



2010

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### Recommended Citation

Theresa Glennon, *Choosing One: Resolving the Epidemic of Multiples in Assisted Reproduction*, 55 Vill. L. Rev. 147 (2010).

Available at: <https://digitalcommons.law.villanova.edu/vlr/vol55/iss1/5>

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2010]

## Article

### CHOOSING ONE: RESOLVING THE EPIDEMIC OF MULTIPLES IN ASSISTED REPRODUCTION

THERESA GLENNON\*

#### INTRODUCTION

**F**ERTILITY treatments have helped many individuals and couples exchange the heartbreak of infertility for the joys of parenthood. However, as patients traverse the anxious path of infertility treatment, they are often directed toward practices that greatly raise health risks by increasing the chance of multiple gestations.<sup>1</sup> This Article highlights features of the context surrounding “assisted reproduction”<sup>2</sup> that steer potential parents toward choices that heighten health risks to them and their hoped-for children.

The decision-making context patients confront in assisted reproduction leads many toward treatment choices that markedly increase the probability of twins, triplets, and higher order births. As a result, 30%-35% of the births related to assisted reproduction are multiples.<sup>3</sup> The high percentage of multiple gestations and multiple births impose signifi-

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\* Jack E. Feinberg, Professor of Law, James E. Beasley School of Law at Temple University. I am grateful for financial and institutional support for this research from the Beasley School of Law and its Dean, Joanne A. Epps. I benefited greatly from the input of my colleagues, including Mark Anderson, Susan DeJarnatt, Jeff Dunoff, Rick Greenstein, and Andrea Monroe. I would also like to thank Scott Gordon, Jamie Kim, Matthew Morley, and Athas Nikolakakos for their terrific research assistance, and Shane Brengle for his able assistance in the last stages of this project. All errors are my own.

1. See LIZA MUNDY, *EVERYTHING CONCEIVABLE: HOW ASSISTED REPRODUCTION IS CHANGING MEN, WOMEN, AND THE WORLD* 210-20 (2007) (showing that multiple births, while still lauded in society, present myriad dangers to mother and children); Stephanie Saul, *Grievous Choice on Risky Path to Parenthood*, N.Y. TIMES, Oct. 12, 2009, at A1, available at <http://www.nytimes.com/2009/10/12/health/12fertility.html> (detailing risks associated with in vitro fertilization, intrauterine insemination, and high potency hormones).

2. This Article uses the broader term, “assisted reproduction,” as inclusive of hormone therapy, intrauterine insemination, and in vitro fertilization (IVF). Assisted reproductive technology, or ART, is used only to refer to various approaches to IVF.

3. See CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP’T OF HEALTH AND HUMAN SERVS., *ASSISTED REPRODUCTIVE TECHNOLOGY (ART) REPORT: NATIONAL SUMMARY* (2007) [hereinafter CDC, 2007 ART NATIONAL SUMMARY], <http://apps.nccd.cdc.gov/ART/NSR.aspx?SelectedSelectedYear=2007#b> (stating findings). “Multiple births” refers to births from the same pregnancy. *Id.*

cant health risks on both mothers and their children.<sup>4</sup> Indeed, the public health community views the dramatic rise in multiple births resulting from assisted reproduction as a preventable epidemic.<sup>5</sup> Public health experts emphasize that much more needs to be done to prevent the multiple pregnancies caused by assisted reproduction.<sup>6</sup> This policy imperative, however, runs head long into the market-based and institutionally fractured approach to fertility treatment in the United States.

Until recently, debates over how to reduce the high rates of twins and triplets related to assisted reproduction were largely confined to medical literature. Public inattention to the issue of multiple births ended abruptly on January 26, 2009, when Nadya Suleman gave birth to eight babies in California.<sup>7</sup> The resulting media frenzy began with praise for the hospital teams that successfully delivered the children.<sup>8</sup> Public amazement, however, quickly transformed into public outrage.<sup>9</sup> Some editorialists and bloggers denounced Suleman's decision to transfer six embryos—two of which twinned—through in vitro fertilization (IVF) and called for investigation into the fertility doctor who performed the procedure.<sup>10</sup>

4. See Saswati Sunderam et al., *Assisted Reproductive Technology Surveillance—United States, 2006*, MORBIDITY & MORTALITY WKLY. REP., (Coordinating Ctr. for Health & Info. Serv., Ctrs. for Disease Control and Prevention, U.S. Dep't of Health & Human Servs., Atlanta, Ga.), June 12, 2009, at 1, 11, available at <http://www.cdc.gov/mmwr/pdf/ss/ss5805.pdf> (finding women with multiple-gestation pregnancies at increased risk for hemorrhage and hypertension, and that infants born in multiple-birth delivery have increased risk for prematurity, low birth weight, infant mortality, and long-term disability). Contrary to popular belief, the health risks for twins are significant. See Sheree L. Boulet et al., *Perinatal Outcomes of Twin Births Conceived Using Assisted Reproduction Technology: A Population-Based Study*, 23 HUM. REPROD. 1941, 1945 (2008), available at <http://humrep.oxfordjournals.org/cgi/reprint/23/8/1941> (finding that twin deliveries related to IVF faced 3.3% chance that one or both twins would die shortly before or within one year of birth, 61% chance of one or both being low birth weight, 10.5% chance one or both would have very low birth weight, 55.3% chance of being preterm, and 10.2% chance of being very preterm).

5. See Maurizio Macaluso et al., *A Public Health Focus on Infertility Prevention, Detection, and Management*, 93 FERTILITY & STERILITY 16.e1, 16.e4 (2010), available at [http://www.cdc.gov/art/PDF/Macaluso\\_2008\\_Fertility-and-Sterility.pdf](http://www.cdc.gov/art/PDF/Macaluso_2008_Fertility-and-Sterility.pdf) (finding that certain methods of assisted reproduction carry lower risk of multiple delivery).

6. See *id.* (highlighting risks of popular methods of assisted reproduction and explaining need for greater research into safer alternatives).

7. See Scott Michels, *Octuplet Mom Filed Workers Compensation Claims*, ABC NEWS, Feb. 5, 2009, <http://abcnews.go.com/TheLaw/Story?id=6806753&page=1> (describing public reaction to Suleman's delivery of octuplets).

8. See Raquel Maria Dillon, *Octuplets Born in California Doing 'Very Well'*, ASSOCIATED PRESS, Jan. 27, 2009, [http://www.pantagraph.com/news/article\\_00f708d1-5f31-5254-b2e9-d9a0434e0f7.html](http://www.pantagraph.com/news/article_00f708d1-5f31-5254-b2e9-d9a0434e0f7.html) (discussing appearance of doctors on ABC's *Good Morning America*).

9. See *Octuplets' Mom: 'All I Ever Wanted'*, CNN.COM, Feb. 6, 2009, <http://www.cnn.com/2009/US/02/06/octuplets.mom/index.html> (reporting on public skepticism over Suleman's ability to properly care for her fourteen children).

10. See Jennie Eng, *Eight's a Crowd for Some in Debate Over In-Vitro Fertilization*, DAILY FREE PRESS, Feb. 17, 2009, <http://www.dailyfreepress.com/eight-s-a-crowd-for-some-in-debate-over-in-vitro-fertilization-1.1481683> (highlighting criticisms of

Others expressed fury at the significant costs to taxpayers for the children's care or concern for the children's well-being.<sup>11</sup> As a result of this national focus, several state legislatures considered legislation to limit the number of embryos transferred in IVF.<sup>12</sup>

These legislative responses, however, focused on avoiding such unusual yet highly publicized events rather than on tackling the more common structural problems related to assisted reproduction.<sup>13</sup> Efforts to avoid future sets of octuplets have diverted attention from the common yet risky practices that create such a high rate of multiples: first, the widespread use of fertility drugs to stimulate the development of multiple eggs at one time, which may then be fertilized naturally or through intrauterine insemination; and second, the routine IVF practice of transferring two or

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Suleman's use of assisted reproduction); *see also* Stephanie Saul, *Birth of Octuplets Puts Focus on Fertility Clinics*, N.Y. TIMES, Feb. 11, 2009, at A1, available at <http://www.nytimes.com/2009/02/12/health/12ivf.html> (discussing push for greater regulation of fertility industry following Suleman's delivery of octuplets). On October 20, 2009, it was reported that the fertility doctor who treated Suleman was expelled from the American Society for Reproductive Medicine. *See* Kimi Yoshino, *Doctor Who Treated Octuplets Mom Ejected from Society of Reproductive Medicine*, L.A. TIMES, Oct. 20, 2009, available at <http://www.latimes.com/news/local/la-me-octuplets-doctor20-2009oct20,0,4363432.story> (discussing disciplinary action against physician). The Medical Board of California has also initiated a legal action against Dr. Kamrava for three counts of gross negligence, acts of repeated negligence, and inadequate record keeping; convictions on these charges could result in suspension or revocation of his medical license. *See* *Accusation at 6-13, Johnston v. Kamrava*, No. 06-20009-197098 (Med. Bd. of Cal., Dep't of Consumer Affairs, Dec. 22, 2009), available at <http://blogs.findlaw.com/courtside/2010/01/octomoms-doctor-michael-kamrava-sued-by-ca-medical-board.html>.

11. *See* *Octuplets Mom Enrages California Taxpayers*, CBS NEWS, Feb. 12, 2009, <http://www.cbsnews.com/stories/2009/02/12/national/main4795528.shtml> (cataloguing various public criticisms of Suleman's decision to have additional children when she was unemployed).

12. *See* Kimi Yoshino & Jessica Garrison, *Stricter Rules on Fertility Industry Debated*, L.A. TIMES, Mar. 6, 2009, available at <http://articles.latimes.com/2009/mar/06/nation/na-octuplets-laws6> (discussing proposed bills in California, Georgia, and Missouri that would limit number of embryos physicians can use in in-vitro fertilization). For a detailed discussion of proposed fertility legislation at the state level, see *infra* notes 139-46 and accompanying text.

13. Legislative responses to highly unusual but extremely salient events often address issues of immediate public concern but typically ignore larger or more common structural issues. *See, e.g.*, Ronald Burns & Charles Crawford, *School Shootings, the Media, and Public Fear: Ingredients for a Moral Panic*, 32 CRIME L. & SOC. CHANGE 147, 152-55, 164-65 (1999) (positing that recent state and federal responses to juvenile crime have been largely disproportionate given that such crime has steadily decreased over past thirty years); David A. Singleton, *Sex Offender Residency Statutes and the Culture of Fear: The Case for More Meaningful Rational Basis Review of Fear-Driven Public Safety Law*, 3 U. ST. THOMAS L.J. 600, 623-25 (2006) (characterizing statutes prohibiting sex offenders from living in close proximity to schools as irrational and proposing new framework for evaluating such statutes). *See generally* Timur Kuran & Cass R. Sunstein, *Availability Cascades and Risk Regulation*, 51 STAN. L. REV. 683, 687-88, 735-36, 764-65 (1999) (arguing that entrepreneurs, social activists, and special interest groups regularly exploit highly publicized events to promote legislative agendas).

three embryos at one time. In fact, none of the proposed legislation following the octuplets' birth addressed these routine practices.<sup>14</sup>

The significant risks associated with multiple gestations raise an obvious question: why, despite strong evidence that single-embryo transfer is the best way to reduce multiple gestations, do most women in the United States still use treatment approaches—hormone therapy or implanting multiple embryos in IVF—that often lead to multiple gestations? These practices stand in sharp contrast to several European countries, where women more commonly use IVF to transfer only one embryo at a time.<sup>15</sup> An important part of the answer to this puzzle lies in the context in which potential parents in the United States find themselves as they face decisions about assisted reproduction.

Federal and state governments and agencies have failed to fulfill their responsibility to address many of the public health consequences of fertility treatment.<sup>16</sup> As a result, market dynamics, fertility specialists and their associations, and disjointed bits of federal and state regulation combine to shape the context in which fertility treatment decisions are made.<sup>17</sup> This decision-making context disserves would-be parents and their hoped-for children by delinking treatment decisions from the long-term individual, public health, social, and economic costs of multiple births.<sup>18</sup>

This Article critically analyzes the dominant approach to understanding patient choice in the assisted reproduction context. Drawing upon well-established findings in cognitive psychology and behavioral economics, it examines how patients are steered toward choices about assisted reproduction that disserve their long-range interests and well-being and reduce social welfare.<sup>19</sup> While those who justify the high rate of multiple births may assert that patients prefer to carry more than one child at a time, they fail to acknowledge how profoundly patients' preferences are influenced by the context in which they are expressed.<sup>20</sup> As described more fully below, this context drives patients toward the fastest and least

14. See Yoshino & Garrison, *supra* note 12 (describing proposed legislation). For a description of current legislative proposals regarding assisted reproduction, see *infra* notes 139-46 and accompanying text.

15. For discussion of fertility treatment practices in four European countries, see *infra* notes 224-321 and accompanying text.

16. For a discussion of current federal and state legislation governing fertility treatment, see *infra* notes 114-46 and accompanying text.

17. For a detailed discussion of how market dynamics affect patient decision-making in the fertility context, see *infra* notes 147-66 and accompanying text.

18. See Guido Pennings, *Multiple Pregnancies: A Test Case for the Moral Quality of Medically Assisted Reproduction*, 15 HUM. REPROD. 2466, 2467-69 (2000) (criticizing current medical guidelines governing in vitro fertilization and proposing new framework aimed at reducing rate of multiple pregnancies).

19. For a discussion of the cognitive psychology and behavioral economics research on assisted reproduction, see *infra* notes 93-113 and accompanying text.

20. See, e.g., Norbert Gleicher et al., *The Desire for Multiple Births in Couples with Infertility Problems Contradicts Present Practice Patterns*, 10 HUM. REPROD. 1079, 1081-83 (1995) (evaluating attitude of fertility patients to multiple births).

expensive available route to conception and fragments the decision-making framework in ways that obscure the serious risks and long-term economic costs associated with multiple gestations—risks and costs that can have a tremendous impact on patients' lives and the lives of their children.<sup>21</sup>

Cognitive psychologists and behavioral economists have identified the influence that decision-making contexts have on shaping decisions. In view of this influence, these commentators encourage close examination of the ways in which institutions structure choices to drive individual decisions.<sup>22</sup> This understanding of human behavior makes it imperative that we identify the features of the fertility care environment that lead patients toward decisions that place their families' health at risk.

This Article enriches the literature on assisted reproduction in several ways. First, it contributes to the sparse legal literature in this area. While the issues surrounding multiple births associated with assisted reproduction have been widely discussed in medical literature, they have only recently drawn the attention of legal academics.<sup>23</sup> This Article seeks to inform and promote a dialogue among legal scholars, lawyers, and policymakers in a position to advance reform efforts regarding the unnecessary health risks created by assisted reproduction practices. Second, the Article analyzes legal and institutional strategies that other countries have used to address the risks created by multiple gestations related to assisted reproduction. This comparative perspective highlights shortcomings in the U.S. approach to assisted reproduction and advances understanding of the strengths and limits of alternative policy options.<sup>24</sup> Third, this Article joins a growing body of literature that examines contextual influences on

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21. For a discussion of how economic factors impair patient decisions in the fertility context, see *infra* notes 147-66 and accompanying text.

22. See, e.g., Cass Sunstein & Richard Thaler, *Libertarian Paternalism Is Not an Oxymoron*, 70 U. CHI. L. REV. 1159, 1161-63, 1188-90 (2003) (examining and defending paternalistic effect of institutional rules on daily behavior).

23. See, e.g., Naomi Cahn & Jennifer M. Collins, Colloquy, *Eight Is Enough*, 103 NW. U. L. REV. 501, 507-13 (2009), <http://www.law.northwestern.edu/lawreview/colloquy/2009/22/LRColl2009n22Cahn&Collins.pdf> (discussing current and proposed regulation of fertility treatment); Kimberly D. Krawiec, Colloquy, *Why We Should Ignore the "Otomom,"* 104 NW. U. L. REV. 120, 128-31 (2009), <http://www.law.northwestern.edu/lawreview/colloquy/2009/34/LRColl2009n34Krawiec.pdf> (criticizing proposed regulations on assisted reproduction); Mary Ann Davis Moriarty, *Addressing In Vitro Fertilization and the Problem of Multiple Gestations*, 18 ST. LOUIS U. PUB. L. REV. 503, 516-18 (1999) (advocating expansion of current fertility regulations); Carson Strong, *Too Many Twins, Triplets, Quadruplets and So On*, 31 J.L. MED. & ETHICS 272, 277-78 (2003) (calling for greater self-regulation among fertility doctors); Urska Velikonja, *The Costs of Multiple Gestation Pregnancies in Assisted Reproduction*, 32 HARV. J.L. & GENDER 463, 481-93, 501-04 (2009) (arguing for increased regulation of assisted reproduction).

24. These justifications do not, of course, exhaust the rationales for engaging in comparative law inquiries. See, e.g., Otto Kahn-Freund, *On the Uses and Misuses of Comparative Law*, 37 MOD. L. REV. 1, 2 (1974) (finding that investigations into foreign law may be useful in "preparing the international unification of law," "giving legal effect to a social change shared by a foreign country with one's own country,"

individual decision-making.<sup>25</sup> Drawing upon this interdisciplinary research, this Article suggests ways that public and private actors should reshape the assisted reproduction decision-making context to guide patients toward one healthy baby.

The structure of this Article proceeds as follows. Section I provides an overview of relevant fertility treatments and the risks associated with multiple births, as well as an assessment of the efficacy of single-embryo transfer in IVF—the method most likely to reduce multiple births. Section II briefly surveys recent scholarly work exploring the situational, cognitive, and emotional constraints on human decision-making. These literatures undermine the dominant approaches to patient autonomy used to justify current practices. Section III identifies and evaluates the factors that shape assisted reproduction decision-making through the lens of cognitive psychology and behavioral economics. This discussion highlights many features of the current system that influence patient decisions. Section IV provides a comparative perspective by reviewing actions taken by Sweden, the United Kingdom, Belgium, and Finland to reshape the assisted reproduction decision-making context and to strengthen the link between assisted reproduction and the longer term health and well-being of patients and their children. Section V details several ways that state and federal officials can employ insights from behavioral economics and the European experience to promote an approach to assisted reproduction that places the health and welfare of patients and their hoped-for children first.

#### I. MULTIPLE GESTATIONS: THE AVOIDABLE RISKS OF ASSISTED REPRODUCTION

The health risks for mothers and children associated with multiple births, including twins, conflict with our popular images of multiples.<sup>26</sup> Thanks to major advances in medical care during pregnancy and the neonatal period, most twins live healthy, active lives. At the same time, they and their pregnant mothers face numerous increased health risks, including low birth weight, premature birth, and disability. This Section first examines the primary methods of assisted reproduction and reviews the rate at which these treatments result in multiple births. It then explains how single-embryo transfer in IVF can greatly reduce the rate of multiple gestations related to assisted reproduction. Finally, it describes the health

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and “promoting at home a social change which foreign law is designed to express or produce”).

25. See generally DAN ARIELY, *PREDICTABLY IRRATIONAL: THE HIDDEN FORCES THAT SHAPE OUR DECISIONS* (2008); RICHARD H. THALER & CASS R. SUNSTEIN, *NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS* (2008).

26. See, e.g., *Gosselin Twins' Special Delivery*, June 3, 2009, [http://www.theinsider.com/news/2241723\\_Gosselin\\_Twins\\_Special\\_Delivery](http://www.theinsider.com/news/2241723_Gosselin_Twins_Special_Delivery) (reporting on twins featured in reality television show *Jon & Kate Plus 8*).

risks to mothers and children associated with multiple gestations and assesses related economic and psychological costs.

