

WHY WE SHOULD IGNORE THE “OCTOMOM”

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I. INTRODUCTION

Few familiar with the story of Nadya Suleman—a single, low-income, California mother of six who recently gave birth to octuplets conceived through in vitro fertilization (IVF)—do not instinctively react with outrage.¹ Fourteen children (or even one) are a daunting number under the best of conditions, and the conditions surrounding the Suleman births are far from ideal. Yet, as the old saying goes, “hard facts make bad law,” and Suleman, dubbed “the Octomom” by the media, exemplifies the truth of this adage.

Suleman’s hard facts have led not only to bad regulatory reform proposals, but also to public fury and social hysteria. Critics have heaped both fascination and scorn on Suleman, and legislators, policymakers, and others have called for a variety of new restrictions on the use of assisted reproductive technologies (ARTs) in response to the Octomom controversy.²

The most recent and thoughtful of these proposals is from Naomi Cahn and Jennifer Collins, who advocate a variety of ART-related reforms, including record-keeping requirements, limits on the number of embryos that can be transferred during any single IVF cycle, informed consent rules, and insurance coverage regulation.³ Not surprisingly, given the high quality and inventiveness of prior work from each of these authors, the Cahn and Collins framework for ART governance has much to recommend it.

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¹ The CDC defines “assisted reproductive technology” as “[a]ll treatments or procedures that involve surgically removing eggs from a woman’s ovaries and combining the eggs with sperm to help a woman become pregnant.” U.S. DEP’T OF HEALTH AND HUMAN SERVS., 2006 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES 525 (2008) [hereinafter ART SUCCESS RATES], *available at* <http://www.cdc.gov/ART/ART2006/508PDF/2006ART.pdf> (link). One of the most common ARTs is in vitro fertilization (IVF), which “involves removing eggs from a woman’s ovaries, and fertilizing them outside her body,” and then transferring the embryos into the uterus. *Id.* at 526. Other common ARTs include gamete intrafallopian transfer (GIFT) and zygote intrafallopian transfer (ZIFT). *Id.* at 525.

² Naomi R. Cahn & Jennifer M. Collins, *Eight Is Enough*, 103 NW. U. L. REV. COLLOQUY 501 (2009), <http://www.law.northwestern.edu/lawreview/colloquy/2009/22/LRColl2009n22Cahn&Collins.pdf> (discussing the Suleman case and the responses by state legislators, the media, academics, and others) (link).

³ *See id.*

I take issue, however, with the Cahn and Collins embryo-transfer limit proposal and argue in this response that such a limit would produce fewer benefits and higher costs than Cahn and Collins assume. Moreover, if the fertility industry is to be subjected to greater oversight, such oversight should stem from a balancing of what is to be gained and lost in the process, rather than through a hasty response to a sad and disturbing—but aberrant—case.

Although the total costs and benefits of any reform proposal are ultimately a function of the resulting regulatory operations and are thus difficult to predict in advance, the likely limits of the Cahn and Collins proposal are demonstrated by the regulatory examples they invoke—the British Human Fertilisation and Embryology Authority (HFEA) and the United Network for Organ Sharing (UNOS). The fact that Cahn and Collins do not provide the most persuasive examples in support of their suggested reforms does not itself render their proposal flawed. Yet, an examination of these examples demonstrates the meager public health benefits likely to attend government-mandated embryo-transfer limits and the high costs of such regulation.

II. THE LIMITED PUBLIC HEALTH BENEFITS OF EMBRYO-TRANSFER LIMITS

Unlike some of the Suleman-inspired reform proposals, which are designed primarily to protect embryos or to restrict ART access to patients meeting certain age, marital status, or income qualifications, Cahn and Collins defend their proposal on the basis of the health risks and public costs associated with multiple births from ARTs.⁴ Currently, decisions regarding the number of embryos to transfer and, ultimately, fetuses to carry to term, are left to patients and their doctors. Although the American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART) have issued practice guidelines in an effort to reduce the incidence of multiple births from ARTs, the guidelines are not mandatory and are customizable according to the conditions of the individual patient.⁵ Given the mixed evidence on the efficacy of industry self-regulation in other contexts, some critics are understandably skeptical that such guide-

⁴ For example, a recent Georgia bill supported by pro-life groups was ostensibly designed to reduce the risk of multiple births from ARTs by capping transfers at two or three embryos per cycle, depending on the patient's age. But, by limiting the number of embryos that could be created in a single cycle to the number to be transferred in that cycle (the law also prohibited cryopreservation or destruction of embryos), the legislation actually encouraged, rather than discouraged, multiple embryo transfers up to the two- or three-embryo maximum. See S.B. 169, 2009–2010 Sess. § 19-7-66 (Ga. 2009) (as introduced). See also *infra* notes 35–36 and accompanying text (discussing the Georgia bill); Cahn & Collins, *supra* note 2, at 504 (discussing other proposed reforms that would limit ART access to those who are married, meet income limits, or otherwise pass some test of parental fitness).

