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## Eight is Enough

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## Eight is Enough

Naomi R. Cahn & Jennifer M. Collins \*

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, however, quickly turned ugly when the media revealed that the mother was thirty-three year-old Nadya Suleman, who is single, unemployed, and already caring for six other children under the age of eight. As Ellen Goodman of the Boston Globe described it, the "mood of the country has gone 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 many other families with high-order multiples have received. The cable show "Jon & Kate Plus 8," for example, 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, celebrate their birthdays each year with reporter Ann Curry, who has followed the children since their births and does an annual feature on the family for the Dateline news show. Indeed, the public fascination with these families dates back at least to the famous Dionne quintuplets of the 1930s, who were treated as a tourist attraction by the Canadian government and visited by more than three million people over a ten year span.<sup>4</sup>

Now consider the reactions to Nadya Suleman's story. The director of the Center for Human Reproduction termed the births a "medical

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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. See CNN, Octuplets' births surprise California doctors, Jan. 27, 2009, available at <http://www.cnn.com/2009/HEALTH/01/26/california.octuplets/>

<sup>2</sup> Ellen Goodman, *We can agree: Octuplets case is just nuts*, BOSTON GLOBE, Feb. 6, 2009.

<sup>3</sup> See Susan Stewart, *Big Brood Spawns Big Ratings*, NY TIMES, Feb. 15, 2009.

<sup>4</sup> See CNN, *The Dionne Quintuplets: A Depression Era Freak Show*, Nov. 19, 1997 (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).

catastrophe.”<sup>5</sup> A columnist for the Los Angeles Times called her story “grotesque” and “bizarre,” and criticized her “manifest irresponsibility.”<sup>6</sup> A San Francisco writer deemed her “misguided and clearly troubled.”<sup>7</sup> Even her own parents have vehemently criticized Suleman, with her father calling her “absolutely irresponsible” and questioning her mental stability<sup>8</sup> and her mother describing Nadya’s actions as “unconscionable.”<sup>9</sup>

So what accounts for these different reactions? The cultural backlash against Suleman has focused on three separate but related issues. The first set of concerns revolves around Suleman herself, and specifically her ability to parent fourteen young children successfully. Disclosures about her 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 three of her older children receive SSI payments and thus appear to have some kind of special needs, and she lives with her parents in a three bedroom house that may be going into foreclosure.<sup>10</sup> Her defenders see these criticisms against Suleman as mother-blaming. A second set of concerns revolves around the medical procedures at the fertility clinic that treated her. How could a fertility clinic agree to implant a woman under the age of thirty-five with at least six embryos during an in vitro fertilization (IVF) procedure? The leading fertility industry group asserts that this was contrary to its recommended guidelines. A final set of issues concerns more fundamental questions about screening parents. How could a clinic agree to provide a single woman who already has six children with treatment that could double the number of children she has? 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

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<sup>5</sup> See Judith Graham, *Wishes vs. Risky Treatment*, CHI. TRIBUNE, Feb. 5, 2009 (reporting comments of Dr. Norbert Gleicher).

<sup>6</sup> Tim Rutten, *The Excesses of Nadya Suleman*, L.A. TIMES, Feb. 11, 2009.

<sup>7</sup> Debra Saunders, *Dysfunctional Familymaking*, SFGATE.COM, Feb. 8, 2009.

<sup>8</sup> See The Huffington Post, *Octuplet Grandfather to Oprah: I Question her Mental Situation*, posted Feb. 20, 2009, available at [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)

<sup>9</sup> See MSNBC, *Octuplets’ Grandmother Criticizes Daughter*, Feb. 9, 2009, available at <http://www.msnbc.msn.com/id/29098465/>.

<sup>10</sup> See, e.g., Rutten, *supra* note 6. Judgments about her race, explicitly acknowledged or not, may also be a factor.

