

FEDERALIZING EMBRYO TRANSFERS: TAMING THE WILD WEST OF REPRODUCTIVE MEDICINE?

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Abstract

This article addresses the oft-spoken urban myth that the field of assisted reproductive technologies (ART) is a wholly unregulated medical subspecialty, leaving cowboy physicians to abuse vulnerable patients and disregard the well-being of ART-induced offspring. The birth of octoplets in January 2009 fueled this myth and launched a campaign to regulate the field by restricting the number of embryos allowed for transfer in any single IVF cycle. This article critiques the merits of a federal law codifying embryo transfer limits in the provision of infertility care.

Drafting a federal embryo transfer law is easy enough, but assuring enforcement by regulators and compliance by physicians and patients presents near insurmountable barriers. Even if such a law set out sensible clinical guidelines on the number of embryos to transfer, validating that practitioners have complied with statutory standards may require invading patient privacy in a wholly distasteful manner. Moreover, data collected on the effectiveness of civil fines in the regulatory setting suggest rampant undercollection, casting doubt on fine-based penalty's capacity to deter banned conduct. Still other data suggests that criminal penalties fare no better, as both prosecutors and juries are reluctant to penalize a physician who, in good faith, responds to a patient's plea for help.

Compliance with embryo transfer limits are in doubt not just because traditional penalty structures are ineffective, but because patients and physicians are incentivized by the high cost and low reimbursement rates for infertility care to prefer more embryos be transferred to maximize the chances for a live birth. When multiple births, particularly twins, is a preferred outcome based on financial constraints, looking to a stand-alone embryo transfer law to curb the high rate of multiples will have little effect. Instead, this article argues that now is the time to ease the financial burden by including infertility care in the package of essential health benefits being developed under the 2010 Patient

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Protection and Affordable Care Act. Matching the burden of embryo transfer limits with the benefit of coverage will have a real and lasting impact on the public health concerns that legitimately coalesce around multiple births.

INTRODUCTION

An urban myth has dogged the world of assisted reproductive technologies (ART) since its emergence over three decades ago. Reproductive medicine, observers exclaim in both shouts and whispers, is the “wild west of medicine,” conjuring up an image of lawless, greedy physicians preying upon desperate wannabe parents, swathed in abject disregard for their patients’ welfare or that of the children the patients long to birth.¹ At the heart of the myth is an assertion that reproductive medicine is entirely unregulated, and thus subject only to the good or ill will physicians and patients bring to the examination room. Like most urban myths, this modern folklore about the ART cowboy is overwhelmingly false. Nevertheless, its persistent appearance in academic and popular print is worthy of exploration, if only to understand why ART has earned this notorious reputation and contemplate whether and how affected stakeholders should respond. This article will deconstruct and analyze the ART urban myth through a critique of existing and proposed legislation governing the practice of reproductive medicine.

Current defenses of the sufficiency of ART regulation are particularly challenging in light of the well-publicized birth of IVF-conceived octuplets outside Los Angeles in January 2009, an event that reinvigorated enthusiasm for displaying and targeting ART as a medical free-for-all deserving of its pejorative renegade label.² Nadya Suleman, quickly dubbed “Octomom,” and her brood are the embodiment of medical outliers—not only have the octuplets become the longest living octuplets in recorded history, mother and babies appear to have dodged the morbidity and mortality bullet that often accompanies

1 See Karen Wright, *Human in the Age of Mechanical Reproduction*, DISCOVER (May 1, 1998), <http://discovermagazine.com/1998/may/humanintheageofm1443> (describing ART as an unregulated “world where a dead man can impregnate a stranger . . . and where a child can have five parents”). Even more colorful phraseology has been used to describe the regulation of ART. Brooks A. Keel, professor of obstetrics and gynecology and associate dean for research at the University of Kansas School of Medicine in Wichita, proffered, “A woman gets more regulatory oversight when she gets a tattoo than when she gets IVF.” Rick Weiss, *Fertility Innovation or Exploitation? Regulatory Void Allows for Trial—and Error—Without Patient Disclosure Rules*, WASH. POST, Feb. 9, 1998, at A1. R. Alta Charo, a professor of law at the University of Wisconsin and a member of President Clinton’s National Bioethics Advisory Commission, put it this way: “We have in many respects far better protections for hamsters than for human fertility patients.” *Id.*

2 See, e.g., Debora Spar, *Taming the Wild West of Assisted Reproduction*, COLUM. SPECTATOR (Feb. 26, 2009), <http://www.columbiaspectator.com/2009/02/26/taming-wild-west-assisted-reproduction>.

multiple pregnancy.³ The medical risks associated with multiple pregnancy, particularly higher order multiples, include maternal circulatory and respiratory maladies that can be permanently disabling or even fatal, and fetal complications that can impact the child's sensory, mobility and cognitive development.⁴ Despite, or possibly because of this picture of health, the Suleman clan is firmly established as the poster family for public outcries over the untamed state of ART law. As proof positive, during a 2010 hearing in which Suleman's treating physician, Michael Kamrava, faced charges before the Medical Board of California, the prosecuting attorney proclaimed the doctor acted like "a cowboy" by disregarding established guidelines for embryo transfer.⁵ While language shapes perception, in the case of ART—perception is undoubtedly influenced by language.

Public and academic reaction to the Suleman case, and what it represents, has ranged from demands for a total regulatory takeover of ART to calls for minor tweaks in the system. While a comprehensive overhaul of reproductive law is highly unlikely, advocacy for small changes are gaining support. One such proposal—aimed at reducing high-order multiple births—urges Congress to enact a federal law limiting the number of embryos transferred in any single IVF cycle.⁶ Limiting embryo transfers to one or two per cycle, advocates say, would reduce the high rate of ART-induced multiple births in the U.S. which has stubbornly hovered at around one-third of all IVF births.⁷ Would such a tweak help

3 Laura T. Coffey, *As Octuplets Turn 1, the Real Work Is Just Starting*, TODAY.COM (Jan. 26, 2010), http://today.msnbc.msn.com/id/34984163/ns/today-today_people/t/octuplets-turn-real-work-just-starting/#.T2fESMWPWf4.

4 The case for avoiding multiple pregnancy is often made in medical terms. As one recent medical journal article explains, "There are well-documented increases in maternal morbidity and mortality from gestational diabetes, hypertension, cesarean delivery, pulmonary emboli, and postpartum hemorrhage in addition to fetal, neonatal, and childhood complications from neurologic insults, ocular and pulmonary damage, learning disabilities and retardation, and congenital malformations." R. Stillman, K. Richter, N. Banks & J. Graham, *Elective Single Embryo Transfer: A 6-Year Progressive Implementation of 784 Single Blastocyst Transfers and the Influence of Payment Method of Patient Choice*, 92 FERTILITY & STERILITY 1895, 1900 (2009).

5 See *Judge Recommends Probations for Octomom's Fertility Doc*, NBC L.A. (Jan. 24, 2011), <http://www.nbclausangeles.com/news/local-beat/Octomom-Doctor-114508064.html>.

6 See, e.g., Naomi R. Cahn & Jennifer M. Collins, *Eight Is Enough*, 103 NORTHWESTERN U. L. REV. COLLOQUY 501 (2009); David Orentlicher, *Multiple Embryo Transfers: Time for Policy*, 40 HASTINGS CENTER RPT. 12 (May–June 2010).

7 See CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T. OF HEALTH AND HUM. SERVS., 2008 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 75 (2010), available at http://www.cdc.gov/art/ART2008/PDF/ART_2008_Full.pdf (explaining "[f]or fresh-nondonor cycles, the percentage of multiple-infant live births decreased 14 percent since 1999, from 37 percent of all live births in 1999 to 32 percent in 2008") [hereinafter 2008 ART REPORT].

debunk the ART urban myth? Even if so, would a statutory limitation on embryo transfers be legally permissive, clinically sensible, or administratively enforceable? In my view, as long as infertility care remains outside the package of health benefits available to those in need of treatment, the answer to each query is no.

This article explores the merits of a federal law limiting the number of embryos transferred in a given IVF cycle. Observationally, I posit that Congress is unlikely to enact such a law, given its historic (mostly) hands-off approach to ART,⁸ the import of assisted conception to American families who show little enthusiasm for limiting embryo transfers,⁹ and the divisive political battle that routinely accompanies proposed legislation aimed at reproductive medicine.¹⁰ Leaving to others a more robust discussion of the (un)likelihood and political (in)feasibility of such a bare mandate limiting embryo transfers,¹¹ this article considers four aspects of any such tweak in the current system. First, Part I sets out the legal landscape into which any new federal law would settle, revealing that current ART regulation springs from a trilogy of sources—public law, quasi-public law and private law—which combine to regulate and influence clinical practices in the field. Next, Part II highlights the prominence of federalism in the regulation of health law, casting doubt on

8 To date, the only federal law to specifically address the practice of reproductive medicine was enacted in 1992. See Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. §§ 263a-1-a-7 (2010).

9 Currently in the U.S., three out of every 100 children born are conceived with medical assistance. According to an annual report published by the Centers for Disease Control and Prevention (CDC), in 2009 (the most recent year for which figures are available) there were 60,190 children born in the U.S. who were conceived using in vitro fertilization. See CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T. OF HEALTH AND HUM. SERVS., 2009 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 15 (2011), available at http://www.cdc.gov/ART/ART2009/PDF/ART_2009_Full.pdf (last visited Mar. 13, 2012). In addition to IVF births, an estimated 60,000 children are born annually via artificial insemination by donor (AID). See Inst. for Sci., Law & Tech. Working Grp., *ART Into Science: Regulation of Fertility Techniques*, 281 SCIENCE 651 (1998). Births via IVF and AID bring the total number of children born through assisted conception to roughly 120,000; the total birth rate for 2009 was 4,130,665. See CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T. OF HEALTH & HUM. SERVS., BIRTHS: FINAL DATA FOR 2009, 60 NATIONAL VITAL STATISTICS REPORTS, Nov. 3, 2011, at 1, available at http://www.cdc.gov/nchs/data/nvsr/nvsr60/nvsr60_01.pdf. Thus, total ART births in the U.S. in 2009 comprised about 2.9% of all live births.

For a discussion of ART patient attitudes toward regulating embryo transfers to reduce multiple pregnancy, see *infra* text accompanying note 251.

10 See *infra* text accompanying notes 257–59 (discussing the failed state legislative attempts to limit embryo transfers in the wake of the Nadya Suleman births).

11 See John A. Robertson, *The Octuplet Case—Why More Regulation Is Not Likely*, 39 HASTINGS CENTER RPT. 26 (2009). The “bare mandate” refers to a law unaccompanied by improvements in access to insurance coverage for infertility care, as discussed in Part IV.

the legal viability of a national law purporting to dictate medical practice standards - an area traditionally reserved for state actors.

Part III explores the possible language and predicted effectiveness of a federal embryo transfer law. Building upon existing law requiring ART clinics to annually report their pregnancy success rates for national publication, this Part suggests that adding mandatory reporting of embryo transfers could be easily accomplished but less easily monitored by appointed regulators. Moreover, selecting clinical standards would be problematic, forcing lawmakers to choose between a modest proposal likely to win industry support and a draconian approach more likely to dramatically reduce multiple birth rates. Once clinical embryo transfer standards are considered, the focus turns to penalty alternatives. Looking to empiric data on the effectiveness of civil and criminal penalty structures in regulatory and medical settings, Part III suggests that physicians may be more responsive to the threat of licensure revocation for breaching established standards than traditional modes of punishment. Overall, Part III argues that drafting, monitoring, and enforcing federal embryo transfer limits would present serious challenges for lawmakers and regulators.

Finally, Part IV delves into physician and patient incentives for breaching current industry-generated embryo transfer limits. From the patient's perspective, incentives to bypass suggested restrictions are well-described, driven by a desire to parent more than one child coupled with the constraints imposed by a lack of health insurance coverage for most ART treatment. Physicians likewise respond to ART's competitive, "cash-only" financial environment, trying to satisfy patient demands and financial limitations, while striving to produce high success rates for public scrutiny. These patient and provider incentives, Part IV asserts, suppress the likelihood a bare embryo transfer law would be effective in reducing the U.S. ART-inspired multiple birth rate. While it is empirically clear that reducing embryo transfers reduces multiple pregnancy, what remains unclear is whether and how to implement practice guidelines within existing political, medical and insurance parameters. In the end, Part IV argues a tweak in the system will only be effective if accompanied by robust health insurance coverage for infertility care. The recently enacted Patient Protection and Affordable Care Act¹² provides a timely opportunity to tackle the issue of multiple births through a two-pronged approach, combining clinical restrictions with coverage for ART. Injecting benefits and burdens into the ART world may finally tame its wild west reputation.

12 Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119. Some of the statutory provisions of the Affordable Care Act were subsequently amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029.

I. Regulating Reproductive Medicine: A Trilogy of Sources

Reproductive medicine is a subspecialty field of medical practice devoted to diagnosing and treating infertility. Physicians who practice in this field undergo rigorous training. After graduating from medical school, a physician interested in reproductive medicine must complete a residency in Obstetrics & Gynecology (Ob/Gyn), and then a fellowship in Reproductive Endocrinology & Infertility (REI).¹³ Like all areas of medical practice, reproductive medicine is subject to quality control through a variety of mechanisms, most notably licensure of physicians by state-based medical boards, application of practice standards established by professional societies, and private tort litigation. But unlike virtually every other area of medical practice, reproductive medicine has been uniquely assailed as unregulated and is frequently the subject of calls for greater governmental oversight. Why this special demand on the provision of ART—those medical services that enable the infertile to achieve biologic parenthood? The answer, of course, is the children.

The unitary goal of ART is to produce healthy offspring. Paradoxically, while medical therapies are directed at patients, outcomes are measured by the well-being of any resulting children.¹⁴ As third party beneficiaries of ART's application, the resulting children take on an emotional symbolism that can steer attention away from the internal doctor/patient relationship to the external product of that relationship. Measuring the merits of ART through this child-centered lens has enhanced public perceptions that the field is in dire need of comprehensive oversight and reform.¹⁵ That is, even when the use of ART

13 According to the American Society for Reproductive Medicine (ASRM) website, "Reproductive Endocrinologists are Obstetrician-Gynecologists with advanced education, research and professional skills in Reproductive Endocrinology & Infertility. These highly trained and qualified physicians treat Reproductive Disorders that affect children, women, men, the mature woman, and infertility in both men and women." *ASRM Affiliated Groups*, AM. SOC'Y REPROD. MED., <http://www.asrm.org/detail.aspx?id=150> (last visited July 6, 2010).

14 For example, the Centers for Disease Control and Prevention (CDC) annually collects data on success rates at the nation's ART clinics, measured by pregnancies and live births. See *Fertility Clinic Success Rate and Certification Act of 1992*, 42 U.S.C. § 263a-1 (2011). No data is likewise collected on the health outcomes of women who undergo fertility treatment at those clinics.

15 Ample scholarship has been devoted to exploring the relationship between the perception of children (born and unborn) as a vulnerable population in need of protection and the justification for state action purporting to provide such protection. See, e.g., Helen M. Alvare, *The Case for Regulating Collaborative Reproduction: A Children's Rights Perspective*, 40 HARV. J. ON LEGIS. 1, 4-5 (2003); Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603 (2003) (calling on the Food and Drug Administration to consider restricting or withdrawing fertility drugs used to induce ovulation due to the high number of multiple pregnancies, which pose harm to women and offspring); Jennifer L. Rosato, *The Children of ART (Assisted Reproductive Technology): Should the Law Protect Them From Harm?*, 2004 UTAH L. REV. 57, 62 (2004) (advocating a system of state and federal reform whose "overall goal would be to provide the children of ART needed protection from known harms").

is successful—healthy offspring are born to a healthy woman—mishaps or malfeasance by medical personnel that accompanied that birth will be the target of significant hand-wringing.

This observation is not to say that human error in ART, intentional or otherwise, should not be cause for concern; rather, it is to point out that the birth of a healthy ART child is not necessarily a sign of health in the ART system. In fact, a series of very public and very unfortunate ART events have firmly disaggregated the birth of healthy offspring from the legitimate and appropriate use of ART. It seems fair to say that through these debacles, ART has acquired its reputation as the “wild west of medicine.” In each case, the ART professional’s bad behavior—ranging from simple negligence to active criminality—was well-publicized and well-situated to serve as a clarion call for greater governmental scrutiny of the field.

Consider, for starters, the case of Dr. Cecil Jacobson, a Northern Virginia fertility doctor who used his own sperm to impregnate over 70 unwitting patients. Following a 1992 trial, Dr. Jacobson was convicted of 53 counts of fraud and perjury. He served five years in a federal prison, all the while protesting his innocence.¹⁶ A few years later the world learned that doctors at the UCI Center for Reproductive Health in Orange County, California stood accused of stealing eggs and embryos retrieved from younger patients and implanting them in older patients, without either woman’s knowledge or consent. The alleged motive for this gametic shell game? Money and glory. Younger eggs, even when mixed with older sperm, are more likely to produce a successful outcome, thus yielding profits and praise for the treating physicians.¹⁷ In all, it is believed that more than a dozen children were born of this malfeasance, costing the University of California millions of dollars in settlement

16 See *Fertility Doctor Fathers 75*, DOMINION POST, July 18, 2006, at 3 (the reporter noting “[t]here was no law against using his own sperm to impregnate patients”).

17 Once the UCI scandal made front page news in May 1995, two of the three accused physicians fled the U.S., taking refuge in their home countries of Mexico and Chile. The two remain at large, the subject of federal criminal indictments. A third doctor, not believed to have actively participated in the egg/embryo misappropriation, was later convicted of fraudulently billing insurance companies and sentenced to house arrest. See Jack Leonard & Stuart Pfeifer, *UCI Fertility Doctor Seized in Argentina*, L.A. TIMES, Jan. 20, 2001, <http://articles.latimes.com/2001/jan/20/news/mn-14827>; Catherine Saillant, *Fugitive in UCI Fertility Clinic Scandal Held in Mexico*, L.A. TIMES, Dec. 28, 2010, <http://articles.latimes.com/2010/dec/28/local/la-me-fertility-arrest-20101228>.

costs, not to mention a sequelae of reputational harm.¹⁸

Debauchery in ART is not reserved to the criminal realm; plenty of misdeeds have been the result of simple negligence. Cases involving laboratory mix-ups are particularly painful, often producing emotional custody battles that pit genetics against biology.¹⁹ In one New York fertility clinic, a white patient became pregnant with twin boys, one white and one black, because a lab technician mistakenly swapped two couples' embryos on the day of transfer.²⁰ The white couple's "successful" use of ART wrought tremendous pain and suffering to the black couple whose embryo was negligently misdirected. After a two-year legal battle, the black child was ordered returned to his genetic parents, but the trauma caused irreparable harm to the parties as well as the industry.

Against this shaky backdrop, the world met Octomom, an out-of-work, single woman whose IVF-conceived octuplets joined six existing children amid a media feeding frenzy. While initial attention fixated on the sheer novelty of Nadya and the infants, the undercurrent

18 See *id.*; Marcida Dodson, Randal C. Archibold & Scott Martelle, *Fertility Case Plaintiffs Agree on Settlements*, L.A. TIMES, Aug. 16, 1997, <http://articles.latimes.com/1997/aug/16/news/mn-22936>; Davan Maharaj & Hope Hamashige, *Dr. Stone of UCI Clinic Found Guilty of Fraud*, L.A. TIMES, Oct. 31, 1997, <http://articles.latimes.com/1997/oct/31/news/mn-48648>. The UCI scandal is also detailed in MARY DODGE & GILBERT GEIS, *STEALING DREAMS: A FERTILITY CLINIC SCANDAL* (2003). After the UCI, California lawmakers responded to the alleged malfeasance of Drs. Asch, Balmaceda, and Stone by enacting a criminal law designed to deter and punish tampering with gametic material. Senate Bill 1555, enacted on September 25, 1996, adds § 367g to the Penal Code, and provides as follows:

(a) It shall be unlawful for anyone to knowingly use sperm, ova, or embryos in assisted reproduction technology, for any purpose other than that indicated by the sperm, ova, or embryo provider's signature on a written consent form.

(b) It shall be unlawful for anyone to knowingly implant sperm, ova, or embryos, through the use of assisted reproduction technology, into a recipient who is not the sperm, ova, or embryo provider, without the signed written consent of the sperm, ova, or embryo provider and recipient.

(c) Any person who violates this section shall be punished by imprisonment in the state prison for three, four, or five years, by a fine not to exceed fifty thousand dollars (\$50,000), or by both that fine and imprisonment.

