

## EIGHT IS ENOUGH

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### INTRODUCTION

On January 26, 2009, the nation's second set of live-born octuplets was delivered at a California hospital.<sup>1</sup> The public fascination with this unusual event quickly turned ugly when the media revealed that the new mother was thirty-three-year-old Nadya Suleman, a single, unemployed woman already caring for six other children under the age of eight. As Ellen Goodman of the *Boston Globe* described it, upon discovery of Suleman's identity, the mood of the country went "from 'Gee whiz' to 'Are you kidding?'" in a matter of days.<sup>2</sup>

The reaction to Nadya Suleman's new family stands in stark contrast to the enthusiastic reception for many other families with high-order multiples. For example, the cable show *Jon & Kate Plus 8*, which features a family with a set of sextuplets and a set of twins, is currently one of cable television's highest-rated shows.<sup>3</sup> The McCaughey septuplets, born in 1997, are similarly famous: for example, they celebrate their birthdays each year with *Dateline* reporter Ann Curry.<sup>4</sup> Indeed, public fascination with high-birth families dates back at least to the famous Dionne quintuplets of the 1930s, who were treated as a tourist attraction by the Canadian govern-

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<sup>1</sup> Remarkably, the doctors were surprised by the arrival of octuplets; they had only been expecting to deliver seven babies. CNN, *Octuplets' Births Surprise California Doctors*, CNNHEALTH.COM, Jan. 27, 2009, <http://www.cnn.com/2009/HEALTH/01/26/california.octuplets/> (link).

<sup>2</sup> Ellen Goodman, *The Ethical Failures of Fertility Treatment*, BOSTONGLOBE.COM, Feb. 6, 2009, [http://www.boston.com/bostonglobe/editorial\\_opinion/oped/articles/2009/02/06/the\\_ethical\\_failures\\_of\\_fertility\\_treatment/](http://www.boston.com/bostonglobe/editorial_opinion/oped/articles/2009/02/06/the_ethical_failures_of_fertility_treatment/) (link).

<sup>3</sup> See Susan Stewart, *Big Brood Spawns Big Ratings*, NYTIMES.COM, Feb. 12, 2009, [http://www.nytimes.com/2009/02/15/arts/television/15stew.html?\\_r=1&scp=1&sq=octuplets+stewart&t=nyt](http://www.nytimes.com/2009/02/15/arts/television/15stew.html?_r=1&scp=1&sq=octuplets+stewart&t=nyt) (link).

<sup>4</sup> See, e.g., Ann Curry, *Eight is Great for the McCaughey Septuplets*, MSNBC.COM, Jan. 15, 2006, <http://today.msnbc.msn.com/id/10867824/> (describing Curry's visit to the children for their eighth birthday) (link); Ann Curry, *After Ten Years, New Adventures for Septuplets*, Dec. 12, 2007, <http://www.msnbc.msn.com/id/22223331/> (link).

ment and who were visited by more than three million people over a ten-year span.<sup>5</sup>

Compare the reactions to Nadya Suleman's story. The medical director of the Center for Human Reproduction termed the births a "medical catastrophe."<sup>6</sup> A columnist for the *Los Angeles Times* called her story "grotesque" and "bizarre," and criticized her "manifest irresponsibility."<sup>7</sup> A San Francisco writer deemed her "misguided and clearly troubled."<sup>8</sup> Even her own parents vehemently criticized Suleman; her father called her "absolutely irresponsible[]" and questioned her mental stability,<sup>9</sup> while Nadya's mother described her actions as "unconscionable."<sup>10</sup>

The cultural backlash against Suleman has focused on three separate but related issues. The first set of concerns revolves around Suleman herself—specifically, her ability to parent fourteen young children. Disclosures about Suleman's background came fast and furious after the children's birth: she is single, she is unemployed, she has been receiving disability payments for several years, at least two of her older children receive Supplemental Security Income (SSI) payments and thus may have some kind of special needs, and while undergoing her most recent fertility treatment, she lived with her parents in a three-bedroom house that may be going into foreclosure.<sup>11</sup> Judgments about her race, explicitly acknowledged or not, may also be a factor.<sup>12</sup> Her defenders see these criticisms against Suleman as a form of "mother-blaming."<sup>13</sup>

A second set of concerns revolves around the medical procedures that led to the octuplets' birth. The fertility clinic that treated Suleman agreed to implant her with at least six embryos during an in vitro fertilization (IVF)

<sup>5</sup> See *The Dionne Quintuplets: A Depression-Era Freak Show*, CNN.COM, Nov. 19, 1997, <http://www.cnn.com/US/9711/19/dionne.quints/> (describing how the Canadian government removed the girls from their parents and housed them at "Quintland," earning the government and nearby businesses around a half-billion dollars in profits) (link).