⁵ Am. Soc'y for Reprod. Med., *Guidelines on the Number of Embryos Transferred*, 90 FERTILITY & STERILITY S163, S163 (2008) (recommending a sliding scale of one to five embryos transferred, depending on the age of the patient, prior success with fertility treatment, and other factors) (link).

lines will sufficiently address multiple births from ARTs.⁶ These fears are further fueled by the Suleman case, evidence of lax compliance with other ASRM/SART guidelines,⁷ and rising national multiple-birth rates.

The national incidence of twins and higher-order (triplet or more) multiple births has increased substantially in recent decades.⁸ These increases are a cause for concern to health care professionals and policymakers because the health risks to mother and children increase with each additional fetus, often resulting in expensive neonatal and ongoing medical care. For example, twins are seven (and triplets twenty) times more likely than singletons to die during the first month of life.⁹ Moreover, multiples are more likely to be born prematurely and at low birth weight, leading to a variety of complications of the circulatory system, lungs, intestines, eyes, and brain, and higher rates of cerebral palsy and other disabilities.¹⁰

In considering the role of ARTs in multiple births, and the potential role of government regulation in controlling this problem, it is helpful to consider two separate sets of figures: (1) the percentage of total U.S. multiple births attributable to ARTs, as opposed to other causal factors; and (2) the incidence of multiples as a percentage of live births from ARTs.¹¹ The first measure provides some indication of the state's ability to control multiple births through embryo-transfer regulation. As will be seen, although ARTs are a contributor to multiple births in the United States (especially higher-order multiples), much of the increase in multiple births is attributed

⁶ Cf. Michael Lenox, *Do Voluntary Standards Work Among Corporations? The Experience of the Chemicals Industry*, in MAKING GLOBAL REGULATION EFFECTIVE IN DEVELOPING COUNTRIES: WHAT ROLE FOR SELF-REGULATION? 62 (Dana L. Brown & Ngaire Woods eds., 2007) (demonstrating the incentives and impediments to effective industry self-regulation and reviewing some of the empirical literature in the field).

⁷ Aaron D. Levine, *Self-Regulation, Compensation, and the Ethical Recruitment of Oocyte Donors I*, (unpublished manuscript, on file with the Northwestern University Law Review) (analyzing a dataset of oocyte donor recruitment advertisements in college newspapers and concluding that almost half offer compensation in amounts deemed "inappropriate" or "requiring justification" under ASRM guidelines); Jim Hawkins, *Financing Fertility*, 47 HARV. J. ON LEGIS. (forthcoming 2010) (analyzing the websites of all SART-member clinics and finding substantial noncompliance with member guidelines on refund programs).

⁸ AM. SOC'Y FOR REPROD. MED., *MULTIPLE PREGNANCY AND BIRTH: TWINS, TRIPLETS, & HIGHER ORDER MULTIPLES—A GUIDE FOR PATIENTS* 3 (2004), available at <http://www.asrm.org/Patients/patientbooklets/multiples.pdf> (reporting that "the twin birth rate has increased by more than 50% since 1980," and the rate of higher-order multiple births has increased even more) (link); CTRS. FOR DISEASE CONTROL AND PREVENTION & NAT'L CTR. FOR HEALTH STATISTICS, *VITAL AND HEALTH STATISTICS, TRIPLET BIRTHS: TRENDS AND OUTCOMES, 1971-94*, at 1 (1997) [hereinafter *TRIPLET BIRTHS*], available at http://www.cdc.gov/nchs/data/series/sr_21/sr21_055.pdf (reporting similar numbers) (link).

⁹ AM. SOC'Y FOR REPROD. MED., *supra* note 8, at 6.

¹⁰ *Id.* at 7-8.

