

371. *Id.* at \*24.

372. Cohen, *supra* note 108, at 353.

would constitute theft or conversion if embryos were treated as property, or manslaughter, kidnapping, or false imprisonment if embryos were treated as persons.

Consider the case of Cora Creed. She discovered that Dr. Parker, who had assisted in the performance of her IVF procedure, had transferred embryos created with her ova and her partner's sperm into another woman.<sup>373</sup> Mrs. Creed sued for malpractice, claiming not property conversion or harm against the embryo but her emotional injuries as damages. However, her malpractice action failed because the injuries claimed were not related to physical trauma to her.<sup>374</sup> The tort of negligence proved insufficient to fill the gap caused by the absence of torts addressing harm to embryos, being neither property nor persons.

Another case illustrating a similar problem is *Doe v. Irvine Scientific Sales Co.*<sup>375</sup> In that case, human albumin used in the culture during an IVF procedure had been exposed to Creutzfeldt-Jakob Disease and the embryos had to be discarded.<sup>376</sup> The progenitors based their claim against the manufacturer of the albumin on their emotional distress, the financial loss they had suffered in obtaining medical services that were now fruitless, and the loss of their potential child.<sup>377</sup> A federal district court held that there was no claim for negligent infliction of emotional distress because the harm was not related to a physical injury to them, no claim for negligence based on pure economic loss, and no claim for loss of life, because the embryo was not yet a person.<sup>378</sup>

In *Frisina v. Women and Infants Hospital* the Superior Court of Rhode Island considered motions to dismiss plaintiffs' suit based on the alleged negligent destruction of their embryos at defendant's IVF clinic.<sup>379</sup> The plaintiffs had alleged negligent infliction of emotional distress (which, under Rhode Island law, would require that the embryos be "victims") and emotional distress following breach of contract.<sup>380</sup> Defendant

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373. *Creed v. United Hosp.*, 190 A.D.2d 489, 490 (N.Y. App. Div. 1993).

374. *Id.* at 492.

375. 7 F. Supp. 2d 737, 738 (E.D. Va. 1998).

376. *Id.* at 739.

377. *Id.*

378. *Id.* at 740-42.

379. No. CIV. A. 95-4037, No. CIV. A. 95-4469, No. CIV. A. 95-5827, 2002 WL 1288784 (Sup. Ct. R.I. May 30, 2002).

380. *Id.* at \*2.

succeeded in dismissing the first claim because embryos could not be treated as persons (and thus were not “victims”), plaintiffs were not physically present to witness their destruction, and their emotional distress had no physical symptoms.<sup>381</sup> The motion to dismiss failed on the second claim because Rhode Island law allows recovery for emotional distress based on the loss of “property” in some circumstances.<sup>382</sup>

These cases are examples of conduct of which most people would disapprove (negligently transferring an embryo into the wrong woman, negligently exposing embryos to disease, and negligently destroying embryos) for which the tort system proves inadequate. Various doctrinal areas of law provide remedies for damage to persons and property, and even sometimes gestating fetuses, but fall short of covering conduct related to *in vitro* embryos. Where, as in *Frisina*, embryos are treated as property, the claims have some chance of success.<sup>383</sup> But so long as they fall outside the legal categories of property and persons, plaintiffs can be left without remedy. Before the creation of *in vitro* embryos, there was no need for legal rules to protect them and their progenitors. General legal rules offered protection against harm to persons and property. However, courts may be unable to use such rules to protect an entity that falls outside established categories.<sup>384</sup>

### iii. Scandal in California

In May 1995, a lawsuit was filed by the University of California at Irvine against three directors of its Center for Reproductive Health.<sup>385</sup> The suit alleged that the doctors stole eggs from some women and transferred them into others, administered unapproved fertility drugs, and performed research on patients without consent.<sup>386</sup> The allegations followed complaints in 1994, internal investigations, and a threat by the National Institutes of Health to pull the

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381. *Id.* at \*8.

382. *Id.* at \*10.

383. *See id.*

384. *See generally* Freeman, *supra* note 39, at 6 (“Courts [in common law systems] find themselves constricted by policies, concepts and categories invented to deal with the issues of another age.”).

385. Weber & Marquis, *supra* note 171.

386. *Id.*

University's funding.<sup>387</sup>

The police and state district attorney investigated the matter, but were concerned that many of the alleged activities did not fall under any provisions of the penal code.<sup>388</sup> Orange County prosecutors ended up concluding that they could not prosecute embryo theft because under theft and embezzlement laws, a value would need to be assigned to the embryo.<sup>389</sup> In fact, California's embezzlement statute contained no valuation language, but did require that the entity appropriated be property.<sup>390</sup> In addition to these legal problems, prosecutors faced the practical problem that two of the directors had fled the country.<sup>391</sup> The remaining director, whose involvement in the scandal was the least direct, was convicted for mail fraud in federal court as a result of misreported insurance claims.<sup>392</sup>

This case offers an example from criminal law of the same types of problems discussed above. Sometimes, alternative means of bringing an action exist (intentional infliction of emotional distress in the *Del Zio* case and mail fraud in the California scandal), but this is not guaranteed. When technological change creates the potential for harmful conduct that falls outside existing rules designed to deal with similar conduct, in other words, when existing rules are shown to be uncertain or under-inclusive, courts may not be effective regulators.

#### b. Problems with the Tort Law Generally

Other problems faced by potential plaintiffs have less to do with the fact that the technology is new, and thus outside existing legal categories, and more to do with hurdles frequently faced by litigants. For example, causation problems may prevent patients suing a clinic after failure to become pregnant even if they can prove that the clinic's negligent practices resulted in a low success rate.<sup>393</sup> The harm here is

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387. *Id.*

388. *See id.*

389. *See Daar, supra* note 351, at 646.

390. CAL. PENAL CODE § 503. *See also Daar, supra* note 351, at 646-47.

391. Nick Anderson & Esther Schrader, *\$10-Million Accord with UC Reported in Fertility Scandal*, L.A. TIMES, July 19, 1997, at A1.

392. Peter M. Warren, *Fertility Doctor Vows to Win Back his Job; US Irvine: Sergio Stone, Who Was Linked to the Scandal that Closed the University's Clinic, Says He Will Challenge his Firing*, L.A. TIMES, Mar. 21, 2000, at B8 (describing the doctor's involvement).

393. *See ISLAT Working Group, ART into Science: Regulation of Fertility*

diffuse; many people suffered a reduced chance of success, but no one person can claim that they would otherwise have been successful. Alternatively, numerous practitioners may have been involved in a single course of treatment, and it may be difficult to pinpoint the person responsible for causing harm.<sup>394</sup> Tort law itself may develop to eliminate such problems, but the process is slow.<sup>395</sup>

Tort law also deals poorly with problems that involve multiple competing variables.<sup>396</sup> Molding technology to satisfy safety and environmental standards is an example of such a problem; a technical modification that might be appropriate for avoiding one kind of accident might have other disadvantages. Tort law, which considers accidents on a case-by-case basis, tends to focus on the design feature leading to the injury in question without examining the effects of engineering decisions in their entirety.<sup>397</sup> The overall effect of tort law and the technological modifications it engenders may thus be to increase the total risk of harm.

### c. Problems with Courts

The manner in which judges and juries gain expertise in the technology underlying a case is less than ideal. When a case turns on technical information, courts usually rely on expert testimony to provide it. When the evidence presented by each side differs, cross-examination is the primary vehicle by which each party tries to undermine the other's position. While useful for exposing bias, lies, minor inconsistencies, and unfounded assumptions, cross-examination will not necessarily

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*Techniques*, 281 SCIENCE 651, 651 (1998).

394. I.R. Hill, *Liability and In-Vitro Fertilization*, 25 MED. SCI. L. 270, 270-71 (1985).

395. See David L. Bazelon, *Governing Technology: Values, Choices, and Scientific Progress*, in BIOTECHNOLOGY IN SOCIETY: PRIVATE INITIATIVES AND PUBLIC OVERSIGHT 75, 77 (Joseph G. Perpich ed., 1986). In some sense, significant movements in legal doctrine (in particular in areas of employer and manufacturer liability) can be attributed to technological change.

396. See Thomas Barton, *Justiciability: A Theory of Judicial Problem Solving*, 24 B.C. L. REV. 505, 550 (1983); Thomas D. Barton, *Common Law and Its Substitutes: The Allocation of Social Problems to Alternative Decisional Institutions*, 63 N.C. L. REV. 519 (1985); Lon L. Fuller, *Adjudication and the Rule of Law*, 54 AM. SOC'Y INT'L L. PROC. 1 (1960); see also RICHARD A. EPSTEIN, *SIMPLE RULES FOR A COMPLEX WORLD* 238 (1995); STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE* 57 (1993).

397. See Bazelon, *supra* note 395, at 75-76 (discussing trade-offs involving technology).

place the judge or jury in a position to understand the bases for different expert views.<sup>398</sup> It is easier to trip up the bad scientist than to resolve legitimate differences in scientific or technical opinion. The information that goes into crafting a statute or rule generally comes in more varied and useful forms. Cost-benefit analyses and risk assessments can provide a sensible basis for policy formation, and differences of opinion between experts can be resolved in more informal settings. Policy-makers also have greater means of understanding the information presented to them than do judges and juries. Even with the assistance of parties' experts or court-appointed ones,<sup>399</sup> judges and juries may be compelled to rely on their own technically inexperienced understandings.

### 3. Professional Societies

The law of negligence operates best as a deterrent when potential defendants know what conduct they should avoid. Acting alone, the law of negligence only deters conduct that people think a court will find to be unreasonable. The existence of guidelines can ensure that practitioners are aware of what is expected of them, and can simultaneously educate judges and juries. For example, the ASRM issues guidelines of relevance to IVF clinics.<sup>400</sup> Thus many scholars are of the view that tort law, when viewed against the background of these professional guidelines, provides a suitable means of reducing unsafe practices in the medical arena, including IVF.<sup>401</sup>

Some authors question whether professionals are the

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398. See Barry R. Furrow, *Governing Science: Public Risks and Private Remedies*, 131 U. PA. L. REV. 1403, 1461 (1983) (pointing out that cross-examination can reveal underlying biases, unstated assumptions, and methodological shortcomings in expert evidence); Joseph Sanders, *From Science to Evidence: The Testimony of Causation in the Bendectin Cases*, 46 STAN. L. REV. 1, 47-51 (1993) (describing how the focus on credibility, putative biases, and minor inconsistencies can make cross-examination less useful for the fact finder); see also SHEILA JASANOFF, *SCIENCE AT THE BAR* 211 (1995).

399. Obviously, court-appointed experts are limited to jurisdictions in which this option is available.

400. ASRM Website, at <http://www.asrm.org/Media/Practice/practice.html> (last visited Feb. 4, 2005).

401. See, e.g., MICHAEL S. BARAM, *ALTERNATIVES TO REGULATION* 70 (1982); Harry D. Krause, *Artificial Conception: Legislative Approaches*, 19 FAM. L.Q. 185, 198 (1985); David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 78 FERTILITY & STERILITY 932, 938 (2002); Robertson, *Decisional Authority*, *supra* note 54; John A. Robertson, *Assisted Reproductive Technology and the Family*, 47 HASTINGS L.J. 911, 921 (1996).

appropriate standard-setters for a technology.<sup>402</sup> Although they are clearly well-placed to evaluate evidence regarding risks,<sup>403</sup> there is concern that professional interests, including the profit motive, might be placed ahead of patient and social interests.<sup>404</sup> Self-regulation may be effective at clarifying what constitutes good conduct and marginalizing incompetent practitioners, but it may not take account of broader concerns. Much depends on the nature of the body preparing guidelines. For example, RTAC, which creates guidelines for the practice of IVF in Australia, includes seven consumer representatives.<sup>405</sup> However, the members are not democratically elected and thus cannot claim to reflect broader social values. Issues of importance to the public, that do not coincide with the concerns of professionals and their patients, may be better addressed in a democratic forum.

Another difficulty with professional regulation is the relative lack of transparency.<sup>406</sup> For example, many ASRM practice guidelines are only available to members or at a fee.<sup>407</sup> Legislation is more readily available and is subject to greater public scrutiny. Professional codes of conduct may also lack a direct enforcement mechanism. Violation of the rules is only deterred if either there are legal consequences or consumers are generally aware of the infraction. Professional organizations can encourage compliance by educating consumers on the existence and importance of the rules. Legislation can also increase observance of professional codes by mandating or encouraging compliance.

Where the pressure to conform to a professional code of conduct is sufficiently great, they can be a useful means of regulation. Because organized professional groups are usually aware of ongoing technological developments, professional

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402. See, e.g., Hilary Rose, *Victorian Values in the Test-Tube: The Politics of Reproductive Science and Technology*, in *REPRODUCTIVE TECHNOLOGIES: GENDER, MOTHERHOOD AND MEDICINE* 151, 172 (Michelle Stanworth ed., 1987).

403. See, e.g., Johnson, *supra* note 350, at 408.

404. Cohen, *supra* note 108, at 349-50.

405. Website of the Fertility Society of Australia, *RTAC – Composition of Committee*, at <http://www.fsa.au.com/rtac/committee.htm> (last visited Apr. 7, 2005).

406. See, e.g., Johnson, *supra* note 350, at 409.

407. For example, ASRM charges for copies of most Practice Committee guidelines. See ASRM Website, at <http://www.asrm.org/Media/Practice/practice.html> (last visited Apr. 7, 2005).



standards are likely to be up to date.

#### 4. Legislators

Legislation is required to institute in any state regulatory regime, although varying amounts of discretion are conferred on an administrative agency or other body to interpret and implement the law. Generally speaking, greater legislative control ensures greater democratic legitimacy and visibility.<sup>408</sup> Legislation speaks “with greater force and authority in the public eye” than judicial, professional, or administrative regulation.<sup>409</sup> However, where technological change is ongoing, legislation may be insufficiently flexible. As discussed in Part II.G, statutory rules risk being over-inclusive or under-inclusive with respect to future incarnations of a technology. It is generally harder (and more expensive) to have legislation amended to take into account further technological change than to have similar changes made by a professional organization or administrative agency. Even where legislation delegates power to an agency, the empowering legislation may become outdated and prove difficult to amend.