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; in Missouri, legislation was introduced to impose limits on the number of embryos that could be implanted.<sup>11</sup>

The debate about whether and how to regulate the fertility industry is certainly not new.<sup>12</sup> But Suleman's story has thrown two kinds of proposals into particularly sharp relief. The first set of proposals revolves around increased regulation of the medical procedures themselves. For example, some commentators have urged that the United States adopt mandatory limits on the number of embryos that can be transferred, as some other countries have done. 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.<sup>13</sup> These issues are difficult and important, and the Suleman case has begun a conversation about more meaningful regulation of the medical procedures used by the fertility industry. Indeed, as we develop further below, we support such initiatives, including more stringent record-keeping of information related to donors and more meaningful limits on the number of embryos that may be transferred in any single IVF procedure.<sup>14</sup>

But we are far more troubled by a second set of proposals arising out of the Suleman backlash: some commentators have urged the imposition of restrictions on which individuals may receive fertility treatment. Margaret Somerville, for example, who founded the McGill Centre for Medicine, Ethics and Law, argued that we should regulate access to reproductive technology in the same way that we regulate access to

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<sup>11</sup> See Ga. S.B. 169 (the "Ethical Treatment of Human Embryos Act"), available at [http://www.legis.ga.gov/legis/2009\\_10/pdf/sb169.pdf](http://www.legis.ga.gov/legis/2009_10/pdf/sb169.pdf); Mo. H.B. 810, available at <http://www.house.mo.gov/content.aspx?info=/bills/091/bills/hb810.htm> (requiring compliance with ASRM recommendations on implantation). Placing limits on 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, *Crocketuplets Hijacking the Octuplets Backlash to Restrict IVF*, Slate.com (March 5, 2009), available at <http://www.slate.com/id/2212876/pagenum/all/>.

<sup>12</sup> See, e.g., NAOMI R. CAHN, *TEST TUBE FAMILIES* (2009); DEBORA SPAR, *THE BABY BUSINESS* (2006); Judith F. Daar, *Regulating Reproductive Technologies: Panacea or Paper Tiger?*, 34 Hous. L. Rev. 609 (1997).

<sup>13</sup> See Cahn, *supra* note 12, at 61.

<sup>14</sup> We save for another piece, however, detailed answers to many questions in this area, including issues relating to how to regulate donors and what to do about insurance.

adoption, and that if a “single woman with six children, living with her parents, and still studying” would not be permitted to adopt a child, then she should not be permitted to receive fertility treatments like IVF either.<sup>15</sup> Under this theory, women with a certain number of children, or with limited financial resources, should be precluded from receiving any further fertility treatment. Somerville also suggests that a patient’s age, and perhaps her marital status, should be relevant. Some providers have already tried to impose limitations on the basis of sexual orientation, such as a California clinic that refused to perform an intrauterine insemination procedure on a patient involved in a lesbian relationship.<sup>16</sup> Indeed, many clinics already say they would reject patients based on their marital status or sexual orientation,<sup>17</sup> and some states have laws that apply only to the use of reproductive technology by married couples. Other countries have similarly imposed such restrictions.<sup>18</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

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<sup>15</sup> See Margaret Somerville, *Examining Society’s Role: Adoption gives us a model for the appropriate use of new reproductive technology*, OTTAWA CITIZEN, Feb. 11, 2009.

Somerville is also very concerned about the case of a 60 year-old Canadian woman who just gave birth to twin boys after traveling to India to receive IVF treatment, using donor eggs and her husband’s sperm.

<sup>16</sup> See, e.g., *North Coast Women’s Care Medical Group, Inc. v. Superior Court*, 44 Cal.4th 1145, 189 P.3d 959, 81 Cal.Rptr.3d 708 (2008); Joanna Grossman, *The California Supreme Court Rules That Fertility Doctors Must Make Their Services Available to Lesbians, Despite Religious Objections*, Findlaw, Sept. 2, 2008 (discussing case).

<sup>17</sup> See Andrea D. Gurmankin, Arthur L. Caplan & Andrea M. Braveman, *Screening Practices and Beliefs of Assisted Reproductive Technology Programs*, 83 FERTILITY & STERILITY 61 (2005); Judith Daar, *Accessing Reproductive Technologies: Invisible Barriers, Indelible Harms*, 23 BERK. J. GENDER & JUST. 18, 54 (2008).

<sup>18</sup> See Radhika Rao, *Equal Liberty: Assisted Reproductive Technology and Reproductive Equality*, 76 GEO. WASH. L. REV. 1457, 1458, 1459 (2008) (describing German and Italian regulatory schemes); Crystal Liu, *Note: Restricting Access to Infertility Services: What is a Justified Limitation on Reproductive Freedom? The Categorical Exclusion of Single Women and Same-Sex Couples from Infertility Services and its Role in Defining What Constitutes Justified and Unjustified Limitations on Reproductive Freedom*, 10 MINN. J.L. SCI. & TECH. 291, 305-310 (2009) (describing how in Victoria, Australia, from 1984 to 1997, only married couples could access infertility services).

that requiring some medical assistance in order to conceive means that infertile individuals should have to tolerate such restrictions.