¹¹ I rely on various live birth rate measures throughout this section for a variety of reasons, including ease of comparability to other relevant measures. However, live birth measures will, to some extent, understate the costs of multiple pregnancies, as not all multiple pregnancies end in live birth.

to natural factors and non-ART fertility therapies. The state's ability to control the health risks associated with multiple births through embryo-transfer regulation is, therefore, necessarily limited.

The second measure, together with other data, goes to the probability that governmental oversight of embryo transfer will improve current medical practice. As will be shown, the currently low (and decreasing) incidence of higher-order multiple births as a percentage of live ART births leaves little room for improving such rates through government oversight. There is more room for improvement in twin numbers (though ART twin births account for only 16% of the nationwide total). It is unlikely, however, that the United States has the political will for the single-embryo transfer (SET) limits that have successfully reduced the rate of twin births from ARTs in some countries—and with good reason.

A. National Multiple-Birth Rates

Multiple-birth rates in the United States have increased in recent decades.¹² Although the Centers for Disease Control and Prevention (CDC) estimate that some of the increase in multiples is due to the fact that women today tend to have children at a later age, and older women (even without the intervention of fertility treatment) are prone to multiples, the bulk of the increase is attributed to the growing use of fertility treatments.¹³ The CDC ascribes a large portion of that increase—particularly in the case of higher-order multiples—to the use of ovulation-induction (OI) therapies, either alone or in combination with intrauterine insemination (IUI), rather than to ARTs.¹⁴ Embryo-transfer limits thus would have no effect on these major contributing factors to rising multiple-birth rates.

Nonetheless, ARTs are a contributor to multiple births in the United States, constituting an estimated 16% of all twin births in 2003, as compared to 63% from natural conception and 21% that are categorized as “unexplained,” but are attributed to OI therapies not involving ARTs.¹⁵ ARTs are thought to account for a higher percentage of higher-order multiple births, however, representing 45% of triplet and 30% of quadruplet-or-more

¹² TRIPLET BIRTHS, *supra* note 8, at 1.

¹³ *Id.*

¹⁴ *Id.* at 9 (estimating that one-third of higher-order multiples are the result of fertility-enhancing drugs without ARTs). Cf. Ctrs. for Disease Control and Prevention, *Contribution of Assisted Reproductive Technology and Ovulation-Inducing Drugs to Triplet and Higher-Order Multiple Births—United States, 1980–1997*, 49(24) MMWR WEEKLY 535 (June 23, 2000), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4924a4.htm> (reporting that the lack of reliable information on the use of ovulation-inducing drugs not associated with ARTs complicates the ability to estimate their impact on multiple birth rates) (link).

¹⁵ Richard P. Dickey, *The Relative Contribution of Assisted Reproductive Technologies and Ovulation Induction to Multiple Births in the United States 5 Years After the Society for Assisted Reproductive Technology/American Society for Reproductive Medicine Recommendation to Limit the Number of Embryos Transferred*, 88 FERTILITY & STERILITY 1554, 1557–58 (2007). This compares to the 1997 rates of 11%, 73%, and 16%, respectively. *Id.*

births in 2003 (a decrease from the 1997 figures of 49% and 54%, respectively).¹⁶ In contrast, 18% of triplets in 2003 (20% in 1997) were naturally conceived, whereas 37% (31% in 1997) were conceived through OI.¹⁷ For quadruplet-or-more births, the corresponding figures are 8% for natural conception (7% in 1997) and 62% for OI (39% in 1997).¹⁸

These data reveal the first limitation on embryo-transfer regulation as a means to control multiple births: by definition, embryo-transfer limits will impact only a portion of multiple births, and, in particular, have no ability to influence multiple births owing to OI therapies that do not involve embryo transfer, which currently constitute a staggering 62% of quadruplet-or-more multiples and 37% of total triplet births. This alone is not a reasonable objection to embryo-transfer limits that otherwise promise substantial public-health benefits, but it is a useful reminder that such limits will not fully address rising rates of multiple births in the United States.