The history of IVF legislation in Victoria provides a good example of this problem. Not only did the original 1984 Act hinder the use of embryo biopsy for six years,<sup>410</sup> but it was drafted in such a way that it prohibited GIFT.<sup>411</sup> This was amended in 1987.<sup>412</sup> The current Act regulates fertilization procedures, defined as any of:

- (a) the medical procedure of transferring to the body of a woman a zygote formed outside the body of any woman; or
- (b) the medical procedure of transferring to the body of a woman an embryo formed outside the body of any woman; or
- (c) the medical procedure of transferring –
  - (i) an oocyte,<sup>413</sup> without also transferring sperm, to the body of a

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408. Of course, much depends on operation of the democratic process.

409. REPRODUCTION & RESPONSIBILITY, *supra* note 142, at 189.

410. See Karen J. Dawson & John F. Leeton, *The Regulation of Assisted Reproductive Technology in Australia: Issues and Solutions*, 163 MED. J. AUSTL. 204, 204 (1995). Embryo biopsy is the removal of cells from an early IVF embryo in order to carry out genetic testing to evaluate the suitability of the embryo.

411. See, e.g., Infertility (Medical Procedures) Act, No. 10,163, 1984, §§ 3, 5 (Austl., Vic.).

412. See Infertility (Medical Procedures) (Amendment) Act, 1987, § 13A (Austl., Vic.).

413. This is defined in the Infertility Treatment Act, 1995, § 3 (Austl., Vic.).

woman; or

(ii) sperm (other than by artificial insemination) to the body of a woman; or

(iii) an oocyte and sperm to the body of a woman.<sup>414</sup>

Yet it is always possible that the technology will mutate further, rendering even this relatively broad definition obsolete. For example, if prior to 2003 it had become possible to incubate an embryo in an artificial womb for an extended period of time, this conduct would not have been regulated. Since 2003, such conduct has been prohibited.<sup>415</sup> Yet it is still possible that technological change will create loopholes in the regulatory regime. Language cannot be completely technology-neutral; it is impossible to draft legislation with sufficient precision and clarity that addresses every possible future technical variation.<sup>416</sup>

Similar problems have arisen in the United Kingdom. The legislation prohibited one cloning technique, replacing the nucleus of a cell of an embryo with another nucleus.<sup>417</sup> However, another technique involving transplanting a nucleus from a human cell and placing the nucleus in an unfertilized ovum, did not fall within that prohibition. This newer cloning technique was not within the contemplation of the British Parliament in 1990 when it passed the UK Act. There was some initial uncertainty as to whether the UK Act even required a license for the newer technique.<sup>418</sup> Section 3(1) of the Act requires a license to “bring about the creation of an embryo” or to “keep or use an embryo.” The procedure described above would only require a license if the entity created were an “embryo” for the purposes of the Act. The rather confusing and self-referential definition of an “embryo” in the Act is found in section 1(1):

In this Act, except where otherwise stated –

(a) embryo means a live human embryo *where* fertilisation is complete,

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as an ovum from a woman not including a parthenogenetic oocyte.

414. Infertility Treatment Act, No. 63, 1995, § 3 (Austl., Vic.).

416. See Colin Tapper, *Judicial Attitudes, Aptitudes and Abilities in the Field of High Technology*, 15 MONASH U.L. REV. 219, 228 (1989).

417. Human Fertilisation & Embryology Act (UK Act), 1990, § 3(3)(d) (U.K.).

418. Placing a human embryo created by means other than fertilization has since been banned in the United Kingdom. See Human Reproductive Cloning Act, 2001, c. 23, § 1(1) (Eng.).

and

(b)references to an embryo include an egg in the process of fertilisation,

and, for this purpose, fertilisation is not complete until the appearance of a two cell zygote.<sup>419</sup>

In standard IVF, a human egg is fertilized with human sperm; the Act is clear that the product of this process, as well as the entity in transition, is an embryo. But although the entity created by the cloning process is similar (except that it is almost genetically identical to the human from whose cell the nucleus was extracted), the process of fertilization is not involved. The question of whether an embryo produced by cloning was an “embryo” came before the House of Lords in the case of *R (on the application of Quintavalle) v. Secretary of State for Health*.<sup>420</sup> The House of Lords held that, on a proper interpretation of the statute, the product of the cloning process was an embryo. The word “where” in the definition of embryo was held to create a temporal restriction, rather than to refer to a particular process. However, prior to this case, the new cloning technique generated uncertainty.

Because the legislature often lacks foresight as to ongoing technological change, the question is often raised as to when legislative regimes ought to be established. Perhaps we need to wait until we have a good understanding of the technology and its risks and benefits.<sup>421</sup> On the other hand, there may be advantages to intervening at a stage when a technology is still developing so that lawmakers can influence the development.<sup>422</sup> Delay may allow the choices made by professionals to become fixed as a result of material equipment, economic investment, and habit.<sup>423</sup> In some cases, it may even lead to irreversible harm to the entities or values that would

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419. UK Act, § 1(1) (emphasis added).

420. [2003] UKHL 13, [2003] 2 WLR 692.

421. See generally REPRODUCTION & RESPONSIBILITY, *supra* note 142. See also Comments by George Annas, *quoted in* Anne Taylor Fleming, *New Frontiers in Conception*, N.Y. TIMES, July 20, 1980, § 6, at 14.

422. See TRIBE, *supra* note 346, at ch. II; Sørensen, *supra* note 30, at 19, 23; Stewart Russell & Robin Williams, *Social Shaping of Technology: Frameworks, Findings and Implications for Policy*, in SHAPING TECHNOLOGY, GUIDING POLICY 37, 62 (Sørensen & Robin Williams eds., 2002). For similar comments in the specific context of IVF, see BONNICKSEN, *supra* note 91, at 6, 9.

423. See Langdon Winner, *Do Artifacts Have Politics*, in TECHNOLOGY AND THE FUTURE 148, 155 (Albert H. Teich ed., 9th ed. 2002); MAZUR, *supra* note 91, at 123; WESTRUM, *supra* note 24, at 77-78.

otherwise have been protected.<sup>424</sup>

The question of when to intervene need not be absolute. Andrea Bonnicksen, for example, argues in favor of incrementalism; laws should be created as harms are anticipated, but cautiously, so as not to outpace society's experience of a technology.<sup>425</sup> The slower approach also allows the government time to assess the success and limitations of other means of regulation, including the market, general tort and criminal laws, and professional control. In New South Wales, for example, the new draft legislation on ART assumes the existence of professional regulation and focuses only on issues going beyond RTAC's mandate. The incremental approach can also be criticized as creating a makeshift system of regulation and risking political avoidance of important issues.<sup>426</sup> An alternative approach is to create mechanisms that increase the likelihood that legislation will be kept up to date.<sup>427</sup>

##### 5. Administrative Agencies<sup>428</sup>

Agencies are better able to keep the law abreast of new developments, because they are focused on a narrower range of issues than are legislatures. Thus, even though administrative regulations, like legislation, are textual they are more easily adapted to ongoing technological change.<sup>429</sup>

Government agencies are diverse even within a single jurisdiction, and differences between jurisdictions can make comparison seem a futile exercise. Thus it has been said that

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424. See WESTRUM, *supra* note 24, at 13-16 (discussing the ability of society to manage its technology).

425. See BONNICKSEN, *supra* note 91, at 112-13.

426. See, e.g., Jean M. Eggen, *The "Orwellian Nightmare" Reconsidered: A Proposed Regulatory Framework for the Advanced Reproductive Technologies*, 25 GA. L. REV. 625, 667, 692 (1991).

427. This will be easier in some jurisdictions than in others because the speed of legislative response varies. See, e.g., Cass Sunstein, *Problems with Rules*, 83 CAL. L. REV. 953, 1005-06 (1995).

428. United Kingdom and Australia have a different government structure than the United States and the term "administrative agencies" might in some contexts be misleading. However, in the context of IVF regulation, the U.K. and Australian authorities to which power has been delegated are relatively similar to U.S. administrative agencies. The references to administrative agencies throughout include these bodies.

429. See Kerry Petersen, *The Regulation of Assisted Reproductive Technology: A Comparative Study of Permissive and Prescriptive Laws and Policies*, 9 J.L. & MED. 483, 497 (2002).

an agency like HFEA could not operate in the United States,<sup>430</sup> although a Hastings Center Report is in favor of establishing a similar entity here.<sup>431</sup> What administrative bodies do have in common is expertise and flexibility advantages over legislatures. In particular, they have greater access to information about particular cases, clinics, and technologies and face fewer procedural hurdles in making or changing rules.<sup>432</sup>

A statute coupled with administrative regulation is thus more flexible than a statute that attempts to cover the field, but less flexible than professional regulation. The more power delegated to the agency to make and interpret law, the more flexible the resulting regime. Goal-oriented statutes that set out the goals considered important to the legislature, allowing the agency to decide how those goals might be achieved in regulation is the most flexible.<sup>433</sup> Similarly, legislation that prescribes standard-like criteria, leaving the development of rules and application of the standards to an administrative agency, is more flexible than legislation prescribing rule-like criteria. However, because the enabling statute must define and limit the agency's power in some ways, the inflexibility problems of legislation are never fully solved. If too much power is delegated (for example, delegating power to make any law without limit), the process loses democratic legitimacy.

Unlike professional organizations, agencies are not directly associated with an interest group. However, they are susceptible to "capture" by such groups.<sup>434</sup> In particular, they have little incentive to publicize broad criticisms of the technology being regulated,<sup>435</sup> especially if their funding structure is linked to license fees.<sup>436</sup> Whether or not there are

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430. See REPRODUCTION & RESPONSIBILITY, *supra* note 142, at 189.

431. THE HASTINGS CTR., REPROGENETICS AND PUBLIC POLICY: REFLECTIONS AND RECOMMENDATIONS S18 (July-Aug., 2003).

432. In the United States, administrative agencies must satisfy the requirements of the Administrative Procedure Act, 5 U.S.C. §§ 551-59 (2000) in making rules. Regulations made under the UK Act must in some circumstances be approved by parliament, UK Act, § 45(4), and there is a procedure set out for approval of the Code of Practice, UK Act, § 26.

433. See Rubin, *supra* note 322, at 411-15 (discussing the effectiveness of goal-oriented legislation).

434. See, e.g., S. SMITH & A. SUTTON, THE HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY: A CRITIQUE OF ITS FIRST REPORTS (1992-94) 9-11 (1995) (criticizing HFEA).

435. See MAZUR, *supra* note 91, at 126-27.

436. See, e.g., SMITH & SUTTON, *supra* note 434, at 10, 21. *But see* Hagger,

issues of capture, administrative agencies, like professional organizations, may not be the most appropriate arbiter of controversial ethical and moral issues.<sup>437</sup> Such issues are best left to elected representatives.

#### 6. Combined Response

This Part has set out the advantages and disadvantages of various regulators—the market, courts, professional organizations, legislative bodies, and administrative agencies. Any particular goal might be achieved through one or more of these mechanisms. Two of the mechanisms (the market and courts) operate in the background and do not require any steps to implement. Professional regulation can be encouraged, but is difficult for an outsider to set in motion.

Interested citizens and scholars are therefore most likely to press for legislative change, either alone or facilitated by a new or existing agency. Such proposals, however, should take account of background mechanisms and, if relevant, professional regulation or the potential for professional regulation. It is possible that certain types of regulation, otherwise desirable, can be omitted from legislation because existing mechanisms are adequate. Thus the draft New South Wales bill on assisted reproduction does not duplicate the functions of RTAC.<sup>438</sup>

#### C. AN EXAMPLE: THE PROBLEM OF MULTIFETAL PREGNANCY

In order to illustrate the benefits of alternative forms of regulation, this Section compares how different institutions in different jurisdictions have responded to one problem generated by IVF, high rates of multifetal pregnancies (twins, triplets, etc.). Such pregnancies pose risks to the health of both mothers and their children-to-be. While multiples do occur naturally, there is a strong correlation between multifetal pregnancies and the use of ART, including IVF.<sup>439</sup> This fact gives rise to arguments that certain practices ought to be prohibited, restricted, or discouraged, and hence leads to calls for regulation. Like all such arguments, they are contestable.

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*supra* note 239, at 17-18.

437. See SMITH & SUTTON, *supra* note 434, at 26.

438. See generally Assisted Reproductive Technology Bill, 2003 (N.S.W.).

439. See generally Anne Lynch et al., *Assisted Reproductive Interventions and Multiple Birth*, 97 OBSTETRICS & GYNECOLOGY 195 (2001).

Altering the way in which IVF is practiced may decrease the effectiveness of the procedure in terms of its primary goal, achieving pregnancy and live birth. Further, direct restrictions on what IVF practitioners may do affects the procreative liberty of their patients, and may therefore be undesirable or even contrary to international or constitutional norms.<sup>440</sup>

Consider the goal of reducing the risk of high order multifetal pregnancies (triplets and higher-order) without significantly affecting IVF success rates and without preventing patients from making use of these techniques in order to have children, except where their interest in procreating is outweighed by the risks to their offspring. Individuals may differ in articulating the circumstances in which the risk of harm is sufficiently severe to trump procreative liberty. Nevertheless, there is wide agreement on a goal such as this. One could craft alternative goals that might give more or less weight to considerations of procreative liberty as against the risk of harm to future children, or that reduce the rate of twins as well as triplets.<sup>441</sup> In such a case, the conclusions may be different, but the analysis would be similar. Having chosen a goal, it is possible to analyze how different types of regulation and different regulators might work to achieve it.