<sup>6</sup> Posting of Judith Graham to Triage, *Doctors on the Octuplets: It's Medical Negligence*, Feb. 5, 2009, <http://newsblogs.chicagotribune.com/triage/2009/02/doctors-on-the-octuplets-a-medical-catastrophe.html> (reporting comments of Dr. Norbert Gleicher) (link).

<sup>7</sup> Tim Rutten, *The Excesses of Nadya Suleman*, LATIMES.COM, Feb. 11, 2009, <http://www.latimes.com/news/opinion/commentary/la-oe-rutten11-2009feb11.0,1768472.column> (link).

<sup>8</sup> Debra J. Saunders, *Dysfunctional Familymaking*, SFGATE.COM, Feb. 8, 2009, <http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2009/02/08/INRC15MOCA.DTL> (link).

<sup>9</sup> See *Octuplet Grandfather to Oprah: I Question Her Mental Situation*, THE HUFFINGTON POST, Feb. 20, 2009, [http://www.huffingtonpost.com/2009/02/19/octuplet-grandfather-to-o\\_n\\_168448.html](http://www.huffingtonpost.com/2009/02/19/octuplet-grandfather-to-o_n_168448.html) (link).

<sup>10</sup> See *Octuplets' Grandmother Criticizes Daughter*, ASSOCIATED PRESS, Feb. 9, 2009, available at <http://www.msnbc.msn.com/id/29098465/> (link).

<sup>11</sup> See, e.g., Rutten, *supra* note 7; *Octuplet Grandfather to Oprah: I Question Her Mental Situation*, *supra* note 9.

<sup>12</sup> See Bridget J. Crawford & Lolita Buckner Innis, *Multiple Anxieties: Breaching Race, Class, and Gender Norms with Assisted Reproduction* (Cleveland-Marshall Legal Studies Paper, No. 1360453, Mar. 19, 2009), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1360453](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1360453) (link).

<sup>13</sup> See, e.g., *id.*

procedure. The leading fertility industry group asserts that this decision was contrary to its recommended guidelines that women under the age of thirty-five have no more than two embryos implanted during any single IVF attempt.<sup>14</sup>

A final set of issues concerns more fundamental questions about screening parents. Many wonder how a clinic could agree to provide a single mother of six with a fertility treatment that might—and did—double her number of children. This particular debate echoes larger cultural concerns over the changing American family, including calls for two parents (one of each sex) for every child.

In response to these concerns, commentators and legislators are calling for new, more restrictive regulation of the fertility industry. Shortly after the octuplets were born, Georgia Right to Life helped get legislation introduced that would limit the number of eggs that could be fertilized in any IVF cycle to no more than the number that would be transferred into the woman.<sup>15</sup> In Missouri, legislation was introduced to impose limits on the number of embryos that could be implanted.<sup>16</sup>

Although the debate about whether and how to regulate the fertility industry is certainly not new,<sup>17</sup> Suleman's story has thrown two kinds of proposals into particularly sharp relief. The first set of proposals seeks to increase regulation of assisted reproductive technologies ("ART") via the doctors that perform them. For example, some commentators urge the United States to adopt mandatory limits on the number of embryos that can be implanted, as other countries have done.<sup>18</sup> Although the American Society of Reproductive Medicine has issued guidelines regarding the appropriate number of embryos to transfer, adherence is entirely voluntary and, quite obviously, not universal. The issues entwined with such restrictions are difficult and important, and the Suleman case has begun a conversation

<sup>14</sup> See Am. Soc'y Reprod. Med., *Guidelines on Numbers of Embryos Transferred*, 90 FERTILITY & STERILITY S163, S163 (2008) (link).

<sup>15</sup> See Ethical Treatment of Human Embryos Act, S.B. 169, 150th Gen. Assem., 1st Reg. Sess. (Ga. 2009) (link).

<sup>16</sup> See H.B. 810, 95th Gen. Assem., 1st Reg. Sess. (Mo. 2009) (requiring compliance with the American Society of Reproductive Medicine's recommendations on implantation) (link). Placing limits on assisted reproductive technology ("ART") procedures can be part of a "right to life" agenda because of beliefs that embryos are persons and that ART is morally wrong. Accordingly, arguments for regulating ART risk alignment with an anti-abortion agenda, and must be crafted carefully. See, e.g., William Saletan, *Crooktuplets: Hijacking the Octuplets Backlash to Restrict IVF*, SLATE, Mar. 4, 2009, <http://www.slate.com/id/2212876/pagnum/all/> (arguing that the chief purpose of the Georgia bill is not to "help women" but "to establish legal rights for embryos") (link).