B. Multiple Births as a Percentage of Live ART Births

The second relevant measure bearing on the likely effectiveness of embryo-transfer regulation is the rate of multiples as a percentage of live ART births. Twin births as a percentage of live births from all ART cycles decreased slightly and unevenly from 1996 through 2006, from 31% to 29%.¹⁹ Higher-order multiple births as a percentage of live births from all ART cycles also decreased during the same time period, from 7% in 1996 to 2% in 2006.²⁰

These figures reveal a second limitation on the benefits of embryo-transfer restrictions. The currently low incidence of higher-order multiple births as a percentage of live ART births—currently 2%, nearly all of it triplets²¹—which has been steadily decreasing since 1996, leaves little room for improvement via government intervention. Naturally, all higher-order multiple births are a cause for concern, and I do not mean to suggest otherwise. But the rate cannot be brought below zero, and there is reason to believe that ongoing industry efforts at doctor and patient education, rising insurance coverage of fertility treatments, scientific advances in embryo culture and preservation techniques, and increased scrutiny due to the

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ ART SUCCESS RATES, *supra* note 1, at 76 (reporting twin-birth rates that fluctuate between 31% and 32%, then steadily decrease starting in 2002). This is significantly higher than the spontaneous twin rate of about one in 250 pregnancies. AM. SOC'Y FOR REPROD. MED., *supra* note 8, at 5.

²⁰ ART SUCCESS RATES, *supra* note 1, at 76. This compares to the spontaneous pregnancy birth rates of one in 8,000 for triplets and one in 700,000 for quadruplets. AM. SOC'Y FOR REPROD. MED., *supra* note 8, at 5.

²¹ Ctrs. for Disease Control and Prevention, *supra* note 14 (reporting that triplets comprised 89.2% of all higher-order multiple births in 1996 and 91.2% in 1997); Dickey, *supra* note 15, at 1558 (reporting the percentages of twins, triplet, and quadruplet or more births from ARTs, natural causes, and OI).

Suleman controversy may combine to produce further reductions even in the absence of new regulation.²²

Moreover, although some experts dispute the contention that twin births from ARTs are a negative outcome, the current medical consensus both domestically and internationally is that twin pregnancies increase health risks to both mother and children.²³ If so, then the CDC data suggest that the far higher incidence of twins as a percentage of live ART births, rather than the lower incidence of higher-order multiples, is both the most logical source for public concern and the multiple-birth rate most amenable to reduction through increased oversight of embryo-transfer practices. Yet, it is unlikely that the United States has the political will for the SET limits—or, even less likely, the aggressive selective fetal reduction—that have reduced the rate of twin births from ARTs in some countries. Tellingly, neither have most other lawmakers, including those in the United Kingdom.²⁴ As elaborated below, there are good reasons for this reticence, particularly in a system of private provision of fertility and other health care services, such as exists in the United States.²⁵ But the reality, nonetheless, is that the embryo-transfer limits contemplated by U.S. commentators and lawmakers are unlikely to significantly impact ART twin rates.

1. Embryo-Transfer Regulation in the United Kingdom

Unlike the U.S. system of industry self-regulation, the United Kingdom imposes mandatory limits on the number of embryos that can be transferred during a single IVF cycle. Currently, those limits are two embryos per cycle for women younger than forty, and three embryos for women forty and older.²⁶ Effective January 1, 2009, HFEA took steps designed to further reduce multiple births from ARTs, including a “One At A Time” policy that requires fertility centers to document the reasons for transferring more than a single embryo in any case where single-embryo transfer is medically indicated.²⁷ The policy does not impose a mandatory single-embryo limit, however, and does not supplant the existing HFEA two- and three-embryo

²² See Am. Soc’y for Reprod. Med., *supra* note 5; Zdravka Veleva et. al., *Elective Single Embryo Transfer with Cryopreservation Improves the Outcome and Diminishes the Costs of IVF/ICSI*, 24 HUMAN REPROD. 1632, 1636–38 (2009).

²³ Compare, e.g., *IFFS Surveillance 2007*, 87 FERTILITY & STERILITY S19 (Howard W. Jones, Jr. et al. eds., 2007) (discussing risks to mother and children in twin pregnancies) (link), and AM. SOC’Y FOR REPROD. MED., *supra* note 8, at 6–8 (same), with Norbert Gleicher & David Barad, *Twin Pregnancy, Contrary to Consensus, Is a Desirable Outcome in Infertility*, 91 FERTILITY & STERILITY 2426, 2426 (2009) (arguing that the medical consensus that twin births from ARTs are a negative outcome to be avoided is flawed).

²⁴ See *IFFS Surveillance 2007*, *supra* note 23, at S19–S22 (reporting embryo-transfer limits and multiple-birth minimization strategies across nations).