#### 1. The Nature of the Problem

Multifetal pregnancy poses risks to the woman carrying the pregnancy as well as the fetuses she carries. It increases the risk of complications in pregnancy including pre eclampsia, gestational diabetes, and maternal anemia.<sup>442</sup> Children who were born as one of a multiple may suffer problems as a result of the higher probability of being born prematurely and with lower birth weight.<sup>443</sup> For example, one study showed that “more than half of all twins and [more than] 90% of triplets are born preterm or [of low birth weight].”<sup>444</sup> This increases the

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440. See *supra* Part IIB.

441. See generally François Olivennes, *Double Trouble: Yes a Twin Pregnancy is an Adverse Outcome*, 15 HUM. REPROD. 1663 (2000).

442. VIRGINIA J. BALDWIN, *PATHOLOGY OF MULTIPLE PREGNANCY* 355-56 (1994).

443. AM. SOC'Y FOR REPRODUCTIVE MED., *FACT SHEET: MULTIPLE GESTATION AND MULTIFETAL PREGNANCY REDUCTION*, available at [http://www.asrm.org/Patients/FactSheets/Multiple\\_Gestation-Fact.pdf](http://www.asrm.org/Patients/FactSheets/Multiple_Gestation-Fact.pdf) (last visited Apr. 7, 2005).

444. Elizabeth Arias et al., *Annual Summary of Vital Statistics – 2002*, 112

odds of infant mortality and disability.<sup>445</sup> In 1996, for example, 16% of all neonatal deaths were multiples, and multiples “were seven times more likely than were singletons to die within the first year of life.”<sup>446</sup> Newborns in high order multiple pregnancies may suffer from respiratory distress, intraventricular hemorrhage, motor and speech delay, and other problems associated with premature birth.<sup>447</sup> Later in life, there is a correlation between multiple birth and behavioral problems and reduced cognitive function.<sup>448</sup>

In addition to health problems, parents face additional financial burdens.<sup>449</sup> Costs relating to delivery are higher for multiple births and will be borne either by the parents or else by society as a whole in the form of insurance premiums or taxes.<sup>450</sup> There are also psychological consequences from multiple births for parents, siblings, and the children themselves.<sup>451</sup> Financial and psychological risks are compounded if one or more of the children suffers from a significant disability. In addition, because the link between multiple births and ART is well-known, parents may face social stigma or be questioned about their fertility status and whether their children were conceived “normally.”<sup>452</sup>

One “solution” to the problems of multifetal pregnancy is

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PEDIATRICS 1215, 1221 (2003).

445. See Barbara Luke & Louis G. Keith, *The Contribution of Singletons, Twins, and Triplets to Low Birth Weight, Infant Mortality and Handicap in the United States*, 37 J. REPROD. MED. 661, 662 (1992).

446. Bernard Guyer et al., *Annual Summary of Vital Statistics – 1997*, 102 PEDIATRICS 1333, 1339 (1998).

447. See Schlomo Lipitz et al., *High-order Multifetal Gestation – Management and Outcome*, 76 OBSTETRICS & GYNECOLOGY 215, 216-17 (1990).

448. See Adnan T. Bhutta et al., *Cognitive and Behavioral Outcomes of School-Aged Children Who Were Born Preterm: A Meta-Analysis*, 288 JAMA 728, 735-36 (2002); L. John Horwood et al., *Cognitive, Educational and Behavioral Outcomes at 7 to 8 years in a National Very Low Birthweight Cohort*, 79 ARCH. DIS. CHILD FETAL NEONATAL ED. F12 (1998).

449. See Nanette Elster & Institute for Science, Law, and Technology (ISLAT) Working Group on Reproductive Technology, *Less is More: The Risks of Multiple Births*, 74 FERTILITY & STERILITY 617, 620 (2000).

450. See generally, e.g., Tamara L. Callahan et al., *The Economic Impact of Multiple-Gestation Pregnancies and the Contribution of Assisted-Reproduction Techniques to Their Incidence*, 331 NEW ENG. J. MED. 244 (1994).

451. See Elster & ISLAT Working Group, *supra* note 449, at 621.

452. Marcia A. Ellison & Janet E. Hall, *Social Stigma and Compounded Losses: Quality-of-life Issues for Multiple Birth Families*, 80 FERTILITY & STERILITY 405, 407-08 (2003).



multifetal pregnancy reduction, in which one or more fetuses are terminated in order to increase the chances of survival of the remaining fetuses.<sup>453</sup> Even disregarding anti-abortion arguments, there are reasons why prevention is better than cure. Reduction can create a risk of miscarrying the entire pregnancy and may lead to feelings of loss and guilt.<sup>454</sup> As a practical matter, women may refuse to undergo selective reduction.

High multiple birth rates are not an inevitable consequence of reproductive technologies. There are choices that can be made to reduce rates of multiple birth. In the case of IVF, the probability of multiple gestation increases with the number of embryos transferred into a woman's uterus in a single cycle.<sup>455</sup> When forty countries in America, Europe and Asia were classified into "[three] groups depending on the number of transferred embryos (<2.5, 2.5-3, >3), the percentage of triplets increased from 1.1% to 3.2% to 5.0%" respectively.<sup>456</sup> Reducing the number of embryos transferred thus reduces the risk of multiple pregnancy. In addition, studies suggest that, at least for patients with a good prognosis, transfer of more than two embryos does not increase the chances of success.<sup>457</sup>

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453. AM. SOC'Y FOR REPRODUCTIVE MED., *supra* note 443.

454. See Am. Coll. of Obstetricians and Gynecologists, *Multifetal Pregnancy Reduction*, in ETHICS IN OBSTETRICS AND GYNECOLOGY 43 (2d ed. 2003) (based on the AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, SELECTIVE EMBRYO REDUCTION: ETHICAL GUIDANCE FOR THE OBSTETRICIAN-GYNECOLOGIST, ACOG COMMITTEE OPINION 215 (1999)).

455. See Allan Templeton & Joan K. Morris, *Reducing the Risk of Multiple Births by Transfer of Two Embryos After In Vitro Fertilization*, 339 NEW ENG. J. MED. 573 (1998).

456. J. De Mouzon, *Incidence of High Order Multiple Gestation Associated with ART: Registry Data Past and Present*, paper presented at Bertarelli Foundation, First Global Conference, Nov. 20-21, 1999, Bethesda, Md., available at [http://www.bertarelli-foundation.ch/docs/GC\\_1999\\_abstracts.pdf](http://www.bertarelli-foundation.ch/docs/GC_1999_abstracts.pdf) (last visited Apr. 7, 2005).

457. See F. Devreker et al., *Comparison of Two Elective Transfer Policies of Two Embryos to Reduce Multiple Pregnancies Without Impairing Pregnancy Rates*, 14 HUM. REPROD. 83, 87-89 (1999); Ozkan Ozturk & Allan Templeton, Letter, *In-Vitro Fertilisation and Risk of Multiple Pregnancy*, 359 LANCET 232 (2002); C. Staessen et al., *Avoidance of Triplet Pregnancies by Elective Transfer of Two Good Quality Embryos*, 8 HUM. REPROD. 1650, 1652 (1993); Murat Tasdemir et al., *Two Instead of Three Embryo Transfer in In-Vitro Fertilization*, 10 HUM. REPROD. 2155, 2157-58 (1995); Templeton & Morris, *supra* note 455, at 576-77. Previously, it had been suspected that the transfer of more embryos increased the chance that an embryo would implant. See R.G. Edwards, *In-vitro Fertilisation and Embryo Replacement: Opening Lecture*, 442 ANNALS N.Y. ACAD. SCI. 1, 17 (1985).

Although the requirements for a patient to be treated as having a good prognosis differed between studies, all would include patients less than thirty-five years old who had not previously attempted ART where at least four embryos were created (one study required that at least one embryo be of good quality). As a result, many experts recommend transfer of either one<sup>458</sup> or two<sup>459</sup> embryos in such patients. These recommendations depend on the ability to obtain a sufficient number of high quality embryos and accurately assess their chance of implantation.<sup>460</sup>

The numbers of embryos<sup>461</sup> transferred in IVF procedures in the United States are shown in the following chart (Figure 1).

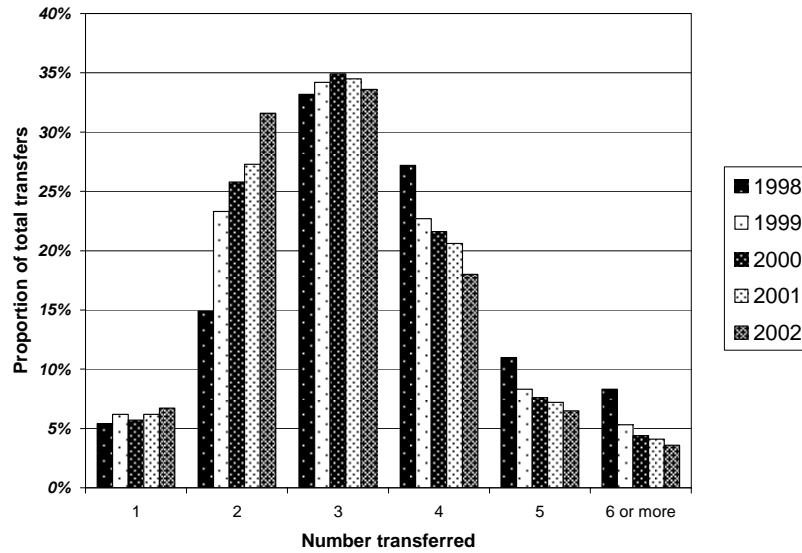
FIGURE 1: NUMBER OF EMBRYOS TRANSFERRED DURING ART CYCLES USING FRESH NON-DONOR EMBRYOS IN THE UNITED

458. See, e.g., T. Coetsier & M. Dhont, *Avoiding Multiple Pregnancies in In-Vitro Fertilization: Who's Afraid of Single Embryo Transfer?*, 13 HUM. REPROD. 2663 (1998); David Gardner et al., *Single Blastocyst Transfer: A Prospective Randomized Trial*, 81 FERTILITY & STERILITY 551 (2004); Jan Gerris & Eric Van Royen, *Avoiding Multiple Pregnancies in ART – A Plea for Single Embryo Transfer*, 15 HUM. REPROD. 1884 (2000); Jan Gerris et al., *Prevention of Twin Pregnancy After In-Vitro Fertilization or Intracytoplasmic Sperm Injection Based on Strict Embryo Criteria: A Prospective Randomized Clinical Trial*, 14 HUM. REPROD. 2581, 2583-86 (1999); H.G.M. Lukassen et al., *Two Cycles with Single Embryo Transfer Versus One Cycle with Double Embryo Transfer: A Randomized Controlled Trial*, 20 HUM. REPROD. 702 (2005); B. Stromberg et al., *Neurological Sequelae in Children Born After In-Vitro Fertilisation: A Population-Based Study*, 359 LANCET 461, 464 (2002). De Sutter et al., *Single Embryo Transfer and Multiple Pregnancy Rate Reduction in IVF/ICSI: A Five Year Appraisal*, 6 REPRODUCTIVE BIOMEDICINE ONLINE, available at <http://www.rbmonline.com/Article/836> (May 30, 2003); *Single Embryo Transfer, A New Understanding of Factors for Success*, MED. NEWS TODAY, June 30, 2004, available at <http://www.medicalnewstoday.com/newssearch.php?newsid=10107> (last visited Apr. 7, 2005).

459. See, e.g., Nicholas M. Fisk & Geoffrey Trew, *Two's Company, Three's a Crowd for Embryo Transfer*, 354 LANCET 1572 (1999); Brian Lieberman, *An Embryo Too Many?*, 13 HUM. REPROD. 2664, 2666 (1998); Jan Roest et al., *A Triplet Pregnancy After In Vitro Fertilization Is a Procedure-Related Complication That Should Be Prevented by Replacement of Two Embryos Only*, 67 FERTILITY & STERILITY 290, 294 (1997).

460. See generally Gerris & Royen, *supra* note 459; Helen Pearson, *Test Could Boost IVF Success*, NATURE.COM, May 13, 2004, at <http://www.nature.com/news/2004/040510/full/040510-7.html> (subscription service) (last visited Apr. 8, 2005).

461. The statistics also include eggs transferred in GIFT procedures. In 2002, GIFT accounted for only 0.2 percent of transfers. CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 23, at 37.

STATES<sup>462</sup>

In light of the risks outlined above, the numbers of transferred embryos seem unjustifiably high. Although it is possible that the high numbers of embryos transferred could be due to large numbers of poor prognosis patients, this seems unlikely. Age and number of previous attempts are two strong indicators of success,<sup>463</sup> and were two of the factors taken into account by studies considering the effectiveness of two embryo transfer.<sup>464</sup> In 2002, women less than thirty-five years old accounted for approximately 44% of fresh non-donor embryo transfers (transferring an average of 2.7 embryos per cycle) and 55.5% of cycles were commenced by women undergoing their first treatment.<sup>465</sup> While transfer of more embryos may be necessary in some patients, the transfer of more than two in the majority of cases more likely reflects clinic failure. Some

462. Uses data from reports issued by the Centers for Disease Control and Prevention, available at <http://www.cdc.gov/reproductivehealth/art.htm> (last visited Apr. 7, 2005).

463. CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 23, at 22, 32.

464. *See supra* note 457 and accompanying text.

465. CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 23, at 25, 31.

clinics with poor laboratory culture conditions and ineffective protocols attempt to compensate by transferring large numbers of embryos to increase their success rate.<sup>466</sup>

This is unlikely to be resolved by patient pressure for safer outcomes. In fact, patients may place pressure on clinics to transfer more embryos than might be appropriate. Infertile couples often prefer, or at least have no objection to, multifetal pregnancies.<sup>467</sup> In some cases, this may be the result of lack of information about the risks of multifetal pregnancy, but there are other factors. Patients who have been unable to conceive may be looking for a two-child or three-child family. They may be aware of, but reluctant to contemplate, the difficulties of raising multiples. Patients are also concerned about the time taken to achieve pregnancy and the costs of treatment, which are incurred on a per cycle basis.<sup>468</sup> These costs, as opposed to the costs of pregnancy and birth, which are usually covered by insurance, are usually incurred by the patient themselves. Thus, although single embryo transfer for some patients may be as cost-effective as double embryo transfer in the short term and more cost-effective over the long term,<sup>469</sup> the patient's

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466. See Richard Bronson, *How Should the Number of Embryos Transferred to the Uterus Following In-Vitro Fertilization Be Determined to Avoid the Risk of Multiple Gestation?*, 12 HUM. REPROD. 1605, 1606 (1997); Kenneth Faber, *IVF in the US: Multiple Gestation, Economic Competition and the Necessity of Excess*, 12 HUM. REPROD. 1614, 1615 (1997).

467. See N. Gleicher et al., *The Desire For Multiple Births in Couples with Infertility Problems Contradicts Present Practice Patterns*, 10 HUM. REPROD. 1079 (1995) (recommending modifying clinical practice rather than altering patient opinion); G.M. Hartshorne & R.J. Lilford, *Different Perspectives of Patients and Health Care Professionals on the Potential Benefits and Risks of Blastocyst Culture and Multiple Embryo Transfer*, 17 HUM. REPROD. 1023 (2002) (many infertile patients were aware of and prepared to accept risks of multiple pregnancy); Ginny L. Ryan et al., *The Desire of Infertile Patients for Multiple Births*, 81 FERTILITY & STERILITY 500 (2004) (study showed that one in five women listed a multiple birth as their most desired outcome of fertility treatment); see also Gardner, *supra* note 458, at 554 (discussing difficulty of recruiting for a study on single blastocyst transfer); James Goldfarb et al., *Attitudes of In Vitro Fertilization and Intrauterine Insemination Couples Toward Multiple Gestation Pregnancy and Multifetal Pregnancy Reduction*, 65 FERTILITY & STERILITY 815 (1996) (finding that couples tend to have a favorable attitude to twins and triplets but less so toward quadruplets).

468. See Christopher J. De Jonge & Don P. Wolf, Editorial, *Embryo Number for Transfer Should Be Regulated*, 68 FERTILITY & STERILITY 784, 785 (1997).

469. See Paul De Sutter, *A Health-Economic Decision-Analytic Model Comparing Double with Single Embryo Transfer in IVF/ICSI*, 17 HUM. REPROD. 2891 (2002); P. Wolner-Hanssen & H. Rydhstroem, *Cost-Effectiveness Analysis of In-Vitro Fertilization: Estimated Costs Per Successful Pregnancy*

perspective may be skewed.

## 2. Common Law Does Not Create Sufficient Incentives

As discussed in Part V.B.2 above, existing rules enforced by courts can create incentives to eliminate or modify risky behavior. As discussed below, existing rules have not created a sufficient incentive to deter the transfer of unsuitably high numbers of embryos.

### a. Contract

If patients are aware of the risks of multifetal pregnancy, and limit the scope of their consent to the transfer of a small number of embryos, they can be compensated for damages incurred if more than the agreed number of embryos are transferred. In the United Kingdom, Peter and Patricia Thompson signed a consent form after their initial consultation at the Sheffield Infertility Centre, agreeing to have two embryos transferred.<sup>470</sup> Defendant argued that the Thompsons orally communicated a change of heart (though the judge did not find this credible), and three embryos were transferred.<sup>471</sup> Triplets were born in March 1997.<sup>472</sup> The Thompsons succeeded against the infertility center in a suit for breach of contract.<sup>473</sup>

Such cases do not, however, address the broader problem. The Thompsons were either well-informed or lucky signing a consent form that provided for the transfer of two embryos. Other couples, due to poor information or emotional and financial factors, will agree to transfer more embryos than may be appropriate. Even couples who prefer to transfer fewer embryos are unlikely to limit their consent explicitly. There may also be limited opportunities for most patients to assess the risks of multifetal pregnancy when giving consent; indeed, women are sometimes required to decide how many embryos to transfer at the time of the procedure.<sup>474</sup>

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*After Transfer of One or Two Embryos*, 13 HUMAN REPRODUCTION 88 (1998).

470. Clare Dyer, *Triplets' Parents Win Right to Damages for Extra Child*, 321 BRIT. MED. J. 1306 (2000).

471. *Id.*

472. *Id.*

473. *Id.*

474. See Ellison & Hall, *supra* note 452, at 411.

## b. Tort

Tort actions against practitioners for harm suffered due to multifetal pregnancy following the transfer of too many embryos are unlikely to be successful. There are significant causation problems. The transfer of six embryos carries with it a high risk of conceiving triplets. If six embryos are transferred, and triplets result, the defendant will be able to argue that the same result could have followed from a transfer of fewer embryos. The difference in risk is difficult to measure because it depends on the patient's age, the number of previous failed IVF attempts, the quality of the embryos used, and the nature of the patient's infertility.

Because tort actions following a multiple pregnancy are unlikely to succeed, the risk of litigation is unlikely to deter practitioners from transferring more embryos than might be appropriate. Nevertheless, tort law may create an incentive for practitioners to advise patients of the risks of multiple pregnancy. This reduces one of the market failures (lack of information) but may not affect the patient's willingness to take risks as a consequence of their desperation or financial circumstances.<sup>475</sup>

## 3. Attempting to Address Market Flaws – United States

The introduction of ARTs, including IVF, into the United States has had a significant impact on the proportion of births involving multiples. The rates of triplet and higher order multiples per 100,000 births increased from 29 in 1971 to 37 in 1980 (following FDA approval of two ovulation-inducing drugs)

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475. See Hartshorne & Lilford, *supra* note 467, at 1027-28 (noting that patients are more willing to accept the risks of multiple pregnancy than their doctors and clinicians); Ryan et al., *supra* note 467, at 502-03 (It was found that the desire for multiple births was significantly associated with lower family income and longer duration of pregnancy, but not associated with knowledge about triplet gestation outcomes. However, the desire for multiple births was also associated with limited knowledge about the outcomes of twin gestation.).

and then to 193.5 in 1998 (following the introduction of IVF).<sup>476</sup> The three biggest contributors to the triplet and higher order birth rate are IVF and related technologies, ovulation-inducing drugs, and increasing maternal age.<sup>477</sup> In 1998, for example, 56% of the infants born in the United States using IVF and related procedures were one of multiples as compared with the national average of 3%.<sup>478</sup>

There is currently no mandatory limit on the number of embryos that can be transferred in the United States. Many practitioners oppose mandated restrictions on the grounds that individual patient factors, including age, need to be taken into account in determining how many embryos to transfer.<sup>479</sup> While some practitioners favor at least a professionally recommended limit,<sup>480</sup> legislatively mandated limits on embryo transfer are generally opposed.<sup>481</sup> The New York State Task

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476. Centers for Disease Control, *Contribution of Assisted Reproductive Technology and Ovulation-Inducing Drugs to Triplet and Higher-Order Multiple Births – United States, 1980-1997*, 49 MORBIDITY & MORTALITY WKLY. REP. 535, 536 (2000); Joyce A. Martin et al., *Births: Final Data for 2000*, 50 NAT'L VITAL STAT. REP. 1, 19 (2002).

477. See Martin, et al., *supra* note 476, at 19.

478. Centers for Disease Control, *Use of Assisted Reproductive Technology – United States, 1996 and 1998*, 51 MORBIDITY & MORTALITY WKLY. REP. 97, 99 (2002).

479. See, e.g., Foad Azem et al., *Transfer of Six or More Embryos Improves Success Rates in Patients with Repeated In Vitro Fertilization Failures*, 63 FERTILITY & STERILITY 1043, 1045-46 (1995) (recommending transfer of six or more embryos for women with repeated IVF failures); Maria Bustillo, *Imposing Limits on the Number of Oocytes and Embryos Transferred: Is It Necessary/Wise or Naughty/Nice?*, 12 HUM. REPROD. 1616, 1617 (1997); Ian Craft & Talha al-Shawaf, Correspondence, *Limiting the Number of Oocytes and Embryos Transferred in GIFT and IVF*, 303 BRIT. MED. J. 185 (1991); Howard W. Jones, Jr. & Jean Cohen, *ART – The Number to Transfer*, 76 FERTILITY & STERILITY S12, S13 (2001); Roelof J. van Kooij et al., *Age-Dependent Decrease in Embryo Implantation Rate After In Vitro Fertilization*, 66 FERTILITY & STERILITY 769, 774 (1996) (recommending three embryos in women over 38); Laura A. Schieve et al., *Live-Birth Rates and Multiple-Birth Risk Using In Vitro Fertilization*, 282 JAMA 1832 (1999); Eric A. Widra et al., *Achieving Multiple-Order Embryo Transfer Identifies Women over 40 Years of Age with Improved In Vitro Fertilization Outcome*, 65 FERTILITY & STERILITY 103, 107 (1996) (recommending transfer of four or more embryos in women over 40). But see Selim Senoz et al., *An IVF Fallacy: Multiple Pregnancy Risk is Lower for Older Women*, 14 J. ASSISTED REPROD. & GENETICS 192 (1997).

480. See, e.g., Howard W. Jones, Jr., *Multiple Births: How Are We Doing?*, 79 FERTILITY & STERILITY 17 (2003); Howard W. Jones, Jr. & John A. Schnorr, *Multiple Pregnancies: A Call for Action*, 75 FERTILITY & STERILITY 11 (2001); Jonge & Wolf, *supra* note 468.

481. See generally, e.g., Mina Alikani & Klaus Wiemer, *Embryo Number for Transfer Should Not be Strictly Regulated*, 68 FERTILITY & STERILITY 782

Force on Life and the Law considered recommending a limit on the number of embryos transferred, but opted for professional standards instead.<sup>482</sup> Its reasoning (which is fairly typical) was as follows:

In general, legislation is an inappropriate vehicle for making medical treatment decisions, particularly those involving complex and evolving clinical variables. In the context of ARTs, the appropriate number of embryos and/or oocytes to transfer may vary considerably from case to case, depending on the patient's age, the number of previously failed attempts, the condition of the embryos, or other factors. The optimum number is also subject to change as clinicians develop better methods for evaluating embryo condition prior to transfer and for improving the likelihood of implantation. Limits set by legislation are unlikely to keep pace with these developments.<sup>483</sup>

The ASRM Practice Committee has consistently sided with those seeking flexibility. In 1994, it chose not to impose any limit on the number of embryos that could be transferred, however, it recommended that the number be chosen so that no quadruplets and no more than 1% to 2% triplet pregnancies were anticipated.<sup>484</sup> In 1998, it repeated its conclusion that there should be no limit on the number of embryos that could be transferred.<sup>485</sup> Instead, it suggested that clinics create their own guidelines based on internally generated statistics.<sup>486</sup> In the absence of sufficient data at a clinic, it suggested that between three and five good embryos be transferred, depending on the patient's profile, taking into account factors such as age and prior treatment history.<sup>487</sup> This was revised in November 1999, when the recommendation was changed to between two

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(1997); David Adamson & Valerie Baker, *Multiple Births from Assisted Reproductive Technologies: A Challenge that Must Be Met*, 81 FERTILITY & STERILITY 517, 522 (2004); Bronson, *supra* note 466, at 1606; Faber, *supra* note 466, at 1616; Larry I. Palmer, *In-Vitro Fertilization as a Social Experiment*, 12 HUM. REPROD. 1617 (1997); Jamie Grifo et al. (on behalf of SART), Commentary, *We are Due for a Correction... and We are Working to Achieve One*, 75 FERTILITY & STERILITY 14 (2001); see also Andrea L. Bonnicksen & Robert H. Blank, *The Government and In Vitro Fertilization (IVF): Views of IVF Directors*, 49 FERTILITY & STERILITY 396 (1988).

482. N.Y. STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 191, at 170.

483. *Id.* But see ISLAT Working Group, *supra* note 393, at 652 (recommending a mandatory limit of four embryos).

484. Ethics Comm. of the American Fertility Soc'y, *Ethical Considerations of Assisted Reproductive Technologies*, 62 FERTILITY & STERILITY 1S, 37S (1994).

485. AM. SOC'Y FOR REPROD. MED., GUIDELINES ON NUMBER OF EMBRYOS TRANSFERRED (1998).

486. *Id.*

487. *Id.*



and five embryos.<sup>488</sup> These guidelines were flexible and standard-like, allowing adjustment for “individual clinic conditions”. The guidelines used terms such as “usually” and addressed only “good quality” embryos, thus allowing for deviation.<sup>489</sup> The most recent version of the guidelines was published in 2004 and uses less flexible language.<sup>490</sup> ASRM also seeks to educate patients about the risks of multiple births and publishes a patient information guide on the issue.<sup>491</sup> The ACOG Committee on Ethics basically agrees with the ASRM Practice Committee, although it is working towards the goal of single embryo transfer.<sup>492</sup>

Perhaps because of the weak preferences expressed until recently in professional guidelines, they have not been followed by all practitioners. In response to criticism regarding the high rates of non-compliance, SART has threatened loss of membership,<sup>493</sup> although it has not carried out this threat.<sup>494</sup>

The United States has not relied solely on professional mechanisms to alleviate the problems of multiple births. The Centers for Disease Control and Prevention publish statistics pursuant to the Fertility Clinic Success Rate and Certification Act that include indicators of the performance of each clinic. For the first time, the 2001 statistics (published in 2003) showed the number of singleton births per cycle for each reporting clinic as a measure of success.<sup>495</sup> If this becomes a

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488. AM. SOC'Y FOR REPROD. MED., GUIDELINES ON NUMBER OF EMBRYOS TRANSFERRED (1999), *available at* <http://www.fertilityoregon.com/forms/NoEmbryosTransferred.pdf> (last visited Apr. 8, 2005).

489. *Id.*; N.Y. STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 191, at 170.