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Perhaps the most difficult question raised by the Suleman case and other high order births is whether government regulation can be justified *at all* in the context of ART. There is a powerful case to be made that the law should abstain from this area entirely. ART involves extraordinarily personal social and medical choices and raises critical issues related to patient autonomy and freedom in matters of reproductive choice. Moreover, the cultural stigma traditionally associated with infertility may argue for less public attention to these issues.

Let's begin with the question of patient autonomy, the idea that individuals ordinarily have the right to determine for themselves the appropriate course of any medical treatment that they receive. For example, doctors may not treat a patient without her consent, and patients have a right to be informed of the risks and benefits of any procedure before they undergo it.<sup>19</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 have deemed to be unsafe,<sup>20</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 agenda. Indeed, federal and state governments have often cited the need to regulate risk to justify a host of limitations on individual autonomy; some better-known examples include mandatory vaccinations, speeding limits, and seatbelt and helmet laws. Autonomy has thus always been modified by risk, and we believe it is that principle which 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>21</sup> Children who are part of a multiple birth are far more likely to be born premature and at a low birth

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<sup>19</sup> See Marsha Garrison, *Regulating Reproduction*, 76 GEO. WASH. L. REV. 1623, 1631-32 (2008) (describing the implications of the principle of patient autonomy).

<sup>20</sup> See *id.* at 1632 (describing how the FDA has “the authority to deny access to drugs and medical devices found to be unsafe or ineffective”).

<sup>21</sup> See *id.* at 1644 (stating that “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.

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, social-economic, health and growth problems.”<sup>22</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 – her choices also create risk for third parties, the children who might be born as a result of the pregnancy attempt.<sup>23</sup> It is this potential risk to third parties, against which any potential children are obviously helpless to defend themselves, which seems to us to outweigh concerns for patient autonomy and justify at least some minimal government intervention.

But patient autonomy is not the only competing value. The principle of freedom in matters of reproductive choice is also of paramount concern, 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.<sup>24</sup> Regulating the number of embryos that may be transferred of course does not compel a woman to reproduce against her will, so that concern is not implicated, but it may indeed reduce the likelihood that a woman will *successfully* be able to reproduce. This is an important and powerful counter-argument to regulation; if transferring more embryos increases the chance of a successful pregnancy, perhaps government regulation should not stand in the way. But just as autonomy has always been modulated by risk, this particular aspect

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<sup>22</sup> *See id.* at 1644.

<sup>23</sup> There are public costs as well, ranging 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. 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>24</sup> *See generally* John 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”).

of reproductive freedom has always been modulated by concerns for the rights and freedom of others. We do not allow individuals to become parents at any cost; for example, you may quite obviously not appropriate another person's child in order to parent or force another woman to serve as a surrogate. Society has therefore always been willing to draw some line that it will not cross in furthering any particular individual's quest to become a parent.

The key questions here involve protecting an individual's interest in becoming a parent<sup>25</sup> by ensuring informed consent while simultaneously protecting society's interests in healthy children and appropriate market regulation that, for example assures against power and informational imbalances. Potential lines that might be drawn involve the number of embryos to be transferred, the amount of record-keeping on all aspects of ART, how to ensure informed consent, and measures for keeping the market safe. We explain why regulation in these areas is appropriate, notwithstanding the long history of comparatively little oversight of the fertility industry.

Regulation over reproductive technology by the state and federal government is limited; the fertility industry self-regulates through non-binding guidelines and suggestions on ethical practices, and physicians are subject to various licensing requirements.<sup>26</sup> There are numerous possible reasons for the comparative lack of market oversight, including the tendency for scientific advances to outpace the law, the limited use of the technology until the 1980s, and the secrecy and stigma surrounding infertility, making it not a topic for public discussion. Moreover, reproductive technology taps into deeply conflicting cultural perspectives on parenthood and other social issues,<sup>27</sup> such as stem cell research, abortion, and sex itself.

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<sup>25</sup> For discussion of the right not to procreate, see I. Glenn Cohen, *The Constitution and the Rights Not to Procreate*, 60 STAN. L. REV. 1135, 1148-65 (2008); I. Glenn Cohen, *The Right Not to be a Genetic Parent*, 81 S. CAL. L. REV. 115 (2008).