<sup>17</sup> See NAOMI R. CAHN, TEST TUBE FAMILIES: WHY THE FERTILITY MARKET NEEDS LEGAL REGULATION (2009); DEBORA L. SPAR, THE BABY BUSINESS: HOW MONEY, SCIENCE, AND POLITICS DRIVE THE COMMERCE OF CONCEPTION (2006).

<sup>18</sup> See, e.g., Radhika Rao, *Equal Liberty: Assisted Reproductive Technology and Reproductive Equality*, 76 GEO. WASH. L. REV. 1457, 1458–59 (2008) (describing German and Italian regulatory schemes) (link).

about more meaningful regulation of the medical procedures used by the fertility industry. Indeed, as we develop further below, we support several such initiatives.<sup>19</sup>

We are far more troubled, however, by a second set of proposals arising out of the Suleman backlash: those that urge placing restrictions on which individuals may receive fertility treatment. Margaret Somerville, founder of the McGill Centre for Medicine, Ethics, and Law, argues that we should regulate access to reproductive technology in the same way that we regulate access to adoption.<sup>20</sup> In her opinion, if a “single woman with six children” and “living with her parents” would not be permitted to adopt a child, then she should not be permitted to receive fertility treatments such as IVF either.<sup>21</sup> Under this theory, women with a certain number of children, or with limited financial resources, should be precluded from receiving fertility treatment. Somerville also suggests that a patient’s age, and perhaps her marital status, should be relevant considerations. Some ART providers have already tried to impose access limitations on the basis of sexual orientation.<sup>22</sup> Indeed, many ART clinicians say they would choose to reject patients based on their marital status or sexual orientation,<sup>23</sup> and some states have laws that permit the use of reproductive technology only by married couples.<sup>24</sup>

Issues related to access are also weighty and difficult, but our conclusion here differs from our position about regulating the medical procedures themselves: neither fertility clinics nor the state should be in the business of restricting access to reproductive technology. We do not require financial litmus tests or impose limits on family size for individuals who are able to conceive without reproductive technology, and we do not believe that requiring some medical assistance in order to conceive means that infertile individuals should have to tolerate such restrictions.

Perhaps the most difficult question raised by the Suleman case and other high-order births is whether government regulation can be justified *at*

<sup>19</sup> We save for another piece, however, detailed answers to many questions in this area, such as issues relating to how to regulate sperm, egg, and embryo donors, including both anonymous donors and those known to the recipient, and what to do about insurance.

<sup>20</sup> See Margaret Somerville, *Examining Society’s Role*, OTTAWACITIZEN.COM, Feb. 11, 2009, <http://www.ottawacitizen.com/opinion/Examining+society+role/1275699/story.html> (link).

<sup>21</sup> *Id.* Somerville is also troubled by the case of a sixty-year-old Canadian woman who gave birth to twin boys after traveling to India to receive IVF treatment using donor eggs and her husband’s sperm. *Id.*

<sup>22</sup> See, e.g., *N. Coast Women’s Care Med. Group, Inc. v. San Diego County Superior Court*, 189 P.3d 959 (Cal. 2008) (ruling that a California clinic could not rely on religious objections and refuse to perform an intrauterine insemination procedure on a lesbian patient) (link).

<sup>23</sup> See Andrea D. Gurmankin et al., *Screening Practices and Beliefs of Assisted Reproductive Technology Programs*, 83 FERTILITY & STERILITY 61, 66 (2005); Judith F. Daar, *Accessing Reproductive Technologies: Invisible Barriers, Indelible Harms*, 23 BERKELEY J. GENDER L. & JUST. 18, 54 (2008).

<sup>24</sup> Oklahoma, for example, limits the use of artificial insemination to a husband and a wife. See OKLA. STAT. ANN. tit. 10, § 553 (West 2007).

all in the context of ART. Before evaluating each set of proposals in further detail, we turn first to this threshold issue.

### I. SHOULD WE REGULATE?

There is a powerful case to be made that the law should abstain from regulating ART entirely. ART involves extraordinarily personal social and medical choices, and raises critical issues related to patient autonomy and freedom of reproductive choice. Moreover, the cultural stigma traditionally associated with infertility may argue for less public attention to these issues. Nevertheless, we believe that some limited regulation is justifiable.

#### A. Patient Autonomy

We begin with the question of patient autonomy, the idea that individuals ordinarily have the right to determine for themselves the most appropriate course of medical treatment. Doctors may not, for example, treat a patient without her consent, and patients have a right to be informed of the relevant risks and benefits of any medical procedure before undergoing it.<sup>25</sup> But there have always been limitations to this core principle of autonomy. Patients do not have a right to receive medical procedures or medications that the Food and Drug Administration has deemed unsafe,<sup>26</sup> and they do not have the right to compel others to undertake risks, such as submitting to bone marrow transplants, in order to further their own health agendas. Indeed, federal and state governments often cite the need to regulate risk in justifying limitations on individual autonomy. Better-known examples of such limitations include mandatory vaccinations, speed limits, and seatbelt and helmet laws. Autonomy has thus always been modified by risk, and we believe it is that principle that is relevant in the ART context.