490. Am. Soc'y for Reprod. Med., Guidelines on the Number of Embryos Transferred, 82 FERTILITY & STERILITY 733 (2004) [hereinafter Embryo Transfer Guidelines], *available at* <http://www.asrm.org/Media/Practice/NoEmbryosTransferred.pdf> (last visited Apr. 8, 2005).

491. See AM. SOC'Y FOR REPROD. MED., MULTIPLE PREGNANCY AND BIRTH: TWINS, TRIPLETS & HIGHER ORDER MULTIPLES: A GUIDE FOR PATIENTS (2004), *available at* <http://www.asrm.org/Literature/patient.html> (last visited Apr. 15, 2005).

492. AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, *supra* note 454, at 42.

493. Grifo, et al., *supra* note 481, at 14.

494. Carson Strong, *Too Many Twins, Triplets, Quadruplets, and So On: A Call for New Priorities*, 31 J.L. MED. & ETHICS 272, 276-77 (2003).

495. See CDC Website, *at* <http://www.cdc.gov/node.do/id/0900f3ec8000ec28> (last visited Apr. 7, 2005).

common basis for comparing the performance of different clinics, it is likely to reduce the pressure on poorly performing clinics to transfer more embryos in order to increase their success rate. Information disclosures may thus serve to enhance appropriate competition and improve performance.<sup>496</sup>

Increased insurance coverage for IVF and related services may also decrease patient pressures to risk multifetal pregnancies.<sup>497</sup> This is because, unless covered by insurance, couples must bear the cost of multiple IVF attempts but not the costs associated with multifetal pregnancy.<sup>498</sup> This hypothesis is borne out in surveys on the link between insurance coverage and multiple births. One survey suggests that mandated insurance coverage for IVF leads to a decreased number of embryos transferred and hence a lower multiple birth rate per cycle.<sup>499</sup> A more recent survey indicates that this may only apply in states with mandatory insurance requirements that do not restrict the number of IVF cycles covered.<sup>500</sup> Thus, state legislation mandating insurance coverage for IVF may reduce multiple births.

It will take time to see whether these federal and state measures reduce the rates of multiple pregnancies by reducing the number of embryos practitioners are willing to transfer. Thus far, there are signs that the situation is improving, if slowly. Figure 1 reflects a slow decline in the number of embryos transferred per cycle. The average number of embryos transferred per cycle began decreasing in 1997, with the steepest decline (an 11.1% decrease) between 1998 and 1999.<sup>501</sup> This coincides with the publication of the 1998 ASRM guidelines, which for the first time specified how many embryos

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496. See generally Sage, *supra* note 320.

497. See *supra* note 137 and accompanying text.

498. Faber, *supra* note 466, at 1615.

499. D. Frankfurter et al., *Insurance Mandates for IVF Coverage Effectively Lower Multiple Births Per Embryo Transfer*, 70 FERTILITY & STERILITY 51S (1998).

500. Meredith A. Reynolds et al., *Does Insurance Coverage Decrease the Risk for Multiple Births Associated with Assisted Reproductive Technology?*, 80 FERTILITY & STERILITY 16 (2003). See generally Tarun Jain et al., *Insurance Coverage and Outcomes of In Vitro Fertilization*, 347 NEW ENG. J. MED. 661 (2002); William D. Schoff, *Impact of Insurance Coverage on In Vitro Fertilization Practice Patterns: A Complex Relationship*, 80 FERTILITY & STERILITY 30 (2003).

501. Tarun Jain, *Trends in Embryo-Transfer Practice and in Outcomes of the Use of Assisted Reproductive Technology in the United States*, 350 NEW ENG. J. MED. 1639, 1641 (2004).

ought to be transferred for particular classes of patients, although other factors may also have played a role.<sup>502</sup> There are not yet any data on the effect of the more strongly worded and precise 2004 guidelines.<sup>503</sup>

In part as a consequence of these changes in practice, the number of triplets and other higher order multiple births per 100,000 in the United States declined from 193.5 in 1998 to 180.5 in 2000.<sup>504</sup> The percentage of live-born infants conceived using ARTs that were triplets or higher order decreased from 13.5% in 1997 to 9.9% in 2000.<sup>505</sup> The reports issued by the Centers for Disease Control and Prevention show a similar trend, especially for triplets (see Figure 2).

FIGURE 2: PROPORTION OF ART BIRTHS USING FRESH NONDONOR EGGS OR EMBRYOS THAT ARE SINGLETONS, TWINS, OR HIGHER ORDER: 1998-2002<sup>506</sup>

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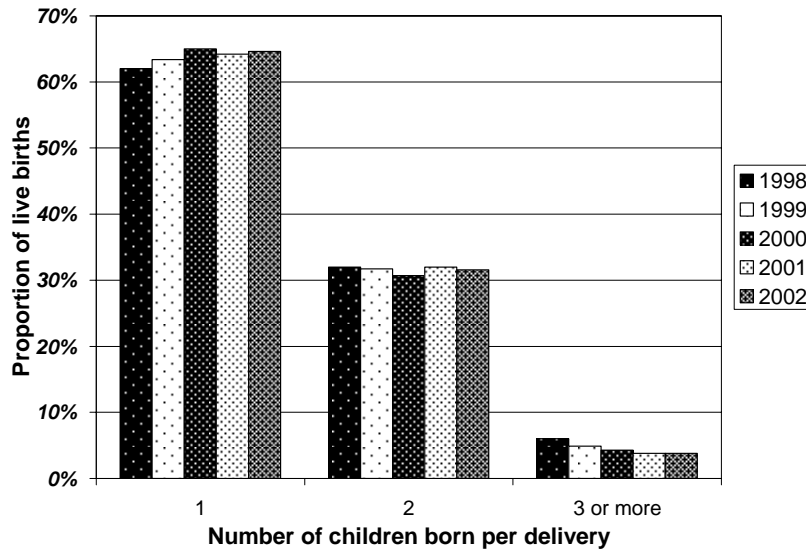
502. *Id.* at 1641, 1643-44.

503. See Embryo Transfer Guidelines, *supra* note 490.

504. Martin et al., *supra* note 476, at 19.

505. Meredith A. Reynolds et al., *Trends in Multiple Births Conceived Using Assisted Reproductive Technology, United States, 1997-2000*, 111 PEDIATRICS 1159, 1160 tbl.1 (2003).

506. The information is taken from the reports available at <http://www.cdc.gov/reproductivehealth/art.htm> (last visited Apr. 7, 2005). Note that the large difference in these figures compared to those above is due to the differences in what is being measured (proportion of live infants versus proportion of live births).



The United States preference for slow improvement in reducing the incidence of multiples is partly cultural and partly pragmatic. There are political forces, in addition to professional groups, opposing regulation as a means of reducing the number of multifetal pregnancies. RESOLVE, a patient advocacy group, is against imposition of mandatory limits on the number of embryos transferred.<sup>507</sup> The current approach is seen as reducing the number of multifetal pregnancies without limiting the ability of medical practitioners to make a decision to transfer greater numbers of embryos when appropriate. At least according to SART's website, this approach has some supporters in Europe, too.<sup>508</sup>

#### 4. Strong Professional Regulation – Australia

In most states of Australia<sup>509</sup> and in New Zealand, there is

507. Letter from Bonnie Gilbert, Acting Executive Director, RESOLVE, to Mr. O. Carter Snead, General Counsel, President's Council on Bioethics (Apr. 15, 2003).

508. See SART Website, at <http://www.sart.org/whatis.html> (last visited Mar. 21, 2005).

509. In South Australia, no more than three embryos may be transferred in a single cycle. Reproductive Technology (Code of Ethical Clinical Practice) Regulations, 1995, § 5 (S. Austl.). Approximately 6 % of cycles are carried out on patients resident in South Australia. JISHAN H. DEAN & ELIZABETH A. SULLIVAN, AUSTL. INST. OF HEALTH AND WELFARE, ASSISTED CONCEPTION SERIES NO. 7, ASSISTED CONCEPTION: AUSTRALIA AND NEW ZEALAND: 2000

no mandatory limit on the number of embryos that may be transferred. However, the number of embryos transferred per cycle is on average significantly less than in the United States, as illustrated in Figure 3.

FIGURE 3: NUMBER OF EMBRYOS TRANSFERRED DURING FRESH NON-DONOR ART CYCLES IN AUSTRALIA AND NEW ZEALAND AS COMPARED TO THE UNITED STATES IN 2002.<sup>510</sup>



There are various possible explanations for the difference, other than cultural factors. Like ASRM, RTAC has issued guidelines on the transfer of multiple embryos, but its recommendations are more rule-like than the 1999 ASRM guidelines.<sup>511</sup> The RTAC Code of Practice provides:

RTAC requests that Centres consider very carefully the need to transfer more than two oocytes or embryos in each treatment cycle. Exceptional clinical circumstances may justify more than two oocytes/embryos to be transferred but there should be good documentation to support such decisions. Despite all care multiple

AND 2001, at 25 tbl.21 (2003), available at <http://www.npsu.unsw.edu.au/ac7.pdf> (last visited Mar. 29, 2005).

510. See *supra* Part V.C.2 fig.1; JOANNA BRYANT ET AL., AUSTL. INST. OF HEALTH AND WELFARE, ASSISTED CONCEPTION SERIES NO. 8, SUPPLEMENT TO ASSISTED CONCEPTION: AUSTRALIA AND NEW ZEALAND: 2002, at 6 tbl.W3 (2004), available at <http://www.npsu.unsw.edu.au/art8high.htm> (last visited Mar. 29, 2005).

511. It is not yet known whether the more rule-like 2004 ASRM guidelines will reduce the number of multiple births in the United States.

births may occur and the patient(s) should be warned of this possibility together with attendant risks of multiple pregnancy. The availability (or otherwise) of selective reduction should be discussed as clinically appropriate.<sup>512</sup>

This provision is clarified in Attachment F to the Guidelines, which explains:

The phrase *in exceptional circumstances* must not be interpreted liberally. For women 40 years and older the higher genetic abnormality rate may make it permissible to transfer three embryos or oocytes. Each case should be considered on its merits and patients must be warned that high order multiple pregnancies can occasionally occur at any age . . . . RTAC will request additional information from clinics reporting unacceptably high numbers of multiple pregnancies.<sup>513</sup>

RTAC regards as “unacceptable” twin rates of more than 20%.<sup>514</sup> RTAC may reduce the recommended number of embryos for transfer.<sup>515</sup>

There are also greater incentives for clinics in Australia to heed RTAC’s advice than for clinics in the United States to follow ASRM guidelines. In particular, participation in government drug subsidies and research grants depend on RTAC membership.<sup>516</sup> RTAC also inspects clinics and monitors performance to ensure compliance with its Code of Practice, whereas SART allows its members to ignore guidelines without consequence. In Victoria, which accounts for about 22% of IVF, ISCI, and GIFT cycles, collectively,<sup>517</sup> RTAC membership is mandatory. In addition, licensed centers in Victoria are required to put a notation on a patient’s medical record of the number of oocytes or embryos transferred and, if more than two, the reasons for the decision.<sup>518</sup> However, although there are few available data for comparison, it does not seem that Victoria is achieving more than New South Wales in reducing the number of high order pregnancies.<sup>519</sup>

512. FERTILITY SOC’Y OF AUSTL., *supra* note 268, at 5.1.

513. *Id.* Attachment F.

514. INFERTILITY TREATMENT AUTH., CONDITIONS FOR LICENCE 2.5.4 (5th ed. 2004).

515. Michael Bradley, *Push to Curb Multiple IVF Births*, THE AGE, Mar. 8, 2004, *available at* <http://www.theage.com.au/articles/2004/03/07/1078594239255.html> (last visited Apr. 7, 2005).

516. *See supra* notes 284, 285 and accompanying text.

517. Dean & Sullivan, *supra* note 509, at 25 tbl.21.

518. *See* INFERTILITY TREATMENT AUTH., *supra* note 514; FERTILITY SOC’Y OF AUSTL., *supra* note 268, Attachment F.

519. In 2000, 0.8% of all births of at least 20 weeks gestation in New South

Perhaps as a result of the reduced number of embryos transferred, Australia has less of a problem with high order multiples than the United States. In 2002, 0.6% of all Australian ART deliveries were triplets (there were no higher order deliveries), whereas in the United States, 3.8% of births following fresh nondonor IVF cycles, 2.3% of births following frozen nondonor IVF cycles, and 2.8% of births following fresh donor IVF cycles resulted in triplet or higher order deliveries.<sup>520</sup> The data described here are insufficient to draw firm conclusions. However, it would seem that professional regulation can help reduce the number of high order multifetal pregnancies, especially when there are strong incentives for compliance.<sup>521</sup> Both the United States and Australia have reduced the number of multifetal pregnancies without preventing practitioners from making an individualized decision to transfer greater numbers of embryos when the chance of pregnancy is otherwise poor.

##### 5. State Regulation – United Kingdom

As in Australia and the United States, the introduction of ART caused an increase in the numbers of multiple births in the United Kingdom. The rates of triplet and higher order multiples per 100,000 births increased from 31 in 1966-1970 to 42 in 1985 and then to 81 in 1989.<sup>522</sup> In 1988, over half of all pregnancies and births in the United Kingdom involving triplets or more were attributed to IVF and GIFT.<sup>523</sup>

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Wales were triplets or higher order, as compared to 1.2% for Victoria. Dean & Sullivan, *supra* note 517, at 44 tbl.70. However, the triplet rate in Victoria had by 2002 decreased to 0.3%; there are no later data for New South Wales. INFERTILITY TREATMENT AUTH., 2003 ANNUAL REPORT 23 (2003), *available at* [http://www.ita.org.au/\\_documents/reports/ITA\\_annualreport03.pdf](http://www.ita.org.au/_documents/reports/ITA_annualreport03.pdf).

520. CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 23, at 20, 46, 50; Bryant et al, *supra* note 510, at 22.

521. There was a significant reduction in the number of high order multiple births in Australia soon after RTAC introduced its recommendation on the number of embryos to transfer. See Helen A. Jonas & Judith Lumley, *Triplets and Quadruplets Born in Victoria Between 1982 and 1990*, 158 MED. J. AUST. 659, 663 (1993).

522. Beverley J. Botting et al, *Background, in THREE, FOUR, AND MORE: A STUDY OF TRIPLET AND HIGHER ORDER BIRTHS 19-21* (Beverley J. Botting et al. eds., 1980).

523. GILLIAN DOUGLAS, LAW, FERTILITY AND REPRODUCTION 114-15 (1991). A separate study found the figure to be 24% for IVF and 11% for GIFT. Malcolm I. Levene et al., *Higher Multiple Births and the Modern Management of Infertility in Britain*, 99 BR. J. OBSTETRICS & GYNAECOLOGY 607, 608 (1992).

The issue of transferring multiple embryos was debated in the United Kingdom from the mid-1980s.<sup>524</sup> Prior to that, multiple pregnancy was accepted by organizations such as the Royal College of Obstetricians and Gynaecologists as justifiable when balanced against the benefits of transferring multiple embryos.<sup>525</sup> The Voluntary Licensing Authority had initially recommended transfer of up to three or four embryos.<sup>526</sup> In 1986, the Voluntary Licensing Authority recommended that no more than three embryos or eggs should be transferred in any single cycle unless there were exceptional circumstances justifying the transfer of four;<sup>527</sup> in 1987, this became part of the guidelines.<sup>528</sup> The decision was controversial.<sup>529</sup> One clinic, the infertility unit at Humana Wellington Hospital, refused to agree in writing to abide by the guideline and consequently lost its license, although it later agreed.<sup>530</sup> Nevertheless, by 1990, compliance was not universal.<sup>531</sup>

In 1991, HFEA imposed a legal restriction limiting the maximum number of embryos that could be transferred in the course of an IVF procedure to three.<sup>532</sup> This was done by introducing a requirement into the Code of Practice that, if breached, could result in loss or variation of a license.<sup>533</sup> It has been suggested that the Voluntary Licensing Authority would

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524. See Price, *supra* note 216, at 43.

525. ROYAL COLL. OF OBSTETRICIANS AND GYNAECOLOGISTS, REPORT OF THE RCOG ETHICS COMMITTEE ON IN VITRO FERTILIZATION AND EMBRYO REPLACEMENT OR TRANSFER 2.5 (Mar. 1983)

526. GUNNING & ENGLISH, *supra* note 3, at 53.

527. See generally Jeremy Laurance, *The Test-Tube Dilemma*, 82 NEW SOC'Y 19 (1987).

528. Price, *supra* note 216, at 43-44.

529. See Ian Craft et al., Letter, *Voluntary Licensing and IVF/ET*, 1 LANCET 1148, 1148 (1987); Ian Craft et al., Letter, *Licensing Work on IVF and Related Procedures*, 1 LANCET 1373, 1373 (1987); David C. Anderson, *Licensing Work on IVF and Related Procedures*, 1 LANCET 1373, 1373 (1987); Martin Richards and Frances Price, Letter, *Licensing Work on IVF and Related Procedures*, 1 LANCET 1373, 1373 (1987); Ian Craft et al., Letter, *How Many Oocytes/Embryos Should be Transferred*, 2 LANCET 109, 109 (1987); Paul A.L. Lancaster, Letter, *How Many Oocytes/Embryos Should be Transferred*, 2 LANCET 110, 110 (1987).

530. GUNNING & ENGLISH, *supra* note 3, at 56; see also Laurance, *supra* note 527, at 19.

531. HUMAN FERTILISATION AND EMBRYOLOGY AUTH., ANNUAL REPORT 2 (1992).

532. HUMAN FERTILISATION AND EMBRYOLOGY AUTH., CODE OF PRACTICE 7.6 (1st ed. 1991).

533. Human Fertilisation & Embryology Act (UK Act), 1990, § 25(6) (U.K.).



have taken the same step had it continued in operation.<sup>534</sup> Although there are no reports of clinics defying the HFEA limit, there is evidence to suggest that this measure failed to reduce the rates of multiple births in women undergoing IVF.<sup>535</sup> This was perhaps due to the improvements in technique that lead to higher rates of implantation.<sup>536</sup> According to professional opinion at the time, it would have been preferable to reduce the number of embryos to two in younger women, but allow for up to four in older women.<sup>537</sup>

In 2000, the Royal College of Obstetricians and Gynaecologists recommended the transfer of no more than two embryos; this recommendation was adopted by HFEA in 2001, which stated that exceptional circumstances should be documented before three embryos are transferred.<sup>538</sup> HFEA has since restricted multiple embryo transfer further. Paragraph 5.5(vi) of the current Code of Practice requires that information about the risks of multiple pregnancy be provided to individuals seeking treatment.<sup>539</sup> Paragraphs 8.20 and 8.21 require that IVF centers ensure that that women under 40 or those using donated ova receive no more than two embryos, and that other women receive no more than three.<sup>540</sup> There are no exceptions based on individual circumstances.<sup>541</sup>

The change in professional and HFEA recommendations seems to have had a positive effect on the rate of triplets in the United Kingdom. The rate of triplets and higher order

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534. GUNNING & ENGLISH, *supra* note 3, at 119.

535. HUMAN FERTILISATION AND EMBRYOLOGY AUTH., SECOND ANNUAL REPORT 19 (1993).

536. *Id.*

537. Lieberman, *supra* note 243, at 1781.

538. ROYAL COLL. OF OBSTETRICIANS AND GYNAECOLOGISTS, THE MANAGEMENT OF INFERTILITY IN TERTIARY CARE 10 (2000); Press Release, Human Fertilisation & Embryology Authority, HFEA Reduces Maximum Number Of Embryos Transferred in Single IVF Treatment from Three to Two (Aug. 8, 2001), *available at* <http://www.hfea.gov.uk/PressOffice/Archive/HFEAreducesmaximumnumberofembryostransferredinsingleIVFtreatmentfromthreetotwo> (last visited Apr. 7, 2005).

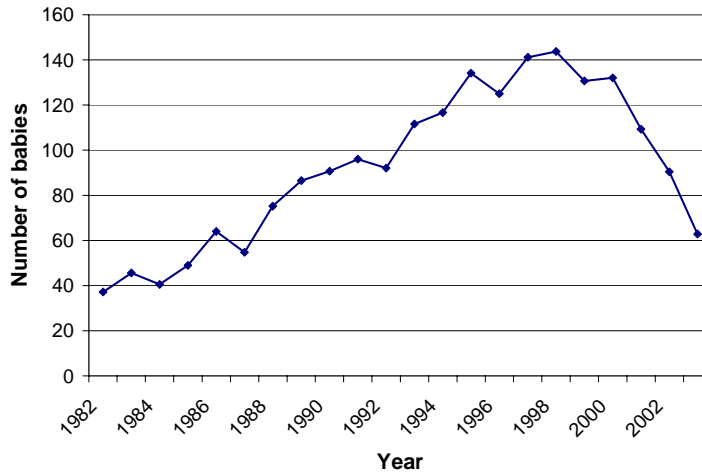
539. *See* HUMAN FERTILISATION AND EMBRYOLOGY AUTH., CODE OF PRACTICE, *supra* note 532, at para. 5.5(vi). HFEA has published a leaflet for this purpose. Human Fertilisation & Embryology Authority, Avoiding Multiple Births: Deciding How Many Embryos to Transfer, *available at* <http://www.hfea.gov.uk/HFEAPublications/HFEAleaflets> (last visited Apr. 7, 2005).

540. *Id.* at paras. 8.20-.21.

541. *See id.*

multiples per 100,000 births (including stillbirths) went from 132.0 in 2000, to 109.2 in 2001, to 90.4 in 2002 to 63.9 in 2003.<sup>542</sup> This reversed a fairly consistent uptrend (Figure 4).

FIGURE 4: U.K. BABIES PER 100,000 BORN ONE OF TRIPLETS OR MORE<sup>543</sup>



The rigidity of HFEA's approach, while creating general benefits by reducing the rate of multiple births, significantly restricts the freedom of individual patients and their clinicians. The case of *R (on the application of the Assisted Reproduction and Gynaecology Centre) v HFEA*<sup>544</sup> is illustrative. Between June 1996 and July 2000, Mrs. H underwent eight IVF treatment cycles, in each of which three embryos were placed in her uterus.<sup>545</sup> The medical director at the clinic treating her, Mr. Taranissi, was of the view that the risk of multiple

542. Based on data available from the Office of National Statistics in the United Kingdom; OFFICE FOR NAT'L STATISTICS, DATASET PBH61, available at <http://www.statistics.gov.uk/statbase/xsdataset.asp?vlnk=4793&More=Y> (last visited Apr. 7, 2005). The difference between the U.S. and U.K. data cannot be explained by differences in the proportion of births following ART procedures, which is about 1% in both countries. See HUMAN FERTILIZATION & EMBRYOLOGY AUTH., FACTS AND FIGURES, available at <http://www.hfea.gov.uk/PressOffice/Factsandfigures> (last visited Apr. 7, 2005); CENTERS FOR DISEASE CONTROL AND PREVENTION, *supra* note 23, at 13.

543. OFFICE FOR NAT'L STATISTICS, *supra* note 542.

544. [2002] EWCA Civ 20.

545. *Id.* at [17].

pregnancy was non-existent and believed that it was necessary to transfer more than three embryos to have a reasonable chance of achieving pregnancy.<sup>546</sup> HFEA rejected Mr. Taranissi's request to transfer more than three embryos, and judicial review of its decisions was unsuccessful. Restrictions on the freedom of clinicians to determine what is best for each individual patient in the context of multiple embryo transfer is the most common criticism of HFEA by clinics.<sup>547</sup>

Interestingly, while the United Kingdom restricts how many embryos may be transferred in the course of IVF, HFEA has no power to limit the number of eggs transferred in a GIFT procedure unless donor gametes are used.<sup>548</sup> The irony of this was observed by Mr. Taranissi in the course of his correspondence with HFEA: “[S]hould [Mrs. H’s] tubes be patent, GIFT procedure with the replacement of an unlimited number of eggs would have been an accepted medical practice.”<sup>549</sup> Biological circumstance thus affects a patient’s ability to increase her chance of pregnancy where the need for more than three eggs is considered clinically necessary. By the same token, HFEA is unable to directly influence the number of multifetal pregnancies arising in the context of GIFT, although it can give guidance.<sup>550</sup> While there is no data on the statistical effect of this loophole, anecdotal evidence suggests that, although GIFT is rarely used in the United Kingdom, some practitioners do transfer far more than two eggs per cycle.<sup>551</sup> This is despite the fact that GIFT is mostly carried out in HFEA licensed clinics and that, according to a survey conducted by HFEA in 1994, there is no evidence of “inappropriate” use.<sup>552</sup>

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546. *Id.* at [18].

547. SECOND QUINQUENNIAL REVIEW OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY, REPORT TO UK HEALTH MINISTERS 5.33 (Oct. 1, 2000).

548. GIFT is only subject to the UK Act if donor gametes are used. Human Fertilisation & Embryology Act (UK Act), 1990, § 4(1)(b) (U.K.). This could be altered by regulation. *Id.* § 4(3).

549. R v. HFEA at [20] (quoting July 9, 2000 letter from Mr. Taranissi to HFEA).

550. UK Act § 25(3).

551. R. Winston, *The UK National Policy Towards the Prevention of High Order Multiple Gestation*, paper presented at Bertarelli Foundation, First Global Conference, November 20-21, 1999, Bethesda, MD, available at [http://www.bertarelli-foundation.ch/docs/GC\\_1999\\_abstracts.pdf](http://www.bertarelli-foundation.ch/docs/GC_1999_abstracts.pdf) (last visited Apr. 7, 2005).

552. HUMAN FERTILISATION AND EMBRYOLOGY AUTH., FOURTH ANNUAL

## 6. Conclusions

This Part looked at four different regulatory approaches: professional guidelines supplemented by government intervention (United States), professional guidelines with strong incentives to comply (New South Wales), professional guidelines with mandated compliance (Victoria), and regulation by a government authority using a clear rule (United Kingdom). The choice as to which regime is optimal in dealing with the problem of multiple gestation will depend on the goal. Generally speaking, codes of practice prepared by a professional organization are likely to offer more flexibility than those prepared by an administrative agency. If one is concerned about procreative liberty and the importance of keeping decisions within a therapeutic relationship, the former course may be more attractive. On the other hand, there are advantages in ensuring that guidelines are taken seriously, either by creating incentives in legislation (New South Wales) or by making compliance mandatory (Victoria). Much will also depend on the content of the guidelines proffered (the ASRM guideline allows for the transfer of more embryos than the RTAC code of practice). Government may be able to exercise some influence in encouraging professional organizations to tighten standards and adopt internal enforcement mechanisms.<sup>553</sup> The United States approach has been successful at reducing rates of multifetal pregnancy, but is apparently less successful than the approaches in Australia and the United Kingdom. If the goal is to reduce the numbers of multifetal pregnancies without unnecessarily reducing a patient's likelihood of having a child, the Australian approaches seem best. These would also be less likely to run into constitutional difficulties than a strict limit on the number of embryos that can be transferred.<sup>554</sup>

A decision to abstain from state regulation in order to assess the potential of professional regulation is not

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REPORT 21 (1995).

553. The President's Council on Bioethics recommended greater enforcement of existing professional guidelines. See REPRODUCTION & RESPONSIBILITY, *supra* note 142, at 218-19.