Most people who turn to assisted reproduction do so because of a decreased ability to conceive.<sup>27</sup> A couple can be deemed infertile if no gestation has taken place after one year of unprotected intercourse.<sup>28</sup> There are several factors and reasons that cause couples to face infertility. Significant causes of infertility include male subfertility, ovulatory dysfunction, poor cervical mucus, tubal disease, and unexplained subfertility.<sup>29</sup> After unexplained causes of subfertility, ovulatory dysfunction is the most common cause of infertility, leading patients to seek primary care for the failure to become pregnant.<sup>30</sup>

Two common assisted reproduction practices lead to multiple gestations. The cheapest practice—known alternately as hormone therapy, ovulation induction, super ovulation, and ovarian stimulation, or more colloquially described as “taking fertility drugs”—involves the use of hormones to increase the number of mature eggs produced in one menstrual cycle.<sup>31</sup> In many cases the first fertility drug treatment used is clomiphene citrate, a drug that raises levels of the hormone FSH.<sup>32</sup> This treatment carries a 10% risk of multiple gestations.<sup>33</sup> If that is not successful or treatment with clomiphene citrate is not indicated, gonadotropins may be tried. This treatment greatly raises the risk of multiple pregnancies, as the number of eggs fertilized is difficult to control unless the eggs are extracted by the physician, fertilized, and replaced one at a time through IVF.<sup>34</sup> Some medical professionals advocate mild ovarian stimulation to

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27. See Johannes Evers, *Female Subfertility*, 360 LANCET 151, 151 (2002) (finding that what is commonly referred to as “infertility” is actually “subfertility,” a decreased ability to conceive, rather than true infertility, defined as absolute inability to conceive). This Article uses the more commonly used term, “infertility,” but is intended to include both conditions. Because this Article focuses on the effects of infertility on patient decision-making, not all of the analysis is relevant to those homosexual and heterosexual couples who use fertility treatments for other reasons. However, many of the issues addressed, such as the financial constraints and reliance on physician recommendations, apply to all individuals and couples using fertility treatments for whatever reason.

28. See *id.* at 151-52 (distinguishing between “infertility” and “subfertility”).

29. See *id.* at 152 (describing causes of subfertility).

30. See *id.* at 157-58 (describing study results).

31. See Richard P. Dickey et al., *Relationship of Follicle Numbers and Estradiol Levels to Multiple Implantation in 3,608 Intrauterine Insemination Cycles*, 75 FERTILITY & STERILITY 69, 70 (2001) (describing ovulation induction therapy); Bart C.J.M. Fauser et al., *Multiple Birth Resulting from Ovarian Stimulation for Subfertility Treatment*, 365 LANCET 1807, 1808-10 (2005) (explaining process of ovarian stimulation).

32. See Alaina V. Jose-Miller et al., *Infertility*, 75 AM. FAM. PHYSICIAN 849, 854 (2007) (describing frequent use of clomiphene citrate by doctors to stimulate fertility in women with ovulatory dysfunction).

33. Edward Hughes et al., *Clomiphene Citrate for Unexplained Subfertility in Women*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS, Jan. 2010, at 1, 5.

34. See Dickey et al., *supra* note 31, at 69 (noting that more studies have found association between gonadotropin therapy and increased risk of multiple births).



minimize multiple gestations in the use of this method, but even this approach has had limited success in reducing multiple gestations.<sup>35</sup>

Patients may also combine hormone therapy with intrauterine insemination (IUI). IUI is a broadly used term that encompasses several different practices, all of which involve first giving the woman hormone treatment to increase egg production, and then introducing sperm into the female reproductive organs by means other than sexual intercourse.<sup>36</sup> With unexplained subfertility, IUI combined with ovarian stimulation is less demanding and expensive than IVF, and therefore popular as an alternative treatment before IVF, especially with young couples.<sup>37</sup> In IUI, the sperm is typically concentrated into a small volume and “washed” of non-gamete materials, then injected using a catheter directly into the uterus.<sup>38</sup> Combining hormone therapy with IUI may increase the chances of a pregnancy with multiples.<sup>39</sup> The United States does not collect any data on the frequency of the use of these methods or their outcomes.<sup>40</sup> Nonetheless, there is data indicating that hormone therapy used with or without IUI results in many of today’s extremely high order births.<sup>41</sup> Those without the money for the far more expensive treatment option, IVF, are more apt to use fertility drugs to treat infertility.<sup>42</sup>

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than have not); Fauser et al., *supra* note 31, at 1807 (finding that use of ovarian stimulation leads to “raised chances of (higher order) multiple pregnancies”).

35. See Bernard Cohlen et al., *Correspondence, Multiple Pregnancy After Assisted Reproduction*, 366 LANCET 452, 452 (2005) (finding that randomized trials applying “a mild stimulation protocol with strict cancellation criteria show reasonable pregnancy rates per cycle (13–34%) and no multiple pregnancies”); Norbert Gleicher et al., *Reducing the Risk of High-Order Multiple Pregnancy After Ovarian Stimulation with Gonadotropins*, 343 NEW ENG. J. MED. 2, 6 (2000) (concluding that ovarian stimulation “that is less intensive than is currently customary may reduce the incidence of high-order multiple pregnancy in infertile women, though only to a limited extent and at the expense of overall pregnancy rates”).

36. See Fauser et al., *supra* note 31, at 1807 (describing intrauterine insemination technique).

37. See Evers, *supra* note 27, at 157 (finding that IVF has higher dropout rate than IUI or ovarian stimulation therapy because of its more demanding form of treatment).

38. See Willem Ombelet et al., *Intrauterine Insemination After Ovarian Stimulation with Clomiphene Citrate: Predictive Potential of Inseminating Motile Count & Sperm Morphology*, 12 HUM. REPROD. 1458, 1460 (1997) (describing insemination procedure).

39. See Saul, *supra* note 1, at A1 (noting that Centers for Disease Control and Prevention study found that IUI causes more multiple births than IVF).

40. See Macaluso et al., *supra* note 5, at 5 (finding that “there is no population-based information on the success rates or on the adverse health outcomes that are associated with non-ART approaches to infertility treatment”); Saul, *supra* note 1, at A1 (noting that intrauterine insemination is not tracked by any government agency).

41. See Fauser et al., *supra* note 31, at 1809-10 (comparing results from three large clinical trials).

42. See MUNDY, *supra* note 1, at 222.

The second practice that results in higher rates of multiple pregnancies is IVF itself. IVF relies on the same hormones used in hormone therapy to increase the number of eggs produced.<sup>43</sup> A physician monitors the development of the eggs by ultrasound or hormone levels in the patient's blood. When the eggs are mature, they are extracted and placed on a petri dish, where they are fertilized with sperm.<sup>44</sup> This fertilization may be done with a process called intracytoplasmic sperm injection (ICSI), by which the sperm is injected directly into the egg.<sup>45</sup> The resulting embryos are transferred into a woman's uterus through the cervix.<sup>46</sup>

Unlike hormone therapy, IVF allows precise control over the number of embryos implanted, and thus over the incidence of multiple gestations. Nevertheless, in the United States, multiple embryos are often implanted, which greatly increases the risk of multiple gestations. In 2006, only 11% of embryo transfers involved one embryo, 46% involved two embryos, and 43% involved three or more.<sup>47</sup> These numbers are surprising given the growing medical consensus that single-embryo transfer is a preferable course of treatment for many patients who have a good prognosis.<sup>48</sup> The University of Iowa has demonstrated that it is quite possible to use single-

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43. See Sunderam et al., *supra* note 4, at 2 (explaining in vitro fertilization method).

44. See *id.* (describing procedure).

45. See CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY & FERTILITY CLINIC REPORTS 1, 3 (2006) [hereinafter CDC, 2006 ART SUCCESS REPORT], available at <http://www.cdc.gov/ART/ART2006/508PDF/2006ART.pdf> (describing use of intracytoplasmic sperm injection (ICSI)). ICSI is now used in approximately 60% of the attempts at IVF. See *id.* at 39 fig.27 (reporting statistics). For ease of reference, ICSI is not separately discussed, and where the abbreviation IVF is used, it is intended to be inclusive of IVF that involves ICSI.

46. See *id.* at 39 (describing injection procedure). There are two relatively rare practices related to IVF known as gamete intrafallopian transfer (GIFT) and zygote intrafallopian transfer (ZIFT). See *id.* (discussing alternative procedures to ICSI). Both of these procedures implant into the fallopian tubes instead of the uterus. See *id.* (distinguishing GIFT and ZIFT procedures from ICSI); see also Fernando Zegers-Hochschild et al., *The International Committee Monitoring Assisted Reproductive Technologies and the World Health Organization (WHO) Glossary on ART Terminology*, 24 HUM. REPROD. 2683, 2686-87 (2009) (defining GIFT and ZIFT procedures). They differ in that GIFT implants the unfertilized eggs into the fallopian tubes directly after they are removed. See Zegers-Hochschild et al., *supra*, at 2686 (describing GIFT procedure). ZIFT is more similar to IVF in that the eggs are fertilized in vitro and transferred to the fallopian tubes. See *id.* at 2687 (describing ZIFT procedure). Both GIFT and ZIFT are rarely practiced in the United States and each represent less than 1% of the ART procedures tracked by the CDC. See CDC, 2006 ART SUCCESS REPORT, *supra* note 45, at 89 (finding that both GIFT and ZIFT procedures were used in less than 1% of assisted reproduction procedures in 2006).

47. See CDC, 2006 ART SUCCESS REPORT, *supra* note 45, at 44 (reporting findings).

48. See Ginny L. Ryan et al., *A Mandatory Single Blastocyst Transfer Policy with Educational Campaign in a United States IVF Program Reduces Multiple Gestation Rates Without Sacrificing Pregnancy Rates*, 88 FERTILITY & STERILITY 354, 357 (2007) (study showing mandatory single embryo transfer yielded "excellent pregnancy rates").

embryo transfer to reduce this high rate of multiples while providing effective infertility treatment.<sup>49</sup> Furthermore, a recent study found that couples with unexplained infertility can save money while reducing the risk of conceiving multiples by reducing the number of IUI attempts prior to beginning IVF.<sup>50</sup> It should be noted, however, that IVF is often attempted after other simpler procedures and treatments have been tried, due to the taxing, surgical, and painful nature of IVF procedures.<sup>51</sup>

Numerous studies have shown that single-embryo transfer provides the best opportunity to prevent multiple gestations.<sup>52</sup> For example, in one 2003 clinical study, patients up to age thirty-seven with two or more good quality embryos were offered the option of single-embryo transfer.<sup>53</sup> The study found that the twinning rate of patients undergoing single-embryo transfer was reduced to 4%, compared to a 65% twinning rate for patients who underwent double-embryo transfer.<sup>54</sup> Further, single-embryo transfer often means that there will be unused embryos that can be frozen and used for a second or even third implantation if the first is not successful, or if the patient elects to conceive a subsequent child.<sup>55</sup> Frozen embryo cycles are considerably less expensive and less stressful for patients. Though one cycle involving a single-embryo transfer does not yet match the pregnancy or live birth rates achieved by implanting two or

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49. See *id.* (reporting mandatory single-embryo transfer led to decrease in twin rates while producing favorable pregnancy rates).

50. See Richard H. Reindollar et al., *A Randomized Clinical Trial to Evaluate Optimal Treatment for Unexplained Infertility: The Fast Track and Standard Treatment (FASTT) Trial*, FERTILITY & STERILITY (forthcoming 2010) (manuscript at 10, article in press) (stating that accelerating ART process by eliminating use of gonadotropin/IUI decreases time to pregnancy and overall cost of ART process).

51. See Evers, *supra* note 27, at 156-57 (comparing studies in which patients received in vitro fertilization following ovarian stimulation); Astrid Højgaard et al., *Friendly IVF: Patient Options*, 16 HUM. REPROD. 1391, 1395 (2001) (finding that patients undergoing in vitro fertilization experienced severe side effects, whereas patients receiving clomiphene citrate therapy reported almost no side effects); Interview by Jamie Kim with Dr. Myong Jee Kim, OB/GYN Physician, in Houston, Tex. (Aug. 18, 2009) (noting invasive nature of IVF).

52. See, e.g., David Adamson & Valerie Baker, *Multiple Births from Assisted Reproductive Technologies: A Challenge that Must Be Met*, 81 FERTILITY & STERILITY 517, 521 (2004) (finding that elective single-embryo transfer can reduce twin rates in United States by half); Amy Criniti et al., *Elective Single Blastocyst Transfer Reduces Twin Rates Without Compromising Pregnancy Rates*, 84 FERTILITY & STERILITY 1613, 1616 (2005) (finding that elective single-embryo transfer significantly reduced twin pregnancy rates); A. Tiitinen et al., *Elective Single Embryo Transfer: The Value of Cryopreservation*, 16 HUM. REPROD. 1140, 1141, 1143 (2001) (concluding that elective single-embryo transfer results in very acceptable pregnancy risks with low rate of twins).

53. See C. Guerrero et al., *Elective Single Blastocyst Transfer Reduces Multiple Rates Without Compromising Pregnancy Rates*, 90 FERTILITY & STERILITY S367, S367 (Supp. 2008) (stating study results).

54. See *id.*

55. See *id.* (finding that 100% of single-embryo transfer patients had extra embryos available for cryopreservation, whereas only 68% of double-embryo transfer patients had extra embryos).

more embryos, the disparity is not great.<sup>56</sup> The discrepancy between single-embryo transfer and double-embryo transfer pregnancy rates disappears when a second transfer cycle using frozen embryos is included.<sup>57</sup> IVF programs in Sweden, Finland, Belgium, and the United States have had great success with single-embryo transfer when patients are carefully selected for this procedure.<sup>58</sup>

Multiple gestations can occur without medical intervention. At least 17% of twins born in the United States in 2006, however, were born as a result of IVF.<sup>59</sup> In 2006, 44% of infants born through the use of assistive reproductive technology (ART) were twins, while another 5% were triplets or higher order multiples.<sup>60</sup> Hormone therapy carries a 25% risk of twinning, and a 5% risk of producing triplets or higher order births.<sup>61</sup> These statistics undercount the number of multiple gestations initiated through

56. *See id.* (finding single blastocyst transfer clinical pregnancy rate of 78% and live birth rate of 66% compared to double blastocyst transfer clinical pregnancy rate of 84% and live birth rate of 77%); *see also* Zdravka Veleva et al., *Elective Single Embryo Transfer with Cryopreservation Improves the Outcome and Diminishes the Costs of IVF/ICSI*, 24 HUM. REPROD. 1632, 1635-36 (2009) (finding elective single-embryo transfer combined with freezing of extra embryos more effective at minimizing risk of multiple births and less expensive than conventional double-embryo transfer).

57. *See* PETER BRAUDE, ONE CHILD AT A TIME: REDUCING MULTIPLE BIRTHS AFTER IVF 34-36 (2006), available at [http://www.hfea.gov.uk/docs/MBSET\\_report\\_Final\\_Dec\\_06.pdf](http://www.hfea.gov.uk/docs/MBSET_report_Final_Dec_06.pdf) (“The discrepancy is reduced or eliminated when pregnancies following a subsequent frozen/thawed transfer cycle are added, when some trials have found no significant differences for pregnancy rates between single embryo transfer and DET [double embryo transfer].”); Diane deNeubourg & J. Gerris, *What About the Remaining Twins Since Single-Embryo Transfer? How Far Can (Should) We Go?*, 21 HUM. REPROD. 843, 844 (2006) (finding that cryopreservation is especially important to ensuring high success rates with elective single-embryo transfer).

58. *See, e.g.*, Criniti et al., *supra* note 52, at 1613 (finding that elective single-embryo transfer in carefully chosen patients significantly reduced risk of multiple pregnancies when compared to double-embryo transfer); Sylvie Gordts et al., *Belgian Legislation and the Effect of Elective Single Embryo Transfer on IVF Outcome*, 10 REPROD. BIOMED. ONLINE 436, 437-39 (2005) (noting sharp reduction in twin pregnancies following use of single-embryo transfer); Macaluso et al., *supra* note 5, at 5 (citing studies in which elective single-embryo transfer plus second cycle with frozen embryos achieved success rates similar to double-embryo transfer); Zdravka Veleva et al., *Elective Single Embryo Transfer in Women Aged 36-39 Years*, 8 HUM. REPROD. 2098, 2099-3000 (2006) (finding that single transfer of fresh embryo followed by frozen embryo transfer rate resulted in higher cumulative pregnancy rates and lower cumulative multiple pregnancy rates in women aged thirty-six to thirty-nine compared to conventional double-embryo transfer). For an extended analysis of single-embryo transfer, *see generally* SINGLE EMBRYO TRANSFER (Jan Gerris et al. eds., 2009).

59. *See* Sunderam et al., *supra* note 4, at 9 (citing data).

60. *See id.* at 10-11 (citing data).

61. *See Side Effects of Gonadotropins*, PATIENT'S FACT SHEET (Am. Soc'y of Reprod. Med., Birmingham, Ala.), 2005, available at [http://www.asrm.org/uploadedFiles/ASRM\\_Content/Resources/Patient\\_Resources/Fact\\_Sheets\\_and\\_Info\\_Booklets/Gonadotropins-Fact.pdf](http://www.asrm.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/Gonadotropins-Fact.pdf) (citing data). Here, “hormone therapy” refers to the injection of gonadotropins. *See id.* (explaining therapy).

IVF or hormone therapy because they exclude multiple gestations that are selectively reduced or end in a miscarriage of one or more fetuses.<sup>62</sup> Those who choose multifetal reduction often do so under extremely difficult circumstances. Patients may be informed that multifetal reduction not only means eliminating one or more developing fetuses, but also places the entire pregnancy at risk.<sup>63</sup> On the other hand, if patients decide against multifetal reduction, they and their children face other serious risks.<sup>64</sup>

Multiple gestations, including twins, create serious health risks for mothers and their children.<sup>65</sup> Multiple gestations raise serious individual and social issues, including myriad health, welfare, and economic concerns.<sup>66</sup> Mothers of multiples face greater risks of harmful conditions such as pre-eclampsia, preterm labor and delivery, and gestational diabetes.<sup>67</sup> Mothers carrying multiple fetuses are also often hospitalized prior to delivery, endure prolonged bed rest, and experience higher rates of Caesarean delivery.<sup>68</sup>

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62. "Selective reduction" involves the termination of some of the developing fetuses in a multifetal pregnancy. See Practice Comm. of the Am. Soc'y for Reprod. Med., *Multiple Pregnancy Associated with Infertility Therapy*, 86 FERTILITY & STERILITY S4, S106-10 (2006) [hereinafter ASRM, *Multiple Pregnancy*]. In fact, it is impossible to know the extent to which selective reduction impacts these statistics in the United States because neither the CDC nor the ART industry tracks the figures. See Liza Mundy, *Too Much to Carry?*, WASH. POST, May 20, 2007, at W14 ("There is no way to know how many pregnancies achieved by fertility treatment start out as triplets or quadruplets and are quietly reduced to something more manageable. The U.S. Centers for Disease Control and Prevention, which publishes an annual report on fertility clinic outcomes, does not include selective-reduction figures because of the reluctance to report them. The industry doesn't publish them, either.").

63. See AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, ACOG COMMITTEE OPINION No. 369, at 3 (2007) (describing risk of pregnancy loss and patient struggles with emotional and ethical issues related to fetal reduction).

64. See MUNDY, *supra* note 1, at 253-72 (showing reduction is often best way to guarantee one or more healthy babies).

65. See, e.g., BRAUDE, *supra* note 57, at 23-27; Boulet et al., *supra* note 4, at 1945.

66. See Martin H. Johnson & Kerry Petersen, *Instruments for ART Regulation: What Are the Most Appropriate Mechanisms for Achieving Smart Regulation?*, in REGULATING AUTONOMY: SEX, REPRODUCTION AND FAMILY 169, 173-80 (Shelley Day Sclater et al. eds., 2009) (suggesting changes to regulations to meet needs of various problems posed by multiple gestations).

67. See ASRM, *Multiple Pregnancy*, *supra* note 62, at S106 (identifying maternal complications with multiple gestation).

68. See Patricia Katz et al., *The Economic Impact of the Assisted Reproductive Technologies*, 4 NATURE CELL BIOLOGY & NATURE MED. S29, S30 (2002) (describing increased costs associated with multiple gestation); see also Doris M. Campbell & Allan Templeton, *Maternal Complications of Twin Pregnancy*, 84 INT'L J. GYNECOLOGY & OBSTETRICS 71, 71-73 (2004) (caesarean section deliveries constituted 30% of multiple births, compared to only 12.5% of singleton births).