²⁵ See *infra* notes 37–38 and accompanying text.

²⁶ HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY, CODE OF PRACTICE § G.8.5.1. (2008) [hereinafter CODE OF PRACTICE] (link).

²⁷ See *id.* at § G.8.5.4–5.

limits.²⁸ Although these new single-embryo efforts have not been in effect long enough to measure their impact on U.K. multiple-birth rates, an examination of the impact of the HFEA mandatory embryo-transfer rules suggests several further limitations on the potential benefits of government-imposed embryo-transfer limits.

Not surprisingly, regulations limiting the number of embryos transferred to two or three per cycle have a greater impact on higher-order multiples than on twin birth rates. For example, the most recent HFEA report shows that higher-order multiple births constitute .33% of live births from ARTs in the United Kingdom.²⁹ The corresponding twin rate, however, is 22.32%, which, though lower than the corresponding U.S. rate, is still substantial.³⁰ International data reveal a similar trend in other countries: two-embryo transfer limits primarily impact the incidence of higher-order multiples, and have little-to-no effect on the incidence of twins.³¹

Moreover, another variable—health care benefits that cover fertility treatments—may largely drive differences in multiple-birth rates between the United States and much of Western Europe, including the United Kingdom. The United Kingdom, like many countries that restrict embryo transfers,³² provides national health coverage for a limited number of fertility treatment cycles, which reduces both the per-cycle success rate in some patient groups and the economic incentive to transfer more embryos in any cycle.³³ As a result, lower multiple-birth rates in the United Kingdom may be largely a product of health benefit coverage, rather than of government regulation. This is especially true of the twin rate, which is likely unaffected by the two- and three-embryo transfer limits in force in the United Kingdom during the relevant measurement period. Similar reductions in

²⁸ Letter from Professor Lisa Jardine, Chair of the Human Fertilisation & Embryology Authority, to Colleagues CH (08)(03) (Sept. 30, 2008), <http://www.hfea.gov.UK/489.html> (link).

²⁹ HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY, FACTS & FIGURES 2006: FERTILITY PROBLEMS AND TREATMENT 14 (Oct. 2008) [hereinafter FACTS & FIGURES], available at <http://www.hfea.gov.uk/381.html> (link).

³⁰ *Id.*

³¹ *IFFS Surveillance 2007*, *supra* note 23, at S19 (noting that the standard practice of two-embryo transfer in many countries produces "the expected marked reduction in triplet pregnancies without a reduction in twin rates").

³² *See id.* at S14–S16 (documenting national fertility treatment coverage regimes), S20–S21 (documenting embryo-transfer limits across countries).

³³ The current standard in England is three IVF or intra-cytoplasmic sperm injection (ICSI) cycles for women aged 23–39 and meeting the NHS definition of infertility. Human Fertilisation & Embryology Authority, *NHS Fertility Treatment* [hereinafter *NHS Fertility Treatment*], <http://www.hfea.gov.uk/1896.html> (last visited Sept. 9, 2009) (link). Other U.K. countries offer fewer cycles. *Id.* However, implementation, and thus funding, levels vary even across England, meaning that in some regions fewer or (rarely) no cycles are funded and many areas have waiting lists. *Id.* *See also infra* notes 39–44 and accompanying text (discussing shortcomings in the U.K. system).

multiple-birth rates are seen in the United States when ARTs are covered by insurance.³⁴

2. Embryo-Transfer Proposals in the United States

The above analysis suggests that the U.S. fertility industry is already making progress in reducing higher-order multiple births from ARTs and is likely to continue to do so. It further acknowledges that there is more room for improvement in ART twin rates, and that if embryo-transfer regulation such as that proposed by Cahn and Collins is to effectively address ART twin births, then SET is the mechanism most likely to do so.

Is the United States likely to implement SET limits as a matter of state or federal law? Should it? Current ASRM guidelines; opposition from the fertility industry, consumer interest groups, and many health care researchers and policymakers; disagreement on the public-health benefits of mandatory SET policies; and the experiences of Georgia and Missouri—states that proposed embryo-transfer limits in the wake of the Suleman controversy—suggest not.