554. See *supra* Part II.B.3. Although the health of the mother and her future children could be compelling government interests, a limit that did not take into account the circumstances of the woman would likely be considered unduly burdensome because it may significantly reduce the ability of some women to bear a child. Cf. *Planned Parenthood v. Casey*, 505 U.S. 833, 876-79 (1992).

irreversible. Legislation has been introduced in New South Wales that would control only those aspects of IVF that either are not dealt with by RTAC or are important politically.<sup>555</sup> If the state decides to intervene, there may be advantages in some fields to allowing professional organizations to craft the rules (subject always to the possibility that they will be overridden by legislation or regulation). Such rules are more likely to factor in professional concerns (such as the need for flexibility) and are easier to update with improvements in technology and scientific understanding. On the other hand, there are some areas, particularly those that generate social controversy such as cloning, that are best left to a democratic forum. What is important is that the benefits of alternative forms of regulation are considered before proposing new legislation.

## VI. RESOLVING UNCERTAINTY

As discussed in Part II.E above, technological change can bring about uncertainty in the law. No state of uncertainty is irresolvable; the question might be answered if it arises in a legal case or the law might be changed by legislation or regulation.. If uncertainty arises in the context of a statutory scheme administered by an agency, the agency may have power to decide on an interpretation of the legislation.<sup>556</sup> Of course, the resolution reached may be ambiguous, incomplete, or contain latent ambiguities that future technological change may reveal.

There are two reasons why excess uncertainty might be thought undesirable: (1) litigation may be required to resolve disputes where the law is unclear; and (2) the fact of uncertainty may be problematic in itself, as it may, for example, impede the growth of a market. If the second concern applies to a significant extent, so that the uncertainty itself has wide-ranging effects, the need for prompt action will trump most of the considerations raised here.<sup>557</sup> That is not to say that these considerations are not relevant, only that they will usually be outweighed. The focus in this Part is therefore on

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<sup>555</sup>. See *supra* notes 291-295 and accompanying text.

<sup>556</sup>. In the United States, an agency's interpretation may be entitled to judicial deference. See *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843-44, 865 (1984).

<sup>557</sup>. This concern may also be overestimated. See Mary L. Lyndon, *Tort Law and Technology*, 12 *YALE J. ON REG.* 137, 154-56 (1995).

situations where the primary reason to resolve an uncertainty is to avoid disputes.

#### A. DISADVANTAGES OF LEGISLATION – THE LIMITS OF WORDS

Fear of uncertainty is often a driver for legislation. Thus both legal scholars and law reform organizations frequently move from the existence of uncertainty to the need for legislation without further analysis. Sometimes, that jump can be justified because the uncertainty itself causes problems. However, when there is no specific need to resolve the uncertainty promptly, it is important to consider the disadvantages that are associated with pursuit of a legislative solution.

The first factor to consider is the cost of pursuing legislation. The time of political staff, legislators, committees and the parliament or congress itself is valuable. The real question is whether the cost of legislation (or, where relevant, administrative action) exceeds the cost (for the parties and the government) of a judicial decision. This is impossible to measure in the abstract, and will depend on predictions as to the likelihood of litigation and the number of cases it may take to resolve the uncertainty. Where a statutory rule is uncertain, there are no other factors to consider.

When the uncertain rule is found in the common law, there are flexibility losses in taking the rule out of the judicial realm and placing it, reformed, into legislation. In particular, a statutory rule risks greater over-inclusiveness or under-inclusiveness in its application to new situations.<sup>558</sup> A statute resolving uncertainty will only apply to those situations within the possible scope of the language used. Each time the technology evolves beyond what the legislature had contemplated, it is possible that new uncertainties will surface or that the rule will become over-inclusive or under-inclusive. This is evident from the history of laws governing gamete donation; the legislation employed in many jurisdictions to resolve issues related to paternity did not apply to the use of egg donation.<sup>559</sup> Thus a decision to move an uncertain common

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<sup>558</sup>. See *supra* Part II.G.

<sup>559</sup>. Thus, as of 2001, 42 states had laws regulating sperm donation whereas only five states had addressed oocyte donation. NAT'L CONFERENCE OF STATE LEGISLATURES, GENETICS POLICY REPORT: REPRODUCTIVE TECHNOLOGIES 9 (2001). See *generally supra* notes 134-135 and accompanying text.

law rule to a certain statutory rule needs to take account of costs, not only the costs of the initial enactment, but also of future enactments following further technological change.

It may seem as if an alternative solution would be technologically-neutral drafting. The problem could be resolved if initial legislation used terms like vehicle instead of horse-drawn carriage, gamete instead of sperm, and so forth. Drafters, however, are limited by foresight. If technological change is unpredictable, it is difficult to allow for it in advance. It would have been prescient but surprising for legislation referring generally to assisted reproduction rather than to artificial insemination to have been enacted before the 1970s.

There is another sense in which the common law is more flexible than legislation. Such a rule can be altered or overturned by some courts and by legislation, whereas, unless unconstitutional, statutory rules can only be amended by legislation. Of course, judges can interpret the words in a statute to accommodate advances in technology, including within the scope of a statute conduct that was not possible at the time it was drafted. But judges are limited to the words; it would require a fair degree of judicial creativity to decide that an automobile is really a horse-drawn carriage, that an egg is the same as a sperm, or that a machine can be the “body of a woman.” In such circumstances, a statutory rule must wait until the legislature has time to address the problem. A common law rule can be adjusted or further clarified (if necessary) as soon as it becomes the subject of a formal dispute.

#### B. A POSSIBLE SOLUTION – DELEGATION

The reason why many statutes fail to keep up with technological change is that the legislative process is cumbersome. If rules are formulated in legislation, the limits inherent in the words used continue until the legislation can be amended. However, legislation can be designed to give other institutions (such as agencies and courts) room to maneuver in interpreting legislation in light of technological change. This can be done by (1) delegating to an administrative agency the power to resolve uncertainties, (2) employing broad language so as to allow maximum scope for interpretation, or (3) creating standards rather than rules, thus allowing the agency or courts to make adjustments. While these mechanisms can reduce problems in legislation, they do not eliminate them entirely. Delegation is never complete, as some limits are inevitably

spelled out in the legislation.

#### C. DISADVANTAGES OF THE COMMON LAW –LIMITED POSSIBILITIES AND BURDENED LITIGANTS

The common law seems to hold an advantage over legislation. This advantage has to be weighed against possible objections to judicial resolution of uncertainty. Most significantly, the common law is stuck within its own paradigms. While legislatures are only restricted by the boundaries of any constitution and, in the case of a state, federal legislation, judges are more limited. An area of uncertainty might allow a judge a choice between alternatives, but creative solutions that may be possible in a legislative context may not be possible judicially.

When the manner of resolving the uncertainty will have important policy implications or may implicate community values, judges may not be the most appropriate decision-makers. For example, the status of an embryo may be a matter of legitimate community concern best resolved by democratic means.

In addition, judges may be at a disadvantage because they consider one case at a time. Statutes are typically drafted from a broader perspective despite the fact that politics will inevitably thrust some examples to the forefront of drafters' minds. Entire legal regimes, together with exceptions and transitional provisions can be enacted simultaneously. The content of and exceptions to common law rules tend to evolve more slowly in response to specific scenarios. This enables flexibility but can create problems of consistency.<sup>560</sup>

In addition to these issues, a failure to legislate may lead to inequity in the burden of costs required to clarify the uncertainty. If legislation is enacted, these costs are ultimately borne by taxpayers. If the question is left to the common law, the cost of disputes falls on the litigants.

#### D. AN EXAMPLE: CONTROL OF EMBRYOS

It is thus apparent that there are a number of factors to be considered in choosing to resolve uncertainty through legislation. To illustrate how these factors play out in a specific context, consider the example of uncertainty related to the

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<sup>560</sup> See, e.g., Heard, *supra* note 112, at 929; Lorne Elkin Rozovsky, *Legal Aspects of Human and Genetic Engineering*, 6 MANITOBA L.J. 291, 295 (1975).



control over cryopreserved (frozen) embryos in the event of a dispute between a man and a woman who, prior to separation or divorce, had commenced IVF treatment together. The issue really involves two questions: (1) what is the status of an embryo and what decisions can be made regarding them, and (2) who is authorized to make such decisions. The focus here is on the second question. In the United Kingdom, this question was resolved by legislation through the requirement of unwithdrawn consent by the gamete sources for transfer or continued storage of embryos. Victoria has similar legislation, except that the unwithdrawn consents of the spouses (or cohabiting heterosexual partners) of the gamete sources and the woman being treated are also required for transfer and, in the absence of agreement, the embryos remain in storage for the statutory period.<sup>561</sup> In the United States, the question was resolved by courts in those states where disputes arose. New South Wales also has no legislation and there have been no proceedings in which the control of embryos has been in dispute. The draft Assisted Reproductive Technology Bill, 2003 (N.S.W., Austl.) would have a similar effect to the United Kingdom legislation.<sup>562</sup> Because no different issues arise, the law in Victoria and New South Wales will not be discussed separately.

### 1. United Kingdom

The control of an embryo's fate when gamete sources wish to prevent its use is determined by the UK Act. Section 12(c) provides that it is a condition of every license granted that the provisions of Schedule 3 to the Act be complied with.<sup>563</sup> Paragraph 6(3) of Schedule 3 provides that:

An embryo the creation of which was brought about in vitro must not be received by any person unless there is an effective consent by each person whose gametes were used to bring about the creation of the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents.<sup>564</sup>

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561. Infertility Treatment Act, 1995, §§ 8, 9, 12-15, 53 (Vic., Austl.).

562. Assisted Reproductive Technology Bill, 2003, §§ 16-18, 22, 28 (N.S.W., Austl.).

563. Human Fertilisation & Embryology Act (UK Act), 1990, § 12(c) (U.K.). It is unclear to what extent either progenitor could maintain a private right of action against a clinic. See Michael Freeman, *Medically Assisted Reproduction*, in *PRINCIPLES OF MEDICAL LAW* 546, 582-83 (Ian Kennedy & Andrew Grubb eds., 1998).

564. UK Act, sched. 3, para. 6(3).

“Effective consent” is defined in paragraph 1 to be a written consent that has not been withdrawn.<sup>565</sup> Consent may only relate to one or more purposes listed in paragraph 2(1) of Schedule 3, namely (1) use in providing treatment services to the person giving consent or that person and another specified person together, (2) use in providing treatment services to persons not including the person giving consent, or (3) use for the purposes of any project of research.<sup>566</sup> The written consent must specify the maximum period of storage (if less than the statutory maximum), must state what is to happen to the gametes or embryo if the person giving the consent dies or becomes incapacitated, and may also specify storage conditions.<sup>567</sup> Consent may be amended or withdrawn by written notice to the person storing the embryo.<sup>568</sup> However, the consent cannot be amended or withdrawn once the embryo has been “used” in providing treatment services or for the purposes of any project of research.<sup>569</sup> A person giving consent must be informed of the right to amend or withdraw it at the time consent is given.<sup>570</sup>

Essentially, either gamete provider can, acting alone, decide to destroy the embryos. This effectively protects the right not to reproduce as against the right to reproduce. This is a simple rule to follow—it has little uncertainty, but also little flexibility.

Consider the following version of events. Ms. Evans discovered in the course of seeking treatment for infertility that she had serious tumors in both her ovaries and needed to have them removed.<sup>571</sup> Because she still wanted children, she and her partner, Mr. Johnston, agreed that she should first attempt to harvest some eggs. Her eggs would be fertilized with Mr. Johnston’s sperm and frozen for use after the surgery.<sup>572</sup> Ms. Evans, concerned that Mr. Johnston might leave her, raised the possibility of freezing her eggs, rather than the shared

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565. *Id.* para. 1.

566. UK Act, sched. 3, para. 2(1).

567. *Id.* para. 2(2).

568. *Id.* para. 4(1).

569. *Id.* para. 4(2).

570. *Id.* para. 3(2).

571. *Evans v. Amicus Healthcare Ltd.*, [2004] 2 WLR 713, at [4], *aff’d* [2004] EWCA Civ 727.

572. *Id.* at [4-6].

embryos, with a nurse at the clinic.<sup>573</sup> The nurse informed her that egg freezing was not offered at the clinic and that, if she wished to pursue this option, she would have to speak with the treating physician.<sup>574</sup> At that point, her partner reassured her that egg freezing was unnecessary, that they were not going to split up and that he wanted to be the father of her children.<sup>575</sup> The consent forms signed by Ms. Evans and Mr. Johnston consented to the use of the embryos for the treatment of the couple, but noted the right of either party to withdraw or amend the consent.<sup>576</sup> The form contained no provision for either party to consent to the treatment of Ms. Evans alone.<sup>577</sup> Embryos using the gametes of Ms. Evans and Mr. Johnston were thereafter used to create embryos, which were frozen as planned.<sup>578</sup> The relationship between Ms. Evans and Mr. Johnston came to an end; Ms. Evans wished to have the embryos transferred to her uterus and Mr. Johnston wished to have them destroyed.

In the case of *Evans v. Amicus Healthcare Ltd.*,<sup>579</sup> the trial judge and the court of appeal held that even on these facts (which in the actual case were subject to dispute), Ms. Evans could not use the frozen embryos because: (1) that use would not constitute treatment together with Mr. Johnston, which is the only use of the embryos to which Mr. Johnston had consented; and (2) the UK Act does not permit a gamete provider to give irrevocable consent in advance to the use of embryos derived in part from his gametes.<sup>580</sup> Thus, any reassurances by Mr. Johnston cannot prevent him from withdrawing his consent.<sup>581</sup> The court also concluded that the UK Act was not contrary to European law.<sup>582</sup>

The *Evans* case itself could have been foreseen by Parliament. The head of the section in the Department of Health that has responsibility for policy on assisted conception and embryology gave evidence in the *Evans* case that indicated

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573. *Id.* at [5].

574. *Id.*

575. *Id.* at [5-6].

576. *Id.*

577. *Id.* at [7-10].

578. *Id.* at [12-14].

579. [2004] EWCA Civ 727.

580. *Id.* at [295-96].