1996 Cal. Legis. Serv. ch. 865 (S.B. 1555) (West). To date, no physician has been charged or prosecuted under the law.

19 See *IVF Mix-Up Heads for Court*, BBC NEWS, July 8, 2002, <http://news.bbc.co.uk/2/hi/health/2115522.stm> (summarizing a few cases across Europe and the U.S. in which laboratory mix-ups involving sperm, eggs or embryos resulted in the birth of offspring).

20 *Perry-Rogers v. Fasano*, 715 N.Y.S.2d 19, 21–22 (App. Div. 2000); see also *Robert B. v. Susan B.*, 135 Cal. Rptr. 2d 785, 786 (Ct. App. 2003) (embryo from married couple using husband's sperm and donor egg mistakenly implanted in single woman intending to gestate donor embryo, resulting in birth of wholeblood siblings to different mothers).

of displeasure with the state of ART regulation began to gain strength. In at least three states, Octomom-inspired bills were introduced into the legislature, though none emerged as enacted law.²¹ In addition to these formal acts, a wealth of commentary began to fill the pages of academic and popular publications, unifying around the mantra, “There ought to be a law” that would prevent the emergence of any future Octomoms (or Septomoms, or Sextomoms, and so on).²² Implicit in this advocacy is a presumption that no such specific regulatory system exists. The oft-referenced “wild west of medicine” further presumes that *no* regulation of ART exists. Neither presumption is correct, but both are best understood through the lens of a global perspective on ART regulation, rather than comparing the field to other subspecialty practices within a domestic sphere.

Approaching ART regulation from a global perspective tends to yield a binary view of the legal landscape. Countries are seen as either adopting comprehensive regulation of the field, or yielding to a laissez-faire approach with no extant regulation. Examples of countries perceived to be in the “everything is regulated” include England, Canada, and Italy. The U.S., on the other hand, is classified on the “nothing is regulated” list.²³ Like most generalizations, there is some truth to these overbroad classifications. National laws have been enacted in the U.K., Canada and Italy that affect clinics in these countries,

21 Georgia Senate Bill 169, entitled, the “Ethical Treatment of Human Embryos Act,” was drafted by the Bioethics Defense Fund and supported by the Georgia Right to Life. Introduced in February 2009, the bill would have limited the number of embryos available for transfer in a single IVF cycle to 2 or 3 depending on the age of the patient. The bill also prohibited all forms of embryo research, outlawed cryopreservation of embryos, banned discard of embryos for any purpose, while defining an “in vitro embryo” as a “biological human being.” The bill was revised to just prohibit human reproductive cloning, and was never passed. See *Georgia General Assembly*, GA. GEN. ASSEMB., http://www.legis.state.ga.us/legis/2009_10/sum/sb169.htm (last visited July 9, 2010). In Missouri, lawmakers introduced a simple bill that would have codified the ASRM guidelines on embryo transfer, but the proposed act, H.B. 810, failed to gain support. See H.B. 810, 95th Gen. Assemb., 1st Reg. Sess. (Mo. 2009), available at <http://www.house.mo.gov/content.aspx?info=/bills091/bills/hb810.htm> (last visited July 9, 2010). A California bill, S.B. 674, designed to place fertility clinics under the jurisdiction of the California Medical Board was passed by the state legislature, but vetoed by Gov. Schwarzenegger who critiqued the bill as not going far enough to strengthen regulation of all outpatient surgery centers, including ART clinics. See California Senate Journal of October 12, 2009, 2498, available at [ftp://www.leginfo.ca.gov/pub/senate-journal/sen-journal-0x-20091012-2471.PDF](http://www.leginfo.ca.gov/pub/senate-journal/sen-journal-0x-20091012-2471.PDF) (last visited Apr. 2, 2012).

22 See, e.g., Cahn & Collins, *supra* note 6 (concluding some regulation of ART is justifiable in the wake of Octomom); Deborah Spar, *As You Like It: Exploring the Limits of Parental Choice in Assisted Reproduction*, 27 LAW & INEQUALITY 481 (2009) (suggesting ART be regulated in a manner similar to adoption); Urska Velikonja, *The Costs of Multiple Gestation Pregnancies in Assisted Reproduction*, 32 HARV. J.L. & GENDER 463 (2009) (arguing for increased regulation of assisted reproduction).

23 See, e.g., Porsha L. Cills, *Does Donating Sperm Give the Right to Withdraw Consent? The Implications of In Vitro Fertilization in the United Kingdom and Canada*, 28 PENN ST. INT’L L. REV. 111 (2009) (hailing the UK and Canada as “leaders” in regulating ART, describing Italy’s “national legislation” addressing assisted conception, and noting that the U.S. lacks any such scheme).

respectively.²⁴ The U.K. in particular is hailed as a stellar example of comprehensive ART regulation, having enacted a national licensure scheme for fertility clinics in 1990.²⁵ In these so-called comprehensive jurisdictions, ART regulation operates as a top-down scheme in which a national body sets practice guidelines and requirements, directing which services each clinic can (and cannot) provide. But even within this tightly controlled regime, some practices remain unregulated, or more commonly, are done surreptitiously or outside the jurisdiction in defiance of national policy.²⁶

On the flipside, regulation in the free-for-all countries does exist, but as narrow, targeted laws aimed at specific areas, rather than as federal legislation deputizing national boards to oversee the industry countrywide.²⁷ In the U.S., regulation of ART can be divided into what I'll call a source trilogy, consisting of three distinct bases from which regulatory activity arises: public ordering, quasi-public ordering, and private ordering. Public ordering encompasses all formal public law surrounding ART, including enacted statutes and promulgated regulations. In some cases, enacted law applies to ART even though such

24 See Human Fertilisation and Embryology Act, 1990, c. 37 (U.K.); Assisted Human Reproduction Act, S.C. 2004, c. 2 (Can.); Andrea Boggio, *Italy Enacts New Law on Medically Assisted Reproduction*, 20 HUM. REPROD. 1153 (2005), available at <http://humrep.oxfordjournals.org/cgi/content/full/20/5/1153> (last visited June 20, 2012).

25 The Human Fertilisation and Embryology Act grew out of a government-commissioned study chaired by Mary Warnock in the 1980s. Today, the Human Fertilisation Embryology Authority is "[d]edicated to licensing and monitoring UK fertility clinics and all UK research involving human embryos, and providing impartial and authoritative information to the public." See HUM. FERTILISATION & EMBRYOLOGY AUTH., <http://www.hfea.gov.uk/25.html> (last visited Jan. 11, 2011).

26 The most well-documented example of defiance of national law by ART patients is captured by the growing phenomenon of cross-border reproductive care, wherein citizens of a country that prohibits or limits access to certain reproductive technologies travel to another jurisdiction to receive these services. A study conducted by the European Society of Human Reproduction and Embryology (ESHRE) indicates that cross-border ART travel is on the rise within the European Union, due largely to legal restrictions in several of the member nations. See F. Shenfield et al., *Cross Border Reproductive Care in Six European Countries*, 25 HUM. REPROD. 1361, 1361 (2010). Examples of ART practitioners steering patients toward friendlier venues for prohibited procedures also abound. See Anthony Blackburn-Starza, *Liverpool Hospital to Investigate "Sex Selection" Claims*, BioNews, Feb. 22, 2011, http://www.bionews.org.uk/page_89606.asp?dinfo=5g0yGJzm1NKk1eqXeS1UigGD (detailing investigation of UK clinic doctor who allegedly helped patient access sex selection on embryos for family balancing, a technique banned under the HFEA). For a thorough discussion of harms associated with medical tourism, including reproductive tourism, see I. Glenn Cohen, *Protecting Patients with Passports: Medical Tourism and the Patient-Protective Argument*, 95 IOWA L. REV. 1467 (2010).

27 Spain, for example, a country that attracts other Europeans to its shore for its open access to IVF and egg donation, outlaws practice of commercial surrogacy. See Richard Storrow, *Travel Into the Future of Reproductive Technology*, 79 U. MO. KAN. CITY L. REV. 295, 298 (2010).

application was never contemplated at the time the statute was enacted.²⁸

Quasi-public ordering refers to self-regulatory schemes developed and monitored by affected stakeholders. The practice of reproductive medicine has a long history of self-regulation. Critics of self-regulation in general rightly observe that any internally derived scheme, including that governing ART, contains deficiencies and weaknesses that necessarily impact effectiveness. Private ordering as a regulatory system refers to the conduct of private individuals operating within the tort system that impact practice within the field. Though the vast majority of private tort actions never transmute into formal law (i.e., common law disseminated via published court opinions), their very existence can have a tremendous impact on other actors in the field who feel vulnerable to similar claims. Filing, or even the threat of filing, a lawsuit can alter practices from the sheer distaste of being embroiled in litigation. ART regulation as seen through the source trilogy is briefly described below.

A. Public Ordering

Enacted laws that directly govern or affect ART are found on both federal and state rolls. Though none of the statutes can be considered comprehensive (regulating each action of each provider) as a whole the laws are geared toward providing patients accurate and up-to-date information about clinical outcomes, and assuring some level of quality control throughout the industry. The quality control measures in place are designed to promote health and safety in the embryology laboratories, as opposed to controlling the number of embryos that are transferred in any given cycle. There is no dispute that the number of embryos transferred has a direct effect on health and safety—for both patient and offspring—but as argued herein, the lack of an explicit law delineating this aspect of clinical practice does not mean that the practice is entirely unregulated in a broader sense.²⁹

Turning to enacted law, at the federal level a nearly twenty year old law has effectuated a comprehensive reporting scheme that enables prospective patients to investigate ART practices on a clinic-by-clinic basis. The Fertility Clinic Success Rate and Certification

28 See *In re Baby M.*, 537 A.2d 1227 (N.J. 1988) (invalidating surrogate parenting arrangements for violating state law, enacted long before the practice of surrogacy was known in the state, prohibiting the payment of money in connection with adoption).

29 The sentiment has been expressed more generally by Professor John Robertson, whose review of a book critical of the unregulated nature of ART explains, “[t]he absence of an overarching legal code specifically for assisted reproduction does not mean that all rules are absent, nor that all questions be settled in advance.” John A. Robertson, *Commerce and Regulation in the Assisted Reproduction Industry*, 85 TEX. L. REV. 665, 682 (2006–07) (reviewing DEBORAH L. SPAR, *THE BABY BUSINESS: HOW MONEY, SCIENCE, AND POLITICS DRIVE THE COMMERCE OF CONCEPTION* (2006)).

Act of 1992³⁰ was born out of a concern that fertility clinics were misleading prospective patients about pregnancy success rates in an era when reporting of such data was completely voluntary.³¹ FCSRCA contains two essential components. First, it requires standardized reporting of pregnancy success rates to the Secretary of Health and Human Services through the Centers for Disease Control (CDC), which in turn makes data available to the public. As a result of this law, the vast majority of ART clinics in the U.S. annually report their success rates and a host of other data to the CDC, which publishes a comprehensive report detailing national statistics, as well as specific information about each reporting clinic.³² The CDC has published an annual ART Success Rate Report since 1997, and each report is now available online at the CDC website.³³

A second part of the Act empowers the CDC to develop a model program for certification of embryo laboratories that can be adopted by each state. The CDC issued the final version of the model certification program in 1999, but to date no state has adopted the program into law. Thus, direct federal regulation of ART can be described as an active reporting requirement and a dormant certification program. While FCSRCA remains the sole piece

30 42 U.S.C. §§ 263a-1-a-7 (2010).

31 The bill which became the Fertility Clinic Success Rate and Certification Act was introduced into the 102d Congress by Representative Ron Wyden (D-Oregon) as H.R. 3940. The hearings on the bill featured witnesses who testified to the misleading advertising practices employed by some fertility clinics. Congressman Henry Waxman (D-California), Chair of the House Subcommittee on Health and the Environment, noted that couples are often misled about ART success rates because some clinics use criteria such as the number of eggs retrieved, number of eggs fertilized, or number of embryo transfers to tout success, rather than the number of live births. To combat such deception, the Act was designed to standardize reporting. *See Fertility Clinic Services: Hearing Before the Subcomm. on Health and the Env't of the H. Comm. on Energy & Com.*, 102d Cong. 1-2 (1992).

32 One criticism of FCSRCA's reporting requirement is the lack of any real penalty surrounding nonreporting. If a clinic fails to report, the law simply requires that the name of the nonreporting clinic be included in the annual report. This "shaming" technique is drawn from § 263a-5:

The Secretary, through the Centers for Disease Control, shall not later than 3 years after October 24, 1992, and annually thereafter publish and distribute to the States and the public—

(1) (A) pregnancy success rates reported to the Secretary under section 263a-1(a)(1) of this title and, in the case of an assisted reproductive technology program which failed to report one or more success rates as required under such section, the name of each such program and each pregnancy success rate which the program failed to report . . .

42 U.S.C. § 236a-5 (2010). On average about eight percent of all U.S. fertility clinics do not report their success rates to the CDC, and thus find themselves listed as nonreporters in the annual report. *See ART Report 2007, supra* note 7, at 5, 580-82 (stating that 436 clinics reported information about the outcomes of ART cycles to the CDC while 39 clinics were listed as nonreporters).

33 A compendium of all the CDC ART reports is available on the agency website at <http://www.cdc.gov/art/> (last visited Aug. 2, 2010).

of federal legislation drafted to specifically address ART practices, other federal regulatory schemes have been appropriately applied to the field, even though they were not originally intended to capture practices that, in some cases, did not yet exist at the time the federal law took effect.³⁴ Several federal agencies are active in ART oversight as a result of these broad regulatory schemes.

In addition to the CDC, the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) are authorized to regulate aspects of ART through regulatory enactments. The FDA is charged with protecting the public health by assuring the safety, efficacy, and security of drugs, medical devices and biological products, including human gametes. In 2005, the FDA issued comprehensive regulations requiring tissue banks to test donors and donated tissues for a host of diseases including HIV, hepatitis, and syphilis. In addition, tissue banks are now required to ask donors a series of questions to determine their risk factors for particular diseases. While the FDA regulations are not aimed exclusively or directly at ART clinics, they do impact the practice of reproductive medicine when donor gametes are used.³⁵

The jurisdiction of CMS is invoked under the Clinical Laboratory Improvement Act of 1988 (CLIA),³⁶ providing for federal certification of clinical laboratories. CLIA applies to laboratories engaged in the “examination of materials derived from the human body” for purposes of disease diagnosis, prevention, or treatment. While CLIA authorizes federal authorities to maintain quality control over clinical labs, clarifying regulations published in 1992 limit CLIA’s jurisdiction to lab tests used in the diagnosis of infertility, such as semen and blood analysis. The procedures performed in embryology labs, which are not considered diagnostic, do not fall under CLIA’s mandate.³⁷

34 For example, the Food, Drug, and Cosmetic Act of 1938 first authorized a federal agency—the Food and Drug Administration—to “demand evidence of safety for new drugs, issue standards for food, and conduct factory inspections.” See U.S. Food and Drug Administration, *Regulatory Information*, available at <http://www.fda.gov/RegulatoryInformation/Legislation/default.htm> (last visited Aug. 3, 2010). Further amendments to the Act expanded the jurisdiction of the FDA to include assurance of drug effectiveness (1962) and safety and effectiveness of medical devices (1976). *Id.* The regulation of human tissues and tissue-based products, which significantly broadened the agency’s oversight over ART, became effective in 2005. See Human Cells, Tissues, and Cellular and Tissue-Based Products, 21 C.F.R. § 1271, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1271> (last visited Aug. 2, 2010) [hereinafter Human Cell, Tissues].

35 See Human Cells, Tissues, *supra* note 34.

36 42 U.S.C. § 263a (2010).

37 See ASRM Monograph, *Oversight of Assisted Reproductive Technologies*, 6–7 (2010), available at http://www.asrm.org/Oversight_of_ART/ (last visited Jan. 12, 2010).

Direct regulation of ART at the state level falls into three distinct categories: disposition of gametes and embryos, parentage assignment and informed consent.³⁸ In fact, the majority of U.S. states have adopted at least one—and in many cases several—laws that deal directly and exclusively with the practice of reproductive medicine, in contrast with the single federal statute enacted to address ART reporting. In general, state law regulates the relationships that form around ART (between and among patients, physicians, and third party donors and surrogates) rather than the medical practices used within the field. For example, while nearly half of all states have some enacted law on surrogate parenting arrangements,³⁹ only one state has a law requiring that women electing IVF or artificial insemination undergo a medical examination before treatment can be administered.⁴⁰ To date, no state has adopted a law regulating the number of embryos transferred in any given IVF cycle.

The nature of our federal system, in which states assert authority over the health, safety, and welfare of those within their jurisdiction as an expression of individualized public policy, dictates the concentration of ART laws at the state level. Matters of property law (gamete and embryo disposition); family law (parentage assignment), and tort law (informed consent) are typically captured by state lawmakers; the treatment of ART vis-a-vis these state-oriented legal doctrines is therefore entirely sensible and expected.⁴¹ As discussed in Part II, a federal law regulating the practice of medicine by dictating clinical standards in IVF would be a significant departure from long-standing reliance on the grassroots sensibility of state lawmakers. Congressional activity in an area traditionally left to the states could violate principles of federalism, leaving a federal law vulnerable to an attack on constitutional grounds.

In addition to targeted enacted law, states can affect the practice of reproductive medicine through their medical licensing regimes. Licensing statutes govern entry into the licensed professions, disciplinary actions, and the delivery of health care services

38 See JUDITH DAAR, *REPRODUCTIVE TECHNOLOGIES AND THE LAW* 691–92 (2006) (discussing direct and indirect regulation of ART by states).

39 *Id.* at 465–70 (fifty-state survey of laws affecting surrogate parenting arrangements).

40 N.H. REV. STAT. ANN. § 168-B:13 (2011) (requiring a woman, and her husband if applicable, undergo medical evaluation and demonstrate medical acceptability prior to undergoing IVF).

41 For a comprehensive review of state ART laws, see CHARLES P. KINDREGAN, JR. & MAUREEN MCBRIEN, *ASSISTED REPRODUCTIVE TECHNOLOGY: A LAWYER'S GUIDE TO EMERGING LAW AND SCIENCE* (2d ed. 2011).

by unlicensed persons.⁴² These statutes are typically implemented by medical boards authorized to investigate alleged malfeasance in the practice of medicine, and assess penalties ranging from probation to license revocation.⁴³ ART practitioners, as medical doctors, are required to be licensed by the state in which they practice. Disciplinary actions against ART practitioners can and have been brought by state licensing authorities.⁴⁴

Perhaps the most recent and high profile disciplinary action was the case against Michael Kamrava, the California physician who treated Nadya Suleman. The Accusation, as the initial pleading is called, was filed before the Medical Board of California, Department of Consumer Affairs, by the Attorney General of California on December 22, 2009. The thirteen-page pleading accused Dr. Kamrava of gross negligence based primarily on two behaviors: transfer of excessive embryos in violation of recommended industry standards,⁴⁵ and failure to refer the six-time IVF-seeking patient to a mental health professional for evaluation.⁴⁶ At a trial on the merits in October 2010, Dr. Kamrava cited in his defense his patient's desire to have a large family.⁴⁷ On January 24, 2011, the administrative law judge hearing the case recommended that the doctor be placed on a five-year probation by the state medical board, opting to permit him to retain his medical license.⁴⁸ However, upon

42 BARRY R. FURROW, THOMAS L. GREANEY, SANDRA H. JOHNSON, TIMOTHY STOLTZFUS JOST & ROBERT L. SCHWARTZ, *HEALTH LAW* 59 (2d ed. 2000).

43 See CAL. BUS. & PROF. CODE § 2227 (West 2010).

44 Cecil Jacobson, the fertility doctor described in text accompanying note 16, convicted of fraud and perjury for using his own sperm to "treat" his patients had his license revoked by the Virginia Medical Board. *Conviction Upheld in Fertility Case*, N.Y. TIMES, Sept. 8, 1993, <http://www.nytimes.com/1993/09/08/us/conviction-upheld-in-fertility-case.html>. In 1995, the Medical Board of California revoked the license of Dr. Steven Katz, an ART practitioner who knowingly concealed that he had implanted the wrong embryo in a patient who later gave birth to a child. The concealment continued for nearly a year-and-a-half, when an investigation by the Medical Board prompted Dr. Katz to reveal his error to both the birth mother and the couple whose embryos were mistakenly transferred. See *California Medical Board Revokes Fertility Doctor's License for Implanting Wrong Embryo, Failing To Inform Patient*, MED. NEWS TODAY, Apr. 4, 2005, <http://www.medicalnewstoday.com/articles/22226.php>.

45 The standards cited in the Accusation are the embryo transfer guidelines issued by the American Society for Reproductive Medicine, discussed *infra* in text accompanying notes 53.