Multiple gestations also increase the risk of death for children.<sup>69</sup> The death rate during the first year of life is 0.6% for single births, 3% for twins, and 6% for triplets.<sup>70</sup> More than 60% of twins are born preterm, and 12% of those are born very preterm.<sup>71</sup> Those rates are even higher for triplets, of whom more than 90% are preterm, and 36% very preterm.<sup>72</sup> Multiples are more likely to have low birth weight as well. Fifty-eight percent of twins and 96% of triplets are born with low birth weights, compared to only 7% of singletons.<sup>73</sup> Similarly, 10% of twins and 35% of triplets fall within the even more risky criteria for “very low birth weight,” compared to only 1% of singletons.<sup>74</sup>

Further, disability rates for children who are multiples are higher. Babies born as part of multiples face far greater risks of cerebral palsy, need for neonatal intensive care after birth, and a serious range of mental and physical impairments resulting from premature birth and other complications.<sup>75</sup> Many face behavioral and cognitive problems that require additional services and create substantial barriers to education and employment.<sup>76</sup>

In addition, the costs of delivery, neonatal hospitalizations, and childhood services are dramatically higher because of the elevated health risks associated with multiple gestations. The hospital delivery of twins is twice as expensive per child as delivery of a single baby, and the costs for triplets

69. See Laura A. Schieve et al., *Are Children Born After Assisted Reproductive Technology at Increased Risk for Adverse Health Outcomes?*, 103 *OBSTETRICS & GYNECOLOGY* 1154, 1160-61 (2004) (summarizing adverse relationship between ART and normal human development). See generally Sunderam, *supra* note 4 (summarizing problems associated with ART for infants).

70. See Boulet et al., *supra* note 4, at 1944 (discussing infant death rates for live born infants during first year of life); Joyce A. Martin et al., *Births: Final Data for 2006*, NAT'L VITAL STAT. REP., Jan. 2009, at 7, 21 (explaining survival statistics for multiple births across racial groups).

71. See Martin et al., *supra* note 70, at 21 (summarizing gestational age and birth weight characteristics by plurality in table). “Preterm” means born before thirty-seven weeks of gestation, while “very preterm” is used for those born after less than thirty-two weeks gestation. See Boulet et al., *supra* note 4, at 1942 (defining terms).

72. See Martin et al., *supra* note 70, at 21 (stating statistics of birth weight characteristics of multiples).

73. See *id.* (stating statistics of birth weight characteristics of multiples). “Low birth weight” is less than 2500 grams; “very low birth weight” is less than 1500 grams. See Boulet et al., *supra* note 4, at 1942.

74. See Martin et al., *supra* note 70, at 21 (stating statistics of birth weight characteristics of multiples).

75. See Eric Blyth et al., *Assisted Human Reproduction: Contemporary Policy and Practice in the UK*, in *ASSISTED HUMAN REPRODUCTION: PSYCHOLOGICAL AND ETHICAL DILEMMAS* 1, 1-27 (Dani Singer & Myra Hunter eds., 2003) (discussing the side effects of multiple gestations).

76. See Eugene M. Lewit et al., *The Direct Cost of Low Birth Weight*, *THE FUTURE OF CHILDREN*, Spring 1995, at 35, available at <http://futureofchildren.org/future-ofchildren/publications/journals/article/index.xml?journalid=60&articleid=371&sectionid=2486>.

is four times as high per child.<sup>77</sup> The prematurity and low birth weight related to multiple gestations leads to increased hospital costs, as well as increased health care and education costs throughout the life of the child.<sup>78</sup> Some children may require developmental services such as case management, counseling, and respite care for families.<sup>79</sup> Children who were low birth weight babies are much more likely to repeat a grade in school or to require special education services during school years.<sup>80</sup> Special education significantly increases public education costs.<sup>81</sup>

The families of these children must also absorb numerous costs associated with using health care professionals and disability services at higher rates. They often must endure numerous medical appointments, many during the traditional work day, and provide higher levels of personal care for their children.<sup>82</sup> They may bear out-of-pocket health care expenses and face reduced labor force participation by one parent, often the mother.<sup>83</sup>

The increased stress caused by parenting multiples and children who were low birth weight babies also takes a psychological toll. Mothers and families with twins are more likely to experience adverse psychosocial consequences, reporting greater parenting stress, maternal depression, inability to work outside the home, and likelihood of divorce.<sup>84</sup> Moreover, parents of children who require neonatal intensive care face great stress

77. See 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, 244-49 (1994); Sari Koivurova et al., *Health Care Costs Resulting from IVF: Prenatal and Neonatal Periods*, 19 HUM. REPROD. 2798, 2803 (2004) (showing that prenatal cost per twin is twice cost of single pregnancy while neonatal costs were 3.8 to 7.7 times higher than singletons).

78. See generally Douglas Almond et al., *The Costs of Low Birth Weight*, 120 Q. J. ECON. 1031 (2005); see also Lewit et al., *supra* note 76, at 44-45.

79. See Lewit et al., *supra* note 76, at 44.

80. See *id.* at 44-45 (reporting almost 50% increase in use of special education services by children ages six to fifteen who were less than 2500 grams at birth); see also Stephen Chaikind & Hope Corman, *The Special Education Costs of Low Birthweight*, 10 J. HEALTH ECON. 291 (1991).

81. See Lewit et al., *supra* note 76, at 44.

82. See MUNDY, *supra* note 1, at 225.

83. See Lewit et al., *supra* note 76, at 47.

84. See Charlotte Sheard et al., *Impact of a Multiple, IVF Birth on Post-Partum Mental Health: A Composite Analysis*, 22 HUM. REPROD. 2058, 2062 (2007) ("Despite appearing a low-risk group for post-natal depression, 8.8% of the first time mothers in this study scored above 12 on the EPDS indicating clinically significant symptoms of depression. In answer to the first research question (did first-time IVF mothers of twins or triplets have poorer emotional well-being at 6 weeks post-partum compared to IFV mothers of singletons?) we found a trend toward significance for mothers of multiples to score higher on the EPDS and to score above the cut-off, with 15.6% scoring above 12 compared to only 5.9% of the mothers of singletons. These findings support Klock's (2004) suggestion in her review of the psychological adjustment to twins after infertility, that mothers of multiples will be more vulnerable to depression.").

and are at risk for post-traumatic stress disorder even if their children survive.<sup>85</sup> These psychological consequences can last years.<sup>86</sup>

All of these adverse consequences create the need for additional public and private health, mental health, and educational and social service expenses that are borne by the larger society. While some public health risks are outside human control, the epidemic of multiple births is entirely man-made and exacts a heavy toll on families. As later sections will show, it is an epidemic that can be addressed.

## II. HOW CONTEXT SHAPES FERTILITY PATIENT DECISION-MAKING

Those who support the status quo in U.S. practices concerning multiple-embryo transfer argue that patient autonomy needs protection in the face of impending government regulation.<sup>87</sup> Indeed, the United States Supreme Court has described freedom “from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child” as an essential aspect of the right to privacy.<sup>88</sup> Those who support the status quo, however, fail to fully acknowledge the complicated nature of autonomy.<sup>89</sup>

One classic definition views people as autonomous “when their decisions and actions are their own; when they are self-determining;” and when they are free of coercion.<sup>90</sup> Individuals should act only after critical reflection, which enables their decisions to reflect their “true” selves.<sup>91</sup> Opponents to regulation cite patients’ attitudes that favor the birth of twins as evidence that the high rate of twinning in the United States is the result of deliberate, autonomous decision-making by patients.<sup>92</sup>

Modern theories of behavioral economics, however, reject the idea that through mere critical reflection people always make choices that reflect their true selves. The classical utilitarian view is that people use reason when making a decision to choose the result that will cause them the

85. See Laurie Tarkan, *For Parents on NICU, Trauma May Last*, N.Y. TIMES, Aug. 25, 2009, at D5; see also Richard J. Shaw et al., *The Relationship Between Acute Stress Disorder and Posttraumatic Stress Disorder in the Neonatal Intensive Care Unit*, 50 PSYCHOSOMATICS 131, 131-36 (2009).

86. See Sheard et al., *supra* note 84, at 2064.

87. See, e.g., Norbert Gleicher & David Barad, *The Relative Myth of Elective Single Embryo Transfer*, HUM. REPROD., Feb. 2006, at 5, <http://humrep.oxfordjournals.org/cgi/reprint/del026v1>.

88. See *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972).

89. See Theresa Glennon, *Regulation of Reproductive Decision-making*, in REGULATING AUTONOMY: SEX, REPRODUCTION AND FAMILY, *supra* note 66, at 152.

90. See GERALD DWORIN, *THE THEORY AND PRACTICE OF AUTONOMY* 13 (1988).

91. See *id.*

92. See Gleicher & Barad, *supra* note 87, at 5. For a critique of the evidentiary basis for this assertion, see *infra* note 214 and accompanying text.



greatest personal gain.<sup>93</sup> This idea, however, implies that a person knows all the facts involved and can perfectly weigh all options available to them. Herbert Simon, in his book *Models of Man*, proposes that people are limited by “bounded rationality,” or the inability to gain enough knowledge or fully process the possibilities of any decision.<sup>94</sup> The result of this bounded rationality is a predictable bias in reasoning when people are faced with decisions.<sup>95</sup>

Research on human decision-making continues to challenge the idea that people have fixed preferences that reflect their true selves.<sup>96</sup> Cass Sunstein and Richard Thaler argue that rather than having “clear, stable and well-ordered preferences,” people are “strongly influenced by details of the *context* in which they make their choice. . . .”<sup>97</sup> That is, preferences are, in part, a product of existing social and legal arrangements.<sup>98</sup> It is necessary to highlight here three aspects of the assisted reproduction context that strongly affect patients’ choices: the structure of choice context, the resource context, and the internal context.

The *structure of choice* context focuses on factors that affect how decisions are made. Three factors examined here are: “default rules,” “decisional anchors,” and “framing.” Default rules are the first example of structure of choice.<sup>99</sup> Individuals are apt to go along with default rules, and changes in default rules sway individual choices dramatically.<sup>100</sup> For example, an employee retirement investment plan that treats participation in the plan as the default option includes significantly more employees than one that requires employees to choose to opt in.<sup>101</sup> Accordingly, a

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93. See JOHN STUART MILL, *On the Definition of Political Economy; and on the Method of Investigation Proper To It*, in *ESSAYS ON SOME UNSETTLED QUESTIONS OF POLITICAL ECONOMY* (Longmans, Green, Reader et al. eds., 1874).

94. See HERBERT SIMON, *MODELS OF BOUNDED RATIONALITY: EMPIRICALLY GROUNDED ECONOMIC REASON* 291 (1997).

95. See, e.g., *id.* at 291; Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty: Heuristics & Biases*, 185 *SCI.* 1124, 1127 (1974).

96. For one survey of this critique across various fields of legal thought, see Jane B. Baron & Jeffrey L. Dunoff, *Against Market Rationality*, 17 *CARDOZO L. REV.* 431 (1996). The behavioral economics literature is also subject to dispute. See David A. Hoffman, *The “Duty” to Be a Rational Shareholder*, 90 *MINN. L. REV.* 537, 546-47 (2006).

97. Sunstein & Thaler, *supra* note 22, at 1161; see also Amos Tversky & Itamar Simonson, *Context-Dependent Preferences*, 39 *MGMT. SCI.* 1179, 1187 (1993); Amos Tversky & David Kahneman, *The Framing of Decisions & The Psychology of Choice*, 211 *SCI.* 453 (1981) (stating that decision-makers are influenced by personal perception and frame in which he or she makes decisions comprised of personal characteristics).

98. See Cass R. Sunstein, *Republicanism and the Preference Problem*, 66 *CHI.-KENT L. REV.* 181, 184 (1990) (explaining that highly-contextualized and contingent nature of individual preferences problematizes claims that existing norms maximize preferences: “when preferences are a function of legal rules, the rules cannot, without circularity, be justified by reference to the preferences”).

99. See THALER & SUNSTEIN, *supra* note 25, at 14-16 (2008).

100. See *id.* at 85-87.

101. See *id.* at 110-11.

clinic form that is structured to give consent to the placement of two or more embryos per cycle rather than a single embryo makes multiple-embryo transfer the default option that few patients will choose to reject.<sup>102</sup>

A second factor in examining the structure of choice context involves decisional anchors, or starting points, which are also strongly influential.<sup>103</sup> One type of decisional anchor is the decision that is presented as the norm—the choice that most individuals make.<sup>104</sup> In the context of assisted reproduction, if clinics tell patients that most other patients implant two or three embryos, these numbers become the patients' analytic anchors or starting points, and patients are unlikely to vary from them.

Third, the framing of information also strongly affects decision-making. Framing identifies how the decision is described.<sup>105</sup> For example, individuals considering a risky medical procedure reach different conclusions depending on whether they are told the procedure leaves 90% of patients still alive five years later or 10% of patients dead after five years.<sup>106</sup> Fertility patients may be swayed by framing that emphasizes a possible small increase in their chance of becoming pregnant from implanting multiple embryos while downplaying the risks of multiple gestations or the disturbing nature of selective reduction. Framing can also involve the time frame described as relevant. For instance, the fertility treatment decision may be described solely as maximizing the success of one particular cycle, or it may be expressed as a treatment plan to achieve a healthy pregnancy and baby in a reasonable time frame.

Thus, patient treatment decisions are likely to be strongly influenced by the structure of choice at the fertility clinic. Patients rarely opt out of default rules established by the clinic, are apt to accept the choices listed first or described as the norm, and are swayed by the manner in which their options are framed. The way in which the fertility clinic and treating physician structure patient choices carries the weight of expertise, and patients are unlikely to challenge the advice provided.<sup>107</sup> The structure of choice context created by the fertility clinic cannot help but affect individ-

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102. Many patients sign boilerplate consent forms that state that: [T]hey realize that transferring more than one embryo increases the risk of multiples. The form neatly exempts the fertility doctor from responsibility for adverse outcomes. But in the reproduction field, there is a subterranean conversation going on about how much detail to put in the warning. It's one thing to sign a boilerplate form; it is another thing to be truly counseled.

MUNDY, *supra* note 1, at 244. In interviews, patients revealed that they were not warned or counseled about the chance of multiples beyond a consent form mixed with many others and a short, last minute discussion of the embryo-transfer decision. *See id.* at 243-44.

103. *See* Sunstein & Thaler, *supra* note 22, at 1177-78.

104. *See* THALER & SUNSTEIN, *supra* note 25, at 24.

105. *See id.* at 36-37.

106. *See id.* at 36.

107. *See generally* Andrea D. Gurmankin et al., *The Role of Physicians' Recommendations in Medical Treatment Decisions*, 22 MED. DECISION MAKING 262 (2002).

ual decisions about assisted reproduction, and any plausible approach to the issue of patient autonomy must be cognizant of this context.

Patients also make their decisions in a very specific *resource* context. Some patients lack the resources to attempt assisted reproduction at all, severely limiting patients' decisional autonomy.<sup>108</sup> Resource limitations may also prevent patients from choosing the safest and most effective medical options.<sup>109</sup> A patient who "chooses" to use hormone therapy instead of IVF may do so only because of the inability to finance IVF. That patient cannot "choose" IVF. Likewise, patients' decisions to maximize the chances of pregnancy on the first cycle through multiple-embryo transfer may be determined by their inability to pay for other cycles, not their desire for twins or triplets.

Finally, the *internal* context for decision-making affects individual decisions. Humans do not exhibit perfect rationality. Instead, people are subject to consistent types of errors of judgment and prediction. Notably because people have "bounded rationality," which limits their ability to obtain, process, and interpret information, they use rules of thumb, or heuristics, that are often biased. One example of a rule of thumb is the "availability heuristic," which describes the tendency to over-predict a familiar outcome and under-predict an outcome an individual has never previously encountered.<sup>110</sup> Thus, if a couple knows a family with twins where the outcome was good, they are unlikely to believe that the risks of twinning will affect them.

In addition, individuals exhibit "bounded willpower," which means that individuals make decisions that serve their immediate desires even when they are aware that those decisions undermine their long-term desires.<sup>111</sup> Bounded willpower may lead partners or individuals stressed by infertility to implant a higher number of embryos because they feel pressured to become pregnant in *this* cycle. In so doing, they may undervalue the later stress they will experience if too many embryos successfully implant and they are faced with the serious health risks posed by multiple gestations or the pressure to make the painful decision to reduce one or more developing fetuses.<sup>112</sup> Individuals also have difficulty predicting future emotional states and inaccurately forecast the duration and intensity

108. See JONATHAN HERRING, *MEDICAL LAW AND ETHICS* 301-02 (2006).

109. See MUNDY, *supra* note 1, at 222.

110. See Cass Sunstein, *Moral Heuristics and Moral Framing*, 88 MINN. L. REV. 1556, 1561 (2004).

111. See Christina Jolls, Cass Sunstein & Richard Thaler, *A Behavioral Approach to Law and Economics*, 50 STAN. L. REV. 1471, 1479 (1998).

112. See Pennings, *supra* note 18, at 2467 ("There are strong indications that infertile people's decision-making is mainly guided by their desire to become parents. Their wish for a child makes them underestimate the difficulties of raising a child (let alone more than one child), among which there may be a child with special needs."); see also MUNDY, *supra* note 1, at 243.

of future affective states, such as the experience of a high-risk pregnancy, premature birth, or raising multiple, possibly disabled, children.<sup>113</sup>

These various aspects of the context in which patients make decisions regarding the number of embryos to implant may all affect patients' decision-making. They suggest that individuals' choices are strongly influenced by the environment in which they are made, and that no decision-making context is truly "neutral."

### III. THE DECISIONAL LANDSCAPE OF ASSISTED REPRODUCTION IN THE UNITED STATES

Patients make the assisted reproduction decisions that affect their chances of having a multiple gestation within a complicated landscape. This Section closely examines the landscape within which patients and physicians discuss and make decisions regarding assisted reproduction that may increase or lower the risk of multiple births.

#### A. *Federal Legislation and Agency Action: Fragments and Distorts*

Federal regulation in the area of assisted reproduction is sparse, yet it has had an important effect on the decision-making context related to multiple gestations. The federal government, by creating a definition of "success" for assisted reproductive technology, makes it more difficult for clinics and patients to move toward single-embryo transfer in IVF. Further, the lead federal agency dealing with assisted reproduction, while clearly knowledgeable and concerned about the health risks associated with multiple births related to assisted reproduction, has failed to effectively educate the public, fertility specialists, and patients about such risks.

The United States has not passed comprehensive regulation of assisted reproduction at either the federal or state level.<sup>114</sup> Congress and state legislatures may have avoided tackling this subject because of the highly charged debate concerning the status of human embryos and the desire to avoid regulation in areas of rapid technological change.<sup>115</sup> The United States has refused to fund most research related to the improvement of fertility treatment and laboratory techniques or the health effects of the widespread use of assisted reproduction. In the absence of such regulation, a thriving market-based system of fertility clinics has devel-

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113. See Daniel Gilbert & Timothy Wilson, *Miswanting: Some Problems in the Forecasting of Future Affective States*, in *FEELING & THINKING: THE ROLE OF AFFECT IN SOCIAL COGNITION* 178, 193 (Joseph Forgas ed., 2000); Jeremy Blumenthal, *Law & the Emotions: The Problems of Affective Forecasting*, 80 *IND. L.J.* 155, 167 (2005).

114. See CHARLES P. KINDREGAN & MAUREEN MCBRIEN, *ASSISTED REPRODUCTIVE TECHNOLOGY: A LAWYER'S GUIDE TO EMERGING LAW AND SCIENCE* 78-82 (2006).

115. See DEBORA L. SPAR, *THE BABY BUSINESS: HOW MONEY, SCIENCE, AND POLITICS DRIVE THE COMMERCE OF CONCEPTION* 228 (2006).

oped.<sup>116</sup> Patients seeking treatment for infertility do so through this private, mostly for-profit market.<sup>117</sup>

Federal law is designed to support this market approach by providing consumers with accurate information about success rates for ART employed by individual fertility clinics.<sup>118</sup> It also establishes standards for embryology laboratories. The Fertility Clinic Success Rate and Certificate Act of 1992 requires all ART programs to report annual data to the Centers for Disease Control (CDC) concerning the “pregnancy success rates” per IVF cycle of the program.<sup>119</sup> It ensures that ART programs use certified embryo laboratories by requiring these programs to identify the embryo lab they use.<sup>120</sup> The Act requires the CDC to define pregnancy success rates, taking “into account the effect of age, diagnosis and other significant factors” and to include the live birth rate in relation to the number of ovarian stimulation procedures attempted by ART programs and the number of successful egg retrieval procedures.<sup>121</sup> By focusing on the “per cycle” success rate, the Act undercuts efforts to use single-embryo transfer, which relies on the combination of fresh and frozen embryo cycles to achieve a similar success rate. The Act does not require reporting of the cumulative pregnancy rate for patients.

The Act also requires the CDC to publish and distribute to states and the public the pregnancy success rates provided by ART programs and also to name any programs that fail to provide the required data.<sup>122</sup> In 2007, 430 fertility treatment programs submitted data to the CDC. This data is reported on the CDC website<sup>123</sup> and on the website of the Society of Assisted Reproductive Technology (SART). Most fertility clinics also post their data on their own websites or provide a link to another website where the information is posted.