581. *Id.*

582. [2004] EWCA Civ at [57-74], [106]-[119].

that the Secretary of State for Health preferred a bright-line rule to a fact-sensitive rule in the Act.<sup>583</sup> Democratic institutions are entitled to give weight to the value of certainty in deciding how to craft a legal rule.

However, the British parliament was limited in its ability to foresee the future. We therefore do not know if it would have opted for the same bright-line rule had it thought of the possibility of the following case (which could not have arisen in 1990 because the technology had not yet been developed). Ms. X donates oocytes to Mr. and Mrs. Y, giving her consent. Mrs. Y does not need the nuclear genetic material, but defects in her mitochondria mean that her eggs can only be fertilized through the technique of cytoplasm transfer. A HFEA license is granted<sup>584</sup> and the procedure is performed; some of the embryos produced are frozen. If Ms. X withdraws her consent before the frozen embryos are used, Mr. and Mrs. Y will be unable to have a genetically-related child.<sup>585</sup> Although completely hypothetical, this is an example of how technological change can cause statutory rules to operate in ways not contemplated, and perhaps ways not desired.

## 2. United States

It was established in 1989 in the United States that a couple undergoing IVF treatment with their own gametes have a joint right to control the use of embryos.<sup>586</sup> In *Davis v. Davis*,<sup>587</sup> the Tennessee Supreme Court went on to state in more detail who would control frozen embryos, in the context of a dispute between a couple using their own gametes:

In summary, we hold that disputes involving the disposition of preembryos [early embryos] produced by *in vitro* fertilization should be resolved, first, by looking to the preferences of the progenitors. If their wishes cannot be ascertained, or if there is dispute, then their prior agreement concerning disposition should be carried out. If no prior agreement exists, then the relative interests of the parties in using or not using the preembryos must be weighed. Ordinarily, the party wishing to avoid procreation should prevail, assuming that the

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583. [2004] 2 WLR at [187-88].

584. HFEA is considering an application for research on this technique. See Alastair Dalton, UK Scientists Raise Specter of Babies with Three Parents, THE SCOTSMAN, Oct. 18, 2004, available at <http://news.scotsman.com/scitech.cfm?id=1209592004> (last visited Apr. 10, 2005).

585. This is because Ms. X's gametes were used to produce the embryos.

586. *York v. Jones*, 717 F. Supp. 421, 425-27 (E.D. Va. 1989).

587. 842 S.W.2d 588 (Tenn. 1992).

other party has a reasonable possibility of achieving parenthood by means other than use of the preembryos in question. If no other reasonable alternatives exist, then the argument in favor of using the preembryos to achieve pregnancy should be considered. However, if the party seeking control of the preembryos intends merely to donate them to another couple, the objecting party obviously has the greater interest and should prevail.<sup>588</sup>

The statement that the progenitors' "prior agreement concerning disposition should be carried out" has been subject to some controversy in later cases. In *Kass v. Kass*,<sup>589</sup> a New York case, a prior agreement that the embryos would be donated for research was held to control the embryos' fate. The Supreme Court of Massachusetts refused to enforce a prior agreement in *A.Z. v. B.Z.*<sup>590</sup> Although the court held for various case-specific reasons that the document stating the wife would receive the embryos in the event of a separation was deficient,<sup>591</sup> it went further and stated it would not have enforced the agreement in any event. The court determined it was against public policy to compel a person to become a parent against that person's will, even if that outcome had been previously sought.<sup>592</sup> Similar sentiments were expressed by the Supreme Court in New Jersey in *J.B. v. M.B.*<sup>593</sup> Again, the agreement itself was insufficient, but the court indicated that any agreement would be subject to the right of either party to change his or her mind up to the point of either use or destruction of the embryos.<sup>594</sup> The Iowa Supreme Court reached a similar conclusion in *In re Marriage of Witten*.<sup>595</sup> The agreement in this case provided that the frozen embryos could only be transferred, released, or disposed of with the consent of both husband and wife.<sup>596</sup> The court stated that judges should not enforce *any* agreement between a couple as to the future disposition of embryos when one of them has communicated a change of heart.<sup>597</sup>

An agreement to destroy the embryos was upheld,

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588. *Davis v. Davis*, 842 S.W.2d 588, 604 (Tenn. 1992).

589. 696 N.E.2d 174, 181 (N.Y. 1998).

590. 725 N.E.2d 1051 (Mass. 2000).

591. *Id.* at 1056-57.

592. *Id.* at 1057-59.

593. 783 A.2d 707 (N.J. 2001).

594. *Id.* at 714, 717-19.

595. 672 N.W.2d 768 (Iowa 2003).

596. *Id.* at 772.

597. *Id.* at 782-83.

however, in the Washington case of *Litowitz v. Litowitz*.<sup>598</sup> In that case, the agreement with the clinic provided for the destruction of the embryos (made with the husband's sperm and donated eggs) after five years unless extended "at our request."<sup>599</sup> In fact, neither party wanted the embryos destroyed; the wife wished to have the embryos transferred into a surrogate and the husband wished to donate them to another couple.<sup>600</sup> Nevertheless, the majority of the court upheld the contract.<sup>601</sup> Judge Chambers wrote a separate concurring judgment, in which he stated that it was important to consider equity and public policy in enforcing agreements, but noted that equity and public policy were in accordance with the parties' original intentions.<sup>602</sup>

There is no way to reconcile these cases, although there seems to be great reluctance to enforce agreements to become a parent when a party has later decided against it. When the agreement provides for some other result (destruction or use for research), the results vary by state.

When there is no agreement, or the agreement is not binding on the parties, courts have articulated different tests although the results are largely similar. In *Davis*, the court, using a balancing test, held that the interest of one party in donating the embryos lost to the interest of the other in not becoming a parent.<sup>603</sup> In *A.Z. v B.Z.*, the Massachusetts Supreme Court indicated a court should not give an order that would force one party to become a parent against his or her will.<sup>604</sup> In *J.B. v M.B.*, the New Jersey Supreme Court stated that the party wishing to avoid parenthood would "ordinarily" prevail.<sup>605</sup> Five of the seven judges, however, stated that they expressed no opinion on what would they would have decided if the party wishing to procreate had no other physiological means of doing so.<sup>606</sup> In separate concurring opinions, Judge Verniero and Judge Zazzali stated that in such a situation, the

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598. 48 P.3d 261 (Wash. 2002).

599. *Id.* at 272.

600. *Id.* at 264.

601. *Id.* at 271.

602. *Id.* (Chambers, J., concurring in part and dissenting in part).

603. 842 S.W.2d at 604.

604. 725 N.E.2d at 1059.

605. 783 A.2d at 719.

606. *Id.*

party wishing to procreate ought to prevail.<sup>607</sup> Thus it is likely that Ms. Evans would have had a better chance of success had she undergone the IVF procedure in the United States, though not in Iowa, where the Supreme Court has held that embryos can only be removed from frozen storage with the consent of both gamete providers.<sup>608</sup>

Among clinics, the emphasis seems to be on requiring couples to consider in advance what they wish done with their embryos in the event of divorce or separation. A 1989 survey of embryo cryopreservation in the United States found that twenty-three of the twenty-five SART member programs that reported offering embryo freezing required the patient to designate the disposition of frozen embryos in case of parental death or divorce.<sup>609</sup> ARSM recommends that programs require couples contemplating embryo storage to give written instruction concerning disposition of embryos.<sup>610</sup> The instructions should be amendable but only by both partners.<sup>611</sup> In the absence of an agreement, programs should be able to treat embryos as abandoned after five years and destroy them if diligent efforts to contact the couple fail.<sup>612</sup> The Council on Ethical and Judicial Affairs of the American Medical Association also recommends the use of advance agreements but does not believe they should be mandatory.<sup>613</sup>

### 3. Observations

The main difference between the law in the United Kingdom and the law in the United States is the generality of the rules. The UK Act creates a clear but inflexible rule that may apply to situations in which many would think it inappropriate. Further, it may apply even where further technological change creates a situation beyond the contemplation of the legislature. In the United States, clarification of the law was slow as cases raised new questions

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607. *Id.* at 720.

608. *In re Marriage of Witten*, 672 N.W.2d 768, 783 (Iowa 2003).

609. Fugger, *supra* note 14, at 987.

610. Ethics Comm. of the Am. Fertility Soc'y, *supra* note 484, at 58S-59S; ETHICS COMM. OF THE AM. SOC'Y FOR REPROD. MED., DISPOSITION OF ABANDONED EMBRYOS, *available at* <http://www.asrm.org/Media/Ethics/abandon.html> (last visited Apr. 7, 2005).

611. *Id.*

612. *Id.*

613. COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, *supra* note 193, at E-2.141 (1994).

unanswered by previous cases. As a consequence, more litigation has arisen in the context of cryopreservation and relationship dissolutions in the United States than in the United Kingdom. One advantage of the American approach is that the courts retain the ability to create new exceptions to the general rule as the facts of specific cases demand. The *Evans* case would probably have gone the other way in the United States, and the cytoplasm transfer hypothetical would almost certainly be resolved in favor of the couple.

Problems of uncertainty caused by technological change may be overemphasized. Uncertainty as to the control of embryos following the breakdown of a relationship has few large-scale effects.<sup>614</sup> Such uncertainty is unlikely to deter many couples from using IVF or alter the economics of the reproduction industry.<sup>615</sup> Couples who stay together or reach agreement upon separation will not face any negative consequences as the result of uncertainty in this area. Clinics are not greatly affected because they can maintain the status quo pending judicial resolution of a dispute.<sup>616</sup> The persons most affected are couples who split up and are unable to agree on the disposition of the embryos. In that context, the dispute will rarely create new litigation, as the parties are already likely to be in divorce proceedings, but may add to the existing litigation burden and reduce the likelihood of out-of-court settlement. The amount of thought that has been put into the question of control of embryos in academia likely exceeds that in private practice. The additional burden of litigation for these couples is slight, and the cost of bright-line rules can be significant, as is evident from the *Evans* case. Reaching the best result seems more important than ensuring predictability.

A decision to “wait and see,” observing the common law resolution of uncertainty and enacting a statute only if the resolution is undesirable or any residual uncertainty has undesirable consequences, has advantages. First, if the

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614. See DWORKIN, *supra* note 328, at 69 (commenting that identifying parents of children conceived with donor sperm is a small social problem and thus that there is no need for a speedy or comprehensive solution).

615. See William A. Sieck, Comment, *In Vitro Fertilization and the Right to Procreate: The Right to No*, 147 U. Pa. L. Rev. 435, 465-66 (1998) (discussing the tendency to assume that marriage will last forever, and the difficulty of thinking rationally about the disposition of embryos at the time of treatment).

616. See *In re Marriage of Witten*, 672 N.W.2d at 782-83 (stating that agreements, while not enforceable by one progenitor against the other, would be enforceable by clinics until advised of a change in writing).



common law solution is similar to that what have been enacted in any event, the flexibility of the common law is retained. In particular, the rule is likely to be more adaptable to future technological change. Second, even if a change is sought through legislation, the statute can be crafted to reflect greater experience gained with the technology.

### CONCLUSION

The purpose of this article has been to analyze the types of problems law faces as a consequence of technological change and the means for resolving them. Notions of law struggling to keep up with technology or society facing a “legal vacuum,” while graphic, fail to identify the nature of the problem. Worse, they can lead to the belief that “something” needs to be done, which can lead to a rush to legislate. In fact, while technology can pose problems for law, there are mechanisms other than legislation to deal with these problems. While these may be insufficient or inadequate in particular circumstances (at least in the view of some), they should not be ignored.

Often, there may be advantages in adopting a “wait and see” approach, delaying the enactment of technology-specific solutions until other mechanisms have had a chance to respond to the challenges posed. When the advantages of this approach outweigh the disadvantages, it is not enough to respond that leaving issues to the courts or a professional body is undemocratic. A decision by a political body not to legislate is as democratic as any. While leaving uncertainties to be resolved by courts and regulation to professional bodies in the absence of any monitoring or review might meet with disapproval, the fact that a legislature consciously decides not to take action, while monitoring other developments, is not necessarily an undemocratic result. When uncertainties are satisfactorily resolved by courts or regulatory goals are achieved by professional guidelines, legislation may not be necessary. Nevertheless, professional bodies may not step up to the plate and government encouragement or the threat of stringent legislation may be necessary to provoke them into action. It was such a threat that led to the creation of the Voluntary Licensing Authority in the United Kingdom.<sup>617</sup> To create stronger restrictions on multiple embryo transfer in the

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617. See MICHAEL MULKAY, *THE EMBRYO RESEARCH DEBATE: SCIENCE AND THE POLITICS OF REPRODUCTION* 57-58 (1997).

United States than exist at present, one could either regulate the practice directly or threaten such regulation, hoping to encourage ASRM and SART to adopt more stringent restrictions with greater consequences for non-compliance. Direct regulation will remain as an option if the threat proves to be ineffective.

In some cases, legislation will be the most effective means of achieving a desired result. Looking at a more recent controversy, if one believes that reproductive cloning is unacceptable under any circumstances, a legislative prohibition backed by stringent sanctions is the best means of ensuring that it never takes place. If, however, safety concerns were resolved and one believed that cloning was in principle acceptable, professional regulation could be sufficient to ensure that procedures were carried out responsibly. Some uncertainties, such as whether the spouse of the person cloned has any rights in relation to a frozen cloned embryo upon divorce, could be left to the courts in the first instance. Others, such as whether clones have one or two parents, might be best resolved by legislation, especially if it were felt that lack of certainty would itself cause harm to a cloned child.

There is no single best response to problems posed by technological change. The possible responses will depend on the nature of the problem, and in particular, whether it is the technology itself, lack of regulation, uncertainty, or obsolescence, over-inclusiveness, or under-inclusiveness of existing rules. Legislation will sometimes, but not always, be the best response. Accordingly, when setting out a proposal for law reform in light of technological change, it is necessary to ask not only *how* the law ought to be changed, but also *by whom* and *when*.