When a patient undergoes an ART procedure that results in high-order multiples, two sets of health risks are created: one to the mother and one to the children. Mothers carrying high-order multiples face increased risks of pregnancy complications and even death.<sup>27</sup> Children who are part of a multiple birth are far more likely to be born premature and at a low birth weight. Prematurity and low birth weight are associated with higher risks of infant death and a host of other impairments, including “cerebral palsy[,] vision and hearing problems[,] and long-term motor, cognitive, behavioral,

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<sup>25</sup> See Marsha Garrison, *Regulating Reproduction*, 76 GEO. WASH. L. REV. 1623, 1631–32 (2008) (describing the implications of the principle of patient autonomy) (link).

<sup>26</sup> *Id.* at 1632 (explaining that the FDA has “the authority to deny access to drugs and medical devices found to be unsafe or ineffective”).

<sup>27</sup> *Id.* at 1644 (“Some experts estimate that maternal morbidity is seven times greater in multiple pregnancies than in singleton deliveries and that perinatal mortality rates are four times higher for twins and six times higher for triplets and higher-order births.”). Men who intend to become fathers through ART do not face comparable medical risks.

social-emotional, health, and growth problems.”<sup>28</sup> Choices about the appropriate number of embryos to implant are therefore neither necessarily benign nor neutral—they carry the very real potential for adverse consequences. Importantly, these adverse consequences are not limited to the patient herself; rather, the ART patient’s choices also create risk for third parties: the children who might be born as a result of the pregnancy attempt.<sup>29</sup> It is this potential risk to third parties, against which any potential children are obviously unable to defend, that seems to outweigh concerns for patient autonomy and to justify at least minimal government intervention. In addition to patient autonomy, however, are other values that compete against the health risks to mother and children.

### B. Reproductive Choice

The principle of freedom in matters of reproductive choice is also of paramount concern in discussing restrictions on ART procedures, and we do not believe that anything we say here should serve as a basis for retreating from that principle. In this context, however, we believe that the sort of regulations we endorse below do not impinge upon the core values undergirding reproductive freedom. At its essence, protecting women’s reproductive freedom means that women must retain the right to decide whether or not they want to reproduce, and we must therefore analyze any new proposed regulations to be sure they do not infringe upon this essential right.<sup>30</sup>

Regulating the number of embryos that may be transferred during IVF procedures does not, of course, compel a woman to reproduce against her will, so that concern is not implicated by placing restrictions on ART. But embryo transfer restrictions may indeed reduce the likelihood that a woman will be able to *successfully* reproduce. This is an important and powerful counter-argument to ART regulation: if transferring more embryos increases the chance of a successful pregnancy, then perhaps government regulation should not stand in the way. Just as personal autonomy is modulated by risk, however, reproductive freedom is modulated by concerns for the rights and freedom of others. We do not allow individuals to become parents at any cost; an individual may quite obviously not appropriate another person’s child in order to become a parent, nor force another woman to

<sup>28</sup> *Id.*

<sup>29</sup> Public costs range from health care to education. There is a generally-recognized social obligation to protect children once they come into existence. Of course, the meaning of “come into existence” is highly contested: Louisiana, for example, has adopted legislation recognizing that embryos are “persons,” and the proposed legislation in Georgia accords similar status to embryos. See LA. REV. STAT. ANN. § 9:129 (2008) (“A viable in vitro fertilized human ovum is a juridical person . . . .”) (link); Saletan, *supra* note 16. In arguing for the protection of future children, we are not according personhood to embryos; indeed, if all embryos created in an ART procedure are not transferred, embryos may need to be donated to another infertile patient, used for medical research, stored indefinitely, or destroyed.

<sup>30</sup> See generally John A. Robertson, *Assisting Reproduction, Choosing Genes, and the Scope of Reproductive Freedom*, 76 GEO. WASH. L. REV. 1490, 1492 (2008) (arguing that “society is accustomed to think of reproductive autonomy in constitutional terms as primarily a right not to reproduce”) (link).

serve as a surrogate mother. Society has always been willing to draw some line that it will not cross in furthering any particular individual's quest to become a parent.

In determining where to draw that line, society should strive to protect an individual's interest in becoming a parent, while simultaneously protecting society's interests in healthy children through appropriate market regulation—regulation that will guard, for example, against power and informational imbalances. Discussions about the number of embryos to be transferred during IVF, the amount of ART-related recordkeeping, informed consent requirements, and measures for keeping the market safe may potentially move the United States toward this goal. There has historically been comparatively little oversight of the fertility industry, so these discussions are long overdue. Understanding the reasons the government has thus far abstained from regulation, however, will help frame future decisions.