46 Original Accusation, styled In the Matter of the Accusation Against: Michael Kamrava, MD, Case No. 06-2009-197098 (on file with author).

47 See *Judge Recommends Probations for Octomom's Fertility Doc*, NBC L.A., Jan. 24, 2011, <http://www.nbclosangeles.com/news/local-beat/Octomom-Doctor-114508064.html>.

48 See Lou Posni & Lori Bashdea, *Judge: Octuplets' Mom's Fertility Doctor Should Keep Medical License*, ORANGE COUNTY REG., Jan. 24, 2011, <http://www.ocregister.com/news/kamrava-285381-suleman-judge.html>.

review, the Medical Board announced its decision to exact a harsher penalty and suspended Dr. Kamrava's license to practice medicine on June 1, 2011.⁴⁹ It is interesting to note that Dr. Kamrava lost his license to practice medicine not because he violated formal state law, but because he failed to adhere to voluntary guidelines published by the industry in which he operated.

It is clear from this brief review of ART-related law that calls for a comprehensive, top-down system, in which specific requirements are strictly enforced, have been unanswered. Instead, our public ordering consists mainly of alerting stakeholders to the potential risks and benefits that ART poses. Whether by publishing clinic-specific data at the federal level; clarifying parental rights with respect to gametes, embryos, and offspring at the state level; or prosecuting ill-behaved practitioners under traditional licensure, tort, or criminal law doctrines, formal American law strives to enhance individual (informed) decision-making over generalized standards that defy case-by-case application. Even in the case of extreme malfeasance, applicable law affords a remedy despite the absence of formally enacted practice requirements.

B. Quasi-Public Ordering

Quasi-public ordering, as used herein, refers to the various ways in which the ART community engages in formal self-regulation. The main sources of ART self-regulation are supplied by the American Society for Reproductive Medicine (ASRM), a reproductive medicine and ancillary professionals membership organization founded in 1944. According to the ASRM website:

The Vision of . . . [ASRM] is to be the nationally and internationally recognized leader for multidisciplinary information, education, advocacy and standards in the field of reproductive medicine. The ASRM is a non-profit organization whose members must demonstrate the high ethical principles of the medical profession, evince an interest in infertility, reproductive medicine and biology, and adhere to the objectives of the Society.⁵⁰

49 See Rong-Gong Lin II & Jessica Garrison, *California Medical Board Revokes License of "Octomom" Doctor*, L.A. TIMES, June 2, 2011; Medical Board of California, Department of Consumer Affairs, *Medical Board of California Revokes License of Former Beverly Hills Physician*, June 1, 2011, http://www.mbc.ca.gov/board/media/releases_2011_06-01_kamrava.html. Dr. Kamrava's appeal to the Los Angeles Superior Court to reinstate his license was rejected in December 2011. *Bid Rejected to Reinstate Octomom Doctor's License*, FOX NEWS ONLINE, Dec. 15, 2011, <http://www.foxnews.com/us/2011/12/15/bid-rejected-to-reinstate-octomom-doctors-license/>.

50 AM. SOC'Y FOR REPROD. MED., <http://www.asrm.org/about/> (last visited June 20, 2012).

The ASRM aspirational reference to itself as a leader of “standards in the field” refers to its two main policy-setting bodies: the Practice Committee that issues reports and guidelines on clinical practice and the Ethics Committee that produces periodic statements and guiding principles for physicians and others in the field.⁵¹ All the official work product of the Practice Committee and the Ethics Committee is published in the ASRM’s professional journal, *Fertility & Sterility*, and posted on its website.⁵²

Since 1998, ASRM has issued and updated practice guidelines for embryo transfers, with each version stating as its goal the reduction of ART-related multiple birth rates in the U.S.⁵³ These practice guidelines represent the industry’s attempt at self-regulation in response to the public health concern over multiple birth. In addition to this topic of widespread interest, the ASRM Practice Committee has also focused on other areas of ART concern. Recent reports address the emerging technique of oocyte cryopreservation (egg freezing),⁵⁴ as well as genetic screening of preimplantation embryos.⁵⁵ The Ethics Committee has not weighed in on the issue of embryo transfer guidelines, likely viewing it as a strict clinical, rather than ethical, matter.⁵⁶ The Ethics Committee has weighed in on pressing issues, including the delivery of ART to HIV-infected individuals,⁵⁷ access to ART

51 The author is a current member of the ASRM Ethics Committee.

52 See *Fertility and Sterility, Journals and Newsletters, News and Publications*, AM. SOC’Y FOR REPROD. MED., <http://www.asrm.org/FertilityAndSterility/> (last visited June 20, 2012).

53 See The Practice Committee of the American Society for Reproductive Medicine and the Practice Committee of the Society for Assisted Reproductive Technologies, *Guidelines on the Number of Embryos Transferred*, 92 FERTILITY & STERILITY 1518 (2009) [hereafter Practice Committee Guidelines].

54 See The Practice Committee of the Society for Assisted Reproductive Technologies and the Practice Committee of the American Society for Reproductive Medicine, *Essential Elements of Informed Consent for Oocyte Cryopreservation: A Practice Committee Opinion*, 90 FERTILITY & STERILITY S134 (2008).

55 See The Practice Committee of the Society for Assisted Reproductive Technologies and the Practice Committee of the American Society for Reproductive Medicine, *Preimplantation Genetic Testing: A Practice Committee Opinion*, 90 FERTILITY & STERILITY S136 (2008).

56 Relatedly, the Ethics Committee has addressed the scenario in which patients ask for treatment physicians believe to be futile or for which there is a poor prognosis. In these instances, physicians are within their ethical stead to refuse treatment according to pre-existing clinic guidelines. See The Ethics Committee of the American Society for Reproductive Medicine, *Fertility Treatment When the Prognosis is Very Poor or Futile*, 92 FERTILITY & STERILITY 1194 (2009). This report could assist physicians confronted with patient requests to transfer embryos in excess of ASRM recommended limits.

57 See The Ethics Committee of the American Society for Reproductive Medicine, *Human Immunodeficiency Virus and Infertility Care*, 94 FERTILITY & STERILITY 10 (2010).

by single individuals and members of the gay and lesbian community,⁵⁸ and the ethics of oocyte donation for stem cell research.⁵⁹ Both ASRM groups meet throughout the year in person and via electronic communication to review existing policies and address emerging issues within their realm.

While ASRM is an organization with voluntary membership, the vast majority of U.S. fertility clinics subscribe as members and as members of its affiliate, the Society for Assisted Reproductive Technology (SART). SART is the primary organization for ART physicians and physician group practices, and is responsible for assuring that its members adhere to membership requirements.⁶⁰ As a condition of ASRM membership, clinics must report their clinical outcomes to the CDC in conjunction with the Fertility Clinic Success Rate and Certification Act,⁶¹ must have accredited embryology laboratories, and must adhere to the Practice and Ethics Committee guidelines of the Society.⁶² Failure to adhere to these criteria can result in revocation of membership. Such was the fate of Dr. Kamrava, Nadya Suleman's physician, whose membership was revoked in September 2009 "for conduct injurious to the good order and reputation of the Society and inconsistent with its purposes."⁶³

Self-regulation in general is subject to a common critique that any suggested reforms to emerge from a group of self-interested stakeholders will fail to take into account the potential harms such schemes would visit on third parties. This "tyranny of the stakeholder" critique is no less prevalent in the ART world, where clinical practice guidelines are written by physicians and embryologists whose livelihoods depend upon a steady flow of child-seeking patients. Critics of the ASRM and SART practice guidelines have charged that these industry-friendly groups operate "behind closed doors," refusing to promulgate

58 See The Ethics Committee of the American Society for Reproductive Medicine, *Access to Fertility Treatment by Gays, Lesbians and Unmarried Persons*, 92 FERTILITY & STERILITY 1190 (2009).

59 See The Ethics Committee of the American Society for Reproductive Medicine, *Donating Spare Embryos for Stem Cell Research*, 93 FERTILITY & STERILITY 667 (2009).

60 See *What is SART?*, http://www.sart.org/What_is_SART/. SART includes nearly 400 ART physician practices, representing approximately eighty-five percent of all U.S. fertility practices.

61 See *supra*, note 30.

62 See ASRM Monograph, *supra* note 37, at 9.

63 See *Judiciary Committee Actions*, ASRM, <https://www.asrm.org/detail.aspx?id=2206> (last visited Apr. 3, 2012).

restrictive standards for fear of reducing clinic profits.⁶⁴ This critique is most often lodged at the professional society's "toothless" guidelines on the number of embryos to transfer in a given IVF cycle. While ASRM has issued embryo transfer guidelines for over a decade, critics argue neither the Society nor the guidelines have done enough to quell the epidemic of multiple pregnancy that pervades U.S. ART use.

The supporting data for critics of the ASRM embryo transfer guidelines comes from the near steady rate of twinning that U.S. fertility clinics have experienced for many years. According to the 2008 ART Success Report, the rate of twin births from fresh nondonor IVF cycles declined only slightly over ten years, falling from 32 percent in 1999 to 30 percent in 2008.⁶⁵ This persistent twinning rate is compared to declining multiple birth rates that have been achieved abroad, especially in European countries that operate under comprehensive regulatory authorities.⁶⁶ ASRM "self-regulators" appear to be somewhat sensitive to the critique that they are not doing enough to address the persistent twin rate in the U.S., revising the embryo transfer guidelines five times since their first issue in 1998, with each version recommending fewer transfers per cycle on average.⁶⁷ These downward revisions may have contributed to the decrease in the higher-order multiple birth rate (triplets or greater) which fell from 5 percent in 1999 to 2 percent in 2008.⁶⁸ Defenders of voluntary guidelines cite this data subset as a reason to resist more formal regulation.⁶⁹

In an industry widely perceived to be unregulated, as is ART, those engaged in self-regulation should be vigilant of the generalized and specific criticism the field attracts. Clearly the Nadya Suleman case sharpened those critiques, at least for a time. Interestingly, though no cause and effect is suggested, ASRM recently revised its procedures for producing Practice Committee Guidelines. In August 2010, the Practice Committee drafted new parameters for developing and publishing clinical guidelines for practitioners. The document, entitled, "Practice Committee Guidelines: Procedures for Preparation, Review and Approval" is accompanied by a separate explanation of how evidence used to support

64 See Theresa Glennon, *Choosing One: Resolving the Epidemic of Multiples in Assisted Reproduction*, 55 VILL. L. REV. 147, 176 (2010).

65 See 2008 ART Report, *supra* note 7, at 77.

66 See Glennon, *supra* note 64, at 186–200 (lauding the more aggressive recommendations of European professional association which have been more successful at reducing both twin and multiple pregnancy rates).

67 See *infra* note 139.

68 See 2008 ART REPORT, *supra* note 7, at 77.

69 See Tarun Jain, Stacey Missmer & Mark Hornstein, *Trends in Embryo-Transfer Practice and in Outcomes of the Use of Assisted Reproductive Technology in the U.S.*, 350 NEW ENG. J. MED. 1639 (2004).

each guidelines will be selected. According to Andrew La Barbera, Scientific Director for ASRM, "These documents were developed by the Practice Committee and describe how guidelines will be prepared in the future with the expectation of submitting them to the National Guidelines Clearinghouse."⁷⁰ The new approach to clinical guideline development includes the use of non-committee experts to draft guidelines based on scientific literature. The goal is to make the procedure more rigorous going forward.

The impact of non-binding, industry-sponsored self-regulation can be difficult to measure because formal assessment mechanisms are typically omitted. In ART, the 1992 federal law mandates reporting and publishing of fertility clinic success rates, allowing some assessment of whether physicians are adhering to industry-suggested standards. The most recent published data suggests a trend toward adherence to embryo transfer guidelines, but still an overall transfer rate that exceeds industry-suggested limits.⁷¹ The 2008 CDC ART Success Rate Report notes a decrease in the average number of embryos transferred over a ten year period. In 1999, only 29% of all ART cycles involved a single or double embryo transfer, compared to 62% in 2008.⁷² Still, the average number of embryos transferred in patients under age 35 was 2.2, while the ASRM guidelines recommend only 1–2 embryos for this age group.⁷³ One interesting study found that embryo transfer rates show the greatest decline immediately after the publication of revised (downward) ASRM practice guidelines.⁷⁴ Knowing that self-regulation can have an impact on clinical practice, even if just a temporal impact, may increase its relative weight in the trilogy of regulatory sources that govern the practice of reproductive medicine.

70 E-mail from Andrew La Barbera, Scientific Director, Am. Soc'y of Reprod. Med., to author (Jan. 29, 2011, 4:06 EST) (on file with author). The *Practice Committee Guidelines: Procedures for Preparation, Review and Approval* and the *Method to Select Evidence* drafts are on file with author.

71 In 2008, approximately thirty-eight percent of all ART cycles involved the transfer of three or more embryos, leaving sixty-two percent as single (twelve percent) and double (fifty percent) embryo transfers. See 2008 ART REPORT, *supra* note 7, at 47. Keep in mind that embryo transfer guidelines are age-specific (the older the egg, the more embryos are recommended for transfer). That same year, nearly forty percent of all ART cycles were performed on women ages thirty-eight and older. *Id.* at 17. For this group, ASRM recommended a limit of three cleavage-state embryos be transferred per cycle. See The Practice Committee of the Society for Assisted Reproductive Technology and the Practice Committee of the American Society for Assisted Reproductive Medicine, *Guidelines on the Number of Embryos Transferred*, 86 FERTILITY & STERILITY S51 (2006).

72 See 2008 ART REPORT, *supra* note 7, at 71.

73 See 2006 Practice Committee Guidelines, *supra* note 71.

74 See Judy E. Stern, Marcelle L. Cedars, Tarun Jain, Nancy A. Klein, C. Martin Beaird, David A. Grainger & William E. Gibbons, *Assisted Reproductive Technology Practice Patterns and the Impact of Embryo Transfer Guidelines in the United States*, 88 FERTILITY & STERILITY 275 (2007).

C. Private Ordering

The impact of tort litigation on the practice of medicine has been widely debated, with central themes focusing on whether private lawsuits improve patient safety, reduce medical error or establish appropriate standards of care.⁷⁵ Even without solid data proving a statistical correlation between malpractice filings and regulatory responses, it is clear that the medical industry has reacted to this form of patient complaint. One oft-expressed concern that the ease of filing private lawsuits causes doctors to practice “defensive medicine.” The practice of defensive medicine means that doctors order more tests and consult more subspecialists than is medically optimal for the patient in order to protect themselves from legal liability.⁷⁶ Survey data bears out this relationship between patient access to the legal system and physician behavior. In a 2009 survey of obstetricians and gynecologists, 60% responded they had made one or more changes to their practices as a result of the risk or fear of professional liability claims or litigation.⁷⁷ The percentage of physicians who self-report practicing defensive medicine is even higher in other fields, with 93% of some subspecialists confirming their behavior is effected by the threat of litigation.⁷⁸ While it is beyond the scope of this article to assess whether the practice of defensive medicine improves or reduces the quality of patient care, it seems reasonable to conclude that private lawsuits impact physician behavior as much if not more than formal regulation and industry guidelines.

The impact, if any, that legal liability has had on ART is difficult to appraise compared to other specialties for at least two reasons. First, no published survey data exists documenting ART physician practices in response to the threat of legal liability. Second, the tort jurisprudence surrounding certain aspects of assisted conception is far more complex, and often more limited, than the average medical malpractice case in which a patient must prove

75 See generally Orna Rabinovich-Einy, *Escaping the Shadow of Malpractice Law*, 74 LAW & CONTEMP. PROBS. 241 (2011).

76 See Adam Candeub, *Contract, Warranty, and the Patient Protection and Affordable Care Act*, 46 WAKE FOREST L. REV. 45, 72–3 (2011).

77 Jeffrey Klagholz & Albert L. Strunk, *Overview of the 2009 ACOG Survey on Professional Liability Results*, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNCOLOGISTS, available at <http://www.americancollegeobgyn.com/~media/Departments/Professional%20Liability/2009PLSurveyNational.pdf?dmc=1&ts=20120323T0838229340> (last visited June 20, 2012).

78 See David M. Studdert et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 J. AM. MED. ASS’N. 2609, 2611, 2612 (2005) (noting doctors in fields like ob/gyn, emergency medicine, neurosurgery and others reported a rate of ninety-three percent for practice of defensive medicine).

the elements of negligence. When ART goes awry and no pregnancy ensues, a patient may have a claim for malpractice.⁷⁹ While such a claim seems straightforward from a negligence calculus, a review of case law suggests suits against ART physicians are rare, and those that are brought are largely unsuccessful.⁸⁰ The legal landscape grows more complicated when an ART birth goes awry. Patients who believe their offspring suffered harmed as a result of physician negligence can look to two legal theories for relief: wrongful birth (a parental claim on behalf of an injured child) and wrongful life (a child's claim for damages suffered from an impaired life).⁸¹ While the former claim is recognized in most states, the latter is rarely permitted to proceed because of the courts' reluctance to engage the "implicit claim that the plaintiff child would prefer non-existence to life in an impaired state."⁸² As with negligence claims involving ART practitioners, wrongful birth claims following IVF are rare and mostly resolved in favor of the physician.⁸³

79 A version of this scenario arises when patients claim their physicians mishandled or misdirected embryos left in their control. A few reported cases involve claims for negligent infliction of emotional distress, negligent destruction of property and even wrongful death. *See* *Frisina v. Woman & Infants Hosp. of R.I.*, 2002 R.I. Super. LEXIS 73, at *5, *50 (2002) (permitting plaintiff patients whose embryos were lost or destroyed to proceed to trial against hospital for breach of contract and negligence); *Jeter v. Mayo Clinic*, 121 P.3d 1256 (Ariz. Ct. App. 2005) (dismissing claim for wrongful death but permitting claims for negligence loss of property in embryo loss case).

80 *See Carmichael v. Reitz*, 95 Cal. Rptr. 381 (Ct. App. 1971) (declining to impose strict liability on a physician when his patient suffered a pulmonary embolism after using the drug Enovid, which he prescribed to treat endometriosis); Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 635 n.135 (2003), (citing *Doolan v. IVF Am. (MA), Inc.*, No. 99-3476, 2000 Mass. Super. LEXIS 581 (Nov. 20, 2000)) (rejecting tort claim brought on behalf of child born with cystic fibrosis against fertility clinic for negligence in genetic testing of IVF embryos before implantation); *see also* Joshua Kleinfeld, *Tort Law and In Vitro Fertilization: The Needs for Legal Recognition of "Procreative Injury,"* 115 YALE L.J. 237 (2005) (arguing IVF-related claims fail because the law lacks a category of injury fitted to the particular harms). *But see* *Morgan v. Christman*, No. 88-2311-O, 1990 U.S. Dist. LEXIS 12179 (D. Kan. July 20, 1990) (permitting patient who gave birth to quadruplets to proceed with negligence and informed consent claims against doctor who prescribed fertility drug without disclosing risk of multiple pregnancy).

81 *See* Kate Wevers, *Prenatal Torts and Pre-Implantations Genetic Diagnosis*, 24 HARV. J.L. & TECH. 257 (2010). A third prenatal tort, wrongful conception, claims damages for the birth of an unplanned by healthy child. Given that an ART patient is actively seeking to become pregnant, these claims seem unlikely in a reproductive medicine scenario.

82 *Id.* at 265.

83 *See, e.g.,* *Grossbaum v. Genesis Genetics Institute, LLC*, No. 07-1359, 2011 WL 2462279, at *1–2, *11 (D. N.J. June 10, 2011) (granting summary judgment for genetics lab that performed pre-conception testing against parents of child born with cystic fibrosis); *Paretta v. Medical Offices for Human Reproduction*, 760 N.Y.S.2d 639 (2003) (denying damages for emotion distress to parents of child born with cystic fibrosis following PGD; but permitting expenses for child's future care).

Even if the volume of malpractice cases brought against IVF physicians is low, it is still worth exploring what impact these cases, and threats thereof, have on the delivery of ART services. Assuming ART practitioners react similarly to their colleagues in a litigation environment, we would expect to see an uptick in the practice of defensive medicine. What would the practice of defensive reproductive medicine entail? Claims in which parents seek damages for their child's congenital or genetic anomaly could prompt ART physicians to order or encourage patients to accept pre-conception testing of embryos, even when the progenitors are not at known risk for producing a child with a genetic disorder.⁸⁴ We do know that utilization of prenatal genetic testing is on the rise, though no cause and effect between the fear of legal liability and increased use has yet been suggested.⁸⁵

Drawing back to the clinical syndrome at issue—multiple pregnancy—how does or could the private tort system affect the practice of reproductive medicine in the realm of embryo transfer? If patients felt that their providers were too aggressive in transferring multiple embryos, we might expect to see suits seeking damages for the birth of twins, triplets, etc. We don't.⁸⁶ If patients felt their providers were too timid in transferring too few embryos, we might expect to see suits seeking damages for failed IVF cycles. We don't. Few, if any, published cases against ART providers claim damages caused by the number of embryos transferred in a single IVF cycle. But this lack of empirical data does not necessarily mean that ART practitioners aren't impacted by the threat of litigation, either as to embryo transfer practices or any other aspect of the delivery of care. More research is needed to cull out exactly how the private tort system affects behaviors in reproductive medicine.