<sup>26</sup> For further discussion, see Cahn, TEST TUBE FAMILIES, *supra* note 12; Naomi Cahn, *Accidental Incest*, 32 HARV. J. GENDER & L. 59 (2009). A 1988 Congressional report was prescient in setting out the issues. U.S. Congress, Office of Technology Assessment, *Infertility: Medical and Social Choices* (1988), available at: [http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content\\_storage\\_01/0000019b/80/1e/33/53.pdf](http://www.eric.ed.gov/ERICDocs/data/ericdocs2sql/content_storage_01/0000019b/80/1e/33/53.pdf).

<sup>27</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 lack of oversight); on cultural conflict, see NAOMI CAHN AND JUNE CARBONE, RED FAMILIES V. BLUE FAMILIES (forthcoming 2010).



Over the past several decades, the federal government has taken a few steps towards the regulation of reproductive technology; today, it oversees clinical laboratory services, drugs and medical devices that are used in IVF treatments, has established standards for the safety and use of human tissue such as donor sperm and eggs, and provides monitoring of fertility clinic success rates.<sup>28</sup> Other than through these procedures for safety, federal law does not regulate the medical procedures involved in donation. The government also provides some protection from fraudulent practices, but only in advertising, such as monitoring clinics' reporting of their success rates.<sup>29</sup> Some states also undertake regulation to varying degrees.

The reproductive technology industry also engages in self-regulation through organizations such as the American Society for Reproductive Medicine.<sup>30</sup> The industry has developed a series of ethical guidelines that are not binding, but that contain advice and standards on a variety of topics that go beyond basic ART medical practice, including screening issues.<sup>31</sup> Although most reproductive endocrinologists follow these standards, they are not, as the Suleman case so nicely shows, binding. The occasional "mix-ups" that make their way into newspapers or court remind consumers and the public of the lack of oversight.<sup>32</sup>

In contrast, many European countries take a far more restrictive approach. Their laws are primarily designed to protect the *embryos* created as a result of ART – as is the proposed Georgia law. By contrast, our proposed regulations are justified instead by concern for the infertile patient

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<sup>28</sup> See The Fertility Clinic Success Rate and Certification Act of 1992 (Pub. L. 102-493, 42 U.S.C. 263a-1 et seq.); 21 C.F.R. 1271.1 (2009).

<sup>29</sup> See *id.* The law also required that the government establish a voluntary model program for states to use in certifying embryo laboratories.

<sup>30</sup> See Spar, *supra* note 12, at 34 ("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>31</sup> ASRM, Considerations of Assisted Reproductive Technologies: ASRM Ethics Committee Reports and Statements, available at <http://www.asrm.org/Media/Ethics/ethicsmain.html>. On screening, see Ethics Comm. of ASRM, *Child-rearing Ability and the Provision of Fertility Services*, 82 FERT. & STER. 564 (2004).

<sup>32</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 (2006) (focusing on ART-related mix-ups).

herself and her future children as well as protection for the ethical fertility doctor who does not want to transfer six embryos.<sup>33</sup>

If some governmental regulation might be justifiable, numerous questions arise. What should be the content of any particular regulation? Why should we go beyond voluntary guidelines promulgated by medical organizations and adopt mandatory government regulations? What role should these medical organizations play in drafting and implementing these regulations? Should legislation be enacted on the state or federal level, and by what mechanism should it be enforced? A comprehensive answer to each of these questions is beyond the scope of this short essay and we only offer some preliminary thoughts.

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: the question of possible restrictions on access to ART procedures.<sup>34</sup>

Our discussion here focuses on the embryo issue, one of the most criticized aspects of the Suleman case. We support limits on the number of embryos that could be transferred in any single ART procedure. The risks posed to both patients and future children are simply too great, and the countervailing pressure for both doctors and patients to achieve a pregnancy too strong, to go unaddressed. The ASRM guidelines, developed by fertility practitioners, articulate the parameters of workable guidelines. We also think that some flexibility needs to be built into any proposed regulation. For example, imagine that the proposed regulation for younger patients mirrors the voluntary guideline that is in place now, which states that no more than two embryos should be transferred into a patient under the age of 35. If a particular 34 year-old woman can establish that due to a repeated history of unsuccessful attempts or poor embryo quality that she should be allowed to transfer three embryos on her last ART attempt, then she should be able to make that case.

This hypothetical patient raises important questions in terms of procedure. The need to reconcile generally binding guidelines with the

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<sup>33</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*, N.Y. TIMES, Feb. 11, 2009.