These statutory requirements fragment information in several ways. First, by focusing on clinic pregnancy success rates per cycle, the Act directs prospective patients to focus primarily on this single statistic, rather than seeing pregnancy and birth rates within the larger context of patient care, cumulative birth rates, and the health of their hoped-for children.<sup>124</sup> While these clinic summary tables are published with the caveat that they

116. *See id.*

117. *See id.* at 2-6.

118. *See* Fertility Clinic Success Rate and Certificate Act of 1992, 42 U.S.C. § 263a-1 (2006).

119. *See id.*

120. *See id.*

121. *See id.* § 263a-1 (b).

122. *See id.* § 263a-5(1)(A).

123. *See* Ctrs. for Disease Control & Prevention, Assisted Reproduction Technology: Home (Nov. 11, 2009), <http://www.cdc.gov/ART/>.

124. *See, e.g.,* Hani J. Marcus, Diane M. Marcus & Samuel F. Marcus, *How Do Infertile Couples Choose Their IVF Centers? An Internet-Based Survey*, 83 FERTILITY & STERILITY 779, 779-81 (2005) (presenting U.K. study finding that live birth rates and quality of service are most important factors to patients' selection of clinics).

should not be used to select a clinic, they are an important source of information for those seeking fertility services. Also, because these tables do not contain many other kinds of information that would be crucial to selecting a clinic, they privilege the pregnancy and live birth success rates per cycle that clinics report and fragment it away from other important information.

This highlight on per cycle success rates affects clinics as well. Because fertility clinics are in competition with each other, the Act forces them to compete primarily on per cycle pregnancy rates.<sup>125</sup> Clinics know that the primary tool prospective patients will have when deciding whether to contact them is the success rate report. Consequently, the information gathered in that report becomes of great importance to clinic success, and can have a powerful effect on physicians' decision-making and treatment of patients.<sup>126</sup>

Moreover, the Act separates out one form of assisted reproduction, IVF, and ignores treatment solely through hormone therapy, with or without intrauterine insemination, which is still the most common treatment for infertility in the United States. As the CDC notes on its website, the Act requires that information is gathered and reported only on ARTs, which the CDC defines:

In general, ART procedures involve surgically removing eggs from a woman's ovaries, combining them with sperm in the laboratory, and returning them to the woman's body or donating them to another woman. They do NOT include treatments in which only sperm are handled (i.e., intrauterine—or artificial— insemination) or procedures in which a woman takes drugs only to stimulate egg production without the intention of having eggs retrieved.<sup>127</sup>

Thus, patients considering different forms of treatment are not able to compare success rates and risks for all different treatment modalities, but only those that remove eggs and implant embryos in a woman's body.

Finally, the Act ignores the problem of multiple gestations—a problem that had already been identified in medical literature at the time of the Act's passage in 1992.<sup>128</sup> Congress focused only on two of the many issues associated with fertility treatment: accurate reporting of success

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125. See MUNDY, *supra* note 1, at 237 (citing reproductive endocrinologist who argues "chief upshot [of the CDC reporting requirement] has been to fuel more multiple births").

126. See *id.* at 236.

127. Ctrs. for Disease Control & Prevention, *supra* note 123.

128. See, e.g., Avner Hershlag et al., *Comparison of Singleton & Multiple Pregnancies in In Vitro Fertilization (IVF) & Embryo Transfer (ET)*, 7 J. IN VITRO FERTILIZATION & EMBRYO TRANSFER 3 (1990); Malcolm I. Levene, *Assisted Reproduction & Its Implications for Pediatrics*, 66 ARCHIVES OF DISEASE IN CHILDHOOD 1, 1-3 (1991).

rates for IVF and control over the quality of embryo laboratories.<sup>129</sup> As a result, there is no specific statutory mandate for the CDC to do anything related to the issue of multiple gestations.

The Fertility Clinic Success Rate and Certificate Act of 1992 is the only federal statute related to assisted reproduction. The clear problems with the Act, however, do not absolve the CDC of its failure to take a stronger role regarding multiple gestations. The CDC has a broad mandate to act as one of the nation's leading advisors on public health and to highlight and educate potential patients about public health concerns, such as those raised by the issue of multiple gestations. Although clinic summaries could be a powerful education tool, the CDC has failed to take advantage of this potential. Even on the CDC website, information about risks is difficult to find, and most patients are unlikely to run across such information. While clinic summaries report the average number of embryos transferred and the percentage of pregnancies with twins or triplets, nothing on the face of the national summary report or individual clinic reports explains why these numbers are important. Thus, the multiple gestation statistics are unlikely to affect decision-making where they are not explicitly and clearly linked to the greater likelihood of risks.

A careful reader of the CDC website will find brief information regarding the risks of triplets or higher order births referenced in a link headlined, "How to Read a Fertility Clinic Table." In explaining the chart category described as "percentage of transfers resulting in singleton live births," the CDC states that "[s]ingleton births have a much lower risk than multiple-infant births for adverse infant health outcomes, including prematurity, low birth weight, disability, and death."<sup>130</sup> In relation to the category entitled "percentage of pregnancies with triplets or more," the CDC states:

Pregnancies with multiple fetuses can be associated with increased risk for mothers and infants (e.g., higher rates of caesarean section, prematurity, low birth weight, infant death) and the possibility of multifetal pregnancy reduction.<sup>131</sup>

However, no specific statement addressing the risks associated with twins is made, despite the fact that such a statement may be especially important for women undergoing IVF because of the favorable cultural views of twins.<sup>132</sup> Nor does the CDC website direct patients to more detailed information about the nature and severity of the risks, how likely they are, or what strategies patients can choose to avoid those risks.

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129. See Jennifer Gunning, *Regulating ART in the USA: A Mixed Approach*, in *THE REGULATION OF ASSISTED REPRODUCTIVE TECHNOLOGY* 55, 61-62 (Jennifer Gunning & Helen Szoke eds., 2003).

130. CDC, 2006 ART SUCCESS REPORT, *supra* note 45, at 83-88.

131. Ctrs. for Disease Control & Prevention, *supra* note 123.

132. See MUNDY, *supra* note 1, at 214.

Greater information regarding multiple gestations, such as the risks of preterm birth and low weight babies, is placed in a section of the website that potential patients are unlikely to explore. Instead of a prominent display on the main CDC page concerning ARTs, the data is buried in the National 2006 Assistive Reproductive Technologies [ART] Report.<sup>133</sup> This report is unlikely to attract attention from potential patients for several reasons. First, it does not include the “newest” data, which is what potential patients are most likely to use. Instead, in July of 2009, while clinic summaries report 2007 data, the ART Report is based on 2006 data. While the ART Report is accessible from the same page as the national and clinic summaries, a potential patient is unlikely to peruse a link that does not appear relevant and is based on “old” information.<sup>134</sup> Second, patients are more likely to be interested in the summary tables for individual clinics in their area rather than a national report.

The Act and the CDC approach thus distort rather than aid the decision-making context for both patients and clinics. They also ignore the widespread use of hormone therapy. Moreover, they use a pregnancy and live birth rate *per cycle* as the anchor against which success is measured, rather than the percentage of patients who achieve a healthy baby within some longer time frame. Because of the positive societal view of twins and triplets, the simple presence of multiple birth rate statistics does nothing to dissuade patients who may not understand the associated risks. Finally, by giving legislative approval to the “success per cycle” frame, the Act and the CDC effectively feed into the human predisposition to overvalue the current dilemma—lack of a pregnancy—at the expense of undervaluing the experience of future problems related to multiple gestations.<sup>135</sup>

The CDC’s reticence to effectively educate patients interested in fertility treatments stands in sharp contrast to the concern CDC professionals demonstrate for the risks of multiple pregnancies and the need for a larger frame to link all forms of ART, including ovarian stimulation and IVF, to child and maternal health.<sup>136</sup> In a 2008 article, ten CDC professionals outlined a broad framework for preventing, detecting, and managing infertility.<sup>137</sup> The article invokes the linkage missing from the current approach to infertility. This article, and many others by CDC professionals, however, remains largely in the hidden realm of medical researchers and fertility specialists. To date, the CDC has failed to effectively educate

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133. See CDC, 2007 ART NATIONAL SUMMARY, *supra* note 3; CDC, 2006 ART SUCCESS REPORT, *supra* note 45.

134. Even if patients did navigate to this report and find statistics for preterm births and risks of low weight babies, the report does not explain what the effects of preterm delivery or low weight birth weight are likely to be. In addition, there is no information about how to prevent multiple gestations.

135. For a further discussion of the predisposition to focus on the current dilemma of lack of pregnancy at the expense of future problems stemming from multiple gestations, see *supra* notes 111-13 and accompanying text.

136. See generally Macaluso et al., *supra* note 5.

137. See *id.* at 5.e5.



potential and current patients undergoing fertility treatment about the risks of multiple pregnancies and the options available to avoid these risks.

The Act and the CDC's public approach to infertility fail to encourage patient decisions that promote overall health and welfare. We know that fertility patients begin the process focused on that which is missing from their lives—pregnancy. The Act could have helped patients broaden their frame to focus on the health and welfare of the women and children involved. It could also have emphasized cumulative birth rates, together with the health of mothers and their children, as the decisional anchor by which success is measured.<sup>138</sup> Instead, the Act reinforces per cycle pregnancy success rates as the decisional anchor and narrows the frame of what is considered success to success in *one cycle*. This approach encourages patients to believe that per cycle pregnancy rates are the only important measure of success and to ignore possible future health risks associated with their decisions.

#### B. State Governments: Missing the Mark

In reaction to the public outrage over a California fertility doctor's implantation of six embryos in the young and fertile Ms. Suleman, which resulted in eight babies due to the twinning of two of the six transferred embryos, legislators in several states moved to prevent such higher order pregnancies. Unfortunately, these efforts were not based on a full understanding of the relevant issues. State legislative proposals fail to adequately address one of the major concerns associated with IVF: the high rate of multiples, especially twins. One of the efforts would have even undermined progress on that issue by effectively preventing the development of single-embryo transfer, the approach with the greatest chance of reducing multiple births.

Senators in Georgia introduced Senate Bill 169, which regulated the number of embryos that could be transferred in the context of IVF.<sup>139</sup> The bill restricted the number of embryos to be created to the number that would be transferred in that cycle.<sup>140</sup> It limited patients under age forty or those using donor eggs to two embryos per cycle, and patients age forty and older to three embryos per cycle.<sup>141</sup> The bill required clinics to meet the standards of the American Society of Reproductive Medicine (ASRM).<sup>142</sup> Although it was introduced shortly after the birth of the Suleman children, the bill was designed primarily to further a different agenda. It created a "high duty of care to the living in vitro human em-

138. For a comparative discussion of how the British Human Fertilisation and Embryology Authority more effectively explains those risks to consumers, see *infra* notes 271-74 and accompanying text.

139. See S. 169, 150th Gen. Assem., Reg. Sess. (Ga. 2009) (aiming to amend Chapter 7 of Title 19 of the Official Code of Georgia Annotated).

140. See *id.* § 19-7-66.

141. See *id.* § 19-7-67.

142. See *id.* §§ 19-7-61 to -72.

bryo” by the clinic and physician, banned the intentional destruction of human embryos, and prohibited the creation and storage of frozen embryos for later cycles.<sup>143</sup>

While the bill might have succeeded in reducing higher order multiple births, its ban on frozen embryos would have halted the development of the practice best suited to increasing the proportion of singletons: elective single-embryo transfer followed by cycles using frozen embryos. It would have also raised the cost and physical stress of fertility cycles by requiring every cycle to be based on fresh aspiration of eggs. By chasing the rare (but highly publicized) event, the bill actually would have undermined progress concerning the most common problem associated with fertility treatment: the high percentage of twin pregnancies. Opposed by patient consumer groups such as RESOLVE, as well as the professional associations of fertility specialists including SART and ASRM, the portions of the proposed bill concerning embryo transfer practices were eliminated.<sup>144</sup>

Missouri and California both turned to professional associations for guidance in drafting proposed bills that also failed to pass. House Bill 810 in Missouri would have required physicians practicing in the state to limit the number of embryos implanted to those recommended by the ASRM.<sup>145</sup> The California Senate Bill 674 would have required the state Medical Board of California to “adopt standards that it deems necessary for outpatient settings that offer in vitro fertilizations” and to ensure that fertility centers are overseen by an accrediting agency.<sup>146</sup> Neither of these approaches would have reached the issue of twins because both rely on the requirements of the relevant professional associations, which, as discussed below, have to date largely ignored the problem of twins and have only urged members to “consider” single-embryo transfer. Both also ignored the widespread use of hormone therapy, which is the approach most likely to produce especially dangerous higher order births. Thus, to date, state legislatures have failed to carefully evaluate and adopt an approach likely to reduce the rate of multiple gestations related to assisted reproduction.

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143. *See id.* (explaining that it also included prohibition on cloning and creating embryos for research rather than fertility treatment, and prohibited payment for providing gametes for use in infertility treatment). Furthermore, it provided for specific informed consent requirements and established sanctions for violation of its provisions. *See id.*

144. *See* Resolve: The Nat’l Infertility Ass’n and Supporters Defeat Dangerous Georgia Bill (Apr. 9, 2009), [http://www.resolve.org/site/PageServer?pagename=fmed\\_mccpr040809](http://www.resolve.org/site/PageServer?pagename=fmed_mccpr040809).

145. *See* H.R. 810, 95th Gen. Assem., First Reg. Sess. (Mo. 2009). For a discussion of the ASRM guidelines, see *infra* notes 167-82 and accompanying text.

146. *See* S. 674, 2009-2010 S., Reg. Sess. (Cal. 2009).

C. *How Financial and Economic Considerations Drive Patient Decision-making*

IVF is extremely expensive in the United States. Recent estimates of \$21,000 per couple for a comprehensive infertility treatment cycle make it prohibitively expensive for patients to make multiple tries at pregnancy. The expense leads patients to transfer multiple embryos beginning in the first cycle to achieve pregnancy with as few expensive cycles as possible.<sup>147</sup> These prices are driven by the competitive, for-profit environment of the fertility marketplace. Lack of adequate health insurance coverage for fertility treatments in most states exacerbates the financial stress. In most situations, the much greater costs associated with multiple pregnancies, births, and long-term care are ignored, in large part because they fall not on the fertility clinics, but on hospital, schools, insurance companies, and families.<sup>148</sup> The high cost of fertility treatment, together with greater access to coverage for pregnancy and birth, lead many patients to devalue the longer term and possibly much more expensive outcomes as they struggle to pay for each cycle of treatment. These factors distort the decision-making context in which patients make difficult choices about their health and the health of their hoped-for children.

The high rates charged for IVF treatment in the United States exceed the charges in many other countries. For example, while the average costs in the United States in 2003 were \$12,500 per IVF cycle, the costs in Canada, the United Kingdom, Scandinavia, and Japan were \$8,500, \$6,500, \$5,500, and \$4,000, respectively.<sup>149</sup> In total, assisted reproduction services were a three billion dollar industry in the United States in 2004.<sup>150</sup> These high costs have been attributed in large part to the for-profit status of most fertility clinics, in which the physician-owners benefit from the profits generated by the services offered.<sup>151</sup> This for-profit status shapes the interests of the physicians who treat patients. Physicians must be concerned not only with what is the best procedure for one patient, but also with the effect of their approach on their clinic success rates, their desirability to future potential patients, and their profits.<sup>152</sup> This profit motive may play a critical role in explaining the reluctance of most fertility clinics to shift to single-embryo transfer.

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147. See Reindollar et al., *supra* note 50, at 10 tbl.4 (identifying average cost of conventional infertility treatment from studied group).

148. See Saul, *supra* note 1, at A14 (noting high-risk pregnancy specialist Dr. Brian Kirshon asserts that many couples do not fully appreciate risks associated with multiple gestation and premature birth).

149. See Georgina Chambers et al., *The Economic Impact of Assisted Reproductive Technology: A Review of Selected Developed Countries*, 91 FERTILITY & STERILITY 2281, 2288 (2009) (using 2003 cost data).

150. See SPAR, *supra* note 115, at 3 tbl.1-1.

151. See *id.* at 46-51.

152. See Saul, *supra* note 1, at A14 (explaining doctors will often skip using cheaper oral drugs for more expensive hormone injections, even though oral drugs produce fewer multiples with less monitoring).

Patients typically must use their own or borrowed funds to pay for fertility treatment. In most states, health insurers are not required to include any fertility treatments in their offered insurance coverage.<sup>153</sup> Other states require insurers to offer some forms of coverage, but some of those states impose limitations on that coverage.<sup>154</sup> These limitations often create a decision-making context in which implantation of multiple embryos is made more, rather than less, attractive.

States often permit plans to impose various timing requirements that can negatively affect patient choices. Some states allow health plans to require more than the medically recommended six months to one year of infertility before a patient is eligible for infertility treatment, and at least two states allow insurers to require five years of infertility before receiving coverage for treatment.<sup>155</sup> Lengthy waiting periods greatly increase patient anxiety, making patients less likely to be open to single-embryo transfer, which relies on additional rounds of frozen embryo transfer to achieve the same cumulative success rate. They also narrow the window patients may have for successful treatment. Other states allow health plans to impose upper age restrictions, which also creates panic regarding timing and leads patients to seek riskier multiple implantation.<sup>156</sup> Patients may be squeezed between the conclusion of the waiting period and a quickly approaching upper age limit. Some states may further induce age-related panic by restricting mandated coverage to the patients' own gametes, refusing to cover procedures involving donated eggs or sperm (even if the

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153. See INT'L COUNCIL ON INFERTILITY INFO. DISSEMINATION, STATES MANDATING INSURANCE COVERAGE FOR INFERTILITY AND PREGNANCY LOSS, <http://www.inciid.org/printpage.php?cat=insurance101&id=15> (last visited Mar. 27, 2010); NAT'L CONFERENCE OF STATE LEGISLATORS, STATE LAWS RELATED TO INSURANCE COVERAGE FOR INFERTILITY TREATMENT (2009), <http://www.ncsl.org/programs/health/50infert.htm>.

154. See, e.g., MD. CODE ANN., INS. § 15-810 (LexisNexis 2006). These conditions often also include marriage, making insurance coverage inaccessible to unmarried heterosexual or homosexual couples. See *id.*

155. See, e.g., HAW. REV. STAT. § 431:10A-116.5(a)(4)(A) (2005) (requiring at least five year history of infertility); MD. CODE ANN., INS. § 15-810(c)(3)(i) (requiring two years); TEX. INS. CODE ANN. § 1366.005(3) (Vernon 2009) (requiring five years). Most statutes with time requirements exempt those with certain specified conditions, such as endometriosis or blocked fallopian tube. See, e.g., HAW. REV. STAT. ANN. § 431:10A-116.5(a)(4)(B); MD. CODE ANN., INS. § 15-810(c)(3)(ii); TEX. INS. CODE ANN. § 1366.005(3).

156. See, e.g., CONN. GEN. STAT. ANN. § 38a-536(b)(1) (West 2007) (limiting mandated coverage to fortieth birthday); R.I. GEN. LAWS § 27-18-30(a) (2008) (limiting mandated coverage up to forty-two years); see also AETNA, CLINICAL POLICY BULLETIN: INFERTILITY 1 (2009), [http://www.aetna.com/cpb/medical/data/300\\_399/0327.html](http://www.aetna.com/cpb/medical/data/300_399/0327.html) (explaining that to qualify for coverage of IVF, must first have spent one year trying to conceive naturally, or six months if female is over thirty-five years old, and have unsuccessfully gone through at least three cycles of IUI).

patients pay for the gametes themselves), as older fertility patients are more likely to need donated gametes to reproduce.<sup>157</sup>

Common requirements that patients first try less expensive forms of fertility treatment drive patients to use fertility drugs and IUI, which are difficult to control to prevent multiple pregnancies.<sup>158</sup> Additional requirements that patients endure lengthy treatments that have far lower chances of success before reaching IVF also have the effect of making patients who have endured multiple failures reluctant to accept single-embryo transfer.<sup>159</sup> A few states exclude IVF altogether.<sup>160</sup> State laws that strictly limit the number of IVF attempts for which the insurer must pay or exclude frozen embryo cycles similarly undermine efforts to limit embryo transfer to reduce multiple gestations.<sup>161</sup> This inaccessible or spotty insurance coverage for IVF leads many patients to take out large loans in order to fund IVF, increasing the financial pressure to have a baby as quickly as possible.<sup>162</sup>

Some clinics offer package deals for IVF that allow patients to pay an initially higher price for several rounds of IVF.<sup>163</sup> Others offer “shared risk” programs, which promise to refund a portion of the cost if the IVF cycle is not effective.<sup>164</sup> While patients who choose a package may feel their own financial relief from the pressure of instantaneous success, the packages may simply shift the financial pressures to the clinics themselves.