In sum, while ART is not the subject of comprehensive, top-down federal legislation, it is impacted by activity emanating from three sources: public law, self-regulation and private tort action. Taken as a whole, this source trilogy has and will continue to impact the way ART is delivered in the U.S., especially as the number of IVF-conceived children

84 See Janet Malek & Judith Daar, *A Case for a Parental Duty to Use Preimplantation Genetic Diagnosis for Medical Benefit*, 12 AM. J. BIOETHICS 3 (forthcoming 2012) (arguing physician liability for failure to use genetic testing on embryos could prompt a duty to do so).

85 See Gregory Katz & Stuart O. Schweitzer, *Implications of Genetic Testing for Health Policy*, 10 YALE J. HEALTH POL'Y L. & ETHICS 90, 93 (2010) (documenting the rise in prenatal genetic testing).

86 But see *infra* note 191 (describing Australian couple who, desiring a singleton, sued ART physician for birth of healthy twins).

continues to grow.⁸⁷ To say that ART is the wild west of medicine is to disregard the formal and informal mechanisms in place that shape the practice of reproductive medicine. This is not to say that greater regulation would be unwelcome or unwarranted, but that it would be in addition to existing structures. Thus, any new federal law on embryo transfers would be juxtaposed among regulations already in place. We now proceed to evaluate the merits of such a law, first thinking about the role federalism might play in the law's viability, and then moving to imagine how transfer limits could be effectively drafted and enforced.

II. Federalism Concerns: Congressional Authority to Regulate Health?

In February 2009, less than a month after the Suleman octuplets were born, a group of state senators in Georgia introduced a bill to limit the number of embryos transferred in any IVF cycle performed in the state. Georgia Senate Bill 169 provided, "[w]here a woman under age 40 is to receive treatment using . . . embryos created using her own eggs, . . . no person or entity shall transfer more than two embryos in any treatment cycle."⁸⁸ Other provisions limited women age 40 and over to three embryos per treatment cycle, and all women using embryos created with donor eggs to two per cycle.⁸⁹ The bill contained several penalties, including monetary fines, medical licensure revocation, and loss of credentialing for health care facilities in which violations occur.⁹⁰ The Georgia bill was limited to the practice of reproductive medicine within the state, an activity the legislature has traditionally and exclusively controlled.

While the above-mentioned portions of the Georgia bill never became law,⁹¹ imagine the same language incorporated into a bill introduced in the U.S. Senate. Instead of regulating physicians in one state, the federal practice restrictions would apply to doctors nationwide. Before exploring the steps lawmakers might go through to draft such a bill, and how such limits could be enforced, a threshold inquiry emerges: Would a federal embryo

87 For example, the growth in the patient and offspring ART population alone increases the population of potential plaintiffs in the private tort realm. According to the CDC, "The number of ART cycles performed in the United States has nearly doubled, from 87,636 cycles in 1999 to 148,055 in 2008. The number of live-birth deliveries in 2008 (46,326) was more than two times higher than in 1999 (21,746). The number of infants born who were conceived using ART also increased steadily between 1999 and 2008. In 2008, 61,426 infants were born, which was more than two times higher than the 30,629 born in 1999." 2008 ART REPORT, *supra* note 7, at 65.

88 S.B. 169 § 19-7-67(a), 150th Gen. Assemb., Reg. Sess. (Ga. 2009).

89 *Id.* at § 19-7-67(b)–(c).

90 *Id.* at § 19-7-72.

91 *See supra* note 21.

transfer limit violate principles of federalism? When a federal law ventures into matters traditionally regulated by the states, such as the practice of medicine, its constitutional validity is worthy of examination.

A. Federalism and the 1992 ART Law

The task of drafting and assuring compliance with a federal embryo transfer law is daunting enough as a practical matter, but such regulation may face a greater challenge for its violation of long-held principles of federalism. Federalism, at its core, is the constitutional division of authority between federal and state governments.⁹² The U.S. Constitution creates a federal government of enumerated powers.⁹³ As the Supreme Court explains in *U.S. v. Lopez*, “. . . James Madison wrote: ‘The powers delegated by the proposed Constitution to the federal government are few and defined. Those which are to remain in the State governments are numerous and indefinite.’”⁹⁴ The Court continues, “This constitutionally mandated division of authority was adopted by the Framers to ensure protection of our fundamental liberties . . . [and] reduce the risk of tyranny and abuse from either front.”⁹⁵ One explicit delegation of authority to the federal government is Congress’ power to “regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.”⁹⁶ Whether Congress could regulate embryo transfer limits under the Commerce Clause is unclear, thus prompting federalism concerns.

Concomitant to Congress’ authority to regulate interstate commerce under the Commerce Clause are the states’ authority to regulate in certain areas, including health, even if such laws have a substantial effect on interstate commerce.⁹⁷ According to the Court in *Lopez*, “health laws of every description,” are within the province of the states and cannot be regulated by Congress. These health laws are a small part “of that immense mass of legislation . . . not surrendered to a general government.”⁹⁸ Health law in general and the practice of medicine in particular have been the province of state law. Thus the question arises, if a national embryo transfer law is considered a law regulating either health or the practice of medicine, could it withstand a constitutional challenge that such a law exceeds Congress’ authority to regulate in an area traditionally left to the states?

92 *U.S. v. Lopez*, 514 U.S. 549, 576 (1995) (quoting *Coleman v. Thompson*, 501 U.S. 722, 759 (1991) (Blackmun, J., dissenting)).

93 U.S. CONST. art. I, § 8.

94 *Lopez*, 514 U.S. at 552 (quoting THE FEDERALIST NO. 45 292–93 (C. Rossiter ed., 1961)).

95 *Id.* (citing *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991)).

96 *Id.* (quoting THE FEDERALIST NO. 45, *supra* note 94, at 292–93).

97 *Id.* at 594 (quoting *Gibbons v. Ogden*, 22 U.S. 1, 203 (1824)).

98 *Id.*

A first place to explore is the only existing federal law regulating ART. The Fertility Clinic Success Rate and Certification Act of 1992, as previously discussed, contains two essential mandates. First, FCSRCA mandates that ART programs annually report and the CDC annually publish pregnancy success rates as defined in the Act.⁹⁹ Second, the federal law mandates the CDC develop a model program for the certification of embryo laboratories available for adoption in the states.¹⁰⁰ Arguably, these mandates do not regulate health or medicine per se, because they have no direct impact on patient care. Requiring clinics report usage statistics and pregnancy outcomes does not, at first blush, appear related to the care patients receive.¹⁰¹ Nor does the establishment of standardized laboratory practices for embryo cultivation sound in the practice of medicine - as such standards would guide embryologists in the handling of gametes and embryos before they reach a patient's body. But clearly federal lawmakers had federalism concerns in mind when they drafted FCSRCA.

In the section mandating development of a model embryo program, the Act provides, "In developing the certification program, the Secretary may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs."¹⁰² This admonition that the CDC not supervise or control medical practice in ART programs is a clear acknowledgment of Congress' lack of authority to regulate the practice of reproductive medicine. Clinical judgment about the number of embryos to transfer on a patient-by-patient basis lies at the heart of the practice of medicine. While a patient's age is relevant to this calculus, other factors including diagnosis, prior IVF history and male factor play in role in the treatment plan.¹⁰³ A federal law that actively and directly substitutes for clinical judgment by specifying the number of embryos a physician can transfer in any IVF cycle seems the essence of the practice of medicine. As such, the law should be vulnerable to attack on federalism grounds. Whether FCSRCA could withstand such an attack is unknown, as no state has yet adopted the CDC certification program, and thus

99 42 U.S.C. § 263a-1(a)(1) (2010).

100 *Id.* at § 263a-2(a)(1) (2010).

101 Theoretically, one can imagine that in the competitive ART world, requiring clinics to publish their annual success rates could incentivize them to hand-select patients most likely to give birth (while refusing to treat higher risk women), or treat patients more aggressively (with multiple embryos transferred) in order to improve their annual statistics. No evidence suggests that the federal law has had such an impact on individual practices.

102 42 U.S.C. § 263a-2(i) (2010).

103 Practice Committee Guidelines, *supra* note 53.

no federalism challenge has been mounted. For guidance, we turn to another federal law that also arguably regulates the practice of medicine, and that has been subject to judicial review, the Federal Partial-Birth Abortion Ban Act.

B. Federalism and the Partial-Birth Abortion Act

Judicial guidance on the question of federal authority to regulate ART is virtually nonexistent,¹⁰⁴ but commentators have weighed in on the arguably related arena of federal regulation of abortion. While ART seeks to begin a pregnancy and abortion is used for termination, both clinical practices match physicians and patients in medical scenarios surrounding procreation. Like ART, abortion as a medical practice is mostly regulated at the state level, save a few attempts to ban certain procedures at the federal level.¹⁰⁵ In 2003, Congress enacted and President George W. Bush signed the first federal law regulating abortion practices. The Partial-Birth Abortion Ban Act of 2003 (PBABA) banned the use of certain techniques used in post-first trimester abortions.¹⁰⁶ Shortly after its enactment, the law was challenged by four physicians on constitutional grounds, mostly focused on reproductive liberty and vagueness concerns.¹⁰⁷ Not surprisingly, the case proceeded to the U.S. Supreme Court which granted certiorari on the question whether the Act's lack of a health exception rendered the law unconstitutional.¹⁰⁸ While neither the lower courts nor the Supreme Court showed an interest in evaluating the PBABA on Commerce Clause grounds, academic commentary on the matter flourished.

104 There are no cases that arise under the FCSRCA. But at least one federal court has weighed in on the question of whether a state abortion law violates the federal constitution by infringing on a physician's right to practice in the ART field. In *Lifchez v. Hartigan*, 735 F. Supp. 1361 (N.D. Ill. 1990), infertility specialist Dr. Lifchez brought a class action suit challenging the constitutionality of a provision of the Illinois Abortion Law that prohibited fetal experimentation, on the grounds that the law was vague and it infringed on a woman's right of reproductive freedom. Even though the law specifically exempted "the performance of in vitro fertilization," the court agreed that the language was vague because Dr. Lifchez and other similarly situated physicians would be at risk of prosecution for ART techniques and modifications that are not within the IVF exemption. The court also agreed that the law impermissibly restricted a woman's fundamental right of privacy because it prohibited procedures (for example, embryo transfer and chorionic villi sampling) that should be protected under "a woman's zone of privacy as recognized in *Roe v. Wade*." *Id.* at 1376.

105 In the 1990s, Congress passed two laws banning partial-birth abortion, but both were vetoed by President Clinton. See Tamara F. Kushnir, *It's My Body, It's My Choice: The Partial-Birth Abortion Ban Act of 2003*, 35 LOY. U. CHI. L.J. 1117, 1149–52 (2004) (describing the House and Senate votes and President Clinton's subsequent vetoes).

106 18 U.S.C. § 1531 (2003).

107 *Carhart v. Ashcroft*, 331 F. Supp.2d 805 (D. Neb. 2004).

108 Brief for the Petitioner at 1, *Gonzales v. Planned Parenthood Fed'n of Am., Inc.*, 547 U.S. 1205 (2006).

Both before and after the Court handed down its 2007 decision in *Gonzales v. Carhart* analyzing the constitutionality of the federal law banning partial-birth abortion,¹⁰⁹ scholars debated the Act's ability to withstand a challenge grounded in the Commerce Clause. Before the decision was announced, one scholar opined that the PBABA could pass constitutional muster under current (and recently vacillating) interpretations of the Commerce Clause because "performing partial-birth abortions is a type of 'commerce'—the sale of a service by professionals engaged in a market-oriented enterprise . . . [that] have an effect on interstate commerce significant enough to warrant regulation."¹¹⁰

Under similar reasoning, it is possible to likewise sustain the constitutionality of an ART law because reproductive medicine is a multi-billion dollar industry in which patients, gamete donors, gestational surrogates and physicians move within the several states.¹¹¹ With over 435 fertility clinics nationwide performing nearly 150,000 cycles of IVF annually, odds are good that those who perform, receive and supply ART goods and services travel across state lines in the name of family formation.¹¹² Under this line of analysis, physician conduct is viewed not as the practice of medicine, but rather the delivery of services into the national stream of commerce. As such, any attack on a federal embryo law as usurping the states' exclusive authority to regulate the practice of medicine would fail.

Turning back to whether federal regulation of abortion exceeds Congress' authority, the PBABA's validity under the Commerce Clause remains a mystery because the Court never reached this question in *Gonzales*. Another commentator, writing after the *Gonzales* decision was handed down, remarked that the Act was "inexplicably spared an attack on . . . [the question of] whether it was a proper exercise of Congress' Commerce Clause authority" because opponents of the PBABA failed to raise the issue.¹¹³ This author speculated that had Justice Thomas, the justice "most likely to hold that the PBABA is not

109 550 U.S. 124 (2007).

110 Robert J. Pushaw, Jr., *Does Congress Have the Constitutional Power to Prohibit Partial-Birth Abortion?*, 42 HARV. J. ON LEGIS. 319, 322–23 (2005).

111 See DEBORAH SPAR, *THE BABY BUSINESS* (2006) (documenting the flow of ART commerce within the U.S. and abroad).

112 See 2008 ART Report, *supra* note 7, at 13.

113 Keith S. Alexander, *Federalism, Abortion, and the Original Meaning of the Fourteenth Amendment Enforcement Power: Can Congress Ban Partial-Birth Abortion After Carhart?* 13 TEX. REV. L. & POL'Y 105, 107 (2008). The author speculates that opponents of the federal law intentionally failed to raise the Commerce Clause issue because striking down the PBABA on those grounds would endanger the constitutionality of the Freedom of Access to Clinic Entrance Act, 18 U.S.C. § 248 (2000), which restricts abortion clinic picketing on Commerce Clause grounds. *Id.*

a proper exercise of Congress's commerce power," reached the question of congressional authority to regulate abortion, he would have been hard pressed to uphold the law under the Commerce Clause, but could have salvaged the Act under Congress' enforcement power under the Fourteenth Amendment.¹¹⁴ The PBABA, this author argues, is both a criminal and a health law, meaning it doubly encroaches on the type of police authority traditionally left to the states. For this reason, if challenged under the Commerce Clause, abortion regulation that criminalizes one aspect of the practice of medicine is unlikely to survive Justice Thomas's constitutional scrutiny.¹¹⁵

The ability of a federal embryo law to survive a Commerce Clause attack is likewise unknowable at this time. More recent jurisprudence from the Court suggests a friendlier view of federal regulation aimed at protecting the nation's health. In *Gonzales v. Raich*,¹¹⁶ the court upheld application of the federal Controlled Substances Act to intrastate users and growers of medical marijuana sanctioned under state law. Those challenging the CSA argued that its application to a purely intrastate activity violated the Commerce Clause, because home-grown and home-consumed marijuana has no effect on interstate commerce. The Court disagreed, upholding the CSA as applied. Writing for the majority, Justice Stevens explained that "the regulation is squarely within Congress' commerce power because production of the commodity meant for home consumption, be it wheat or marijuana, has a substantial effect on supply and demand in the national market for that commodity."¹¹⁷

With such a low bar for activating federal authority, if ART services were viewed as commercial in nature, it seems likely a post-*Raich* court would find they impact the national market. If a thimble of home grown medical marijuana could trigger interstate commerce activity, no doubt the exchange of \$3 billion of goods and services annually would fall under Congress' purview.¹¹⁸ While ART is at its core a medical procedure, it is difficult to ignore the significant interstate movement of people, gametes and pharmaceuticals that are integral to the field.

Were Congress to enact a federal embryo transfer law, at the very least it should consider the susceptibility of this health-related regulation to a Commerce Clause attack.

114 *Id.* at 110.

115 *Id.* at 115.

116 545 U.S. 1 (2005).

117 *Id.* at 19.

118 See Spar, *supra* note 111.

Aspects of such a law could be tailored to invite or avoid such a challenge. For example, if criminal penalties are assessed for transfer of excess embryos, as opposed to civil or licensure-based fines, the bill would encroach on both criminal and health regulation, two areas traditionally left to the states. Thus this type of law would be twice invading the states' police power and could trigger a less favorable review by federalism-minded courts. Alternatively, Congress could build the legislative history to reflect the enormous impact ART has on interstate commerce, as a way of anticipating and possibly staving off invalidation under the Commerce Clause. The risks and benefits of regulating embryo transfer under federal law are far more complex than what advocates for such a regime have considered. What advocates have considered is a law reducing overall embryo transfers in the U.S. to which we now turn.

III. A Tweak in the System: Federalizing Embryo Transfers

If Congress were to enact a practice guideline limiting embryo transfers in IVF, what would such a scheme look like and how would the designated enforcer monitor and assure compliance? These answers depend upon a host of factors, including the type of transfer restriction adopted; the selection of the designated enforcer, the nature of the penalty for noncompliance, and the applicability of competing federal and state laws that govern the practice of medicine. Once each of these factors is addressed, a scheme for establishing and monitoring compliance of embryo transfer restrictions can coalesce around existing models or emerge as a newly envisioned approach. What follows are proposals for several statutory schemes, along with companion analyses of the merits of each proposal.

A. Designing Law: Drafting an American-Style ART Law

Designs for requiring, monitoring and assuring compliance with embryo transfer limits are more easily drawn in countries with comprehensive top-down regulatory schemes than in the U.S. where ART clinics operate outside a nationalized licensing system.¹¹⁹

119 For example, in the UK, the Human Fertilisation and Embryology Authority (HFEA) is authorized by national law to prescribe standards of practice and license for all fertility clinics in the country, including both public and private facilities. The HFEA Code of Practice specifies clinical guidelines for the provision of all ART-related treatments, including the number of embryos permitted to be transferred in any single IVF cycle. See Human Fertilisation & Embryology Authority, *Code of Practice* (8th ed. 2009), available at <http://www.hfea.gov.uk/code.html> (limiting women under forty to two embryos per transfer, and those over forty to no more than three in any treatment cycle)[hereinafter *Code of Practice*]. In Sweden, another jurisdiction with a long-standing national regulatory scheme—the 1988 Act on In-Vitro Fertilization—the National Board on Health and Welfare issues guidelines on the number of embryos per cycle to be replaced in its government-licensed clinics. See Glennon, *supra* note 64, at 244.

The absence of a single federal authority imbued with inspection authority and licensure control complicates the task of monitoring and assuring compliance. Any system in which the data collector is not simultaneously authorized to enforce predetermined standards is vulnerable to breakdown as information flows from the gatherer to those charged with collating, assessing and ultimately acting on the data procured. Moreover, even if under a new law the data collector is authorized to impose penalties for excess embryo transfers, the absence of a national clinic licensing system means that individual physicians must be the target of penalty incentives. Incentivizing individual as opposed to institutional behavior would lie at the heart of any U.S. ART law. With these structural realities in mind, a plan for establishing, monitoring and assuring compliance with embryo transfer restrictions can and should be envisioned, if only to assess such a law's prospective usefulness in ultimately reducing the multiple birth rate in the U.S.

1. Bare Bones Law: Mandating Reporting of Embryo Transfers

The primary goal of a national embryo transfer law would be to reduce the incidence of multiple birth, including twins, in the U.S. Secondary goals might include changing patient and physician attitudes toward multiple pregnancy through education so that both populations become less tolerant of this clinical outcome.¹²⁰ Other goals might focus on harmonizing clinical practices across the country, since current state-based practice standards permit variation from jurisdiction to jurisdiction. Thinking through how statutory embryo transfer restrictions could be operationalized, let us assume in a nod toward efficiency existing law could be amended to accomplish all the goals of any such scheme. The 1992 Fertility Clinic Success Rate and Certification Act (FCSRCA), with its two part structure for clinical reporting and certification of embryo laboratories, could be amended to include the three components necessary to achieving clinical reporting and transfer-limitation adherence.¹²¹

First, FCSRCA could adopt mandatory reporting requirements, replacing the current quasi-voluntary system which merely acknowledges—rather than punishes—nonreporting. Second, the law would need to incorporate some type of clinical guideline or restriction that specified the exact number of embryos that could be transferred in each treatment cycle. As suggested below, this critical part of any new law could be developed from existing models in both the U.S. and abroad that address embryo transfer limits. Finally, the revised FCSRCA would need to enhance its penalty language for noncompliance, both

¹²⁰ See Glennon, *supra* note 64, at 193 (discussing HFEA attempts to change “the culture of clinics” to develop strategies to reduce the rates of multiple births).