For example, Georgia Bill 169, originally a far-reaching regulatory scheme that imposed significant restrictions on stem-cell research and fertility treatments—including restrictions on gamete payment and embryo creation, transfer, and destruction—stopped short of SET, capping transfers at two embryos per cycle for women younger than forty and three per cycle for women older than forty.³⁵ None of the provisions restricting fertility treatments withstood vocal and organized opposition from industry and consumer advocacy groups, and the bill now stands as a more limited version that prohibits stem cell research.³⁶ The still-pending Missouri bill seeks simply to mandate existing ASRM recommendations on embryo transfer, which, as previously noted, allow discretion based on each patient's prognosis and history.³⁷ It is thus unclear whether the Missouri bill would add new guidance or enforcement powers to the existing ART governance framework, as state medical boards already have the ability to police doctors and clinics that disregard professional guidelines and the public interest.

³⁴ Bart C. J. M. Fauser et. al., *Multiple Birth Resulting from Ovarian Stimulation for Subfertility Treatment*, 365 THELANCET.COM, Feb. 4, 2005, at 7, <http://image.thelancet.com/extras/04art6002web.pdf> (link).

³⁵ S.B. 169, 2009–2010 Sess. § 19-7-67 (Ga. 2009) (as introduced).

³⁶ See Ethical Treatment of Human Embryos Act, S.B. 169, 150th Gen. Assem., 1st Reg. Sess. (Ga. 2009) (link); Shannon McCaffrey, *Georgia "Octomom" Bill Referred for More Study*, WHITTIERDAILYNEWS.COM, Mar. 5, 2009, http://www.whittierdailynews.com/octuplets/ci_11844350 (discussing opposition to the bill) (link).

³⁷ See H.B. 810, 95th Gen. Assem., 1st Reg. Sess. (Mo. 2009) (link); *supra* note 5 and accompanying text (discussing current ASRM guidelines). Another Missouri bill, introduced around the same time, would require gamete donor registry and the disclosure of identifying information to offspring. H.B. 355, 95th Gen. Assem., 1st Reg. Sess. (Mo. 2009) (link).

Finally, there are legitimate reasons for the resistance to strict embryo-transfer limits, particularly given the realities of the U.S. health care system. Although fertility professionals have made progress in reducing multiple births from ARTs while maintaining pregnancy success rates, their ability to do so depends on a variety of factors, including the patient's age and the underlying cause of infertility, the ability to fund multiple ART cycles, individual clinical expertise and conditions, embryo quality, and cryopreservation techniques. Particularly in the U.S. system of private (or private insurance) payment for ARTs, under which some customers cannot afford multiple IVF cycles, mandatory policies risk reductions in pregnancy success rates that some customers will find unacceptable. It is thus no coincidence that the countries experiencing the greatest success with strict embryo-transfer limits are those with both a well-developed and technically advanced fertility practice and broad public funding of multiple IVF cycles.³⁸

III. THE HIGH COSTS OF EMBRYO-TRANSFER LIMITS

Contrary to the assumption behind many proposals to regulate the fertility (or any other) industry, regulation is not free. Aside from the direct costs associated with enacting, interpreting, and enforcing the regulation, government intervention frequently is accompanied by delays, uncertainty, increased operating and/or production costs, and higher prices. In many cases, these costs are outweighed by regulation's benefits. But embryo-transfer limits are unlikely to produce substantial health benefits in the United States and are likely to impose high costs. These potential costs are illustrated by the two regulatory examples invoked by Cahn and Collins: HFEA and UNOS.

No regulatory system is perfect, and HFEA is no exception. Although U.K. ART multiple-birth rates are lower than those in the United States, they are not dramatically so, and these reductions come at some cost to pregnancy success rates, at least by some measures.³⁹ In addition, although the National Institute for Health and Clinical Excellence (NICE) determined in 2002 that funding should be available for up to three IVF or ICSI cycles for all eligible patients in England, full implementation of this directive has yet to be reached and varies across regions.⁴⁰ Funding decisions are made at the local level by Primary Care Trusts (PCTs), some of which fund none, one, or two cycles, rather than the recommended three.⁴¹

³⁸ See *IFFS Surveillance 2007*, *supra* note 23, at S19–S21.

³⁹ Compare ART SUCCESS RATES, *supra* note 1, at 19 (reporting a live birth rate per cycle started of 28.6% for 2006), with FACTS & FIGURES, *supra* note 29, at 9 (reporting a live birth rate per cycle started of 24.4% for 2006).