157. *See, e.g.*, HAW. REV. STAT. ANN. § 431:10A-116.5(a)(3) (requiring that patient’s oocytes are fertilized with patient’s husbands’ sperm); MD. CODE ANN., INS. § 15-810(c)(2) (same); TEX. INS. CODE ANN. § 1366.005(2) (same).

158. *See* CONN. GEN. STAT. ANN. § 38a-536(b)(5); HAW. REV. STAT. ANN. § 431:10A-116.5(a)(5); 215 ILL. COMP. STAT. ANN. 5/356m(b)(1)(A) (West 2008); N.J. STAT. ANN. § 17:48-6x (West 2008); UnitedHealthcare Ins. Co. of the River Valley, Addendum to Certificate of Coverage Under Group Health Contract, [https://www.uhcrivervalley.com/downloads/brokers/commercial\\_benefit\\_plans/illinois/infertility/ILPIM00004.pdf](https://www.uhcrivervalley.com/downloads/brokers/commercial_benefit_plans/illinois/infertility/ILPIM00004.pdf) (last visited Mar. 27, 2010) (explaining coverage limited to maximum of six oocyte retrievals, which is only covered after other cheaper forms of fertility treatment prove unsuccessful).

159. *See, e.g.*, Saul, *supra* note 1, at A14 (explaining Stansel couple’s insurance plan did not cover IVF and covered only IUI, which is six to eight times cheaper).

160. *See* CAL. HEALTH & SAFETY CODE § 1374.55 (West 2008); N.Y. INS. LAW § 3221(k)(6)(C)(v) (McKinney 2006).

161. *See, e.g.*, CONN. GEN. STAT. ANN. § 38a-536(b)(4) (noting maximum two cycles IVF); MD. CODE ANN., INS. § 15-810(d) (noting maximum three cycles IVF per live birth).

162. *See* Melissa Jacoby, *The Debt Financing of Parenthood*, 72 LAW & CONTEMP. PROBS. (UNC Legal Studies Research Paper No. 1335534, 2009), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1335534](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1335534).

163. *See, e.g.*, Advance Reproductive Care, Inc., Introduction, [http://www.arcfertility.com/family\\_building/index.html](http://www.arcfertility.com/family_building/index.html) (last visited Mar. 27, 2010) (describing itself as national physician organization providing various packages patients can purchase if being treated by network physician).

164. *See, e.g.*, New England Fertility Inst., Shared Risk IVF, <http://www.nefertility.com/ivf/ivf/shared-risk-ivf.htm> (last visited Mar. 27, 2010) (offering shared risk program that will refund 40%-80% of cost of first cycle of IVF if it does not result in pregnancy of nine weeks).

The packages and guarantees give clinics a strong financial incentive to achieve a pregnancy quickly to avoid additional costs that would reduce their profits.<sup>165</sup>

Assisted reproduction lacks a consistent source of funding that links fertility treatment costs to the greater costs associated with multiple pregnancies. If instead, patients are carefully selected for elective single-embryo transfer, this approach could prove cost-effective when the costs of IVF treatment, pregnancy care, and neonatal and pediatric care are considered together.<sup>166</sup> However, health insurance practices have not yet linked these costs—even though in those states with mandated coverage, the insurance carrier is likely to cover other medical costs related to pregnancy, birth, and pediatric care.

#### D. *The Role of Professional Associations in Resisting Change*

Through lack of regulation, the federal government and states have deferred to professional associations to develop practice guidelines for the treatment of infertility. Unlike the fertility professional associations in Sweden, Belgium, and Finland, which are described in Section IV, the leading U.S. fertility specialists' associations have followed rather than led the way on reducing multiple-embryo transfer.

Fertility physicians are likely to belong to one or both of the leading professional organizations: SART and ASRM. SART states that it represents 85% of the IVF clinics in the United States.<sup>167</sup> SART describes itself as “the primary organization of professionals dedicated to the practice of assisted reproductive technologies (ART) in the United States.”<sup>168</sup> It has a range of duties, from professional education to advocacy, and includes among the objectives in its mission statement that “members of SART have worked diligently to protect our patients and the practice of ART from inappropriate external intrusion and regulation.”<sup>169</sup> ASRM is an organization composed of professionals from many different disciplines seeking the “advancement of the art, science, and practice of reproductive medicine.”<sup>170</sup> Along with SART, ASRM has also actively opposed legislation related to the use of ARTs.<sup>171</sup>

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165. See Gina Kolata, *Fertility Inc.: Clinics Race To Lure Clients*, N.Y. TIMES, Jan. 1, 2002, at F1, available at <http://www.nytimes.com/2002/01/01/science/fertility-inc-clinics-race-to-lure-clients.html>.

166. See Veleva et al., *supra* note 56, at 1638.

167. See Soc’y for Assisted Reprod. Tech., What is SART?, <http://www.sart.org/WhatsSART.html> (last visited Mar. 27, 2010).

168. *Id.*

169. *See id.*

170. Am. Soc’y for Reprod. Med., About Us: Mission Statement (Nov. 8, 2008), <http://www.asrm.org/detail.aspx?id=60>.

171. See, e.g., Press Release, Am. Soc’y for Reprod. Med., ASRM Comments on State Legislation (Mar. 5, 2009), available at [http://www.asrm.org/news/article.aspx?id=185&terms=%28+%40Publish\\_To+Both+Sites+or+%40Publish\\_To+ASRM+Only+%29+and+comments+on+state+legislation](http://www.asrm.org/news/article.aspx?id=185&terms=%28+%40Publish_To+Both+Sites+or+%40Publish_To+ASRM+Only+%29+and+comments+on+state+legislation).

In the absence of specific governmental regulation regarding multiple embryo implantations, the ASRM, together with the Practice Committee of SART, has developed practice guidelines that many clinics may follow but that do not carry the force of law.<sup>172</sup> The ASRM Practice Committee develops its guidelines behind closed doors, and the public is not able to see the evidence the Committee weighs in order to reach its recommendations.<sup>173</sup> In fact, the ASRM website states that the Practice Committee reports are provided for “viewing” only, and members must log in to gain access to a copy that can be downloaded and printed.<sup>174</sup>

Rather than providing strong leadership to make single-embryo transfer the anchor for patient and physician decision-making, ASRM guidelines appear designed to give fertility specialists wide discretion in their practices.<sup>175</sup> They recommend transferring no more than two embryos for women up to age thirty-seven who have a “good prognosis,” and three or more for older women, depending on age and other factors.<sup>176</sup> The guidelines merely urge consideration of single-embryo transfer for women under age thirty-five, and do not mention the possibility of single-embryo transfer for patients thirty-five and older.<sup>177</sup> These guidelines have been in effect since 2006 and were recently updated in October of 2009.<sup>178</sup> The changes in 2009 did not revise the number of recommended embryos to be transferred. Rather, the revisions merely added requirements to counsel patients about the risks of multifetal pregnancy when physicians exceed the recommended embryo transfer limits and document the provision of counseling and reasons for exceeding the recommended limits.<sup>179</sup> These guidelines have not had any noticeable impact on the twinning birth rate.<sup>180</sup> Nor has ASRM or SART taken a strong public stance to reduce

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172. See Am. Soc’y for Reprod. Med., Practice Guidelines, <http://www.asrm.org/detail.aspx?id=131> (last visited Mar. 27, 2010) (stating that “[a] Guideline presents a recommended approach to evaluation or treatment but is not intended to describe the only approved standard of practice or to dictate an exclusive course of treatment”).

173. See *id.* (explaining that neither Practice Guidelines themselves nor webpage leading to them describes process of developing Guidelines, allows for open comment, or lists the members of the Practice Committee).

174. See *id.*

175. See Practice Comm. of the Am. Soc’y of Reprod. Med., *Guidelines on Number of Embryos Transferred*, 92 FERTILITY & STERILITY 1518, 1518-19 (2009) [hereinafter 2009 ASRM Embryo Transfer Guidelines], available at <http://www.asrm.org/Media/Practice/practice.html#Guidelines>.

176. See *id.* (explaining number of embryos allowed for transfer with women over the age of forty-three is not limited).

177. See *id.*

178. See Practice Comm. of the American Soc’y of Reprod. Med., *Guidelines on Number of Embryos Transferred*, 90 FERTILITY & STERILITY S163-64 (2008).

179. See 2009 ASRM Embryo Transfer Guidelines, *supra* note 175, at 1519.

180. See, e.g., Stephanie Saul, *The Gift of Life & Its Price*, N.Y. TIMES, Oct. 11, 2009, at A1, available at <http://www.nytimes.com/2009/10/11/health/11fertility.html> (explaining doctors frequently fail to follow guidelines encouraging single-embryo transfer).

twinning rates. While ASRM and SART issued a press release to broadcast the strong reduction in the rates of triplets or higher order births reported in the 2007 SART National Clinic Summary data, they completely ignored the continuing high twinning rate that the new data showed.<sup>181</sup>

ASRM Practice Guidelines on embryo transfer also lag behind the current recommendations of European professional associations.<sup>182</sup> Unlike the professional societies in the several European countries discussed below, SART and ASRM have failed to provide effective leadership regarding the reduction of multiple gestations, including twins. Because their practice guidelines are developed through a closed-door process, it is impossible to know the degree to which this failure stems from concerns that less aggressive forms of fertility treatment might reduce clinic profits or that fertility clinics will refuse to follow tougher guidelines.

Although the main research publication of the ASRM, *Fertility and Sterility*, carries numerous articles on the health risks of multiple births and the successful use of elective single-embryo transfer, ASRM itself has demonstrated reluctance to develop stronger guidelines or encourage governmental regulation to prevent the risky practices that have kept the twinning rate high. Nor has SART or ASRM taken strong steps to educate the public about the risks of multiple gestations related to assisted reproduction. Notably, their websites do not highlight these risks. At most, they publish fact sheets that encourage patients to discuss potential risks with their physicians. Together with a lack of leadership at the governmental level, the failure of the major professional associations to take a lead in shifting practice to single-embryo transfer, as supported by the medical research, has left the United States behind some major European countries in addressing this important public health concern.

#### E. For-Profit and Fragmented Care for Fertility Patients and Their Children

Fertility specialists are also influenced by the decision-making context in which they operate. What influences, then, may shape their decisions

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181. See Press Release, Am. Soc'y Reprod. Med., Triplets and Higher Order Multiple Births from ART are Below Two Percent; SART 2007 Clinic Data Now Online (Feb. 27, 2009), available at [www.asrm.org/Washington/Bulletins/vol11no11.html](http://www.asrm.org/Washington/Bulletins/vol11no11.html) (noting that 32.9% of live births to women under thirty-five were twins); see also CDC, 2007 ART NATIONAL SUMMARY, *supra* note 3 (showing 33.2% of live births to women under thirty-five were twins and another 3.5% were triplets). These figures are slightly higher than those on the SART website, which include only SART member clinics. See SOC'Y FOR ASSISTED REPROD. TECH., ALL SART MEMBER CLINICS: CLINIC SUMMARY REPORT (2007), [https://www.sartcorsonline.com/rpt\\_CSR\\_PublicMultiYear.aspx?ClinicPKID=0](https://www.sartcorsonline.com/rpt_CSR_PublicMultiYear.aspx?ClinicPKID=0) (showing 32.9% twins and 1.8% triplets for women under thirty-five).

182. See, e.g., *Good Clinical Treatment in Assisted Reproduction*, ESHRE POSITION PAPER (European Soc'y of Human Reprod.), June 2008, available at [http://www.eshre.com/binarydata.aspx?type=doc/Good\\_Clinical\\_treatment\\_in\\_Assisted\\_Reproduction\\_ENGLISH.pdf](http://www.eshre.com/binarydata.aspx?type=doc/Good_Clinical_treatment_in_Assisted_Reproduction_ENGLISH.pdf) (explaining European Society of Human Reproduction and Embryology advocates single-embryo transfer for patients under thirty-five with good prognosis and more than one good quality embryo).



about how to present treatment choices to their patients? Two aspects of this context are especially salient: the definition of financial and professional success, and the exclusion of crucial aspects of patient care from the daily experiences of fertility specialists.

Those seeking IVF services obtain them at “fertility clinics.” In 2007, there were 430 fertility clinics that reported information on IVF procedures to the CDC.<sup>183</sup> Many of these clinics are for-profit entities.<sup>184</sup> Some of these for-profit centers are part of a much larger provider network. For example, IntegraMed, a publicly traded company, maintains a provider network of 101 fertility clinics that perform approximately 25% of all IVF procedures nationally.<sup>185</sup> Other fertility clinics belong to financing programs,<sup>186</sup> while some for-profit fertility clinics remain independent. Some of the nation’s fertility clinics are connected to major university research hospitals. These fertility clinics, however, are not always operated as non-profit entities. For example, Boston IVF, which in 2002 performed the greatest number of IVF cycles, is an independent, professionally managed private corporation, although its physicians are affiliated with Beth Israel Hospital and hold teaching appointments at Harvard Medical School.<sup>187</sup> Some fertility physicians also have financial interests in other related providers, such as egg donation services, embryo testing laboratories, and sperm banks.<sup>188</sup>

Fertility clinics often face stiff competition for business.<sup>189</sup> Financial success through clinic practice and the various endeavors of related providers depends on the physicians being viewed as successful.<sup>190</sup> A clinic’s success is often defined by the federally mandated clinic summaries described earlier.<sup>191</sup> These clinic summaries are a crucial factor in patients’ decisions about which fertility clinic to select. Success rates are prominently posted on clinic websites. Often, the statistic that is included on the website is the “pregnancy” rate, which is defined as an ultrasound confirmed pregnancy.<sup>192</sup> Pregnancy rates are often higher than “live birth”

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183. See Ctrs. for Disease Control & Prevention, *supra* note 123.

184. See SPAR, *supra* note 115, at 46-51.

185. See *INMD at a Glance*, INVESTOR FACT SHEET: Q3, 2008, [http://media.corporate-ir.net/media\\_files/irol/10/108428/INMD\\_factsheet\\_010408.pdf](http://media.corporate-ir.net/media_files/irol/10/108428/INMD_factsheet_010408.pdf).

186. See SPAR, *supra* note 115, at 50 (describing ARC Family Building Program, which offers financing plans).

187. See *id.* at 49.

188. See *id.*

189. See Kolata, *supra* note 165.

190. See *id.*

191. For a discussion of the federally mandated clinic summaries, see *supra* notes 118-27 and accompanying text.

192. See, e.g., Boston IVF, IVF Success Rates, [http://www.bostonivf.com/success\\_rates.html](http://www.bostonivf.com/success_rates.html) (last visited Mar. 27, 2010).

rates.<sup>193</sup> Thus, achieving a pregnancy becomes an important factor in communicating the success of fertility doctors and their clinic.<sup>194</sup>

In contrast, other important aspects of patient care are not measured or reported, and prospective patients are not able to find reliable information to determine their quality based on these factors. Specifically, there are no concrete measures for the overall health of their female patients during pregnancy, the use of multifetal reduction, any ill effects that continue past pregnancy, death rates after birth, or health or disability problems faced by the children born through IVF. Professional success is defined as helping clients become pregnant, and may extend to producing live births; these measures are concrete, public, and present for fertility doctors. Other issues are, for the most part, beyond their purview and unrelated to their bottom line or competitiveness.

It is difficult to imagine that physicians and clinic owners are unaffected by the profit motive.<sup>195</sup> No research is available on how for-profit clinic status may affect patient counseling or treatment decisions. Clinic summaries, however, do show that more than 80% of fertility clinics exceed the ASRM's recommendations regarding the number of embryos to be transferred based on patient age, and these recommendations are already overly liberal.<sup>196</sup> In addition, some patients have reported being rejected by clinics due to the fear that they are less likely to become pregnant and will undermine these clinics' per cycle pregnancy success rate.<sup>197</sup>

Fertility specialists are also influenced by the fragmentation of the medical care they provide. Fertility specialists usually do not provide care for women through their pregnancy and delivery or for their newborn and developing children. One important consequence of this fragmentation of care may be that fertility clinics, whose primary measure of success is pregnancy, promote multiple-embryo transfer more than the physicians who care for pregnant women and their children may deem acceptable.<sup>198</sup>

193. See CDC, 2007 ART NATIONAL SUMMARY, *supra* note 3.

194. See MUNDY, *supra* note 1, at 237.

195. See, e.g., Allan Templeton, *Replace as Many Embryos as You Like—One at a Time*, 15 HUM. REPROD. 1662, 1662 (2000) (noting “pressures induced by commercially driven medical practice” and possibility that “concerns surrounding success rates and competition for patients, as well as professional livelihood and status may have distorted a clear assessment of acceptable and appropriate risks following assisted reproduction”).

196. See Stephanie Nano, *Most Fertility Clinics Break the Rules*, ASSOCIATED PRESS, Feb. 20, 2009, available at <http://geneticsandsociety.org/article.php?id=4538>.

197. See Teri Brown, *Fertility Crushers: Are Common Mistakes Keeping You From Conceiving?*, PRECONCEPTION.COM, <http://www.preconception.com/articles/trouble-getting-pregnant/fertility-crushers-5329/> (last visited Mar. 27, 2010).

198. See MUNDY, *supra* note 1, at 239 (noting patients who have something go wrong are likely to blame obstetrician, not fertility specialist). One fertility specialist noted, “It’s not your problem if she leaves with twins and triplets. The obstetrician, he’s the one who has all the responsibility for the problems I created. You don’t see me anymore. . . . It’s a structural problem, and you cannot rely on moral incentives.” *Id.*

This fragmentation may affect patient care and the decisions toward which physicians steer patients in two major ways. First, fertility specialists spend their days focused on the intended parents, who often are desperate to bear children. Second, they are removed from the stressful, and sometimes devastating, experiences of those pregnant with multiples. This combination—intense personal experiences with patients desperate to bear children and absence from pregnancy and beyond—may lead fertility specialists to view the risks of a multiple pregnancy as less important than any potential reduction in immediate efficacy.<sup>199</sup>

Physicians affiliated with fertility clinics often limit their practice to treatment leading to conception and rarely follow a patient past the first trimester of pregnancy.<sup>200</sup> Therefore, the patients of fertility clinic physicians are the intended parents, not the resulting children. The personal, everyday experiences of fertility doctors focus on interacting with women and their partners who are anxious to get pregnant. They watch their patients ride the roller coaster of high hopes, hopes that are dashed any time pregnancy does not result from a treatment cycle, or hopes that are fulfilled if the pregnancy test is positive. They must help patients make decisions about which treatment to undertake, and whether to continue a treatment—decisions that get more difficult with every failed cycle.

In contrast, fertility doctors are not in the room when women undergo multifetal pregnancy reduction. They do not witness women with multiple pregnancies develop pre-eclampsia, spend months on bed rest to prevent miscarriage, or watch their children hastened to the neonatal intensive care unit (NICU). They are neither present for the lengthy time periods some children born as multiples spend in the NICU, nor do they go with the children to the many medical and therapeutic appointments that some face throughout childhood.

Why would profit motive, reputational concerns, and intense involvement with patients only until conception make a difference? These physicians are required to follow informed consent practices that include counseling patients about the various considerations involved in deciding how many embryos to implant. The physician's advice is often the most important factor in patient decision-making in ARTs and other con-

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199. See Pennings, *supra* note 18, at 2469 (recommending this fragmentation be reconsidered and suggesting that fertility specialists conduct multifetal reductions and spend time in labor wards and neonatal units to make these concerns salient for them).

200. See Infertility Procedures and Treatment at U.C. San Diego Regional Facility Center (Sept. 21, 2009), <http://ucsandiegofertility.com/procedures.html> (lacking offer of post-conception treatment); Ovulation Stimulation, IUI, IVF, and More—Infertility Treatment in Alexandria, Northern Virginia, [http://www.metrofertility.com/html/patient\\_services.html](http://www.metrofertility.com/html/patient_services.html) (last visited Mar. 27, 2010) (offering only pre-pregnancy services).

texts.<sup>201</sup> Yet fertility specialists are just as subject to the effects of the decision-making context as their patients. Given the financial, professional, and personal pressures they feel to succeed on the first cycle, these physicians are likely to overplay the benefits of implanting multiple embryos and underplay the risks when giving advice.