¹²¹ Assisted Reproductive Technology Programs Act 42 U.S.C. § 263a-1-a-7 (2010).

for nonreporting of clinical data and for nonadherence to enacted clinical guidelines. Each of these changes to existing federal law are considered below.

a. Adding Mandatory Reporting Language

Amending FCSRCA to impose mandatory annual reporting of the number of embryos transferred in every ART cycle seems simple enough. Currently, the law provides:

... [E]ach assisted reproductive technology . . . program shall annually report to the Secretary through the Centers for Disease Control

(1) pregnancy success rates achieved by such program through each assisted reproductive technology, and

(2) the identity of each embryo laboratory . . . used by such program and whether the laboratory is certified under [this Act].¹²²

A third section, mandating reporting of all embryo transfers, could be added as follows: “(3) the number of embryos transferred into a patient in each assisted reproductive technology.” Adding reporting language for embryo transfers, however, may have little practical effect. Though FCSRCA does not contain this language requiring reporting of embryo transfers, clinics that annually report under the Act do provide this data.¹²³ Patients interested in knowing the average number of embryos transferred in every reporting ART clinic can easily access this information online.¹²⁴ Still, adding mandated reporting of embryo transfer to the federal law may provide an unintended benefit. Critics of FCSRCA charge that public disclosure of individual clinic success rates incentivizes physicians to transfer more embryos than are clinically recommended to boost pregnancy success rates.¹²⁵ Requiring reporting of both embryo transfers per patient and corresponding success rates would provide patients greater insight into clinical outcomes at each facility. Knowing that one clinic transfers more embryos to achieve a similar success rate to another clinic could

¹²² *Id.* § 263a-1(a).

¹²³ See 2008 ART REPORT, *supra* note 7, at 47.

¹²⁴ See, e.g., DIV. OF REPROD. HEALTH, NAT’L CTR. FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION, ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS (2008), available at http://www.cdc.gov/art/ART2008/PDF/ART_2008_Full.pdf (last visited June 20, 2012) (providing embryo transfer data from clinics reporting in 2008).

¹²⁵ See Camille M. Davidson, *Octomom and Multi-Fetal Pregnancies: Why Federal Legislation Should Require Insurers to Cover In Vitro Fertilization*, 17 WM. & MARY J. WOMEN & L. 135 (2010).

signal a more skilled physician and embryologist, though patients should also investigate other factors including age and multiple birth rates.

b. Adding Civil Fines for Nonreporting

Since the reporting requirement of the Act is already drafted as a mandatory requirement (each program “shall” annually report), amendments could be made to the “penalty” section that now addresses noncompliance. Section 5 of the Act directs the CDC to annually publish the pregnancy success rates reported in Section 1, and

in the case of an assisted reproductive technology program which failed to report one or more success rates as required under such section, the name of each such program and each pregnancy success rate which the program failed to report.¹²⁶

A far more meaningful (and behavior-modifying) penalty might be to add a substantial monetary fine for failure to report success rates and embryo transfers. For example, the following language could be added to this provision:

Each assisted reproductive technology program which failed to report one or more pregnancy success rates or one or more embryo transfer rates shall be fined \$50,000 for each annual failure to report. The total fine imposed on a single program shall not exceed \$100,000 annually.

The amount of the fine associated with nonreporting could be calculated to account for (and stave off) potential strategic behavior on the part of a program. If, for example, a program with relatively low success rates concluded that the risk to their existing business posed by reporting unfavorable data—measured by the loss of revenue from prospective patients who go elsewhere for treatment cycles—was greater than the fines themselves, then such a program could decide to pay the fine rather than risk a greater loss of revenue that could be produced by reporting. Certainly there is some fine that is high enough to inspire compliance, but that amount might alternatively produce questions of proportionality between the act and the punishment.¹²⁷

¹²⁶ 42 U.S.C. § 263a-5(A) (2010).

¹²⁷ More problematic may be the willingness and ability of regulators to collect this civil fine, a topic discussed in Part III.B.2.

Once the statute is amended to include mandatory reporting language and an associated penalty structure for nonreporting, the next task would be to codify the clinical standards lawmakers believe would achieve their policy objectives. As previously noted, the rate of ART-related multiple births in the U.S. stands stubbornly at around 32% of all cycles in which live offspring are born.¹²⁸ Notably, only a small fraction of this number includes higher-order multiple births—that is, triplets or greater. Only 1.8% of all ART-related births are higher-order, setting the twin rate at around 30%.¹²⁹ Logically, modalities that reduce the rate of twins will simultaneously reduce the rate of higher-order multiple births as a natural consequence of embryo transfer reduction. Thus, lawmakers could adopt “reduce the rate of ART multiple births” as a generalized objective without having to target specific clinical outcomes. Though subtle, this more generalized goal avoids the perception that Congress is attacking one family in particular (for example, if the goal were to “reduce octuplet pregnancies”), but instead is addressing a more widespread problem.

c. Monitoring Compliance Through Data Collection

Once mandatory reporting requirements for embryo transfer are in place, how would the designated enforcer assure compliance with the statutory scheme? What strategies could be put in place to ensure the accuracy of the data reported? In Part III.A.1.a we assumed that the system for collecting data on embryo transfers would either parallel or piggyback on the existing system used to collect data on ART outcomes under FCSRCA. Recall that FCSRCA requires each ART clinic to “annually report to the Secretary [of Health and Human Services] through the Center for Disease Control . . . pregnancy success rates achieved by such program through each assisted reproductive technology.”¹³⁰ For efficiency sake, it would make sense to utilize the existing reporting structures put in place under the 1992 law, as these structures involve outreach to all fertility clinics known to be in operation in the U.S.

The federal ART reporting structure is described in each annual report; the 2008 report describes the reporting and data collection system as follows:

CDC contracts with a statistical survey research organization, Westat, to obtain the data published in the ART success rates report. Westat maintains a list of all ART clinics known to be in operation and tracks

128 See 2008 ART REPORT, *supra* note 7, at 25 (reporting 31.6% of ART cycles using fresh nondonor eggs or embryos resulted in a multiple-infant live birth).

129 *Id.*

130 42 U.S.C. § 263a-1(a)(1).

clinic reorganizations and closings . . . Westat actively follows up reports of ART physicians or clinics not on its list to update the list as needed. Westat maintains NASS, the Web-based data collection system that all ART clinics use. Clinics either electronically enter or import data into NASS for each ART procedure they start in a given reporting year. The data collected include information on the client's medical history (such as infertility diagnoses), clinical information pertaining to the ART procedure, and information on resulting pregnancies and births.¹³¹

The above description makes clear that the current data collection system relies almost exclusively on self-reporting by individual clinics. Some measures for quality control are in place, including site visits to randomly selected clinics for validation of data. In 2008, members of the Westat Validation Team visited 35 of 436 reporting clinics, and found that “[i]n almost all cases, data available in the medical records on pregnancies and births were consistent with reported data.”¹³² Given this intact and evolved reporting system, it seems both sensible and efficient that any change in federal law requiring disclosure of embryo transfer numbers be incorporated into FCSRCA.

As a practical matter, however, such a change in the law may not be necessary. As previously noted, though not explicitly admonished to do so under the law, the CDC, via Westat, already collects data on the number of embryos transferred in every ART cycle.¹³³ In 2008, for example, embryo transfer data is presented in three separate charts, revealing that 38% of all ART cycles involved the transfer of three or more embryos.¹³⁴ Keep in mind that current clinic reporting is legally nonconsequential; there are no legal penalties either for failing to report¹³⁵ or based on the nature of the data reported. Query whether clinics would be as participatory or forthcoming if penalties were attached to the data reported, as would likely be the case in any new law cracking down on multiple birth rates through the regulation of embryo transfers.

131 2008 ART REPORT, *supra* note 7, at 4.

132 *Id.* at 7.

133 See *supra* text accompanying note 132.

134 2008 ART REPORT, *supra* note 7, at 47 (reporting the number of embryos transferred during ART cycles using fresh nondonor eggs or embryos). The data also show that pregnancy success rates were all higher when two, three, four, five, or more embryos were transferred, as compared to a single embryo transfer. *Id.* at 49.

135 A valid critique of FCSRCA is that it does not have any “teeth” to penalize nonreporters other than through shaming. Clinics that are known to Westat and fail to report their annual data are listed at the end of the report in a section entitled, “Nonreporting ART Clinics for 2008, By State.” About forty programs are listed, roughly ten percent of all known ART clinics in the U.S. See 2008 ART REPORT, *supra* note 7, at 580–82.

Penalizing excess embryo transfers could impact clinic reporting behavior. Any new law should include a mechanism to maximize the veracity of reported data. Under existing law, clinics report specified data on each cycle initiated in a given calendar year. If the number of embryos transferred per cycle were made a required data point, how certain could regulators be that the data reported was accurate? As is now the practice, either the CDC or its contracted surrogate could visit selected clinics to review patient medical records as a quality control measure. But what if the data written in the medical record is in error, either by neglect or intent? Should a federal law authorize the data collector to verify that the medical record is accurate? How might such verification actually take shape?

What if, for example, a patient's medical record indicates that two embryos were transferred (say, in compliance with the new federal law), but that triplets were born of this cycle? Such a clinical scenario is not impossible. The incidence of monozygote twinning has been described in IVF, meaning that a triplet birth could result from a double embryo transfer.¹³⁶ Should regulators have the authority to order genetic testing on the triplets to verify that two of offspring are monozygotic? What if, as another example, a medical record indicates that only one embryo was transferred and that a miscarriage occurred at 10 weeks into the pregnancy. Should regulators have the authority to subpoena the medical records from the physician attending to the patient during miscarriage to spot references to more than one embryonic sac being detected?

As invasive and distasteful as these measures are, they represent the best clinical means to verify the accuracy of embryo transfer reporting. This fact alone should alert us to the competing concerns of individual privacy and societal interests that any federal embryo law must navigate. Clearly the law would not probe into post-treatment medical records (of miscarriages or the genetic provenance of offspring) in order to verify the embryo transfer data contained in the ART chart. But at the same time a clinic whose transfer data indicates compliance with clinical standards, but whose multiple birth rates suggest noncompliance should be subject to some scrutiny by regulators. Short of watching embryo transfers in the operating suite - another ghastly invasion of patient privacy - it is difficult to construct an appropriate method of verification. At the very least, Congress should contemplate the problematic nature of data verification before proceeding to enact federal law mandating reporting and adherence to national embryo transfer limits.

136 See K. I. Aston, C. M. Peterson & D. T. Carrell, *Monozygote Twinning Associated with Assisted Reproductive Technologies: A Review*, 136 REPROD. 377 (2008) (reporting that twin pregnancies occur at a significantly higher rate following IVF compared with the natural incidence).

2. Too Many Choices: Selecting the Clinical Guidelines

Once federal law is either enacted or amended to require reporting of embryo transfers, the query moves to normative concerns. Lawmakers would need to contemplate which clinical configuration would most likely produce the desired outcome—reduction (by what amount?) of ART multiple births. How should Congress formulate the clinical guidelines it intends to impose on practitioners nationwide? At least three choices present themselves, each yielding very different implications for ART patients and practitioners.

a. Incorporation by Reference

First, Congress could simply incorporate by reference the ASRM guidelines on embryo transfers, as the Missouri legislature contemplated doing in the wake of the Suleman births.¹³⁷ The proposed Missouri law provided:

When treating infertility, physicians within the state of Missouri shall not implant more embryos into a human than the current recommendations set forth by the American Society for Reproductive Medicine, or its successor.¹³⁸

A federal law could simply substitute the jurisdictional term “within the United States” for the regional reference to the state of Missouri. Referencing and incorporating into law the “current recommendations” on IVF embryo transfers set forth by the ASRM Practice Committee may garner the most support from ART practitioners, should any support for the overall idea be forthcoming.¹³⁹ Incorporation by reference could be attractive to the practice for at least three reasons. First, referencing “current recommendations” permits the law to remain clinically relevant as technology evolves. Updates in the ASRM practice guidelines based on scientific and patient data would be incorporated by operation of law into the federal statute. The efficiency of such an approach may likewise be attractive to lawmakers. Instead of having to establish a commission to periodically review a set of legislated standards, the law could rely on those efforts already underway in the private sector.

137 See *supra* note 21.

138 H.B. 810, § 334.350, 95th Gen. Assemb., 1st Reg. Sess. (Mo. 2009).

139 The *Guidelines on Number of Embryos Transferred* were originally developed and published by the Society for Assisted Reproductive Technology (SART) and ASRM Practice Committees in 1998, with five subsequent revisions. Thereafter, reference to the ASRM Practice Committee includes the SART Practice Committee as well. See S. Ory, *The American Octuplet Experience: A Transformative Event*, 93 FERTILITY & STERILITY 337 (2010).

A second feature of the incorporation approach that might capture practitioner support is the opportunity for those most clinically knowledgeable about the practice to have input into the regulatory scheme. The ASRM Practice Committee is comprised of physician members, often with differing subspecialties including reproductive endocrinology, ob/gyn and urology. The group meets periodically to review and issue clinical practice guidelines in the field of reproductive medicine. With respect to its published guidelines, the Committee admonishes:

These guidelines have been developed to assist physicians with clinical decisions regarding the care of their patients. They are not intended to be a protocol to be applied in all situations, and cannot substitute for the individual judgment of the treating physicians based on their knowledge of their patients and specific circumstances.¹⁴⁰

While discussion of the benefits, burdens and externalities of allowing professionals to generate the legal standards under which they must operate is beyond the scope of this piece,¹⁴¹ a simple observation can be made that if evolving practice guidelines were incorporated into federal law, ART practitioners would have significant influence on national clinical standards. The notion that physicians be left to write their own rules has evoked expected concerns about the methods, goals and transparencies of such a process. Professor John Robertson nicely summarizes these concerns, warning, "If the guidelines are to be the equivalent of law, then how they are arrived at will have to be more closely scrutinized, the process of writing them opened up, and measures taken to assure they do not simply protect the interest of doctors."¹⁴²

Finally and relatedly, incorporating ASRM guidelines would be a welcome show of congressional deference from the perspective of practicing physicians, which may ultimately boost compliance. ASRM and individual practitioners have long bemoaned the scrutiny and knee-jerk legislating that has, in their view, doggedly accompanied ART.¹⁴³ In the wake of the Suleman births, Steven Ory, a past president of ASRM published on

140 ASRM Practice Committee Guidelines, available at <https://www.asrm.org/Guidelines/> (last visited Jan. 25, 2011).

141 See generally RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 218–19 (8th ed. 2010) (discussing the codification of industry custom as liability rules and its impact on customers and bystanders).

142 Robertson, *supra* note 11, at 28.

143 See David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 78 *FERTILITY & STERILITY* 932 (2002) (arguing that extensive media coverage of ART mishaps contributes to the perception that the industry is unregulated).

editorial in which he acknowledged that public outrage over abuses by ART physicians had reached “a tipping point which demand a more engaged response.”¹⁴⁴ After confessing that professional ART organizations have been historically reluctant to sanction “outlier” practitioners who violate published guidelines, Dr. Ory called upon his colleagues to take a more active role in addressing aberrant clinical practice. “If we are unwilling to assume this role,” he cautioned, “it will ultimately devolve to a group less qualified and if we are silent, critical decisions will be made without our input.”¹⁴⁵ Dr. Ory’s call for action, while admittedly self-protective, represents an attitudinal shift that may usher in an era of greater awareness, regard and adherence to industry-sanctioned guidelines. Congressional incorporation by reference of ASRM guidelines may represent the least undesirable legislative response to the problem of multiple pregnancy, viewed from the industry’s perch.

b. Codification of Existing or Newly Derived Guidelines

A second regulatory option Congress could consider would be to codify specific clinical guidelines that spell out precise parameters for embryo transfer. For example, Congress could codify the ASRM practice guidelines on embryo transfers that exist at the time of enactment. The current guidelines, originally developed and published in 1998 have been reviewed and reissued five times, most recently in August 2009—around nine months after the octuplet birth.¹⁴⁶ As an alternative, Congress could hold hearings to determine what a wider array of participants (perhaps including practitioners from outside the U.S., as well as former and current ART patients) believe to be the appropriate clinical guidelines and then make an independent judgment about what the clinical standards should be. This “fresh” look would be favored by ASRM critics, at least one of whom charges that ASRM has “failed to provide effective leadership regarding the reduction of multiple gestations.”¹⁴⁷ In a highly critical article, Professor Theresa Glennon questions the effectiveness of ASRM guidelines, “developed through a closed-door process” that might favor “clinic profits” over “tougher guidelines.”¹⁴⁸ These guidelines, she posits, “lag behind the current recommendations of European professional associations” which she reports as more successful at reducing both the twin and higher-order multiple pregnancy rates across

144 Ory, *supra* note 139, at 338.

145 *Id.*

146 Practice Committee Guidelines, *supra* note 53.

147 Glennon, *supra* note 64, at 183.

148 *Id.*

their jurisdictions.¹⁴⁹

Assuming Congress did adopt the current ASRM guidelines into law, at least two concerns arise. First, a downside to codifying specific clinical guidelines is the inability of the law to remain current as the industry evolves. Once set numbers are codified, the sheer weight of the political process would disincentivize frequent updating. Another possible downside to the codification of specific clinical parameters is the complexity and nuance that accompany the current guidelines. The current ASRM guidelines set out recommended embryo transfer limits according to patient age, prognosis, embryo quality, and stage of development (3-day embryos vs. 5-day blastocysts). Briefly, for patients with a good prognosis (defined as those with good-quality embryos who have not failed prior IVF attempts), the following limits are recommended:

- A. For patients under age 35, consideration should be given to transferring only a single embryo. No more than two embryos should be transferred.
- B. For patients between 35 and 37, no more than two embryos should be transferred.
- C. For patients between 38 and 40, no more than three embryos should be transferred.
- D. For patients 41-42, no more than five embryos should be transferred.¹⁵⁰

The guidelines also speak to transfer limits when donor eggs are used, and when transfers involve frozen embryos or blastocyst cycles. Importantly, the Practice Committee makes clear that the recommendations are guidelines, susceptible to modification “according to individual clinical conditions.”¹⁵¹ Codifying the role of clinical judgment seems awkward, if not entirely unworkable from an enforcement perspective. In fact, the very nature of guidelines as nondirective and subject to ad hoc modification in the name of individual clinical conditions reveals the flaws in either incorporating or codifying existing (or future) clinical practice guidelines. As discussed in Part III.B, any federal law on embryo transfer would necessarily contain some type of enforcement scheme. Determining whether a particular treatment plan has run afoul of multifactorial and judgment-sensitive guidelines

149 *Id.* at 182.

150 Practice Committee Guidelines, *supra* note 53. The 2009 guidelines represent the fifth revision of these clinical standards since they were first issued in 1998. Each version of the guidelines has called for a progressive reduction in the number of embryos transferred.

151 *Id.*

may be too unwieldy a task for the federal government to undertake.

c. Adopting Strict and Narrow Limits

To avoid the interpretive morass associated with broad guidelines, federal regulators could opt for a third legislative alternative vis-à-vis embryo transfer standards: create and adopt strict and narrow limits. This approach has gained popularity in Europe, particularly in countries that comprehensively regulate (and fund) the provision of ART services. In Sweden for example, a country in which public funding usually supports up to three cycles of IVF, a 2003 law recommends that patients age 38 and younger be limited to single embryo transfer (SET).¹⁵² This recommendation, issued by the National Board on Health and Welfare has significantly reduced the multiple delivery rate from a high of 35% in 1991 to 5% as of 2004.¹⁵³ Interestingly, though SET is the nationally endorsed treatment plan, only two-thirds of all IVF cycles in Sweden employ SET, owing to a combination of the nonbinding nature of the recommendation and the use of double and higher embryo transfers in women aged 38 and older.¹⁵⁴ Still, Swedish physicians and patients are regarded as highly compliant with the SET standard, compared to U.S. stakeholders who are told “consideration should be given to transferring only a single embryo.” In 2008, elective single embryo transfers in the U.S. accounted for just 12% of all fresh non-donor ART cycles—compared to 67% in Sweden.¹⁵⁵

In the United Kingdom, another European example of highly-regulated, publicly-funded IVF, recommendations for embryo transfer are narrower and stricter than those in the U.S. Embryo transfers in the UK are regulated under the Human Fertilisation and Embryology Act, which established the Human Fertilisation and Embryology Authority (HFEA) to draft and publish standards of practice in ART.¹⁵⁶ The HFEA publishes clinical

152 See Olaf Karlström & Christina Bergh, *Reducing the Number of Embryos Transferred in Sweden—Impact on Delivery and Multiple Birth Rates*, 22 HUM. REPROD. 2202 (2007) (reporting that while delivery rates remained stable, multiple birth rates dropped significantly, from thirty-five percent to five percent); *Policy for Reimbursement*, IVF-WORLDWIDE.COM, <http://www.ivf-worldwide.com/Education/policy-of-reimbursement.html> (last visited Apr. 3, 2012).