## II. EXISTING REGULATIONS AND NEW PROPOSALS REGARDING MEDICAL PROCEDURES

We turn now to a brief discussion of existing laws regulating assisted reproduction. We then consider whether new regulation of the medical procedures themselves might be appropriate, before turning in the next section to questions regarding regulation of access to ART technology.

### A. *The Current Lay of the Law*

Currently, regulation over reproductive technology by the state and federal government is limited. The fertility industry mostly self regulates through nonbinding guidelines and suggested ethical practices, though there are various physician licensing requirements.<sup>31</sup> There are numerous possible reasons for this comparative lack of oversight, including the tendency for scientific advances to outpace the law, the limited use of reproductive technology until the 1980s, and the secrecy and stigma surrounding infertility. Moreover, reproductive technology taps into deeply conflicting cultural perspectives on parenthood outside of the nuclear, biological family and other controversial social issues,<sup>32</sup> such as stem cell research, abortion, and even sex itself.

Nevertheless, over the past several decades, the federal government has taken some steps toward regulation—today, it oversees clinical laboratory services, drugs, and medical devices used in IVF treatments; has standards that establish safe use of human tissue, such as donor sperm and eggs; and

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<sup>31</sup> For further discussion, see CAHN, *supra* note 17; Naomi Cahn, *Accidental Incest: Drawing the Line—or the Curtain?—for Reproductive Technology*, 32 HARV. J. L. & GENDER 59 (2009) (link).

<sup>32</sup> See generally Gaia Bernstein, *The Socio-Legal Acceptance of New Technologies: A Close Look at Artificial Insemination*, 77 WASH. L. REV. 1035 (2002) (discussing reasons for the lack of oversight); on cultural conflict, see NAOMI CAHN & JUNE CARBONE, *RED FAMILIES V. BLUE FAMILIES* (forthcoming 2010).

provides monitoring of fertility clinic success rates to protect ART consumers from fraudulent advertisements.<sup>33</sup> Federal law does not otherwise regulate the medical procedures involved in donation.

The ART industry has also engaged in some self-regulation,<sup>34</sup> developing a series of ethical guidelines that contain advice and standards on topics that go beyond basic ART medical practice to include such complex issues as patient screening.<sup>35</sup> Although most reproductive endocrinologists follow these standards, they are not, as the Suleman case so nicely illustrates, binding. The occasional ART “mix-ups” that make their way into newspapers or courts remind consumers and the public at large of the general lack of oversight.<sup>36</sup> By contrast, many European countries take a far more restrictive approach, with laws primarily designed to protect *embryos*<sup>37</sup>—as does the new proposed Georgia law. Our proposed regulations are justified instead by concerns for the infertile patient and her future children, and for the ethical fertility doctor who does not want to transfer six embryos.<sup>38</sup> The Suleman case highlights some of the most pressing areas where regulation is needed, such as the number of embryos transferred, the need for standardized informed consent, and the role of insurance. The case also, somewhat paradoxically, shows one area where we should not regulate: access to ART procedures.<sup>39</sup> This Essay focuses on the embryo limit and access issues, two of the most criticized aspects of the Suleman case.

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<sup>33</sup> See The Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. § 263a-1 to -7 (2006) (link); 21 C.F.R. § 1271.1 (2008) (link).

<sup>34</sup> See SPAR, *supra* note 17, at 34 (observing that “the threat of regulation hangs heavily over the industry, prodding suppliers to conform to a fairly rigorous regime of self-regulation and often to act as if they were anticipating a regulatory response”).

<sup>35</sup> See Am. Soc’y Reprod. Med., Ethical Considerations of Assisted Reproductive Technologies: ASRM Ethics Committee Reports and Statements, *available at* <http://www.asrm.org/Media/Ethics/ethicsmain.html> (link). On screening, see Ethics Comm. of Am. Soc’y Reprod. Med., *Child-rearing Ability and the Provision of Fertility Services*, 82 FERTILITY & STERILITY 564 (2004).

<sup>36</sup> There have been several reported cases of embryos that were wrongly implanted in the wrong woman. See Leslie Bender, “*To Err Is Human*”: ART Mix-ups: A Labor-Based, Relational Proposal, 9 J. GENDER RACE & JUST. 443, 446–453 (2006).

<sup>37</sup> See Rao, *supra* note 18, at 1458–59. Indeed, the very title of the German law makes its intent plain: it is named the “Embryo Protection Act.” See *id.* at 1458.

<sup>38</sup> A doctor might agree to implant more embryos than recommended because of the competition between the more than 400 fertility clinics in this country. Stephanie Saul, *Birth of Octuplets Puts Focus on Fertility Clinics*, NYTIMES.COM, Feb. 11, 2009, <http://www.nytimes.com/2009/02/12/health/12ivf.html?ref=health> (link).