Physicians, like the rest of us, are subject to the availability heuristic. As Professors Sunstein and Thaler explain, the availability heuristic leads people to “assess the likelihood of risks by asking how readily examples come to mind. If people can easily think of relevant examples, they are far more likely to be frightened and concerned than if they cannot.”<sup>202</sup> Given their daily experiences, failure to produce a pregnancy in any particular cycle is a much more salient failure than any longer term serious health consequences faced by their patients and their patients’ children. The consequences their patients face during pregnancy and birth, as well as throughout their children’s lives, are often invisible to fertility specialists.

Thus, when patients make decisions about the number of embryos to implant at one time, they do so in consultation with a physician whose measure of success, both financial and professional, is based on pregnancy rates and birth rates. These physicians, however, do not have the experience with the difficulties of a multiple pregnancy, nor will they care for the patient or their children during pregnancy, delivery, or childhood.

#### F. *Fertility Patients: The Anxiety of Infertility*

Behavioral economics may provide a useful lens through which to view studies of patient attitudes regarding preferences for singleton or twin pregnancies. Although most U.S. fertility patients prefer to have a single child, approximately 20% of such patients express a preference for a twin pregnancy.<sup>203</sup> Patients are united, however, in their preference for

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201. See Christine Glazebrook et al., *Attitudes of Infertile Couples to a Multiple Birth: A Review of the Literature and Results from a Survey*, 3 CURRENT WOMEN’S HEALTH REVS. 43, 45 (2007) (exploring decision-making process).

202. THALER & SUNSTEIN, *supra* note 25, at 25.

203. See Ada Borkenhagen et al., *Attitudes of German Infertile Couples Towards Multiple Births & Elective Embryo Transfer*, 22 HUM. REPROD. 2883, 2885 (2007) (noting that 89% thought twin pregnancy was desirable outcome and 99% of couples preferred having twins over having no biological children at all); Tim J. Child et al., *The Desire for Multiple Pregnancy in Male & Female Infertility Patients*, 19 HUM. REPROD. 558, 559 tbl.I (2004) (showing 39% of female fertility patients desire twins); Suleena K. Kalra et al., *Infertility Patients & Their Partners: Differences in the Desire for Twin Gestations*, 102 OBSTETRICIANS & GYNECOLOGISTS 152, 153 (2003) (stating that 14% of couples preferred twin gestation and 21% of couples had partner with preference for twin gestation); Christopher R. Newton et al., *Factors Affecting Patients’ Attitudes Toward Single- & Multiple-Embryo Transfer*, 87 FERTILITY & STERILITY 269, 275 (2007) (showing that preference for multiple gestation is not limited to patients in United States); Ginny L. Ryan et al., *The Desire of Infertile Patients for Multiple Births*, 81 FERTILITY & STERILITY 500, 501-02 (2004) (“When asked to rank preferred treatment outcomes, 20.3% of patients listed twin, triplet, or quadruplet pregnancies as preferable to a singleton pregnancy . . .”).

a twin or higher order pregnancy over no pregnancy at all.<sup>204</sup> The strongest barrier to patient acceptance of single-embryo transfer therefore seems to be fear of a decline in pregnancy rates.

This fear was evidenced in a University of Iowa study. Most patients were willing to try single-embryo transfer if the pregnancy rates were equivalent or better.<sup>205</sup> Given a hypothetical in which single-embryo transfer would result in a better pregnancy rate than double-embryo transfer, almost all patients (83%) chose single-embryo transfer. When the success rates were equal, 56% chose single-embryo transfer as their preferred approach. However, when patients were informed that single-embryo transfer had a 10% lower chance of success than double-embryo transfer, those favoring a single-embryo transfer dropped to 20%.<sup>206</sup>

The findings of this study are consistent with other studies' findings that patients are not tolerant of a drop in success rate. Even where the pregnancy rate was represented as only 1% lower than the pregnancy rate for double-embryo transfer, the difference was enough to move some patients to reject single-embryo transfer.<sup>207</sup> Thus, most patients who choose to implant two embryos rather than one embryo select this option in order to maximize their chances of becoming pregnant, not because they prefer twins. Most choose to accept the risk of twins in order to improve their chances of having a baby at all.

On the other hand, some patients do express a preference for twins. Those who had experienced a lengthier period of infertility, or who had tried earlier cycles of ART, or who had no other children were more likely to prefer twins.<sup>208</sup> Those who expressed a preference for twins over singletons desired an "instant" family—if they desired two children, twins would seem to fulfill their desire to complete their family without further fertility treatment.<sup>209</sup> Some stated they believed a twin pregnancy might

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204. See, e.g., G.S. Scotland et al., *Safety Versus Success in Elective Single Embryo Transfer: Women's Preferences for Outcomes of In Vitro Fertilisation*, 114 BRIT. J. OBSTETRICS & GYNAECOLOGY 977, 980 (2007); see also Borkenhagen et al., *supra* note 203, at 2885 (stating that "99% of German patients questioned would accept twins, 84% triplets, and 58% quadruplets in preference to no biological child at all . . .").

205. See Ryan et al., *supra* note 48, at 356.

206. See *id.*

207. See Moniek Twisk, *Preferences of Subfertile Women Regarding Elective Single Embryo Transfer: Additional In Vitro Fertilization Cycles Are Acceptable, Lower Pregnancy Rates Are Not*, 88 FERTILITY & STERILITY 1006, 1007 (2007) (showing 10% decrease in single ET preference when single ET effectiveness was reduced by 1%); see also Arno M. van Peperstraten et al., *Why Don't We Perform Elective Single Embryo Transfer? A Qualitative Study Among IVF Patients & Professionals*, 23 HUM. REPROD. 2036, 2040 (2008) (identifying lower success rate per cycle of single-embryo transfer as potential barrier to its use).

208. See Child et al., *supra* note 203, at 559 ("[I]ncreasing desire for multiple birth with increasing length of infertility or previous cycles of assisted reproductive treatment may represent desperation for an 'instant family' . . .").

209. See Liora Baor et al., *En Route to an "Instant Family": Psychosocial Considerations*, 32 OBSTETRICS & GYNECOLOGY CLINICS OF N. AM. 127, 136-137 (2005) (exploring couples' desires to be parents of multiples).

be their only opportunity to have two children, while others thought that twins would be a joy to each other.<sup>210</sup>

These preferences are malleable. In most studies, greater knowledge of the risks associated with multiple gestations reduced patients' desire for more than one child.<sup>211</sup> Some studies showed that patients did not have enough knowledge of the risks associated with twins.<sup>212</sup> For example, in one study, 24% of the participants did not know about the increase in maternal complications associated with twin pregnancies, 51% did not realize that twin pregnancies raised the risk of cerebral palsy, and 70% did not know about the increased risks of mortality.<sup>213</sup> Several studies have demonstrated that the preference for twins can be reduced by fairly simple interventions that address this lack of knowledge, such as a one-page discussion of the risks associated with multiple births and a discussion of those risks with a clinic physician.<sup>214</sup> The physician's opinion influences the number of embryos a patient decides to receive and how patients view

210. See Anja Pinborg et al., *Attitudes of IVF/ICSI-Twin Mothers Towards Twins and Single Embryo Transfer*, 18 HUMAN REPRODUCTION 621, 625 (2003).

211. See Child et al., *supra* note 203, at 560 (explaining that patients informed of risks associated with multiple births decreased their preference for twins); William A. Grobman et al., *Patient Perceptions of Multiple Gestations: An Assessment of Knowledge and Risk Aversion*, 185 AM. J. OBSTETRICS & GYNECOLOGY 920, 923 (2001) ("This comparison, in particular, was made because the medium risk scenario most closely approximates a compilation of actual risks associated with twin gestations. . . . After presentation of the medium risk scenario, the desire for twin gestation was significantly lower than that which women had expressed originally. . . .").

212. See Mary D'Alton, *Infertility & The Desire for Multiple Births*, 81 FERTILITY & STERILITY 523, 523 (2004) ("Women exhibited greater knowledge about triplet outcomes than about those of twins.").

213. See Ryan et al., *supra* note 203, at 502 tbl.2 (deducing from statistic that only 30% of patients with twin pregnancy were aware of risk of infant mortality); Saul, *supra* note 180, at 24 (showing 2006 study revealed record 137,085 twins born, double number of twins born in 1980).

214. See Ryan et al., *supra* note 48, at 354-55 (noting exposure to one page of information and discussion with physician about risks of multiple births reduced preference for twins from 29% to 14% of patients questioned before and after educational intervention). One major opponent of intervention to reduce multiple births argues that data from a survey he conducted shows that "patients with fertility problems express a considerable desire for multiple births, as long as these multiple conceptions do not exceed triplets in number." Gleicher et al., *supra* note 20, at 1082. He also asserts that this same survey shows that women undergoing fertility treatment are aware of the risks. See *id.* The survey instrument, however, did not give participants any opportunity to express a preference for a single birth over a twin or triplet birth. Rather, the survey merely asks participants if they would "have loved to conceive," "have not minded at all to conceive," or if "it would have been upsetting to conceive" twins or higher order births. *Id.* Patients undergoing fertility treatment, when faced with twins or higher order births as the only possibilities, will certainly find twins and triplets acceptable. This study essentially treated twins as the default and anchor from which all other options needed to be considered.

The study also reported that patients were highly educated about the risks of multiple births. The survey, however, did not quiz them about the risks of multiple births, but rather simply asked them if they knew about the risks. This study was also conducted in 1995, long before the practice of single-embryo transfer began

the risks associated with multiple pregnancies.<sup>215</sup> An Australian study found that patient choice for elective single-embryo transfer increased more than 70% over a span of eight years due to a policy in which physicians recommended elective single-embryo transfer and advised patients of the risks associated with multiple-embryo transfers.<sup>216</sup>

Studies have not yet addressed the structure of choice given to patients in clinics as they decide how many embryos to implant, but there is reason to believe that it affects patient decisions. For example, it is likely that clinics treat transfers involving two or more embryos as the norm by which all other choices must be judged. Given that in 2006, 89.3% of transfers in U.S. fertility clinics were two or more embryos, it would be expected that embryo transfers involving two or more embryos is most likely presented as the norm, or the anchor, by which all patient decision-making is made.<sup>217</sup> This may lead patients to assume that they are taking a big risk if they deviate from this norm.<sup>218</sup> In fact, in some clinics, this norm may operate as a default option—unless a patient specifically requests single-embryo transfer, a physician will recommend double-embryo transfer.

The framing of issues to patients may also be relevant. Due to the frustration that patients have felt throughout the process of infertility, the fear that they will never get pregnant, and the great expense associated with each cycle of treatment, fertility doctors are likely to describe pregnancy rates by each cycle rather than describing IVF as a process involving both fresh and frozen cycles. When physicians compare single-embryo transfer to double-embryo transfer per cycle, the pregnancy rate appears lower. If, however, physicians compare rates across two or more cycles, including frozen embryo cycles, the success rates reach equivalency.

While patients answering surveys do not describe financial resources as a major factor in their decision-making, certainly many patients face concrete resource limitations.<sup>219</sup> For example, if they have taken out a high interest loan in order to pay for the first cycle, they may not be eligible to obtain a second loan for another cycle until they have paid off the first loan. Also, many health insurance plans that do cover IVF strictly

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in the United States and before many of the risks related to multiple births were widely studied and reported.

215. See Sheryl de Lacey et al., *Factors and Perceptions that Influence Women's Decisions to Have a Single Embryo Transferred*, 15 REPROD. BIOMED. ONLINE 526, 527 (2007); see also Glazebrook et al., *supra* note 201, at 45 (“Interestingly, the most commonly reported factor to have strongly influenced the couples’ decisions in both the single embryo transfer and double embryo transfer groups was physician’s advice.”).

216. See de Lacey et al., *supra* note 215, at 527.

217. See CDC, 2006 ART SUCCESS REPORT, *supra* note 45 (showing highest percentage of transfer were double-embryo transfers (46%), followed by three embryos (27.5%), one or four embryos (both at 10.7%), and five or more (5%)).

218. See Newton et al., *supra* note 203, at 275.

219. See Ryan et al., *supra* note 48, at 355.

limit the number of cycles covered, which creates further pressure for each cycle to be successful.

The internal cognitive and emotional context of fertility patients may also strongly affect the decision of how many embryos to implant. For example, the availability heuristic may be very powerful in the face of a present desire for children when compared with a longer term risk of problems associated with multiple pregnancies. Most patients undergoing fertility treatment are unlikely to have personal experience with other women or children who have suffered from the effects of twin pregnancies, so those risks are unlikely to be readily available to them.

In addition, it is very difficult to predict future emotional states. Many fertility patients experience tremendous emotional upheaval as they go through the treatment process. Liza Mundy and Peggy Orenstein, among others, have described the anguish that women experience as their efforts to become pregnant fail.<sup>220</sup> The intensity of this emotional state may make it even harder for fertility patients to envision the psychological effects of pregnancy complications, premature birth, or possible disabilities that a twin pregnancy can bring.<sup>221</sup>

The difficulties of emotional forecasting may also relate to the relationship pressures and stigma experienced by infertile couples. Many patients have described the stress that fertility treatments place on the marital relationship.<sup>222</sup> A quick success can be viewed as a way to relieve that marital stress, while patients are unlikely to envision the marital stress that can result from raising twins or higher order sets of children. Pregnancy may also be viewed as a way to alleviate the stigma of infertility, a stigma that is widely experienced by those in fertility treatment.<sup>223</sup> This emotional state, although powerful, makes it difficult to appreciate the later difficulties to be faced as the parents of multiples.

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220. See MUNDY, *supra* note 1, at 40-41; PEGGY ORENSTEIN, *WAITING FOR DAISY: A TALE OF TWO CONTINENTS, THREE RELIGIONS, FIVE INFERTILITY DOCTORS, AN OSCAR, AN ATOMIC BOMB, A ROMANTIC NIGHT AND ONE WOMAN'S QUEST TO BECOME A MOTHER* (2007); see also BAOR et al., *supra* note 209, at 130-33.

221. See MUNDY, *supra* note 1, at 239 (reporting interview with psychologist and former fertility patient noting embryo transfer decisions must often be made quickly). Mundy reports an interview during which a psychologist and former fertility patient describes her choice to transfer two embryos:

"It was irrational. I was tired of going through fertility treatments. I didn't want two [twins]. But not so much that I would have said, 'Just put one in.' I wonder what it is, what it is that leads you to making a not-good decision." And the thing is, she says, fertility doctors carefully avoid making that final call. They make a recommendation, Gulyn points out, and then "they throw it back at you."

*Id.*

222. See Frank M. Andrews, *Stress from Infertility, Marriage Factors and Subject Well-Being of Wives and Husbands*, 32 J. HEALTH & SOC. BEHAV. 238, 239 (1991); see also ORENSTEIN, *supra* note 220 (writing powerfully about stress infertility and infertility treatments placed on her own marriage).

223. See generally Linda M. Whiteford & Lois Gonzalez, *Stigma: The Hidden Burden of Infertility*, 40 SOC. SCI. MED. 27 (1995).



## IV. HOW HAVE SEVERAL EUROPEAN COUNTRIES ACHIEVED REFORM?

Several European countries have taken a strong lead in reducing the rate of multiple gestations related to assisted reproduction. These countries—Sweden, the United Kingdom, Belgium, and Finland—are of interest both for the process through which change occurred and for the particular strategies each country adopted. These strategies are significantly changing the context in which patients make assisted reproduction decisions. While some may involve greater regulation than the United States is ready to adopt, all provide a useful lens through which to consider how to improve fertility treatment practices in the United States.

A. *Sweden: Changing Attitudes, Regulation, and Practice*

Sweden has adopted fairly broad-reaching regulation of assisted reproduction. It has taken the lead in reducing the number of embryos to be implanted in many patients to a single embryo. The shift toward a norm of single-embryo transfer is related to three important aspects of the Swedish context: a broad regulatory approach to assisted reproduction; an integrated medical community in which medical professionals—fertility specialists, obstetricians, and pediatricians—engage in a dialogue about the outcomes of their practices; and a national registry of medical information concerning all children, including those born through assisted reproduction.<sup>224</sup> Due to this focus on the benefits of single-embryo transfer, Swedish patients make decisions about assisted reproduction in a very different environment than their U.S. peers.

In 1988, Sweden passed the Act on In-Vitro Fertilization.<sup>225</sup> This initial Act required that all assisted reproduction be provided in government-licensed clinics, restricted the provision of IVF to married and cohabiting heterosexual couples, and forbade egg donation and donor insemination in the context of IVF.<sup>226</sup> It also established a national registry requiring detailed annual reports.<sup>227</sup> Many of the initially restrictive provisions, however, have been changed through amendment, and Sweden now allows lesbian couples to use IVF and allows donor insemination in the context of IVF.<sup>228</sup> In 1984 Sweden was the first country to remove the

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224. See Olaf Karlström & Christina Bergh, *Reducing the Number of Embryos Transferred in Sweden—Impact on Delivery and Multiple Birth Rates*, 22 HUM. REPROD. 2202, 2202-06 (2007).

225. See RIITTA BURRELL, ASSISTED REPRODUCTION IN THE NORDIC COUNTRIES: A COMPARATIVE STUDY OF POLICIES AND REGULATION 13 (2005), available at [http://www.norden.org/da/publikationer/publikationer/2006-505/at\\_download/publicationfile](http://www.norden.org/da/publikationer/publikationer/2006-505/at_download/publicationfile) (citing The Act on In Vitro Fertilization).

226. See BURRELL, *supra* note 225, at 17-18; Jean Cohen et al., *The Early Days of IVF Outside the UK*, 11 HUM. REPROD. 439, 454 (2005).

227. See Cohen, *supra* note 226, at 454.

228. See *id.*

anonymity of sperm donors, legislating that donors be identified and that children have access to donor information when they reach adulthood.<sup>229</sup>

Access to assisted reproduction in Sweden is aided by public funding for the first three cycles of IVF.<sup>230</sup> Because it can take up to three years to obtain publicly funded treatment, however, many Swedes choose to get private treatment.<sup>231</sup> As a result, about 50% of IVF is publicly funded and the other 50% is funded privately by patients. For those who choose private treatment, no insurance coverage is available.<sup>232</sup> Swedish use of IVF is four times the rate of its use in the United States, where no public funding is available and few health insurers cover the costs.<sup>233</sup> Sweden's change in practices regarding the number of embryos employed in IVF can be seen as a combination of access to compelling health registry data, dialogue among involved professionals, and guidelines restricting the number of embryos to be implanted.<sup>234</sup>

The issue of multiple embryos has long been of great concern in Sweden, and use of single-embryo transfer has taken hold over two decades. In the late 1980s, Sweden first reduced multiple births, and in particular the number of higher order births, by limiting the number of embryos transferred to three.<sup>235</sup> When this approach did not stem the tide of multiple births, IVF clinics initiated a shift towards only two embryos in 1993.<sup>236</sup> This reduction almost completely eliminated triplet and higher order births, but the twin rate remained high.

The troubling health risks associated with twin births were the subject of study through a large national health registry. Sweden maintains large registry studies that allow comparisons between the outcomes for children born through IVF and the outcomes for children born through unassisted conception.<sup>237</sup> Less favorable outcomes noted for children born through IVF were identified as strongly related to the multiple birth rate.<sup>238</sup> Exam-

229. See *id.* (citing Swedish Law no. 1140 20.12.1984).

230. See Corinna Sorenson, *IVF/ART Funding and Reimbursement*, EURO OBSERVER, Autumn 2006, at 6, 7, available at [http://www.euro.who.int/Document/Obs/EuroObserver8\\_4.pdf](http://www.euro.who.int/Document/Obs/EuroObserver8_4.pdf).

231. See *id.* at 6 (citing CURRENT PRACTICES AND CONTROVERSIES IN ASSISTED REPRODUCTION (E. Vayena et al. eds., 2002)).

232. See Karlström & Bergh, *supra* note 224, at 2206.

233. See Karl Nygren & Nyboe Andersen, *Assisted Reproductive Technology in Europe, 1999. Results Generated from European Registers by ESHRE*, 17 HUM. REPROD. 3260 (2002).