⁴⁰ *NHS Fertility Treatment*, *supra* note 33.

⁴¹ *Id.* Wales and Northern Island offer NHS funding for one cycle only and have their own eligibility guidelines. *Id.*

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Moreover, HFEA rules requiring donor registration and limiting egg donor compensation to lost wages and the reimbursement of expenses have caused severe gamete shortages,⁴² and there are waiting times, the length of which vary by region, for many patients using public funding for fertility treatments.⁴³ Rather than dealing with these waitlists, restrictive regulations, and other impediments to treatment, many British citizens pay out-of-pocket for treatment or seek less expensive or cumbersome fertility solutions abroad,⁴⁴ prompting HFEA to recently announce that it planned to revisit some of these policies.⁴⁵

Cahn and Collins look next to UNOS as a regulatory example, arguing that a “quasi-public regulatory system’, like [UNOS] . . . could be responsible for reviewing appeals from patients who believe they warrant exemptions from the guidelines.”⁴⁶ Although it is unclear from their proposal exactly how the fertility-UNOS panel would operate, the analogy to the U.S. organ procurement system as a regulatory model for the fertility industry is even less persuasive than the HFEA comparison.

UNOS performs a laudable—and, in many ways, remarkable—function by procuring organs solely from altruistic donors in the face of great social, legal, and political impediments. But, as is likely to be the case with any organization charged with allocating a scarce and life-saving resource, the UNOS allocation procedures have come under attack.⁴⁷

More fundamentally, the number of Americans on the organ transplant waiting list passed 100,000 last year, and thousands of potential organ recipients die each year while waiting.⁴⁸ With the increasing recognition that our current organ procurement system fails to satisfy demand and results in unnecessary loss of life, medical professionals, politicians, researchers, domestic and international advocacy groups, and others have called for revisions. The suggested changes range from presumed consent rules, tax

⁴² Mark Henderson, *Couples Are “Driven to IVF Tourism by Ethical Disparities Across Europe,”* TIMES ONLINE, July 2, 2007, <http://www.timesonline.co.uk/tol/news/uk/science/article2013609.ece> (link). See CODE OF PRACTICE, *supra* note 26, at § S.7.6.6 (on gamete donor payment), § G.5.11.1 (on donor registry).

⁴³ See *NHS Fertility Treatment*, *supra* note 33.

⁴⁴ Henderson, *supra* note 42.

⁴⁵ *Fertility Donor Pay Debate Call*, BBC NEWS, July 27, 2009, <http://news.bbc.co.uk/2/hi/health/8169890.stm> (link).

⁴⁶ Cahn & Collins, *supra* note 2, at 509 (quoting Marsha Garrison, *Regulating Reproduction*, 76 GEO. WASH. L. REV. 1623, 1648 (2008)).

⁴⁷ See Jim Warren, *IOM Recommends Significant Changes in Current Organ Allocation System to Assure Fairness, Effectiveness*, TRANSPLANT NEWS, July 31, 1999, available at http://findarticles.com/p/articles/mi_m0YUG/is_14_9/ai_n18608850/ (detailing criticisms against UNOS allocation procedures and attempts by the Department of Health and Human Services to exert greater control over the process) (link); DAVID PETECHUK, ORGAN TRANSPLANTATION 39–53 (2006) (discussing organ allocation procedures and related controversy) (link).

⁴⁸ UNOS, *U.S. Transplant Waiting List Passes 100,000*, Oct. 8, 2008, <http://www.unos.org/news/newsDetail.asp?id=1165> (link).

credits, priority for registered donors or their family members on organ waiting lists, and a variety of other financial and nonfinancial incentives.⁴⁹

Despite the introduction of new legislation and the clear dissatisfaction of both the general public and organ transplant professionals, however, the current regulatory scheme remains intact, preventing innovation at either the state or federal level. The organ procurement system thus stands as a stark example of all that can go wrong with even well-meaning government attempts to balance competing private and public interests in the face of moral and political disagreement.

IV. CONCLUSION

As Cahn and Collins and others have noted, it is worth questioning why the Octomom elicited the moral outrage and desire for regulatory intervention that she did.⁵⁰ Suleman was not the first to give birth to multiples, or even to octuplets; nor was she the first parent to have children (including through the use of ARTs) that she could not support. Moreover, Suleman is an unusual case—how many single mothers, with income insufficient to support a large family, and who already have six children, will also have sufficient funds for expensive fertility treatments and insist on transferring six embryos at once? Suleman's story, while regrettable, is not worthy of significant regulatory attention.