153 *Id.* at 2203.

154 *Id.* at 2204 (showing a drop in SET beginning at age thirty-eight, dropping to twenty-six percent in women aged forty-one and older).

155 2008 ART REPORT, *supra* note 7, at 71.

156 See *supra* note 24.

standards in its Code of Practice, now in its eighth edition.¹⁵⁷ The Code of Practice section on multiple births contains the embryo transfer parameters. Labeled as “mandatory requirements,” this portion of the Code sets forth a “strategy to minimise multiple births,” containing a collection of directives that are part aspiration, part instruction. The 2009 Code aspires to reduce the annual multiple birth rate to 20% or lower, down from the 27% rate recorded in 2008.¹⁵⁸ The Code instructs individual centers on how to achieve the 20% goal through a “multilayered approach” combining embryo transfer limits, patient counseling, and individual patient recordkeeping.¹⁵⁹ The transfer limits, according to the HFEA, are as follows:

[Effective in] 2004 . . . a maximum of two embryos can be transferred to women under the age of 40, with no exceptions to this rule. A maximum of three embryos can be transferred in women aged 40 and over.¹⁶⁰

The “no more than two transfers” rule is also accompanied by a requirement that centers document in the patient’s medical record “an explanation of why the patient did not have SET.”¹⁶¹ The UK approach is clearly more stringent, both in terms of quantity and enforceability, than the guidelines offered in the U.S. Whereas the HFEA limits patients under 40 to two embryos, ASRM guidelines suggest this limit only for women age 37 or younger. Whereas the HFEA caps all embryo transfers at a maximum of three, ASRM recommends up to five embryos for patients aged 41–42. Whereas the HFEA limits apply to all ART centers in the UK, each of which risk license revocation for persistent violations, ASRM guidelines are entirely voluntary and carry no penalty other than membership

157 *Code of Practice*, *supra* note 119. According to the HFEA webpage, “The HFEA Code of Practice is intended to help and encourage licensed centres to understand and comply with their legal requirements. It also gives guidance on how centres are expected to go about meeting those requirements.”

158 See Human Fertilisation & Embryology Authority, *Multiple Births Minimisation Strategy: Achievements and Compliance*, *Code of Practice* (8th ed. 2009), available at <http://www.hfea.gov.uk/6195.html>.

159 See Glennon, *supra* note 64, at 189.

160 See Human Fertilisation & Embryology Authority, *Embryo Transfer and Multiple Births*, *Code of Practice* (8th ed. 2009), available at <http://www.hfea.gov.uk/2587.html>.

161 Human Fertilisation & Embryology Authority, *Multiple Births*, *Code of Practice* (8th ed. 2009), available at <http://www.hfea.gov.uk/401.html>.

revocation.¹⁶² Whereas the HFEA incentivizes SET by requiring a written justification in its absence, ASRM merely asks “consideration” of SET protocols.

Adoption of more limited parameters for embryo transfer is attractive for its simplicity, and may even be more effective in reducing multiple births than any other regulatory scheme, but rigid restrictions are vulnerable to significant critique for their failure to yield to individual patient presentation. For example, as has been now well documented, Nadya Suleman had six children born from five IVF cycles prior to the birth of her octuplets. What may be less well known is that Ms. Suleman’s 14 children were the result of 60 embryo transfers performed in seven IVF cycles, the last of which involved transfer of 12 embryos. Perhaps astonishingly true, Ms. Suleman gave birth to four singletons and one set of twins from 48 embryos—an 8 to 1 ratio per child.¹⁶³ Dr. Kamrava’s lawyer said that the doctor transferred so many embryos because his patient had “bad bad ovaries.”¹⁶⁴ Had Dr. Kamrava adhered to ASRM guidelines and transferred one or two embryos, it may be that his patient would have never become pregnant.

Though the impact of a change in Suleman’s treatment plan is impossible to know, what is knowable is that inflexible formulas for embryo transfer that dictate limits only according to patient age will deprive physicians and their patients of the benefits and burdens of clinical judgment. At the very least, if a UK or Swedish-style regulatory approach is adopted, consideration should be given to patient exceptionalism. A regulatory scheme that adopts narrower and more stringent parameters than those currently suggested by ASRM would hold more appeal for ART stakeholders if individual clinical conditions could be taken into account.¹⁶⁵ Instead of treating excess embryo transfers as per se violations of the law, the statute could require physicians to prove—even by clear and convincing evidence—that the particular scenario warranted clinical deviation. Placing the burden of

162 For example, in September 2009 ASRM expelled Michael Kamrava, the Beverly Hills physician who treated Nadya Suleman, for violation of the Society’s practice standards. See Rita Rubin, “*Octomom*” Doctor Expelled From Fertility Group, USA TODAY, Oct. 19, 2009, http://www.usatoday.com/news/health/2009-10-18-octomom-doctor-fertility_N.htm.

163 See *Octomom’s Fertility Doctor Testifies to Keep License*, USA TODAY (Oct. 20, 2010), http://www.usatoday.com/yourlife/health/medical/infertility/2010-10-20-octomom-doctor_N.htm; Original Accusation, *supra* note 46, at 3–5.

164 See *Probation Recommended for Octomom Doctor*, BEVERLY HILLS COURIER, Jan. 24, 2011, http://www.bhcourier.com/article/Local_News/Local_News/Probation_Recommended_For_Octomom_Doctor/74151.

165 The ASRM guidelines already suggest this “exceptionalism” approach. They provide: “[T]hese guidelines may be modified according to individual clinical conditions, including patient age, embryo quality, the opportunity for cryopreservation, and as clinical experience with newer techniques accumulates.” See Practice Guidelines, *supra* note 53, at 1518.

proving exceptional need for deviation on physicians may strike the right balance should U.S. IVF come under federal regulatory control.

In sum, any statutory embryo transfer limits should account for advances in the practice of reproductive medicine, as well as necessary accommodation for individual patient presentation. A law that is strictly numeric—linking age with the number of embryos to be transferred—robs patients and physicians of the exercise of clinical judgment that is essential to the delivery of high quality medical services. Putting standards in place to guide physician judgment, and to help physicians resist patient demands for excess transfers,¹⁶⁶ could have an appreciably impact on multiple birth rates. Incorporating into federal law guidelines that have already won industry approval would make for the smoothest transition from a voluntary to a mandatory system of clinical practice.

B. Designing Penalty and Enforcement Mechanisms

Once reporting mandates and embryo transfer limits are drafted, the final step in any comprehensive federal law is designing a penalty scheme that blends proportionality and practicality while encouraging compliance. Since the U.S. government does not currently license individual ART clinics, nor has there been any serious legislative effort to do so, the penalties associated with embryo transfer violations will be visited upon individual practitioners, rather than on groups of physicians who could be susceptible to enterprise liability for the malfeasance of a single member. Penalties against physicians could take on at least three forms: 1) criminal liability, 2) civil liability in the form of fines, and/or 3) license revocation via referral to a state medical board. Each penalty structure has already been invoked in one or more health care settings, enabling regulators to modify and apply existing statutory language to any proposed law.

1. Criminal Liability for Excess Embryo Transfer

If Congress were to enact a federal embryo transfer law and attach a criminal penalty for violations, it would be converting a currently lawful medical practice into a crime. Criminal statutes that penalize the performance of previously lawful medical procedures are rare but extant.¹⁶⁷ Also within the realm of criminalizing medical practice, there are instances in which physicians are prosecuted for conduct that is not per se unlawful but exceeds practice standards and thus crosses the line into criminality. Examples include assisting in the suicide of a terminally ill patient by prescribing a lethal dose of (lawful)

¹⁶⁶ See *infra* text accompanying note 225.

¹⁶⁷ See *infra* text accompanying note 171.

medication, or prescribing excessive opioids for patients experiencing chronic pain.¹⁶⁸ Contrast these latter cases in which the medical acts exceed the parameters established by licensing and professional authorities, with the criminalization of medical acts long approved as useful, valid and appropriate by these same standard setters. Prosecuting ART physicians for excess embryo transfers would transform a lawful medical practice into a criminal act. While seemingly implausible, Congress has converted lawful medical practices into criminal acts.

Probably the most well-known example of a law criminalizing a previously lawful medical practice is the Partial-Birth Abortion Ban Act of 2003 (PBABA).¹⁶⁹ The 2003 federal law followed prior attempts by state lawmakers to outlaw specific techniques used in post-first trimester abortions, including the Nebraska law struck down by the U.S. Supreme Court in *Stenberg v. Carhart*.¹⁷⁰ The federal law, upheld against constitutional challenges grounded in reproductive liberty and vagueness in *Gonzales v. Carhart*,¹⁷¹ provides, "Any physician who, in or affecting interstate or foreign commerce, knowingly performs a partial-birth abortion and thereby kills a human fetus shall be fined under this title or imprisoned not more than 2 years, or both."¹⁷² The PBABA defines the banned medical procedure in some detail,¹⁷³ and also codifies exceptions to the ban, providing, "This subsection does not apply to a partial-birth abortion that is necessary to save the life of a mother whose life is endangered by a physical disorder, physical illness, or physical injury, including a life-endangering physical condition caused by or arising from the pregnancy itself."¹⁷⁴

Though the statute does not specifically define the clinical circumstances under which the above-described safe harbor can be invoked, the PBABA does provide a framework for assessing whether liability should lie. An accused physician who raises the affirmative

168 See Diane Hoffmann, *Physicians Who Break the Law*, 53 ST. LOUIS U. L.J. 1049, 1062 (2009).

169 18 U.S.C. § 1531 (2003).

170 530 U.S. 914 (2000).

171 550 U.S. 124 (2007).

172 18 U.S.C. § 1531(a) (2003).

173 Under the PBABA, the phrase "partial-birth abortion" means an abortion in which the person performing the abortion "(A) deliberately and intentionally vaginally delivers a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother, for the purpose of performing an overt act that the person knows will kill the partially delivered living fetus; and (B) performs the overt act, other than completion of delivery, that kills the partially delivered living fetus." *Id.* § 1531(b)(1) (2003).

174 *Id.* § 1531(a).

defense supplied by the law “may seek a hearing before the State Medical Board on whether the physician’s conduct was necessary to save the life of the mother whose life was endangered by a physical disorder, physical illness, or physical injury, including a life-endangering physical condition caused by or arising from the pregnancy itself.”¹⁷⁵ These findings are then admissible at the physician’s trial, and may even provide a short delay in the prosecution.¹⁷⁶ Referral of questions of medical fact, i.e., whether a physical condition is life-endangering, to an established professional board seems a more sensible and efficient mechanism for fact-finding than leaving these questions to a lay jury or judge.¹⁷⁷

If Congress wanted to enforce embryo transfer limits by threat of criminal penalties, the PBABA could serve as a useful model for such an enactment. The PBABA sets out the prohibited conduct and consequential penalty, includes exceptions based on individual clinical circumstances, and provides a mechanism for determining the merits of asserted exceptionalism. Using the PBABA, along with a clinical scheme similar to the 2004 UK HFEA “two embryo” recommendations,¹⁷⁸ a federal law criminalizing excessive embryo transfer could read as follows:

(1) Any physician who, in or affecting interstate or foreign commerce, knowingly transfers more than two embryos into a patient under the age of 40, or more than three embryos into a patient age 40 or older, shall be punished by a fine not to exceed fifty thousand dollars (\$50,000), or imprisonment for not more than two years, or both.

(2) Subsection (1) does not apply to embryo transfers that exceed the limits set forth therein if the number of embryos transferred is necessary to significantly increase the likelihood a patient will become pregnant and deliver a single healthy child. In no case shall a physician transfer an excess number of embryos during a patient’s first attempt at embryo transfer. In no case shall a physician transfer more than four embryos into

175 *Id.* § 1531(d)(1).

176 *Id.* § 1531(d)(2).

177 A counterargument is that State Medical Boards are inclined to favor and support “their own,” especially when significant fines or jail time are at stake. Boards could engage in a sort of jury nullification, finding a patient’s condition to be life-threatening strictly for the purpose of sparing the defendant the possibility of conviction.

178 See Human Fertilisation Embryology Authority, *Multiple Births, Section 7.4, Code of Practice*, available at <http://www.hfea.gov.uk/401.html#guidanceSection3909> (last visited June 20, 2012) (limiting embryos transfer to no more than 2 for women under age 40).

a patient at one time.

(3) A defendant accused of an offense under this section may seek a hearing before the State Medical Board on whether the physician's conduct was necessary to significantly increase the likelihood a patient will become pregnant and deliver a single healthy child.

This law, or any criminal law like it, could certainly face challenges on several fronts. Like the PBABA, it could be challenged for violating principles of reproductive liberty, though the interests at stake are inverse. Whereas the PBABA (purportedly) aims to promote the birth of children by denying women the right to terminate their pregnancies at a certain time and in a certain manner, the embryo transfer law aims to reduce the birth of (too many) children by denying women the right to control the nature of their pregnancies (singleton v. multiple). Whether current constitutional jurisprudence governing the right to avoid procreation via contraception and abortion would apply equally, or at all, to the right to access procreation via ART is the subject of much academic discourse, but remains largely unresolved.¹⁷⁹

In addition to concerns about reproductive liberty, the law is susceptible to claims of vagueness. As the Court noted in *Gonzales v. Carhart*, “the void-for-vagueness doctrine requires that a penal statute define the criminal offense with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement.”¹⁸⁰ The above language prohibits any deviation from the age/numerical restrictions if the transfer occurs “during a patient’s first attempt at embryo transfer.” Does this mean her first transfer with the treating physician, or her first attempt ever? If the latter, who is to determine if a patient has previously sought treatment? If she is aware of the limitation for “first-timers” and fabricates a medical history of unsuccessful IVF attempts in order to receive more embryos, can a physician be imprisoned based on the patient’s malfeasance? What about the exemption based on “transfers . . . necessary to significantly increase the likelihood” of pregnancy? Even though this determination is referred to the State Medical Board, a physician would surely need more guidance on this concept to determine whether a particular transfer is authorized.

179 See Deborah L. Forman, *When “Bad” Mothers Make Worse Law: A Critique of Legislative Limits on Embryo Transfer*, 14 U. PA. J.L. & SOC. CHANGE 273 (2011) (summarizing academic literature comparing abortion and ART rights, and analyzing constitutionality of embryo transfer laws under current jurisprudence).

180 550 U.S. at 148–89 (quoting *Kolender v. Lawson*, 461 U.S. 352, 357 (1983); *Posters ‘N’ Things, Ltd. v. U.S.*, 511, 513 (1994)).

Constitutional queries aside, it seems unlikely that a federal embryo transfer law would invoke criminal penalties as a means of enforcement. Prosecuting and imprisoning doctors who help women get pregnant, even too pregnant, is problematic from an expressive, compliance and enforcement perspective. From an expressive perspective, criminalizing excess embryo transfer could be interpreted as devaluing or stigmatizing existing families with triplets, quadruplets, etc., or large families in general.¹⁸¹ By making the act of assisting in the birth of high order multiples illegal, the government could be seen as expressing negative or inappropriate attitudes not just toward existing individuals, but toward the entire infertile community who are susceptible, through no fault of their own, to multiple pregnancy. This state-sponsored attitude, and its ultimate rejection, was displayed in connection with the post-Octomom bill introduced in Georgia in 2009. That bill, S.B. 169, would have, among other things, limited embryo transfers to 2 or 3, depending upon patient age.¹⁸² Politically, the bill pitted those with religious objection to the creation of embryos via IVF against the ART patient and provider population who sought to preserve broad access to treatment.¹⁸³ Ultimately, the embryo restriction provisions were removed from the bill because, according to one political observer, “[R]eligious conservatives underestimated the reaction of couples who have had to cope with infertility.”¹⁸⁴

181 For a discussion of the expressive theories, see Elizabeth S. Anderson & Richard H. Pildes, *Expressive Theories of Law: A General Restatement*, 148 U. PA. L. REV. 1503, 1504 (2000) (explaining that expressivism is a method of evaluating action, “an internal account of existing normative practices, but one with sufficient critical capacity to exert leverage over those practices and to indicate where they ought to be reformed”).

182 See *supra* note 21.

183 While representatives of various religious groups, including the National Catholic Bioethics Center and the Catholic Church in Georgia, enlisted their supporters to work for adoption of S.B. 169, leaders in RESOLVE, a national infertility advocacy organization, and ASRM urged their respective members to oppose the bill as dictating a substandard level of care for those experiencing infertility. See *ASRM Comments on State Legislation*, AM. SOC’Y FOR REPROD. MED. (Mar. 5, 2009), <http://www.asrm.org/news/article.aspx?id=185> (calling the bill “unworkable” because it seeks to “substitute the judgment of politicians for that of physicians and their patients”); RESOLVE, *GA residents! If you’re not a RESOVLE [sic] member . . .*, THE BUMP, Mar. 3, 2009, available at <http://community.thebump.com/cs/ks/forums/thread/11907485.aspx> (RESOLVE web posting asking “Georgia residents who care about open access to the best care possible to let the Committee members know . . . that you oppose these two bills”); *BDF Legislation Addresses “Octomom” Abuses*, BIOETHICS DEF. FUND (Mar. 2, 2009), <http://www.bdfund.org/octomom-abuses> (urging support of “this bill [which] seeks to address a host of problems in addition to the currently highlighted abuse of transferring high numbers of embryos into the womb of a single, unemployed woman”).

184 See Jim Galloway, *Senate Bill Would Prohibit At Least One Form of Embryonic Stem Cell Research*, AJC, Mar. 12, 2009, <http://blogs.ajc.com/political-insider-jim-galloway/2009/03/12/senate-bill-would-prohibit-at-least-one-form-of-embryonic-stem-cell-research>.

Moving briefly to issues of physician compliance and prosecutorial enforcement of laws criminalizing doctor conduct, Professor Diane Hoffmann has written comprehensively about this issue.¹⁸⁵ She bifurcates her analysis into two areas of physician lawbreaking: 1) violations of business related laws, such as those regulating billing and insurance, and 2) violations of patient care related laws, such as those regulating clinical practice and patient well-being. While business lawbreaking is typically motivated by greed, violations of patient care laws are characteristically motivated by a desire help patients in a way the physician deems most appropriate.¹⁸⁶ A law criminalizing excessive embryo transfer is most appropriately categorized as a law relating to patient care, although incentives for transferring more than a recommended number of embryos could be rooted in business motives.¹⁸⁷ Typically the reasons associated with excessive embryo transfer are the physician's judgment that IVF will not succeed if industry recommendations are followed, coupled with patient pressure to transfer a higher number of embryos. With respect to patient pressure, data suggests many who suffer infertility deem multiple birth a desired outcome of treatment.¹⁸⁸

Professor Hoffmann observes that when a physician violates a patient care law, prosecutors are generally reluctant to enforce or charge the offending doctor, and juries are reluctant to convict.¹⁸⁹ The reason for this nullification of the law, she surmises, is a lack of consensus as to the moral validity of a law directing the practice of medicine. "Often," she instructs, "these laws have a moral basis and there is not agreement among the profession or across society as to whether the prohibited actions are wrong as a normative matter."¹⁹⁰

185 See Hoffmann, *supra* note 168.

186 *Id.* at 1062–65.

187 For example, the physicians at the heart of the UCI "egg stealing" scandal were thought to have acted as they did, in part, to shore up the clinic's success in order to attract more (cash paying) patients to the practice. See *supra* notes 17–18. But see Forman, *supra* note 179, at 298 n.173, calling the concern that physicians transfer higher numbers of embryos to post high success rates "overblown."