<sup>39</sup> Ms. Suleman appears to have used a known donor to create her embryos. There are complex issues involved in regulating the donor world to assure protection of all involved. See, e.g., Cahn, *Accidental Incest*, *supra* note 31; Naomi Cahn, *Necessary Subjects: The Need for a Mandatory National Donor Gamete Databank*, 12 DEPAUL J. HEALTH CARE L. 203 (2009).

### B. *New Ways to Regulate*

We support limits on the number of embryos *transferred* in any single ART procedure, although we would not impose limits on the number of embryos *created* in any cycle. The risks posed to both patients and future children are too great, and the countervailing pressure for both doctors and patients to achieve a pregnancy too strong, to remain unaddressed. The American Society for Reproductive Medicine (ASRM) guidelines, developed by fertility practitioners, articulate the parameters of workable guidelines, and build in some flexibility to ensure that they are appropriately sensitive to the situation of each patient. For example, consider the current ASRM guideline that no more than two embryos should be transferred into a patient under the age of 35 “in the absence of extraordinary circumstances.”<sup>40</sup> A regulation that mirrors this directive leaves room for exemptions—a thirty-four-year-old woman might be able to establish, for example, that due to a repeated history of unsuccessful attempts or poor embryo quality, she should be allowed to transfer three embryos on her last ART attempt.

The need to reconcile generally binding guidelines with the potential for flexibility suggests that some sort of administrative agency may ultimately be the best mechanism for ART regulation. One possibility is to create an entity modeled on the British Human Fertilisation and Embryology Authority, a board-directed governmental organization whose members include representatives from various stakeholding constituencies.<sup>41</sup> A second is Professor Marsha Garrison’s suggestion that we look toward a “quasi-public regulatory system,” like that in place in the organ transplant context.<sup>42</sup> This quasi-public system could be responsible for reviewing appeals from patients who believe they warrant exceptions from the guidelines. Each of these alternatives involves creating a federal agency, which ensures that any new ART guidelines are national rather than state-based. This is critical, given the ease with which patients could travel between jurisdictions to circumvent unwelcome state restrictions. Such an agency

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<sup>40</sup> See Am. Soc’y Reprod. Med., *supra* note 14, at S163.

<sup>41</sup> See FAQs about the HFEA, <http://www.hfea.gov.uk/127.html#6> (last visited Apr. 28, 2009) (link).

<sup>42</sup> Garrison, *supra* note 25, at 1648. A national transplant network was established in 1984 “to be run by a private, nonprofit entity, that would maintain regional organ banks and set criteria for donation and receipt of organs.” *Id.* at 1648–49. According to Garrison:

Since 1986, the nongovernmental United Network for Organ Sharing (“UNOS”) has contracted with the federal Department of Health and Human Services (“HHS”) to run this network. The UNOS Board of Directors, composed largely of transplant surgeons, establishes organ transplant policies, but these policies are not implemented until approved by the HHS Secretary. *Id.*

Even Garrison acknowledges that the UNOS approach is not perfect, but it seems to be a possible alternative regulatory scheme.

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could also implement enforcement mechanisms targeted at fertility clinics by imposing fines and handling de-accreditation proceedings.

There are powerful objections to mandatory regulation. As stated above, the higher risks for both mothers and children associated with multiple births provide the primary justification for exploring a new regulatory approach to ART, but it does not necessarily follow that federal government regulation is the best approach. Perhaps we should instead respect the traditional sanctity of the doctor-patient relationship and rely upon physicians to self-regulate, or allow states to experiment with different types of regulation before establishing federal standards. After all, we currently have a healthy tort system to bring medical malpractice claims, and, in addition to the industry's own organizations, there are state medical boards that could potentially sanction their members (indeed, the California medical board is investigating Suleman's physician).

Ultimately, however, we cannot rely on doctors who perform ART to self-regulate. How can a doctor, who has treated a patient through repeatedly unsuccessful pregnancy attempts, be expected to resist a desperate plea to implant just one more embryo?<sup>43</sup> Further, interference in the doctor-patient relationship is hardly unprecedented. Even if patients plead for them, doctors cannot legally prescribe medications that are not FDA-approved; nor can doctors enroll patients in medical studies without complying with informed consent guidelines. It is clear, moreover, that voluntary guidelines have not worked—statistics from 2006, the most recent available, show that almost 4% of ART pregnancies involved three fetuses or more.<sup>44</sup> In sum, when procedures are deemed sufficiently risky, government regulation has traditionally intervened in the doctor-patient relationship, and we believe the risks here are sufficiently great to allow that imposition.

### III. PROPOSALS REGARDING ACCESS

Opening the door to any regulation potentially brings its own set of problems, including increasing financial pressures, inducing patients to travel, and, critically, inducing states to impose regulations on access to ART. We now turn to these issues.