<sup>34</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 26; Naomi Cahn, *Towards a Mandatory Donor Registry*, \_\_ DEPAUL J. HEALTH CARE L. \_\_ (forthcoming 2009).

potential for flexibility suggests that some sort of administrative agency might ultimately be the best mechanism for regulation. One possibility is an entity modeled on the British Human Fertilisation and Embryology Authority, a governmental organization governed by a board that includes representatives from various stakeholding constituencies.<sup>35</sup> A second is Professor Martha Garrison's suggestion that we look toward a 'quasi-public regulatory system,' like that in place in the organ transplant context . . . .<sup>36</sup> This system could be responsible for reviewing appeals from patients who believe they warrant an exception from the guidelines. In addition, a federal agency would ensure that the guidelines are national rather than state-based, an important consideration because of the ease with which patients could travel to another jurisdiction to circumvent any unwelcome state restrictions. Such an agency could also implement enforcement mechanisms targeted toward the fertility clinics, including measures such as fines and loss of accreditation.

There are powerful objections to mandatory regulation. As we have suggested above, we believe the higher risks for both mothers and children associated with multiple births provide the primary justification for exploring a new regulatory approach. But it does not necessarily follow that 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 uniform standards. After all, we 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 the physician in the Suleman case).

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<sup>35</sup> See FAQs about the HFEA, available at

[http://www.hfea.gov.uk/en/385.html#How\\_are\\_HFEA\\_Members\\_appointed](http://www.hfea.gov.uk/en/385.html#How_are_HFEA_Members_appointed).

<sup>36</sup> See Garrison, *supra* note 19, at 1648-1651 (describing the organ transplant approach). 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. 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 policies, but these policies are not implemented until approved by the HHS Secretary. Once implemented, however, UNOS policies are binding on local organ procurement offices." *Id.* at 1648-49. Garrison acknowledges the UNOS approach is not perfect, but it seems to be a possible alternative.

Ultimately, however, we cannot rely on doctors to self-regulate in this context – how can a doctor, who has a long history of working with a patient through repeated unsuccessful attempts at pregnancy, be expected to resist a desperate plea to implant just one more embryo?<sup>37</sup> Further, as discussed above, interference in the doctor-patient relationship is hardly unprecedented – doctors are not allowed to prescribe medications that have not been approved by the FDA, even to patients might be pleading for them, or enroll patients in medical studies without complying with informed consent guidelines. Moreover, voluntary guidelines have not worked. The most recent statistics available, from 2006, show that almost 4% of ART pregnancies involved triplets or more.<sup>38</sup>

When procedures are deemed sufficiently risky, government regulation has intervened in the doctor-patient relationship, and we believe the risks here are sufficiently great to allow that imposition. That said, we recognize the critical role of compassion. Infertility is one of the most difficult life challenges an individual can encounter,<sup>39</sup> and we believe we must do more to facilitate access to treatment. We therefore need to couple any new regulations with increased insurance coverage for ART. Indeed, one of the reasons that individuals are willing to gamble by transferring a large number of embryos is because each individual 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 attempts, the temptation to gamble on any single attempt 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

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<sup>37</sup> Estimates based on government reports are that less than 20% of fertility clinics comply with the voluntary guidelines on numbers of embryos to be transferred in women under the age of 35. Stephanie Nano, *Few Fertility Clinics Follow Embryo Guidelines*, SF GATE, Feb. 21, 2009, available at <http://www.sfchronicle.us/cgi-bin/article.cgi?f=/c/a/2009/02/21/MN2A161S2S.DTL>. 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>38</sup> See Dept. Health & Human Services, *2006 Assisted Reproductive Technology Success Rates* (2008), available at <http://www.cdc.gov/ART/ART2006/508PDF/2006ART.pdf>. Interestingly, only 1.9% of *births* involved triplets or higher orders of multiples, perhaps due to selective reduction.

<sup>39</sup> E.g., David Orentlicher, draft at 12 (permission requested).

comply with their treatment preferences.<sup>40</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 know that multiple attempts with one or two embryos will be covered by insurance, they will feel less pressed to travel overseas, for example, so they can gamble with multiple embryos on a single attempt.<sup>41</sup>

Another powerful objection to regulation is that once we open the door to *any* kind of government interference in fertility treatments, we will see the door opened to the kinds of restriction on access that are being suggested in the wake of the Suleman case.<sup>42</sup> We do not believe that any new government regulations should include attempts to restrict access to fertility treatment by discriminating among potential patients. Clinics should not screen on the basis of pre-existing family size, the financial resources a couple has available to care for any children born as a result of ART, or the marital status or sexual orientation of the patients.<sup>43</sup> Individuals able to conceive without reproductive technology are not subject to these 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>44</sup> Virtually all states, for example, allow gay and lesbian

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<sup>40</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>41</sup> Carbone and Gottheim use Great Britain as an example of this phenomenon. *Id.* at 534.