234. See Karlström & Bergh, *supra* note 224, at 2202.

235. See *id.*

236. See *id.*

237. See CENTRE FOR EPIDEMIOLOGY, NATIONAL BOARD OF HEALTH AND WELFARE, RESEARCH REPORT: THE SWEDISH MEDICAL REGISTRY—A SUMMARY OF CONTENT AND QUALITY (2003), <http://www.socialstyrelsen.se/english>.

238. See, e.g., Torbjörn Bergh et al., *Deliveries and Children Born After In-Vitro Fertilisation in Sweden 1982-95: A Retrospective Cohort Study*, 354 LANCET 1579, 1583 (1999) (stating that medical complications of children born through IVF were caused by multiple gestation, not IVF itself).

ination of these differences in outcomes, along with research studies demonstrating that the cumulative live birth rate could be maintained in a shift to single-embryo transfer, helped fuel a public and professional debate.<sup>239</sup>

In Sweden, approximately one-half of the fertility specialists practice in public units. At these public units, fertility specialists meet with obstetricians on a daily basis and on occasion actually manage deliveries of multiples when they are on call.<sup>240</sup> Thus, many public fertility specialists have ongoing personal experiences with the health risks that multiples and their mothers face.<sup>241</sup>

In addition, annual national medical meetings include all specialists related to reproductive medicine, and active debate takes place at these meetings as well.<sup>242</sup> A few leading professors spearheaded the debate, which also entered the public media.<sup>243</sup> These debates and research results led fertility specialists to begin to shift toward elective single-embryo transfer. This shift hastened when, in 2003, the National Board on Health and Welfare issued new guidelines on the number of embryos to be replaced in one cycle. The National Board adopted the principle that only one embryo may be implanted unless the risk of a twin pregnancy is low.<sup>244</sup> At the outset, this guideline applied to the first two treatment cycles for women below the age of thirty-six where there were two good quality embryos available for use. Later, the recommended age was raised to thirty-eight. As a result, Sweden reduced its twin rate following IVF to 5% with no reduction in its cumulative success rate as measured by live births.<sup>245</sup>

Swedish fertility specialists have adopted the belief that while single-embryo transfer may require some patients to undergo more cycles to achieve success, it is the correct approach due to the striking reduction in multiple births and their accompanying risks.<sup>246</sup> Swedish fertility doctors are largely united in the belief that twin pregnancies compare unfavorably to singleton pregnancies.<sup>247</sup> A full 30% of Swedish fertility doctors ques-

239. See Karlström & Bergh, *supra* note 224, at 2204.

240. See E-mail from Christina Bergh, Dep't of Obstetrics and Gynaecology, Reproductive Med., Inst. of Clinical Sci., Sahlgrenska Univ. Hosp., Göteborg, Swed., to Theresa Glennon, Feinberg Professor of Law, James E. Beasley Sch. of Law at Temple Univ. (Aug. 21, 2009, 12:41 EST) (on file with author).

241. See *id.*

242. See *id.*

243. See *id.*

244. See Karlström & Bergh, *supra* note 224, at 2203.

245. See Karl Nygren, *Single Embryo Transfer: The Role of Natural Cycle/Minimal Stimulation IVF in the Future*, 14 REPROD. BIOMED. ONLINE 626, 626 (2007) (citing data on multiple gestations in Sweden).

246. See Christina Bergh et al., *Attitudes Towards and Management of Single Embryo Transfer Among Nordic IVF Doctors*, 86 ACTA OBSTETRICIA ET GYNECOLOGICA 1222, 1222 (2007) (compiling data on multiple gestations).

247. See *id.* at 1223.

tioned reported that they believed that a 0%-5% rate for twins was acceptable, while more than 60% of doctors questioned set the acceptable range at 6%-10%.<sup>248</sup> None viewed it as acceptable for the twinning rate to rise above 15%, a rate well below the current U.S. rate.<sup>249</sup>

Swedish physicians noted initial resistance to single-embryo transfer by patients. Patients, however, quickly accepted this approach, perhaps due to complete counseling about the risks of multiple pregnancies.<sup>250</sup> The combination of guidelines by the National Board of Health and Welfare, widespread support for single-embryo transfer by fertility specialists, and counseling for patients concerning the risks of multiple pregnancies means that Swedish patients make embryo transfer decisions in a markedly different clinical environment with a different physician-patient dynamic than U.S. patients.

### B. *United Kingdom: A Multilayered Approach*

The United Kingdom also serves as a sharp contrast to the United States' largely laissez-faire approach to the regulation of assisted reproduction. The United Kingdom, which extensively regulates ART, has adopted a multilayer approach to reducing multiple pregnancies. This approach changes the decision-making context for patients by addressing informed consent and patient counseling, requiring clinics to develop a plan to reduce multiple births and justify multiple-embryo transfer in certain patients, and initiating a public education campaign that personalizes the health risks associated with multiple pregnancies, including twin pregnancies.

The United Kingdom regulates the use of a wide range of assisted reproduction, from the storage of donated gametes and IVF, to the Human Fertilisation and Embryology Act (HFE Act).<sup>251</sup> The Act covers:

[A]ll uses of sperm, eggs and embryos for human application and, all research involving the use of live human and admixed embryos. It imposes obligations upon centres to maintain appropriate standards of quality and safety, to give and record information, provide counselling and take account of the welfare of the children born as a result of certain fertility treatments.<sup>252</sup>

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248. *See id.* at 1224.

249. *See id.*

250. *See Pia Saldeen & Per Sundström, Would Legislation Imposing Single Embryo Transfer Be a Feasible Way to Reduce the Rate of Multiple Pregnancies after IVF Treatment?*, 20 HUM. REPROD. 4 (2008).

251. Human Fertilisation and Embryology Act, 1990, c. 37, (Eng.), *amended by Human Fertilisation and Embryology (Quality And Safety) Regulations, 2007, S.I. 1522* (regulating assisted reproduction).

252. HUMAN FERTILISATION & EMBRYOLOGY AUTH. (HFEA), CODE OF PRACTICE § 1.1 (7th ed. 2006), *available at* <http://www.hfea.gov.uk/docs/CodeofPracticeold.pdf>.

The HFE Act does not regulate the use of fertility drugs. Rather, it is specifically designed to broaden the frame used for reproductive decision-making and practices. It also establishes the Human Fertilisation and Embryology Authority (HFEA) to prescribe standards of practice and license fertility clinics. The HFEA does this through the Code of Practice, currently in its eighth edition.<sup>253</sup> This lengthy and detailed document is frequently updated and is designed to address not only safety and efficacy issues, but also the difficult ethical and social issues raised by assisted reproduction.<sup>254</sup> The standards and guidance are developed through consultations with a wide range of stakeholders and are subject to public consultation.<sup>255</sup> They are enforceable through various means, including the decision whether to renew, vary, or revoke a license.<sup>256</sup>

The National Health Service (NHS) provides only limited fertility services and places various restrictions on who will be served and how much fertility treatment will be provided. These limits, as well as lengthy waiting lists, have made the NHS's fertility services inaccessible to many.<sup>257</sup> These restrictions have prompted most patients to enter the private fertility market.<sup>258</sup> The HFE Code of Practice regulates both the NHS and private fertility clinics. The NHS must, however, provide treatment to all eligible children born in the United Kingdom, so it absorbs most of the costs created by the additional number of multiple births. NHS neonatal units have faced crises regarding the growing number of patients needing intensive neonatal care related to the use of IVF.<sup>259</sup>

The United Kingdom's approach to the issue of multiple embryos is embedded within a larger framework of regulation that addresses a broad range of concerns, including the protection of patients' rights regarding informed consent and consideration of the welfare of the child. Its approach was also developed through an expert consultation process. Concerned by the incidence of multiple births related to IVF, the HFEA established an expert panel in 2005 to review evidence concerning the risks of multiple pregnancies and the viability of an elective single-embryo

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253. HUMAN FERTILISATION & EMBRYOLOGY AUTH. (HFEA), CODE OF PRACTICE (8th ed. 2009), available at [http://www.hfea.gov.uk/docs/8th\\_Code\\_of\\_Practice.pdf](http://www.hfea.gov.uk/docs/8th_Code_of_Practice.pdf) (setting forth "[u]ser guide to the Code").

254. See *id.* at 8 (describing "Regulatory Principles," including fairness and child welfare).

255. See HFEA—Consultations & Reviews of Policy (Apr. 21, 2009), <http://www.hfea.gov.uk/122.html>.

256. See HFEA COMPLIANCE AND ENFORCEMENT POLICY § 3 (Sept. 2009), available at [http://www.hfea.gov.uk/docs/Compliance\\_and\\_Enforcement\\_Policy\\_-\\_Version\\_1.0.pdf](http://www.hfea.gov.uk/docs/Compliance_and_Enforcement_Policy_-_Version_1.0.pdf).

257. See JULIAN JENKINS ET AL., KEY FACTS ON INFERTILITY, IVF AND NHS PROVISION, BRITISH FERTILITY SOCIETY FACTSHEET (2005), <http://www.britishfertilitysociety.org.uk/public/factsheets/docs/BFS-keyfacts.pdf>.

258. See Blyth, *supra* note 75; see generally EMILY JACKSON, MEDICAL LAW: TEXT, CASES, AND MATERIALS (2006).

259. See BRAUDE, *supra* note 57 (discussing problem of overstretched neonatal units throughout report).

transfer strategy.<sup>260</sup> At that time, the HFEA Code of Practice restricted the transfer of embryos in women under forty years of age to no more than two, and for women over forty, limited embryo transfer to three.<sup>261</sup> Despite these transfer limits—which were much stricter than those currently promulgated by the ASRM in the United States—twin pregnancies constituted 25% of all IVF pregnancies.<sup>262</sup>

The expert panel included specialists involved with fertility treatment, care for children, and lay persons.<sup>263</sup> The panel's 2006 report employed a broad frame that allowed the experts to link fertility clinic practices with financial and psychological issues, outcomes for children, costs associated with care for multiples, and the collective role of the numerous stakeholders in the system. The panel extensively reviewed the medical literature concerning the health risks associated with multiple births and the failure of the United Kingdom's earlier policy to reduce the twinning rate. It evaluated techniques that have demonstrated success in achieving pregnancy through single-embryo transfer, considered the experience of other countries with reducing multiple births, and identified the barriers that clinicians and patients may face in changing to single-embryo transfer. The report acknowledged that it will take a change in attitude by many stakeholders to effect a significant reduction in twin births. Thus, its recommendations addressed not only clinic practice regarding the number of embryos to be implanted, but also the counseling and education of patients, revision of published tables regarding "success rates" at fertility clinics, and involvement by IVF clinics, NHS commissioners, professional bodies, and patient groups in changing practices and mindsets.<sup>264</sup>

The HFEA also conducted a public consultation on the findings of the expert panel.<sup>265</sup> Finally, in 2008, it issued new guidelines as part of its Code of Practice. It also developed a National Strategy Multiple Births Stakeholder Group, whose work includes medical guidance, education of fertility clinic staff, public education campaigns, a review of how success rates are reported, and advocacy for change to the uneven access to NHS-funded treatment. These moves, lauded by many, are admittedly not without critics.<sup>266</sup> The group has launched a website, [oneatatime.org.uk](http://oneatatime.org.uk),

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260. *See id.* at 8.

261. *See* Braude, *supra* note 57, at 14 (addressing limits on embryo transfer under sixth edition of HFEA Code of Practice, issued March, 2004).

262. *See id.* at 8 (discussing incidence of twin births after IVF). The HFEA CODE OF PRACTICE restrictions had already significantly decreased the number of IVF triplets. *Id.*

263. *See id.* at 3.

264. *See id.*

265. *See* HFEA, THE BEST POSSIBLE START TO LIFE: A CONSULTATION DOCUMENT ON MULTIPLE BIRTHS AFTER IVF 2 (2007), available at [http://www.hfea.gov.uk/docs/The\\_best\\_possible\\_start\\_to\\_life\\_HFEA\\_public\\_consultation\\_paper\\_April\\_2007.pdf](http://www.hfea.gov.uk/docs/The_best_possible_start_to_life_HFEA_public_consultation_paper_April_2007.pdf).

266. *See, e.g.,* Sandy Star, 'One at a Time': An Attack on Choice, SPIKED, Oct. 27, 2008, <http://www.spiked-online.com/index.php?/site/article/5865/>.

which tries to reach patients and professionals, and includes powerful stories of individuals who have had twin pregnancies, with a mix of results.<sup>267</sup>

The HFEA now has a several tiered approach to the issue of multiple embryos. First, the standards and guidelines ensure that patients are fully informed of and counseled on the risks of multiple pregnancies. The counseling standards and the requirements for information to be provided by the clinic consider the issue of multiple pregnancies.<sup>268</sup> Moreover, counseling independent of the clinical decision-making process is required.<sup>269</sup> Patients are not required to accept the offer of counseling, but the doctor should inform them that it is routine.<sup>270</sup>

The clinic is also required to provide certain kinds of information as part of the informed consent process. This information must include “possible side effects and risks of treatment to the woman being treated and any resulting child.”<sup>271</sup> With regard to the risks of multiple pregnancies, all individuals who are considering treatment involving “the use of superovulatory drugs or the transfer of multiple eggs or embryos in any one cycle” must be given “information about the risks of multiple pregnancy for the woman, the fetus and any resulting child(ren).”<sup>272</sup> The information provided must include:

- (a) the higher risk of miscarriage and complications during pregnancy
- (b) the higher rate of premature birth and the problems arising from low birth weight, the higher rate of still birth, and the higher rate of perinatal mortality
- (c) the higher rate of disability and other health problems, plus the potential need for extended stays in hospital before and after birth, and
- (d) the possible practical, financial and emotional impact on the family and any children.<sup>273</sup>

This requirement is reiterated in the context of egg or embryo transfer, requiring clinics to obtain consent to “the proposed number of eggs or embryos to be transferred and the reasons for this (including her acceptance of the risk of multiple births).”<sup>274</sup> The Code of Practice also

267. See *One at a Time, Patients—IVF Patient Stories*, <http://www.oneatatime.org.uk/51.htm> (last visited Mar. 27, 2010).

268. See HFEA CODE OF PRACTICE, *supra* note 253, § 7.5.

269. *Id.* § 3.7.

270. See *id.* § 3.2.

271. *Id.* § 4.2(g).

272. *Id.* § 7.5.

273. *Id.*

274. See HFEA CODE OF PRACTICE, *supra* note 253, § 7.7(a). The clinic must also record the patient’s consent regarding the number to be transferred. See *id.* § 7.7(b).

refers clinicians to an HFEA brochure that outlines the risks of multiple births in vivid fashion.

In addition to these requirements, clinics may not exceed certain guidelines for the number of eggs or embryos to be transferred. The mandatory limits remained the same—women under forty and using their own eggs should receive no more than two embryos in any treatment cycle, and those forty or over should receive no more than three in one treatment cycle.<sup>275</sup> Women using donated eggs or embryos are limited to two embryos at any age.<sup>276</sup>

The Code of Practice seeks to change the culture of clinics regarding embryo transfer by requiring clinics to develop strategies to reduce the rates of multiple births.<sup>277</sup> This recent amendment requires clinics to develop an effective “documented strategy to minimize multiple births.”<sup>278</sup> The clinics’ strategy should ensure that the percentage of all live births that are twins, triplets, or multiples does not exceed the maximum rate determined by the HFEA.<sup>279</sup> The maximum rate is communicated to fertility clinics annually by letter from the Chair of the HFEA.<sup>280</sup> For 2009, the maximum rate was 24%, significantly lower than the current rate in the United States, but far higher than the rates in Sweden and Belgium.<sup>281</sup>

The Code of Practice also instructs fertility clinics to develop criteria for identifying suitable candidates for single-embryo transfer, and if a patient who meets those criteria is given multiple embryos, the burden is on the clinic to record “why the patient did not have SET [single-embryo transfer]” and the “evidence that the risks of a multiple pregnancy were fully discussed with the patient before the procedure.”<sup>282</sup>

Data is not yet available to determine how effective this strategy is at reducing the twinning rate related to IVF.<sup>283</sup> Nevertheless, the United Kingdom’s broad-ranging strategy links the practices of fertility clinics to the risks of multiple births at many levels. Key components of the strategy shift the decision-making context: informed consent practices that include the risks of multiple births; access to counseling independent of the individual physician; involvement of fertility specialists in designing multiple birth reduction plans; and a mandate that clinicians justify deviations from their patient criteria that exceed single-embryo transfer. A strong public

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275. *See id.* § 7.2-7.3.

276. *See id.* § 7.4.

277. *See id.* § 7A.

278. *See id.* (interpreting mandatory requirements).

279. *See id.* § 7A(a).

280. *See, e.g.*, Letter from Professor Lisa Jardine, Chair of HFEA, to HFEA Licensed Centres (Sept. 30, 2008), <http://www.hfea.gov.uk/489.html>.

281. *See id.*

282. HFEA CODE OF PRACTICE, *supra* note 253, § 7A.

283. As of November 7, 2009, the latest data available on the HFEA website was from 2007 and showed that the twin/triplet rate declined from 22.7% in 2006 to 21.4% in 2007. *See* HFEA, Latest UK-IVF Figures—2007 (Oct. 20, 2009), <http://www.hfea.gov.uk/ivf-figures-2006.html#1281>.



education piece also alerts patients to the difficulties of multiple births as they enter the fertility process. None of these strategies eliminates patient autonomy, but they shift the decision-making context to make single-embryo transfer increasingly the norm. Whether this approach will decrease the high rate of twins in the United Kingdom remains to be seen.

### C. *Belgium: Shifting the Economic Incentives*

Rather than create an elaborate regulatory structure such as that seen in the United Kingdom or Sweden, Belgium has addressed the multiple birth rates related to assisted reproduction through targeted funding for IVF procedures that, for many women, must begin with single-embryo transfer. The adoption of this practice depended in large part on the research and advocacy of Belgian fertility specialists, the availability of information necessary to determine the outcomes of children born through assisted reproduction, and the ability of the Belgian government to look at the broader economic and welfare picture of fertility treatment to determine that funding for IVF focused on single-embryo transfer would improve health and welfare and reduce health care and other related costs in the long run.

Belgian fertility doctors began to experiment with elective single-embryo transfer in the mid-1990s.<sup>284</sup> Research arising from those experiments showed that when performed on patients with a good prognosis, the pregnancy rate was similar to the rate for double-embryo transfers.<sup>285</sup> At the same time, these trials saw a very significant reduction in multiple pregnancies.<sup>286</sup> Competition among fertility centers and fear of reducing pregnancy rates prevented doctors from adopting this change without government intervention.<sup>287</sup> The results of these clinical trials set the stage for discussion between Belgian leaders in reproductive medicine and the Belgian Minister of Social Affairs.

As a result, the Minister of Social Affairs adopted a reimbursement scheme, effective July 1, 2003, that provides government funding for laboratory expenses for up to six IVF cycles per woman, until the woman's

284. See, e.g., Paul De Sutter et al., *Single Embryo Transfer and Multiple Pregnancy Rate Reduction in IVF/ICSI: A 5-year Appraisal*, 6 REPROD. BIOMED. ONLINE 464 (2003), <http://www.rbmonline.com/4DCGI/Article/Detail?38%091%09=%20836%09> (discussing implementation and pregnancy rates); see also Jan Gerris, *Elective Single Day 3 Embryo Transfer Halves the Twinning Rate Without Decrease in the Ongoing Pregnancy Rate of an IVF/ICSI Programme*, 17 HUM. REPROD. 2626 (2002), available at <http://humrep.oxfordjournals.org/cgi/reprint/17/10/2626> (addressing IVF and multiple pregnancies).