Finally, Suleman's doctor—currently under investigation by the medical board of California and ASRM—will in all probability pay a price for his actions.⁵¹ Doctor Kamrava has had few public defenders within the medical community, and the fertility industry cannot be happy with the scandal, scrutiny, and increased regulatory threat prompted by the Suleman incident.

This consequence of the Suleman octuplets suggests the most logical mechanism for regulating multiple births from ARTs in the United States today, given the realities of our underlying health care and political systems: *ex post* liability via state and professional sanctions for doctors and clinics engaged in irresponsible conduct. If state authorities and professional medical bodies have so far been insufficiently attentive in these

⁴⁹ See Editorial, *Wait-Listed to Death*, WALL ST. J. ONLINE, Dec. 17, 2008, <http://online.wsj.com/article/SB122948107890913051.html> (link); Op-Ed., Sally Satel, *Death's Waiting List*, NYTIMES.COM, May 15, 2006, <http://www.nytimes.com/2006/05/15/opinion/15satel.html> (link).

⁵⁰ See Cahn & Collins, *supra* note 2, at 501–02; Bridget J. Crawford & Lolita Buckner Inniss, *Social Factoring the Numbers with Assisted Reproduction*, 19 TEX. J. WOMEN & L. (forthcoming 2009) (arguing that the public response to Suleman is classist, racist, and sexist), available at <http://ssrn.com/abstract=1360453> (link); Judith F. Daar, *Assessing Reproductive Technologies: Invisible Barriers, Indelible Harms* 23 BERKELEY J. GENDER L. & JUST. 18 (2008) (discussing attempts to limit ART access on the basis of wealth, race, ethnicity, or marital status).

⁵¹ *Fertility Doc Faces In-Vitro Investigation*, ASSOCIATED PRESS, Feb. 11, 2009, available at <http://www.nbclosangeles.com/news/local-beat/Fertility-Doc-Faces-In-Vitro-Investigation.html> (link).

tasks, then perhaps the Suleman case and the resulting social and political backlash will spur them into action.

Many health care professionals and policymakers are—like Cahn and Collins—legitimately concerned about the public-health effects of multiple ART births. In a perfect world, there may be a regulatory model that maximizes public welfare by appropriately balancing this interest against parental desires and the differing medical needs of fertility patients.

We do not live in that perfect world. In addition to the usual regulatory problems of institutional competence, bureaucratic red tape, and political capture, questions of embryo transfer and multiple pregnancies in many countries, including the United States, inevitably intersect with other politically contentious issues, including the moral and legal status of embryos and abortion.

In the eyes of many, embryo-protection goals are not only worthy and important freestanding goals, but ones that should supersede the goal of multiple-birth reduction whenever the two conflict. Because the solutions to multiple pregnancies from IVF that are most likely to preserve pregnancy success rates include selective fetal reduction, the creation of many embryos from which only the highest quality are transferred, and cryopreservation of excess embryos for possible future cycles, advocates of embryo-transfer limits must recognize that embryo-protection goals are not only distinct from, but are often incompatible with, multiple-birth reduction goals. This tension is demonstrated by the experience in Georgia,⁵² by that of other countries, such as Germany and Italy,⁵³ and by Suleman herself, who reportedly transferred all of her remaining embryos because she was unwilling to destroy any.⁵⁴ The political minefields of abortion and embryo rights thus render it highly unlikely that the United States will implement comprehensive embryo-transfer regulation effectively designed to reduce multiple births anytime soon.

⁵² See June Carbone, *Who Decides What Number of Children Is Right?*, 104 NW. U. L. REV. COLLOQUY 109, 112–113 (2009), <http://www.law.northwestern.edu/lawreview/colloquy/2009/33/LRColl2009n33Carbone.pdf> (link).

⁵³ *IFFS Surveillance 2007*, *supra* note 23, at S12–S13 (discussing Italy's restrictive ART legislation); Henderson, *supra* note 42 (discussing Germany and Italy).

⁵⁴ Jill Stanek, *Octomom's Gift to the Pro-Life Movement*, WORLDNETDAILY, Feb. 25, 2009, <http://www.wnd.com/index.php?pageId=89945> (discussing Suleman) (link).