188 In the case of Nadya Suleman, a physician testifying on behalf of her treating doctor, Dr. Kamrava, at his license revocation hearing told the judge that the patient had insisted that all of her embryos be transferred. According to Dr. Jeffrey Steinberg, "(Kamrava) clearly spelled out over and over and over again that number one, he disagreed with her decision, and that she understands everything, that she's insisting he transfer all the embryos." See Shaya Tayefe Mohajer, *FDA Witness: Octomom Doc Used Experimental Methods*, ASSOCIATED PRESS, Nov. 18, 2010, <http://www.scpr.org/news/2010/11/18/fda-witness-octomom-doc-used-experimental-methods>. See also Forman, *supra* note 179, at 297 (discussing patient pressure to transfer a high number of embryos as a cost and stress saving measure).

189 Hoffmann, *supra* note 168, at 1075.

190 *Id.*

Certainly this ambivalence over the wrongfulness of the prohibited act would apply to excessive embryo transfer. Would each of ART's stakeholders find it morally wrong to transfer more than a recommended number of embryos in a single transfer? How would patients, offspring, and physicians weigh in?

In the main, patients do not think the transfer of a high number of embryos is morally wrong,¹⁹¹ and in fact some may believe the failure to transfer all available embryos is itself a moral wrong.¹⁹² Whether the offspring themselves would find their lives as multiples the result of a morally wrong act poses practical and philosophical questions beyond the scope of this article, but to date no ART physician has been sued on behalf of a child for excessive embryo transfer. Perhaps practitioners who assiduously follow industry guidelines would find excessive transfer worthy of legal rebuke, but even in the extreme case of Nadya Suleman, only one physician testified against Dr. Kamrava in his licensure trial.¹⁹³ Moreover, despite the intense publicity surrounding the case, the administrative law judge hearing the case found Dr. Kamrava grossly negligent in his treatment of Ms. Suleman, but sentenced him to probation rather than revoking his license to practice medicine.¹⁹⁴ While this sentence was later overturned by the Medical Board of California who suspended Dr. Kamrava's license to practice medicine,¹⁹⁵ it is interesting to observe that a judge was unwilling to impose the harshest penalty on a physician whose patient was delighted with her treatment, while fellow physicians ordered him off the doctor roll. The ALJ's decision permitting Dr. Kamrava to continue treating fertility patients could be interpreted as society's unease with punishing doctors who appear to offer good faith,

191 The only publicized case in which a patient sued a physician for excessive embryo transfer occurred in Australia, when a lesbian couple brought suit against their physician for transferring two embryos instead of one, resulting in the birth of healthy twins. The case was ultimately dismissed. *See Lesbian Couple Loses Bid to Sue IVF Doctor Over Birth of Twins When They Wanted 1 Child*, WELT ONLINE, July 25, 2008, <http://www.welt.de/english-news/article2248635/Lesbian-couple-loses-bid-to-sue-IVF-doctor-over-birth-of-twins-when-they-wanted-1-child.html>.

192 For example, the Georgia bill limiting embryo transfers also limited "the number of in vitro human embryos created in a single cycle to the number to be transferred in that cycle in accord with [the transfer limitations set forth in the bill]." *See* Ga. S.B. 169, *supra* note 183, at § 19-7-66 (noting that the bill was drafted by the Bioethics Defense Fund and supported by Georgia Right to Life).

193 *See Witness Testifies "Octomom" Nadya Suleman's Fertility Doctor Improved Treatment, Recordkeeping*, L.A. TIMES, Oct. 20, 2010, <http://latimesblogs.latimes.com/lanow/2010/10/witness-testifies-octomom-fertility-doctor-tried-to-mend-his-ways.html>.

194 *See* Molly Hennessy-Fiske, *Fertility Doctor Who Treated Octuplets Mother Should Retain His License, Judge Says*, CHI. TRIB., Jan. 25, 2011, <http://www.chicagotribune.com/news/local/la-me-kamrava-20110125,0,5303659.story>.

195 *See* Lin & Garrison, *supra* note 49.

albeit bad practice, medical care.

As discussed herein, criminal liability for excess embryo transfer seems a dubious response to public concerns over the high rate of ART-induced multiple birth in the U.S. Factors including tepid prosecutorial efforts to prosecute physicians, jury nullification of normatively ambiguous conduct, and the questionable constitutionality of laws criminalizing medical procedures all suggest such a law is unlikely to emerge, or ultimately succeed. A more likely regulatory scenario lies in a civil penalty structure, based either in fine or license revocation, to which we now turn.

2. Civil Fines for Excess Embryo Transfer

Assessing a civil fine for excess embryo transfer could incentivize greater compliance with published transfer guidelines, especially if the fines were consistently collected by authorized regulators. The notion of civil fines in connection with aberrant medical practice, even aberrant ART practice, is not unprecedented. In California, lawmakers imposed a civil fine for physicians who fail to obtain written informed consent from patients who donate gametic material for third party reproduction. California Business & Professional Code, Section 2260, enacted in 1996 in the wake of the UCI Center for Reproductive Health debacle,¹⁹⁶ provides in relevant part:

(a) A physician and surgeon who removes sperm or ova from a patient shall, before the sperm or ova are used for a purpose other than reimplantation in the same patient or implantation in the spouse of the patient, obtain the written consent of the patient . . .

(d) A violation of this section constitutes unprofessional conduct.

(e) A physician and surgeon who fails, for the second time, to obtain any consent required in subdivision (a) or (b) before transferring sperm or ova from a provider of sperm or ova to a recipient, shall be assessed a civil penalty in an amount not less than one thousand dollars (\$1,000) and not more than five thousand dollars (\$5,000) plus court costs . . . which penalty and costs shall be paid to the individual whose required consent was not obtained.

Under this statute, of which there is no public record of ever having been utilized, the

196 See *supra* text accompanying notes 17–18.

patients are authorized to collect the civil fines, presumably because they are the ones who exclusively suffer the harm when their consent to donate is not obtained. In the case of excess embryo transfers, a similar patient-based enforcement scheme seems unlikely to be enacted, if for no other reason than any resulting harm is not suffered exclusively by the patients who experience excess embryo transfer.¹⁹⁷ Moreover, patients who beseech their doctors to transfer an excess number of embryos, or who consent to such transfers, will lack the clean hands necessary to pursue a civil action against that provider.¹⁹⁸ Those who are unknowingly and unwillingly the recipient of excess embryos will likely have viable tort claims against the physician resting in battery and malpractice, making a civil fine statute either duplicative or inadequate compared to private remedies. Thus, to be effective any civil fine scheme must assign assessment and collection to regulators.

Which state actor is most likely to be tapped by federal lawmakers to administer a civil fine system against ART physicians who transfer excess embryos? The most obvious candidate is the CDC, the agency that currently enjoys the most interaction with the ART community. Since federal law, via FCSRCA, already weds the CDC with ART data reporting, adding a civil penalty for nonreporting (as was earlier suggested)¹⁹⁹ plus a fine for each excess embryo transferred, consolidates ART enforcement within a single federal agency and in a single statutory scheme. A civil fine provision in FCSRCA might provide as follows:

(1) Each physician and surgeon providing assisted reproductive technology treatment shall not implant more embryos into a human being than

[Model 1: set forth in the current recommendations issued by the American Society for Reproductive Medicine, or its successor]

[Model 2: a maximum of two embryos into a woman under the age of 40, or a maximum of three embryos into a woman aged 40 and over]

197 As discussed, earlier, excess embryo transfer can produce medical harm to women and to their resulting offspring. *See supra* note 3. In addition, excessive transfer and its resulting high rate of multiple pregnancy is perceived by some as a steep social cost of ART worthy of redress. *See, e.g.,* Michele Goodwin, *A View from the Cradle: Tort Law and the Private Regulation of Assisted Reproduction*, 59 EMORY L.J. 1059 (2010); Richard J. Hawkins, *Assisted Reproductive Technology and the Externality of Multiple Births*, 2009 MICH. ST. L. REV. 719 (2009); Glennon, *supra* note 64.

198 The equitable doctrine of “unclean hands” may allow a defendant to avoid liability when the plaintiff engages in misconduct or acts in an illegal manner. *See* T. Leigh Anenson, *Limiting Legal Remedies: An Analysis of Unclean Hands*, 99 KY. L.J. 63 (2010–11).

199 *See supra* text surrounding note 127.

(2) Each physician and surgeon who violates Section (1) shall be fined \$10,000 for each embryo transferred that exceeds the limitations set forth therein. The fine for excess embryo transfers shall be imposed regardless of whether the woman into whom the excess embryo or embryos were transferred became pregnant or gave birth as a result of that assisted reproductive technology treatment.

Giving the CDC the authority to assess and collect fines in connection with excess embryo transfers would invest a single agency with all aspect of ART regulation, creating some degree of administrative efficiency at the federal level. Would a civil penalty scheme offer other benefits for ART stakeholders or for society? Some evidence suggests the answer is no.

Recent scholarship casts doubt on the effectiveness of government regulators, particularly federal regulators, to enforce and collect civil fines and penalties that are assessed as part of an enacted regulatory scheme. In an empiric analysis of government collection behavior, Professors Ezra Ross and Martin Pritikin challenged the well-worn contemporary policy assumption that once the state orders offenders to pay a sanction, it will collect the debt.²⁰⁰ In fact, the authors found a “massive gap between penalties imposed ‘on the books’ and penalties collected in reality.”²⁰¹ Data collected from agencies charged with collecting criminal and civil penalties show collection rates in the single digits, with the U.S. Department of Justice collecting less than 4% of criminal penalties and fines it imposes. Other state and federal agencies were found to collect at a similarly dismal rate.²⁰²

While scholars explain that the goals of fine imposition are to deter misconduct, compensate victims and generate government revenue, the current system does not appear to be instrumental in achieving any of these goals. The legal obstacles to robust collection, including pre-judgment restraint of assets, and the impact of bankruptcy and adverse rulings by judges, as well as the offenders inability to pay, contribute to low collection rates. In some instances, however, the authors found that agencies purposefully undercollect debt, making a strategic decision that the resources and effort needed to collect debt exceeds the benefits to both the agency and those charged with debt collection within the administrative

200 Ezra Ross & Martin Pritikin, *The Collection Gap: Underenforcement of Corporate and White-Collar Fines and Penalties*, 29 YALE L. & POL’Y REV. 453 (2011).

201 *Id.* at 454.

202 *Id.* at 456.

structure.²⁰³ While the Ross/Pritikin study does not specifically address the collection history of the CDC, the agency most likely to be charged with civil fine enforcement under a federal embryo transfer law, the general conclusions with respect to white collar offenders are almost as dismal as with “individuals engaged in ‘street crime.’”²⁰⁴ Should physicians be civilly fined under a federal law for excess embryo transfer, existing data suggests it would neither deter such conduct nor provide a sufficient pool of resources to justify the significant costs needed to collect those penalties.

In the end, a federal law imposing civil fines may serve as an incentive for many, perhaps most, physicians to comply with any accompanying statutory restrictions limiting embryo transfer. There are, however, serious logistic and strategic flaws that would likely plague a civil fine option. As noted earlier in Part III.A.1.c, the most likely federal agency to be charged with fine enforcement—the CDC—contracts with a private entity to assist with its responsibilities under the federal Fertility Clinic Success Rate and Certification Act.²⁰⁵ While the CDC does fulfill its statutory duty to “annually . . . publish and distribute to the States and the public . . . pregnancy success rates,”²⁰⁶ it relies heavily on Westat, a survey research organization, to obtain and verify the individual clinic data that comprise the annual report. In fact, in its annual report, the CDC reveals that its personnel are largely hands-off when it comes to contact with individual fertility clinics. Of the 436 clinics (self) reporting data in 2008, Westat visited 35 of those sites as a quality control measure, while “CDC staff members participated as observers in some of the visits.”²⁰⁷

Investing the CDC, or any federal authority, with the power to fine would concomitantly require the agency to interact more intensely with those subject to fine. In the current ART world, the regulator and the regulated remain mostly at arms length. A change in this dynamic will surely require a greater commitment of resources to data collection, data analysis, penalty assessment and fine collection. As scholars have noted, our system of civil penalty assessment and collection is woefully lax, calling into question the value of committing resources to a civil fine system for excess embryo transfer.²⁰⁸

203 *Id.* at 478–81.

204 *Id.* at 486 (reporting only seven percent of ordered restitution collected from selected white collar offenders despite significant wealth streams).

205 *See supra* text accompanying notes 31–32.

206 42 U.S.C. § 263A-5(1) (2010).

207 *See* 2008 ART Report, *supra* note 7, at 7.

208 *See supra* text accompanying notes 201–05.

In addition to these structural legal considerations, a fine system could invite strategic behavior on the part of regulated physicians. Depending upon the dollar amount of any fine, physicians could make a strategic decision to disavow the regulations in order to fulfill a (paying) patient's desire for additional embryos. As discussed in more detail in Part IV, provider adherence incentives in ART are susceptible to dilution by patient pressures for aggressive treatment in this mostly cash-based medical industry. Thus, the vulnerability of a civil fine system to logistic and strategic hurdles invite investigation of another penalty and enforcement mechanism, the revocation of professional licensure.

3. License Revocation for Excess Embryo Transfer

In addition to criminal penalties and civil fines as punishment for excess embryo transfer, lawmakers could consider subjecting a physician's license to practice medicine to restriction or revocation for violating transfer limits. Physicians who violate the federal law on embryo transfers could be referred to the state medical board that issued their license for investigation and disciplinary action. A documented violation, or some prefixed number of multiple violations, could serve as the basis for license revocation. Thus, the penalty would be a civil remedy imposed by federal, and then state, appointed regulators.

Existing statutes offer models for a system of professional license revocation under both federal and state law. The federal model arises under the Partial-Birth Abortion Ban Act, discussed previously in Part III.B.1.²⁰⁹ The PBABA permits a physician charged thereunder to "seek a hearing before the State Medical Board on whether the physician's conduct was necessary to save the life of the mother," an exception set forth in the law.²¹⁰ If a physician seeks such a hearing, "[t]he findings on that issue are admissible on that issue at the trial of the defendant."²¹¹ While the PBABA does not adopt the structure suggested herein – referral to a state medical board for a review of the offending physician's capacity to continue practicing medicine – it does display the possibility that federal law can interact with state licensing authorities. Such interaction, however, is rare. In fact, the PBABA is the only federal law to access the expertise of a state medical board in connection with physician conduct.

State law, on the other hand, specifically refers physicians and other allied health care professionals to the state medical board for violation of statutory practice standards. These laws deem violation of specific treatment or conduct protocols "unprofessional conduct,"

209 See *supra* text accompanying note 107.

210 18 U.S.C. § 1531(d)(1) (2010).

211 *Id.* § 1531(d)(2).

and provide for referral to the state licensing board. Examples of statutory unprofessional conduct include prescribing a controlled substance for non-therapeutic purposes,²¹² excessive use of diagnostic procedures,²¹³ issuance of a contact lens prescription that expires in less than one year,²¹⁴ and failure to provide a written summary describing silicon implants prior to surgery.²¹⁵ In California, where many of the statutory unprofessional conduct laws operate, lawmakers have included ART treatment as a possible basis for licensure referral. A physician who fails to “obtain the written consent of the patient” prior to removing sperm or ova to be used for purposes other than reimplantation in the same patient is guilty of “unprofessional conduct.”²¹⁶

From these existing models, it is possible to fashion a statute that would punish violation of a federal embryo transfer limit by referring the offending physician to the medical board that issued his or her current license. Using the same language suggested for a civil fine statute in Part III.B.2, a license-affecting law could read as follows:

(1) Each physician and surgeon providing assisted reproductive technology treatment shall not implant more embryos into a human being than

[Model 1: set forth by the current recommendations issued by the American Society for Reproductive Medicine, or its successor]

[Model 2: a maximum of two embryos into a woman under the age of 40, or a maximum of three embryos into a woman aged 40 and over]

(2) A violation of Section (1) constitutes unprofessional conduct.

(3) Each physician and surgeon who violates Section (1) shall be referred to the state medical board or equivalent authority that issued and maintains the license or certificate required for that physician and surgeon to lawfully engage in the practice of medicine. Such referral shall be for the purpose of instituting a disciplinary action, including possible suspension or

212 ARIZ. REV. STAT. ANN. § 32-2933(6) (2012).

213 CAL. BUS. & PROF. CODE § 725(a) (2012) (deeming unprofessional conduct “repeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs or treatment, repeated acts of clearly excessive use of diagnostic procedures, or repeated acts of clearly excessive use of diagnostic or treatment facilities as determined by the standard of the community”).

214 *Id.* § 2541.2.

215 *Id.* § 2259.

216 *Id.* §§ 2260(a) & (d).

revocation of a license or certificate authorizing the practice of medicine.

The potential drawbacks to such an approach are at least twofold. First, under what authority could the federal government declare a medical procedure to constitute unprofessional conduct? Federal law does not define “unprofessional conduct” as applied to the practice of medicine; such definitions are left to the states. One state, for example, defines “unprofessional conduct” as “any departure from, or failure to conform to, the minimum standards of acceptable and prevailing medical practice and shall also include, but not be limited to, the prescribing or use of drugs, treatment, or diagnostic procedures which are detrimental to the patient as determined by the minimum standards of acceptable and prevailing medical practice or by rule of the [medical] board.”²¹⁷ Still another declares “unprofessional conduct includes the following acts, whether occurring in this state or elsewhere . . . [v]iolating federal, state, county or municipal laws or regulations applicable to the practice of medicine or relating to public health.”²¹⁸ Thus, while a federal law declaring excess embryo transfer “unprofessional conduct” would be purely hortatory, such a provision would offer state medical boards a basis for pursuing disciplinary action against offending practitioners. As noted above, violation of federal law can serve as the basis for revocation of a state license to practice medicine.²¹⁹

A second drawback to a license revocation penalty scheme is the uncertainty that a medical board will take any action against an offending physician. License revocation in the ART field is rare, though a few physicians have been stripped of their authority to practice as a result of malfeasance. Dr. Cecil Jacobson, the Virginia fertility doctor who used his own sperm to impregnate over 70 patients, was stripped of his medical license after being convicted on multiple counts of fraud and perjury.²²⁰ A California fertility doctor who mixed up two patients’ embryos, and implanted the wrong embryo in one of the patients who later gave birth, also subsequently lost his medical license. In that case, Dr. Steven Katz’s most egregious conduct was his failure to disclose the mistake to either family until a year after the child’s birth, though he learned of the mix-up within minutes

217 GA. CODE ANN. § 43-34-8(a)(7) (2011).

218 ARIZ. REV. STAT. ANN. § 32-2933 (2012).

219 See also *Portales v. Ky. Bd. of Med. Licensure*, 2008 WL 4951983 (Ky. Ct. App. 2008) (doctor’s felony conviction for violating the federal Controlled Substances Act was a sufficient basis for the revocation of his license to practice medicine).

220 See *Conviction Upheld in Fertility Case*, N.Y. TIMES, Sept. 8, 1993, <http://query.nytimes.com/gst/fullpage.html?sec=health&res=9F0CEFD1F3CF93BA3575AC0A965958260>.

of the embryo transfers.²²¹ These cases involve criminal conduct, namely fraud. Would the medical boards be as likely to revoke a physician's license for defying a federal law at a patient's request?

To date, the only peek into the ART sensibility of licensing boards we have is through the Nadya Suleman lens. As previously discussed, the physician who treated Ms. Suleman, Michael Kamrava, was brought before the Medical Board of California in October 2010. While the administrative law judge hearing the case found the doctor had committed gross negligence by implanting an excess number of embryos, he ordered probation rather than license revocation.²²² A few months later, the Medical Board of California revoked Dr. Kamrava's license, citing "an ongoing commitment to . . . public protection."²²³ Dr. Kamrava appealed the six-member Board decision to the Los Angeles Superior Court.²²⁴ In December 2011, the court turned down the doctor's appeal, calling his actions "a serious breach of the standard of care."²²⁵ Whether the public, or the ART community, feel safer now that Dr. Kamrava is no longer practicing medicine is unknown.

In sum, a federal law that attempts to codify embryo transfer parameters will confront legal and practical barriers. In the absence of a federal licensing scheme for ART clinics, any penalties attached to excess embryo transfer will necessarily be meted out against individual practitioners, or possibly physician groups. If the clinics themselves are not at risk for the (bad) acts of their medical personnel, then any penalty structure must rely on the targeted actors' incentives to avoid either criminal, civil, or license liability. Such incentive may arise by a sense of moral duty coupled with an aversion to breaking the law. But it is worth exploring whether other incentives, including a desire for competitive success rates, as well as a desire to help a patient become a biologic parent, could impact a

221 See Donna Horowitz, *Doctor Loses License After Implanting Wrong Embryos*, L.A. TIMES, Apr. 25, 2005, <http://articles.latimes.com/2005/apr/25/local/me-embryo25>. See also *Robert B. v. Susan B.*, 135 Cal. Rptr. 2d 785, 786 (Ct. App. 2003) (resolving parentage of child born as a result of embryo mix-up, court declaring man whose sperm was used to form embryos as legal father over birth mother's objection).