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<sup>43</sup> Estimates based on government reports are that less than 20% of fertility clinics comply with the voluntary guidelines restricting the number of embryos to be transferred into women under the age of 35. Stephanie Nano, *Few Fertility Clinics Follow Embryo Guidelines*, SFGATE.COM, Feb. 21, 2009, <http://www.sfchronicle.us/cgi-bin/article.cgi?f=/c/a/2009/02/21/MN2A161S2S.DTL> (link). The guidelines do allow for some flexibility, so this may overstate the lack of compliance. Doctors also face competitive pressures to report high success rates.

<sup>44</sup> See U.S. DEP'T HEALTH & HUMAN SERVS., 2006 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES 22 (2008), available at <http://www.cdc.gov/ART/ART2006/508PDF/2006ART.pdf> (link). Interestingly, only 1.9% of births involved triplets or higher orders of multiples, perhaps due to selective reduction. *Id.*

### A. Financial Considerations

Although we advocate more regulation, we recognize the critical role of compassion for patients experiencing infertility. Infertility is one of the most difficult life challenges an individual can encounter,<sup>45</sup> and we believe we must do more to facilitate access to treatment. Any new ART regulations must therefore be coupled with increased insurance coverage. Indeed, one of the reasons that individuals are willing to risk their own health and that of their future children by transferring a large number of embryos is because each individual IVF procedure is so expensive that a patient may only be able to afford one or at most two attempts. If patients knew that insurance would cover multiple IVF attempts, the temptation to gamble on any single procedure would be greatly reduced.

June Carbone and Paige Gottheim suggest another potential problem with regulation: imposing limits on embryo transfers might cause us to “lose[] control of the activity altogether” by driving women underground to black market fertility clinics or overseas to doctors who will comply with their treatment preferences.<sup>46</sup> These are legitimate concerns, but our proposal to increase insurance coverage will allay many of them. Most women are not seeking to transfer five embryos because they want quintuplets; they are transferring five embryos because they want a successful pregnancy. If women knew that multiple attempts with one or two embryos would be covered by insurance, they would feel less pressed to travel overseas or to engage in illegal fertility treatments.<sup>47</sup>

### B. Restrictions on Access

Another powerful objection to regulation is the concern that opening the door to *any* kind of government interference in fertility treatments will also open the door to restrictions on ART access, issues that are surfacing in the wake of the Suleman case.<sup>48</sup> We do not believe that any new government regulations should include rules that restrict access to fertility treatment by discriminating among potential patients. Clinics should not screen on the basis of preexisting family size, the financial resources available to care for any children born as a result of ART, or the marital status or sexual

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<sup>45</sup> E.g., David Orentlicher, *Discrimination Out of Dismissiveness: The Example of Infertility* 12 (Apr. 29, 2009) (unpublished manuscript, on file with the Northwestern University Law Review Colloquy).

<sup>46</sup> See June Carbone & Paige Gottheim, *Markets, Subsidies, Regulation, and Trust: Building Ethical Understandings into the Market for Fertility Services*, 9 J. GENDER RACE & JUST. 509, 518 (2006).

<sup>47</sup> See *id.* at 534 (using Great Britain as an example).

<sup>48</sup> See generally Martha M. Ertman, *What's Wrong With a Parenthood Market? A New and Improved Theory of Commodification*, 82 N.C. L. REV. 1, 15 (2003) (“The free market aspects of alternative insemination transactions play a crucial role in making this branch of the parenthood market particularly beneficial to marginalized groups.”). Ertman writes: “I think the private law nature of alternative inseminations, on balance, furthers human flourishing because statutory regulations would likely reflect majoritarian bias against single parents and gay people.” *Id.* at 22.

orientation of potential patients.<sup>49</sup> Individuals able to conceive without reproductive technology are not subject to such restrictions before they expand their families. Indeed, we are confident that any general attempt to impose limits on family size, such as China's one-child policy, would be greeted with horror by the American public. For patients who are single or in a same-sex relationship, the state should not be in the position of barring access to parenthood. There is simply no rational basis for doing so.<sup>50</sup> Virtually all states, for example, permit gay and lesbian parents to serve as foster parents and to adopt; allowing access to reproductive technology is entirely comparable.