285. See De Sutter et al., *supra* note 284, at 465 (discussing implementation and pregnancy rates).

286. See *id.* at 467. Researchers reported that over a five-year period, the number of embryos transferred was reduced from two to one in 20% of the clinic's patients, with a reduction of the twinning rate from 30% to 14%. See *id.* For patients under the age of thirty-six, there was no significant drop in the pregnancy rate. See *id.*

287. See Gordts et al., *supra* note 58, at 439.

forty-third birthday, provided that she receive her treatment at clinics in compliance with the government's funding restrictions.<sup>288</sup> The system provides full funding for laboratory costs and partial reimbursement of "consultation, ultrasonography, endocrine assays, ovum pick up and embryo transfers as well as admission in the hospital and necessary drugs."<sup>289</sup> This additional funding was considered affordable because it was expected to reduce governmental expenses for perinatal costs associated with multiple pregnancies.<sup>290</sup> This approach, which increased access while reducing a serious public health concern and related expenses, was seen as a "win-win" for patients and the government.<sup>291</sup>

The Belgian legislation provides financial support for IVF treatment in an officially recognized center for reproductive medicine that has agreed to follow the government's requirements.<sup>292</sup> For women up to age thirty-five, the first cycle must be limited to one fresh embryo. The second cycle may include one fresh embryo of good quality or two of lesser quality, and at the third and following cycles, two fresh embryos may be transferred. At ages thirty-six through thirty-nine, the first and second cycles are limited to two fresh embryos, and for later cycles there are no restrictions. At ages forty through forty-two, there are no limitations on the number of fresh embryos transferred.<sup>293</sup>

These restrictions on funding eliminated competition between centers based on number of embryos implanted and forced centers to focus on improving the quality of laboratory handling to improve their pregnancy rates.<sup>294</sup> Research on costs concluded that while there will be a significant increase in IVF costs associated with the higher rates of access and faster intake into IVF, these costs are likely to be offset by other substantial cost savings related to pregnancy, delivery, and newborn care.<sup>295</sup>

A second feature of the Belgian system is an online registration of each IVF cycle and any births that take place as a result of the cycle. This information will be useful in assessing the economic and health benefits and costs of the new system.<sup>296</sup> The Belgian system frees physicians to allow patients to go directly to IVF without first trying numerous rounds of hormone therapy. The financial assistance related to following the government's embryo transfer guidelines, along with the changed culture of

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288. *See id.* at 437.

289. Diane de Neubourg et al., *Impact of a Restriction in the Number of Embryos Transferred on the Multiple Pregnancy Rate*, 124 EUR. J. OBSTETRICS & GYNECOLOGY AND REPROD. BIOLOGY 212, 214 (2006).

290. See Willem Ombelet et al., *Multiple Gestation and Infertility Treatment: Registration, Reflection and Reaction—The Belgian Project*, 11 HUM. REPROD. UPDATE 3, 10 (2005), available at <http://humupd.oxfordjournals.org/cgi/reprint/11/1/3>.

291. *See id.* at 3.

292. *See* Gordts et al., *supra* note 58, at 437.

293. *See id.*

294. *See id.* at 440.

295. *See* deNeubourg & Gerris, *supra* note 57, at 213.

296. *See id.* at 214.

the fertility clinics themselves, have led to widespread acceptance of single-embryo transfer.

D. *Finland: Accomplishing Change Through Professional Leadership and Interchange*

Remarkably, Finnish fertility physicians changed their practices regarding multiple-embryo transfers in the absence of regulation or limitations on government funding. While Finland did pass extensive regulation concerning some aspects of assisted reproduction in 2006, it does not have any regulations concerning the number of embryos that may be transferred, nor has it tied public insurance coverage of assisted reproduction to specific practices by IVF clinics. Despite the absence of any regulation or financial incentives, beginning in the 1990s clinical practice in Finland changed dramatically, and the country now has one of the lowest national rates of multiple births related to IVF. This shift was based on extensive research on outcomes for children born through assisted reproduction and the efficacy of single-embryo transfer. It emerged through close dialogue and growing consensus among the relatively small community of fertility specialists, obstetricians, neonatologists, and pediatricians, many of whom have been involved in this research.<sup>297</sup>

The most comprehensive piece of Finnish legislation regarding assisted reproduction went into effect in 2007. The Act on Assisted Fertility Treatments (AAFT)<sup>298</sup> included provisions on the donation and storage of gametes and embryos for fertility treatments. It prohibits the use of genetically manipulated embryos, cloning, and use of embryos used in research.<sup>299</sup> Sex selection of embryos is banned unless necessary to avoid a sex-linked inheritable disease.<sup>300</sup> The AAFT also regulates reimbursement for gamete donors and prohibits anonymous donation.<sup>301</sup> Once eighteen, a person born through the use of donated gamete or embryo is entitled to learn the identity of the donor.<sup>302</sup> The AAFT prohibits surrogacy agreements.<sup>303</sup> It also requires fertility clinics to provide enumerated information to the National Institute for Health and Welfare.<sup>304</sup>

The government partially funds IVF in both public and private clinics.<sup>305</sup> Private clinics initiate approximately 60% of the IVF treatment cy-

297. See Veleva et al., *supra* note 56, at 2100-01.

298. Act on Assisted Fertility Treatment (1237/2006), effective September 1, 2007, available at [www.finlex.fi/fi/laki/kaannokset/2006/en20061237.pdf](http://www.finlex.fi/fi/laki/kaannokset/2006/en20061237.pdf) (unofficial English translation) (regulating assisted human fertilization).

299. See *id.* at Section 4.

300. See *id.* at Section 5.

301. See *id.* at Section 21.

302. See *id.* at Section 22.

303. See *id.* at Section 8, ¶6.

304. Nat'l Inst. for Health & Welfare, Assisted Fertility Treatments 2007-2008 (May 29, 2009), <http://www.stakes.fi/EN/tilastot/statisticsbytopic/reproduction/IVFtreatments.htm>.

305. See Koivurova et al., *supra* note 77, at 2803.

cles in Finland.<sup>306</sup> Expenses that are reimbursed include physicians' consultations, laboratory and radiological examinations, infertility treatment procedures, and drugs.<sup>307</sup> It is estimated that fertility patients in Finland pay approximately 25%-40% of treatment costs, with the National Social Insurance Institution covering the remaining costs.<sup>308</sup> No restrictions on government funding related to reducing the number of multiple pregnancies associated with IVF were imposed. Charges for the various aspects of assisted reproduction are much lower in Finland than in the United States.

Finnish health authorities monitor IVF through two sources that permit researchers to track outcomes related to IVF treatment. Since 1990, all IVF births have been recorded on the Medical Birth Register, which is a mandatory health register.<sup>309</sup> This register includes information on the mother's background, care, and interventions during pregnancy and delivery, and tracks the newborn's outcome through the first seven days.<sup>310</sup> In addition, starting in 1992, statistics based on initiated treatment cycles have been gathered and reported. This includes information on the number of treatments, age of the treated women, causes of infertility, and the number of and results of transferred embryos, including live births, gestational age, and newborn outcomes such as birth weight, perinatal mortality, and congenital anomalies.<sup>311</sup> In addition, information regarding IVF related expenses is submitted to the National Social Insurance Institution for payment with a national identification number, and ultimately available to researchers. These and other authoritative sources of information on IVF treatment and outcomes continuing into the life of the child have provided Finnish researchers with significant insight into the longer range effects of fertility treatment.<sup>312</sup> Such tracking is not currently possible for other forms of assisted reproduction, such as ovulation induction.<sup>313</sup> The data collected by the Finnish government is not used for the purpose of enhancing competition among clinics. Instead, it is published only at the national level rather than at the clinic-specific level.

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306. See Mika Gissler et al., *Monitoring of IVF Birth Outcomes in Finland: A Data Quality Study*, 4 BMC MED. INFORMATICS AND DECISION MAKING 3 (2004), available at <http://www.biomedcentral.com/1472-6947/4/3>.

307. See *id.*

308. See Corinna Sorenson & Philipa Mladovsky, *Assisted Reproduction Technologies in Europe: An Overview*, RES. NOTE (Eur. Comm'n, Eur. Union), May 2006, available at [http://ec.europa.eu/employment\\_social/spssi/docs/social\\_situation/rn\\_assisted\\_reproduction\\_technology.pdf](http://ec.europa.eu/employment_social/spssi/docs/social_situation/rn_assisted_reproduction_technology.pdf).

309. See Gissler et al., *supra* note 306, at 3.

310. See *id.*

311. See *id.*

312. Sari Koivurova et al., *The Course of Pregnancy & Delivery & The Use of Maternal Healthcare Services After Standard IVF in Northern Finland 1990-1995*, 17 HUM. REPROD. 2897, 2902 (2002), available at <http://humrep.oxfordjournals.org/cgi/reprint/17/11/2897>.

313. See *id.*

IVF was introduced to Finland in 1980 by a small group of “pioneer physicians” who, from the outset, gathered informally, were in contact with each other, and exchanged ideas and innovations.<sup>314</sup> The first Finnish IVF baby was born in 1984.<sup>315</sup> As IVF treatment expanded, physicians involved in IVF developed an informal “IVF-club,” which served to socialize young physicians, helping them gain social and professional contacts, information, and education.<sup>316</sup> The fertility treatment community continues to be small; there are only twenty-six IVF clinics in Finland that reported using ART in 2007.<sup>317</sup>

In 1993, multiple deliveries constituted 27% of all IVF-related births in Finland.<sup>318</sup> As of 2007, the rate was 10.8%.<sup>319</sup> This reduction, one of the greatest in the world, has taken place in the absence of legislation or funding requirements that focus on reducing multiple births. Finnish researchers uniformly describe the transition as related to fertility clinics’ voluntary changes in practices. The ability of Finland’s physicians to change practice over a relatively short period of time may be due to the small size and high level of integration of the profession in Finland, which allows for personal communication among leaders at many of the nation’s clinics. This close association may explain the ability of the medical community to respond to findings from several Finnish fertility clinics regarding the risks of multiple pregnancies and the efficacy of single-embryo transfer. It may also be attributable to the leadership of Finnish researchers, who have published extensively on the negative effects of multiple pregnancies resulting from IVF, the efficacy of various techniques used to promote single-embryo transfer, and the economic effects of single embryo-transfer compared to multiple-embryo transfer.<sup>320</sup> Many of these studies have received funding from Finland’s government.<sup>321</sup> This dialogue effectively changed physicians’ attitudes enough to create a striking shift in clinic practices in Finland, and highlights the possible impact of professional associations and research on the decision-making context.

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314. See Maili Malin Silverio & Elina Hemminki, *Practice of In-Vitro Fertilization: A Case Study from Finland*, 42 SOC. SCI. MED. 975, 977 (1996), available at linking hub.elsevier.com/retrieve/pii/0277953695002030.

315. See Reija Klemetti et al., *Comparison of Perinatal Health of Children Born from IVF in Finland in the Early and Late 1990s*, 17 HUM. REPROD. 2192, 2192 (2002), available at <http://humrep.oxfordjournals.org/cgi/reprint/17/8/2192>.

316. See Silverio & Hemminki, *supra* note 314, at 978.

317. See Nat’l Inst. for Health & Welfare, *Assisted Fertility Treatments* (May 29, 2009), [http://www.stakes.fi/EN/tilastot/statisticsbytopic/reproduction/ivftreatments\\_readmore.htm](http://www.stakes.fi/EN/tilastot/statisticsbytopic/reproduction/ivftreatments_readmore.htm).

318. See *id.*

319. See *id.*

320. See, e.g., Gissler et al., *supra* note 306, at 2; Veleva et al., *supra* note 56 (experimenting with single embryo transfer in older women).

321. See, e.g., Klemetti et al., *supra* note 315, at 2197.

## V. RECOMMENDATIONS FOR THE UNITED STATES

How can we reshape the decision-making context in the United States to increase the percentage of single children born through assisted reproduction and reduce the percentage of multiple births? The United States is not likely to follow the overarching regulatory approach taken by the United Kingdom and Sweden, implement national funding to create strong incentives as in Belgium, or find the professional unanimity on the issue that developed in Finland. Nevertheless, it may be able to adopt some of the practices from those and other European countries to link the difficulties that multiples and their parents face to assisted reproduction practices. We can do so by using the insights developed in this Article about the structure of choice context, the resource context, and the internal context in which these decisions are currently made in the United States, and imagining how they could be changed.

What aspects of the structure of choice may be changed? One approach may be to make single-embryo transfer the norm, or the anchor in all IVF treatment. ASRM guidelines currently treat two embryos as the norm for women under thirty-five, and up to five embryos for older women. The ASRM guidelines thus treat the implantation of two or more embryos as the “default” option or decisional anchor, and physicians and patients may hesitate to step below this number. Clinicians may be worried that patients with an unsuccessful cycle will blame them for choosing to go below this norm, while patients may fear that such a deviant choice is wrong and a waste of their time, effort, and money. Rather than continuing to treat multiple-embryo transfer as the norm, ASRM standards should emphasize single-embryo transfer as the most desirable approach, and require that deviations from single-embryo transfer be justified by patient-specific factors.

This approach does not force physicians to put aside their best professional judgment. Like the United Kingdom, it does require physicians to develop a strategy to reduce multiple births and justify deviations from the only approach known to greatly reduce the possibility of twins or higher order births. Should the ASRM be unwilling to adopt this approach voluntarily, federal law could be employed to require that these justifications be submitted with each clinic’s annual statistical report to the CDC.<sup>322</sup>

In addition, the CDC should eliminate the limited and distorting requirements of the Fertility Success Rate and Certificate Act of 1992 and broaden the frame of reference that prospective patients use to select a clinic. Clinic statistics should go beyond per cycle success rates to look at cumulative success rates per patient and include selective reductions, common pregnancy problems associated with multiple births, perinatal out-

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322. See MUNDY, *supra* note 1, at 242 (discussing rejection of idea of requiring clinics to report why they failed to follow guidelines proposed at SART meeting at 2005 ASRM annual meeting).

comes, and outcomes through the first year of life.<sup>323</sup> Rather than steering patients to consider only the per cycle success rate in choosing their clinics, broader information can assist prospective patients to make more informed choices. It can also help prospective patients keep in mind the entire picture concerning the long-term health of their desired family as they make treatment decisions.

Federal law should also be changed to require the CDC to broaden its focus to include all assisted reproduction, not just IVF. Reporting requirements should also include medical approaches to assisted reproduction, such as hormone therapy and IUI. The CDC should increase its collection and publication of research concerning the risks of multiple births related to all forms of assisted reproduction and successful strategies to reduce the rate of multiple births. Further, it should collect and highlight research concerning the risks of hormone therapy, including ovarian stimulation with and without IUI, along with information about IVF. Prospective patients who are choosing between hormone therapy and IVF should be given state of the art information regarding hormone therapy benefits and risks in comparison to the benefits and risks of IVF. Patient registries, similar to those used in Sweden, Belgium, and Finland, would provide researchers, physicians, and policymakers with a broad frame through which to view the effects of fertility treatment.<sup>324</sup>

The CDC can also shape the structure of choice context and broaden the relevant frame by effectively educating patients and physicians about the risks associated with multiple-embryo transfer. It can ensure that fertility clinics receive the most up-to-date information about successful techniques that make single-embryo transfer as effective as possible, such as embryo selection and cryo-preservation techniques. We can look to the United Kingdom's development of the website "One at a Time" to educate potential and current patients and physicians about the risks of multiple-embryo transfer and the best practices to achieve successful pregnancies through single-embryo transfer. This website is not limited to mind-numbing statistics, but also includes personal stories involving a range of IVF outcomes that make these risks salient to those considering fertility treatment.

Another framing strategy that the CDC could adopt is to highlight and reward with special recognition fertility clinics, like the University of Iowa clinic, that have greatly reduced their proportion of multiple births while maintaining strong pregnancy success rates. Access to this information can begin to reframe success as the delivery of a healthy single child

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323. See, e.g., Beth A. Malizia et al., *Cumulative Live-Birth Rates After In Vitro Fertilization*, 360 NEW ENG. J. MED. 236 (2009), available at <http://content.nejm.org/cgi/content/full/360/3/236> (arguing that primary patient interest concerns chance of live birth over entire course of treatment, not per cycle).

324. For a discussion of patient registries used in European countries, see *supra* notes 224-321 and accompanying text.

rather than focusing only on pregnancy and live birth rates per cycle. These and other strategies can be used to redefine success.

The next aspect of the decision-making context that can be changed is the resource context. The extraordinary expenses associated with IVF greatly reduce access to IVF, which is much more controllable than hormone therapy. This expense may lead to multiple gestations only because of lack of access to funding for IVF.<sup>325</sup> All states should adopt Massachusetts's requirement of full coverage for IVF treatment, which in practice has included up to six cycles of IVF. Moreover, states should not permit plans to impose onerous timing requirements, such as lengthy periods of infertility or previous attempts with hormone therapy, which would discourage patients from employing single-embryo transfer.<sup>326</sup> Rather, states should encourage health insurance companies to adopt approaches that foster single-embryo transfer.

Insurers should consider the experience of Belgium in designing their coverage plans. Belgium has sharply reduced its twinning rate related to IVF and other fertility treatments by expanding coverage for IVF and including limits on the number of embryos transferred depending on patient age. Because insurers are in a position to "link up" the expenses related to fertility treatment and the expenses related to pregnancy, perinatal, and pediatric care, they may well find that even in the absence of insurance coverage mandates, it is in their economic interest to gain more control over the fertility treatment process in order to prevent some of the high costs associated with the care of multiples and their mothers.

Professional associations should also address the obvious conflicts of interest faced by physicians who derive great profit from their IVF practices yet are obliged to effectively counsel and provide informed consent to their patients. Clinics should be required to give all patients considering assisted reproduction access to highly trained counselors who are independent of the fertility clinics and their profit motive. They can counsel patients, provide them with information, and educate them about the risks and benefits of various treatment options. This will aid patients in obtaining a perspective that is not shaped by the potential profit to be made from an IVF cycle.

Finally, action should be taken with regard to reshaping the internal context for physician and patient decision-making. In order to address the effects of the availability heuristic, which makes actual experiences much more powerful and more likely to be relied upon than unfamiliar experiences, fertility specialists must witness the outcomes of their treat-

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325. See Press Release, Am. Soc'y for Reprod. Med., Highlights from ASRM09: USA and International Trends in ART—Access and Outcomes (Oct. 21, 2009), <http://www.asrm.org/news/article.aspx?id=2252> (stating that, based on data from International Committee Monitoring ART, ASRM found that "policies that promote access to infertility treatment also promote making those treatments safer and more effective . . .").

326. See AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 63, at 2.



ment beyond the initial excitement of informing patients that they are pregnant. We must re-link fertility treatment to the process of pregnancy, birth, and neonatal care.<sup>327</sup> For example, as part of their ongoing training and continuing education, fertility specialists should be required to spend time in the offices of physicians who treat high risk pregnancies, especially those created through IVF or hormone therapy. They should follow up with their patients throughout the pregnancy, delivery, and perinatal process—visiting their patients if they are hospitalized on bed rest or with pre-eclampsia, or if their children are placed in the neonatal intensive care units. They should also attend multifetal reductions.

The availability heuristic should be employed for patients as well. A short fact sheet and conversation with a physician designed to persuade patients to shift away from a preference for twins can be somewhat effective. However, vivid stories, especially those presented in DVD or other visual format, can bring home the nature of the risks, and the consequences for the quality of life for the parents, to patients who are much more affected by their immediate concern—conception—rather than the longer term consequences of their decisions.

In order to make the potential emotional impact of multiple births more relevant to patients enmeshed in the stresses of infertility, clinics can consider programs that give patients “real” experiences with the consequences of multiple gestations, from decisions about multifetal reduction to living through a month of neonatal intensive care for twins or triplets. Clinics could take their cue from entrepreneurs who have started running pre-retirement “boot camps,” which give those contemplating retirement an opportunity to experience a simulation of actual retirement.<sup>328</sup> Many options can be devised to make the real risks of multiple gestations “available” to fertility physicians and their patients.

These and other changes to the structure of choice, resource, and internal decision-making context for physicians and patients, if successful, would bring real and important health, welfare, and financial benefits to patients and their families as well as the broader society. They can be accomplished without creating an extensive regulatory scheme and without taking away patient choice in assisted reproduction. While such changes may expand the obligations of health insurance companies, the experience in Belgium shows that ultimately broadening access to IVF, while ensuring that it is practiced to reduce multiple births, can save health care dollars in the long run.

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327. For a similar recommendation, see Pennings, *supra* note 18, at 2469.

328. See Tara Siegel Bernard, *A Boot Camp to Prepare for Retirement*, N.Y. TIMES, July 25, 2009, at B1, available at <http://www.nytimes.com/2009/07/25/your-money/25money.html>.

## CONCLUSION

The United States lags in responding to the man-made epidemic of multiple pregnancies and births related to the growing use of assisted reproduction. Through careful examination of the structure of choice, resource, and internal decision-making context in which key reproductive treatment decisions are made, it is possible to uncover the many ways in which physicians and patients are steered towards choices that lead to high risks of multiple gestations. This examination, together with the European perspective on how this crucial public health issue can be effectively addressed, leads to recommendations for changes in practices. These proposed practices can establish a treatment context that encourages patients towards the choices that will best allow them to fulfill their desire for children without fueling the risks that could undermine those same dreams.