<sup>42</sup> See generally Martha Ertman, *What's Wrong With a Parenthood Market?*, 82 N.C. L. REV. 1, 15 (2003) (stating that 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"). She adds, "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.

<sup>43</sup> Restrictions based on financial resources or pre-existing 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 15.

<sup>44</sup> See *In re Marriage Cases*, 183 P.3d 384 (Cal. 2008); *Kerrigan v. Comm'r of Pub. Health*, 957 A.2d 407 (Conn. 2008); *Goodridge v. Dept. of Pub. Health*, 798 N.E.2d 941 (Mass. 2003); cf. *Lewis v. Harris*, 908 A.2d 196 (N.J. 2006); *Hernandez v. Robles*, 855 N.E.2d 1 (N.Y. 2006).

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 like 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>45</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>46</sup> Similarly, Professor Garrison argues that the laws on adoption are an "obvious source of policy guidance" for ART regulation.<sup>47</sup>

These assumptions are questionable. Most families wrestling in silence with the challenge of infertility and paying the bills for treatment out of pocket rather than with the aid of health insurance would surely question the view that the construction of their family is a state struggle rather than a purely private one. Further, even families who conceive entirely "naturally" benefit from the "actions undertaken by health care professionals using research and facilities paid for with taxpayers' money" that Somerville describes as justifying state restrictions on access to ART; they give birth in hospitals and enjoy the benefits of government research on such matters as prenatal care and childbirth medications.

More fundamentally, we think families conceived via ART are not, contrary to Professor Garrison's argument, truly analogous to adoption.<sup>48</sup> Instead, they are much more similar to families conceived without any physician intervention. ART fundamentally involves medical procedures, not the social ones that are at issue with adoption.<sup>49</sup> Further, adoption regulations necessarily focus on the best interests of a *living* child,<sup>50</sup> and

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<sup>45</sup> See Somerville, *supra* note 15.

<sup>46</sup> *Id.*

<sup>47</sup> Garrison, *supra* note 19, at 1629-30; see also Richard F. Storrow, *The Bioethics of Prospective Parenthood: In Pursuit of the Proper Standard for Gatekeeping in Infertility Clinics*, 28 *CARD. L. REV.* 2283, 2294-85, 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, rather than a more complete best-interest test). We are more wary than Professor Storrow about "fitness" determinations, given the dangers (that he recognizes) of the relationship between fitness and eugenics.

<sup>48</sup> Cf. Naomi Cahn, *Perfect Substitutes or the Real Thing?* 52 *DUKE L.J.* 1077 (2003) (critiquing Professor Garrison's approach).

<sup>49</sup> See Bernstein, *supra* note 27.

<sup>50</sup> We also object to adoption regulations that attempt to preclude single, gay, or lesbian individuals and couples from adopting. For a map of existing laws, see National Gay &

adoption inherently requires terminating and then reassigning parental rights, legal steps undertaken only by the state. When evaluating the optimal residential situation for a living child, the government is in essence comparing competing alternatives. For example, in the case of a healthy newborn, there are presumably many families eager and willing to adopt the newborn, and it seems appropriate to consider whether that child would be better off going to a family who already has eight children or to a family who has been unable to have any children at all. In the ART context, we are obviously talking about potential children, and restrictions on access means the future children in question will never be born to this family. Moreover, adoption increasingly involves the wishes of a biological mother, whether it be for some contact with the child through adoption-with-contact arrangements or with respect to placement requests. Consider the involvement of the teen-aged Juno in the 2007 eponymous movie with the lives of the would-be adoptive parents as an example of the types of potential relationships. Even when donors are involved in reproductive technology, that level of participation is literally unheard-of.

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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 doesn't 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, however, we do not believe that either the state or 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 parent. Indeed, they are essential for the future of a vibrant and successful fertility industry *and* vibrant and healthy families.

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Lesbian Taskforce, *Adoption Laws in the U.S.* (2008), available at [http://www.thetaskforce.org/downloads/reports/issue\\_maps/adoption\\_laws\\_11\\_08\\_color.pdf](http://www.thetaskforce.org/downloads/reports/issue_maps/adoption_laws_11_08_color.pdf).