Commentators might respond that ART is more like adoption than natural childbirth, and that while restrictions on family size have no place in the nation's bedrooms, they do have a place in the nation's medical labs and fertility clinics.<sup>51</sup> Margaret Somerville, for example, argues that adoption is the better comparison for ART because "in both cases the resulting families are deliberately constructed with state assistance, rather than simply occurring naturally."<sup>52</sup> Similarly, Professor Garrison argues that the laws on adoption are an "obvious source of policy guidance" for ART regulation.<sup>53</sup>

These assumptions are questionable. First, most families wrestling in silence with the challenge of infertility, paying for treatment out-of-pocket and unaided by insurance coverage, would surely question the view that their family's construction is a state struggle rather than a purely private one. To the extent that the state provides "assistance," it provides similar help to any family involved with health care. Families that conceive "naturally" benefit from "state assistance" to research and medical facilities. "Natural parents" give birth in state-run hospitals and enjoy the fruits of government research on matters of prenatal and early childhood care no less than successful ART patients.

More fundamentally, we think families created via ART are not, contrary to Professor Garrison's argument, truly analogous to families formed

<sup>49</sup> Restrictions based on financial resources or preexisting family size have recently received the most attention, but we have also seen calls for restrictions based on age, marital status, and sexual orientation. See, e.g., Somerville, *supra* note 21.

<sup>50</sup> Cf. *In re Marriage Cases*, 183 P.3d 384 (Cal. 2008) (invalidating a law prohibiting same-sex marriage on state constitutional grounds) (link); *Kerrigan v. Comm'r of Pub. Health*, 957 A.2d 407 (Conn. 2008) (same) (link); *Goodridge v. Dept. of Pub. Health*, 798 N.E.2d 941 (Mass. 2003) (holding that a law banning same-sex marriage lacked a rational basis) (link). *But cf.* *Hernandez v. Robles*, 855 N.E.2d 1 (N.Y. 2006) (upholding a law banning same-sex marriage as having a rational basis) (link).

<sup>51</sup> See Somerville, *supra* note 21.

<sup>52</sup> *Id.*

<sup>53</sup> Garrison, *supra* note 25, at 1629; see also Richard F. Storrow, *The Bioethics of Prospective Parenthood: In Pursuit of the Proper Standard for Gatekeeping in Infertility Clinics*, 28 CARDOZO L. REV. 2283, 2294–95, 2314 (2007) (suggesting that regulation of reproductive technology might fall between adoption and non-assisted reproduction, and that clinics might use a preliminary screen for fitness, not a more complete best-interest test) (link). We are more wary than Professor Storrow about "fitness" determinations given the dangers (that he recognizes) of the relationship between fitness and eugenics.

by adoption. Instead, the better comparison is to families created without physician intervention. Unlike ART, adoption is fundamentally concerned with actual children, not medical decisions.<sup>54</sup> First, adoption inherently requires legal determinations that are solely within the power of the state—to grant an adoption, the state must terminate, and then reassign, parental rights. Second, adoptions increasingly involve the wishes of biological mothers. Consider the significant involvement teenaged Juno had with the would-be adoptive parents of her baby in the 2007 eponymous movie, for example.<sup>55</sup> Even when donors are involved in reproductive technology, that level of interaction between the parties is literally unheard-of. Third, adoption regulations necessarily focus on the best interests of a *living* child,<sup>56</sup> and it is appropriate to consider the best alternatives for that particular child. In the ART context, we are obviously talking about potential children. Restricting a patient's access, by definition, means that the future children in question will never be born.

The possibility of regulation potentially raises complex morality-based issues concerning the scope of government control over families. We believe the government should focus on regulating *medical* procedures, not *family formation*.

#### CONCLUSION

Ultimately, we need to adopt regulations that support the fertility industry while also protecting the interests of patients, children, and the public. Artificial reproductive technology has provided enormous comfort to people who want children. That does not mean, however, that we should not prevent doctors and their patients from creating instant families of eight-plus. The risks to patients and their future children are simply too great to allow us to continue to rely upon purely voluntary guidelines that have been demonstrably unsuccessful. At the same time, neither the state nor individual fertility clinics should be in the business of deciding which individuals are sufficiently “fit” to receive fertility treatments. Narrowly tailored regulation must be designed both to prevent abusive uses of ART procedures that endanger women and future children, and to ensure that patients themselves make the central decision of whether to become parents. Indeed, regulations are essential for the future of a vibrant and successful fertility industry *and* vibrant and healthy families.

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<sup>54</sup> See Sarah B. Lawsky & Naomi Cahn, *Embryo Exchanges and Adoption Tax Credits* (George Washington Law Sch. Pub. Law & Legal Theory Working Paper No. 468, 2009), available at <http://ssrn.com/abstract=1394046> (link).

<sup>55</sup> JUNO (Fox Searchlight 2007).

<sup>56</sup> We also object to regulations attempting to preclude single, gay, or lesbian individuals and couples from adopting. For a map of existing laws, see National Gay & Lesbian Taskforce, *Adoption Laws in the U.S.* (2008), available at [http://www.thetaskforce.org/reports\\_and\\_research/adoption\\_laws](http://www.thetaskforce.org/reports_and_research/adoption_laws) (link).