222 See *supra* note 48.

223 *Medical Board of California Revokes License of Former Beverly Hills Physician*, News Release, MED. BD. OF CAL. DEP'T OF HUM. AFFAIRS, June 1, 2011, http://www.mbc.ca.gov/board/media/releases_2011_06-01_kamrava.html.

224 See Matt Coker, *Michael Kamrava, Fertility Doctor, Loses License*, OC WEEKLY, June 22, 2011, http://blogs.ocweekly.com/navelgazing/2011/06/michael_kamrava_octomom_lose_1.php. If Dr. Kamrava loses this appeal and any further appeals, he can reapply for his medical license three years after the date of its revocation. CAL. BUS. & PROF. CODE § 2307 (West 2010).

225 See *Bid Rejected*, *supra* note 49.

federal scheme regulating embryo transfer.

IV. Incentivizing Adherence: Linking Restrictions with Reimbursement

The barriers associated with drafting and enforcing federal embryo transfer limits are significant, but they should not forestall further discussion about the problem of ART-related multiple births in the U.S. Leading fertility doctors continue to express concern about the persistently high rate of IVF twins, despite the potential sense of irony these warnings can engender.²²⁶ Legal scholars likewise highlight the harms associated with multiple pregnancy and criticize the seeming lack of national will to institute the reforms necessary to combat the problem.²²⁷ Those reforms, most all agree, include pairing restrictions on embryo transfer with meaningful insurance coverage for infertility treatment. As one article laments,

The cost of infertility treatment, especially to those without insurance, can lead some couples to assume the greater risks of multiple gestation. One third to one half of patients in the United States drop out of care after they are visiting the reproductive specialist. For many of these patients, the major reason is the financial barrier to care. For some or all these reasons, up to 80% of patients in some studies find twins an acceptable outcome of treatment.²²⁸

Today we know that patients in the U.S. and abroad who have access to some form of insurance coverage for IVF deliver fewer multiples. For example in Britain and Sweden, countries that cover IVF as part of a national health system, the rate of multiple birth is 27% and 5% respectively,²²⁹ compared to 32% in the U.S.²³⁰ Domestically, in states that mandate coverage for infertility care, multiple birth rates hover around 27%.²³¹ We also stand poised to make significant changes in our health insurance system with the recent

226 See David Adamson & Valerie Baker, *Multiple Births From Assisted Reproductive Technologies: A Challenge That Must Be Met*, 81 FERTILITY & STERILITY 517 (2004).

227 See *supra* note 16.

228 Adamson, *supra* note 226, at 518 (citations omitted).

229 See *supra* notes 155, 160.

230 See *supra* note 7.

231 See J. Ryan Martin et al., *Insurance Coverage and In Vitro Fertilization Outcomes: A U.S. Perspective*, 95 FERTILITY & STERILITY 964, 967 (2011).

enactment of the Patient Protection and Affordable Care Act.²³² Combining what we know about finance-related ART behavior with a unique opportunity to build fertility care into a national health insurance benefits package will be far more effective in reducing multiple pregnancy rates in the U.S. than any stand-alone embryo transfer law.

A. The Impact of Health Insurance Coverage on Multiple Birth Rates

Accessing infertility care can mean voluntary impoverishment for some patients. With the average cost of a single cycle of IVF hovering around \$12,000, this high tech treatment can be out of reach for many or within reach for a single cycle only.²³³ As has been well documented in the legal literature, health insurance coverage for ART in the U.S. is sparse and inadequate, with only a small percentage of Americans fortunate enough to enjoy some reimbursement from their carriers.²³⁴ No federal law requires health insurance carriers to provide coverage for infertility care, leaving any mandates to the states. According to the National Conference of State Legislatures, currently 15 states have passed laws that require insurers to either cover (known as a “mandate to provide” or “hard mandate”) or offer coverage (“mandate to offer” or “soft mandate”) for infertility diagnosis and treatment. Thirteen states have enacted hard mandates, while two are soft mandate jurisdictions.²³⁵ That said, the level of coverage in each state is highly variable.²³⁶

The high cost of unreimbursed IVF inevitably impacts patient and physician behavior. As Professor Deborah Forman observes, “patients . . . seek to maximize their chances in any given cycle, even at the risk of increasing the odds of a multiple birth. Indeed, some patients . . . may actively seek twins as a cost and stress saving measure Physicians are

232 See *supra* note 12.

233 See REPRODUCTIVEFACTS.ORG, <http://www.reproductivefacts.org/search/detail.aspx?id=2356&q=cost%20of%20ivf> (last visited Mar. 23, 2012) (sponsored by the American Society for Reproductive Medicine).

234 See generally Davidson, *supra* note 125; Jim Hawkins, *Financing Infertility*, 47 HARV. J. ON LEGIS. 115 (2010); Elizabeth A. Pendo, *The Politics of Infertility: Recognizing Coverage Exclusions as Discrimination*, 11 CONN. INS. L.J. 293 (2005).

235 The fifteen states with laws that require insurers to cover or offer to cover infertility treatment and diagnosis are Arkansas, California, Connecticut, Hawaii, Illinois, Louisiana, Maryland, Massachusetts, Montana, New Jersey, New York, Ohio, Rhode Island, Texas, and West Virginia. All but California and Texas are “hard mandate” states. National Conference of State Legislatures, *State Laws Related to Insurance Coverage for Infertility Treatment*, NCSL (Apr. 2001), <http://www.ncsl.org/issues-research/health/insurance-coverage-for-infertility-laws.aspx>.

236 For example, mandates for fertility care in California and New York do not include coverage for IVF. CAL. INS. CODE § 10119.6 (2012); N.Y. INS. LAW §§ 3216 (13), 3221 (6), 4303 (2012).

also under pressure to post high success rates, which may influence their decisions about the number of embryos to transfer.”²³⁷ Data from outside the U.S. supports this observation that the greater the financial pressure on patients, the greater the pressure they exert on physicians to transfer more embryos. In 2010, when lawmakers in Australia reduced IVF reimbursement by \$1500, clinics reported “more pressure from cash-strapped patients to implant multiple embryos to boost chances of pregnancy in one cycle.”²³⁸

Surveillance of IVF practices internationally shows that countries that include infertility treatment as part of their national health service have managed multiple births far better than the U.S.²³⁹ In many of these countries, laws are in place limiting embryo transfers, a regime that is easier to enforce when patients do not have to mortgage their homes in order to seek treatment.²⁴⁰ The relationship between insurance coverage and multiple births is also well documented in the U.S. Researchers at Harvard Medical School conducted a study to determine whether coverage for IVF services is associated with increased use of services and improved outcomes for patients and offspring. The Harvard team reviewed the annual data published by the CDC reporting ART success rates²⁴¹ and divided the clinics into three groups, according to the state in which the clinic was located: 1) states that mandate complete insurance coverage for IVF (thirty-one clinics), 2) states that mandate partial coverage for IVF (twenty-seven clinics), and 3) states that did not require any coverage (302 clinics). The results were intuitive: States that do not require insurance coverage have the highest number of embryos transferred per cycle, the highest rates of pregnancy and live birth from IVF, and the highest rates of births of multiple infants (especially three or

237 Forman, *supra* note 179, at 297–98 (citations omitted).

238 Jill Stark & Rachel Browne, *Multiple Births to Cash-Strapped IVF Mums on Rise*, BRISBANE TIMES.COM, May 2, 2010, <http://www.brisbanetimes.com.au/lifestyle/life/multiple-births-to-cashstrapped-ivf-mums-on-rise-20100501-u0a6.html>.

239 See *supra* text accompanying note 229 (comparing multiple pregnancy rates in the UK and Sweden).

240 See Davidson, *supra* note 125, at 174–75 (citing Norbert Gleicher et al., *New Debate: A Formal Comparison of the Practice of Assisted Reproductive Technologies Between Europe and the USA*, 21 HUM. REPROD. 145, 145 (2006)).

241 See *supra* note 6.

more).²⁴²

From an economic standpoint, the researchers argue, the net result of saving health insurance dollars by not covering IVF is more than nullified by a greater expenditure of dollars to care for multiple birth newborns. For example, “[i]n 1991, hospital charges for the delivery of twins were 4 times as high and charges for triplets were 11 times as high as charges for a singleton delivery.”²⁴³ Moreover, the lifetime health care costs to care for multiple birth infants can be staggering due to the higher risk of respiratory distress syndrome, cerebral palsy, blindness and other physical and developmental disabilities that are associated with higher order multiple birth.²⁴⁴ The other side of the equation - the added cost for including IVF in health insurance - supports the cost/benefit argument in favor of coverage. In Massachusetts, the state reputed to mandate the most generous coverage for infertility care, data shows that the law has only minimally affected insurance premiums.²⁴⁵ “[T]he cost of insurance premiums has risen only between 0.2 percent and 0.5 percent annually, or about \$1 a month extra for an average policy, because of the coverage of in-vitro fertilization.”²⁴⁶ Other studies confirm that mandating coverage for infertility care,

242 Tarun Jain, Bernard L. Harlow & Mark D. Hornstein, *Insurance Coverage and Outcomes of In Vitro Fertilization*, 347 N. ENG. J. MED. 661 (2002). The researchers opined,

[a]lthough the rates of pregnancy and live births from in vitro fertilization are higher in states that do not require insurance coverage, so are the rates of pregnancies with three or more fetuses, probably because more embryos are transferred per cycle in these states than in states that require complete insurance coverage. It is also possible that because patients must pay out of pocket in states without mandated coverage, physicians are under pressure to obtain a “successful” outcome the first time and therefore transfer more embryos per cycle. *Id.* at 665.

See also Martin et al., *supra* note 231 (finding clinics in states without insurance mandates have higher pregnancy, live-birth and multiple pregnancy rates because they transfer more embryos than clinics in states with coverage).

243 Jain, Harlow & Hornstein, *supra* note 242, at 665.

244 *Id.*

245 Davidson, *supra* note 126, at 167.

246 *Id.* (citing Mackenzie Carpenter, *Blue Cross Draws Line on In-Vitro Fertilization Procedure*, PITTSBURGH POST-GAZETTE, June 27, 1993, at A1).

including IVF, impacts premiums only a few dollars a year.²⁴⁷

The foregoing discussion linking health insurance coverage with clinical outcomes is superficial at best, omitting inclusion of a number of key factors any meaningful analysis must include. Further exploration of the topic would need to take into account the nation's complex network of public and private health insurance coverage; the fact that fifty million Americans lack health insurance of any kind²⁴⁸; and the impact of the Employee Retirement Income Security Act of 1974 (ERISA), which regulates employee benefit plans, including health benefit plans.²⁴⁹ For purposes of kick starting the discussion, we will look briefly at two options for improving access to coverage for infertility care for many Americans. One option is for Congress to enact a law mandating health insurers provide coverage, much the way some states have mandated care. Another option is for federal lawmakers to include infertility care as an essential health benefit under the newly enacted Affordable Care Act. In either case, linking restrictions on embryo transfers with reimbursement for treatment will be far more effective in reducing multiple births than statutory transfer limits alone.

B. Standard and Emerging Options for Coverage: The Time is Now

The hurdles to drafting and enforcing a federal embryo transfer law may be substantial, as discussed in Part III, but if Congress is truly interested in reducing the incidence of ART-related multiple births, it must think strategically about what motivates stakeholders in reproductive medicine. Patients want healthy children, but they also want to maintain a financially sound lifestyle in which to raise those children. While surveys show that

247 See Edward G. Hughes & Mita Giacomini, *Funding In Vitro Fertilization Treatment for Persistent Subfertility: The Pain and the Politics*, 76 FERTILITY & STERILITY 431 (2001) (reporting providing infertility coverage for all privately insured employee-based health plans would raise annual premiums about \$3.00 at the current level of IVF utilization).

248 See U.S. CENSUS BUREAU, P60-238 INCOME, POVERTY AND HEALTH INSURANCE IN THE UNITED STATES: 2009 (2010).

249 29 U.S.C. §§ 1001–1461 (2011). The importance of ERISA to infertility insurance coverage is that in some cases, particularly when employers self-insure their health insurance coverage, the federal law preempts state laws that relate to employee benefit plans. Thus, even if a state requires insurers to cover infertility treatments, ERISA may preempt such a state law and allow health insurance providers to decline to offer infertility coverage. For a comprehensive analysis of ERISA, see BARRY R. FURROW ET AL., HEALTH LAW 418–60 (2d ed. 2000).

ART patients actively seek twins,²⁵⁰ it is unclear whether respondents would feel the same way if treatment did not involve a “financial gamble.”²⁵¹ In one survey of ART patients, researchers found that lower family income was associated with an increased desire for multiples. The authors surmise that “families with limited means may hope to maximize their results with the fewest possible treatments.”²⁵² Another factor that remains unknown is whether parents of multiples would have preferred serial singleton deliveries, assuming such an opportunity was economically feasible. Such a question is difficult to pose because it requires parents to imagine their existing children at a different age relative to each other, and in a different birth order. Let us assume, based on the medical and psychological strains posed by multiple births, given the choice ART patients would elect serial singleton deliveries over multiple birth.

From the provider perspective, physicians have no seeming motive to produce a multiple birth instead of a singleton. Some argue ART doctors are motivated to report “successful” cycles to the CDC to boost patient recruitment, and thus stack the odds by transferring excess embryos.²⁵³ Intuitively, however, it makes more financial sense for physicians to strive for singleton births, so that patients return for sibling treatment cycles. To a business minded physician, two ART cycles are better than one, especially if both yield a healthy singleton offspring. Thus, so long as IVF yields a healthy live birth, physicians would be as, or more, inclined than their patients to limit embryo transfers to avoid multiple births.

A growing body of data shows that limiting transfers to a single embryo produces higher pregnancy and live birth rates over two consecutive IVF cycles, compared to consecutive double embryo transfers.²⁵⁴ With these odds in their favor, patients would be much more willing to elect, or even submit to, two single transfers so long as the costs

250 See Mary D’Alton, *Infertility and the Desire for Multiple Births*, 81 FERTILITY & STERILITY 523 (2004) (noting twenty percent of women surveyed preferred multiple birth, ninety-four percent seeking twins); W.A. Grobman et al., *Patient Perceptions of Multiple Gestations: An Assessment of Knowledge and Risk Aversion*, 185 AM. J. OBSTETRICS & GYNECOLOGY 920, 920 (2001).

251 Michele Goodwin, *Assisted Reproductive Technology and the Double Bind: The Illusory Choice of Motherhood*, 9 J. GEND. RACE & JUST. 1, 26 (2005).

252 D’Alton, *supra* note 250, at 524.

253 See, e.g., Stephanie N. Sivinski, *Putting Too Many (Fertilized) Eggs in One Basket: Methods of Reducing Multifetal Pregnancies in the United States*, 88 TEX. L. REV. 897, 905–06 (2010); Carson Strong, *Too Many Twins, Triplets, Quadruplets, and So On: A Call for New Priorities*, 31 J.L. MED. & ETHICS 272, 275 (2003).

254 See, e.g., Zdravka Veleva et al., *Elective Single Embryo Transfer with Cryopreservation Improves the Outcome and Diminishes the Costs of IVF/ICSI*, 24 HUM. REPROD. 1632 (2009) (comparing cumulative cycles of fresh then frozen cycles, using single and double embryo transfers).

were the same (or less) than one cycle using two or more embryos.²⁵⁵ Physicians would likewise be more agreeable to a system of single (or reduced) embryo transfer so long as their outcomes remained stable or improved over a given number of cycles. While a stand-alone federal law can impose embryo transfer limits, the success of any such regime hinges on the compliance patients and physicians are willing to provide. Changing patient and physician behavior in the surgical suite will start by neutralizing or reducing the cost each must bear in order to attain their desired results. A federal mandate to cover or subsidize the cost of infertility care, as a companion to embryo transfer restrictions, should provide the necessary incentive for adherence.

A call for expanded insurance coverage for infertility care in the name of reducing multiple births is not new; prior calls have even caught some congressional wind. Over the past decade, a few members of Congress have responded to constituent pleas for increased ART coverage. Past attempts to pass federal legislation requiring insurers cover infertility care have been extant but unsuccessful. Beginning in 1999, Rep. Anthony Weiner (D-NY) introduced The Family Building Act into each session of Congress of which he was a member.²⁵⁶ Similar to a few state “hard mandates,” the bill provided in relevant part that insurers offering group health insurance must provide coverage for infertility care, including IVF.²⁵⁷ Each session, the bill was referred to committee, never to emerge again.²⁵⁸ The likelihood of Congress passing a federal mandate for private insurers to cover infertility care seems dim, increasingly so in light of recent developments in health care reform.

The possibility of increasing insurance coverage for ART care, like reproduction itself, may benefit from timing. On March 23, 2010, President Barack Obama signed into law the Patient Protection Affordable Care Act (Affordable Care Act), “the most far-reaching healthcare reform legislation since the establishment of the Medicare program in 1965.”²⁵⁹

255 This assumes the benefits of a singleton pregnancy and birth outweigh the burdens associated with undergoing an IVF cycle. This further assumes that only patients who are clinically appropriate for single embryo transfer would be treated by this method.

256 H.R. 2706, 106th Cong. (1999). Rep. Weiner introduced the bill into every subsequent session of Congress until the final version, H.R. 697, 111th Cong. (2009). See H.R. 2706, <http://www.govtrack.us/congress/bill.xpd?bill=h106-2706&tab=related> (last visited Apr. 10, 2012). Rep. Weiner resigned from Congress on June 16, 2011. See Raymond Hernandez, *In Chaotic Scene, Weiner Quits Seat in Scandal's Wake*, N.Y. TIMES, June 17, 2011, at A1.

257 H.R. 697, 111th Cong. § 2708 (2009).

258 A similar bill on the Senate side, introduced by Senator Kirsten Gillibrand, likewise failed to garner support. S. 1258, 111th Cong. (2009).

259 See *supra* note 12.

The Affordable Care Act directs the U.S. Department of Health and Human Services (HHS) to establish a minimum level of health benefits, called the essential health benefits, that must be offered by certain health plans, including all plans participating in the individual and small group health insurance markets.²⁶⁰ The law deems certain benefit categories as essential—including emergency services, hospitalization, maternity and newborn care, mental health and pediatric services—but permits HHS to establish additional benefit categories.²⁶¹ HHS is also authorized specify which services and benefits are to be included within a benefit category as an essential health benefit.²⁶² Fertility care, for example, could be included as a benefit within the maternity care category.

The process for determining the essential health benefits began in January 2011, when the Institute of Medicine Committee on the Determination of Essential Health Benefits began to deliberate on the matter at the request of HHS. The IOM recommendations for what services and benefits will be mandated for all insurance plans beginning in 2014 was delivered to as a report to HHS in October 2011.²⁶³ While the IOM panel laid out criteria and methods for HHS to use to determine a minimum set of benefits, the report did not lay out specific benefits. Whether HHS will ultimately recommend that infertility care be included as an essential benefit has been the subject of speculation, but is currently unknown.²⁶⁴

Also unknown is whether the Affordable Care Act will itself survive the many legal challenges it now faces. As of March 2012, twenty-six states had filed joint or individual law suits to overturn the “individual mandate” portion of the law requiring that all persons not covered by governmental or other insurance programs purchase an approved insurance policy or pay a penalty.²⁶⁵ Two federal appellate courts have ruled on the mandate’s

260 See Jessica Mantel, *Setting National Coverage Standards for Health Plans Under Healthcare Reform*, 58 UCLA L. REV. 221 (2010).

261 Patient Protection and Affordable Care Act, *supra* note 12, § 1302(b)(1).

262 Mantel, *supra* note 260, at 229.

263 See INSTITUTE OF MED., *ESSENTIAL HEALTH BENEFITS: BALANCING COVERAGE AND COST*, (Oct. 6, 2011), available at http://books.nap.edu/openbook.php?record_id=13234.

264 See Michelle Andrews, *Health Insurance Rules May Decide Whether Infertility Treatment Is Essential*, WASH. POST, Jan. 24, 2011.

265 26 U.S.C. § 5000 A (2011); see *Health Care Reform and the Supreme Court (Affordable Care Act)*, *Times Topics*, N.Y. TIMES, Mar. 28, 2012, http://topics.nytimes.com/top/reference/timestopics/organizations/s/supreme_court/affordable_care_act/index.html.

constitutionality, with one upholding this portion of the Act,²⁶⁶ and the other finding that requiring individuals to purchase insurance exceeds Congress' authority under the Commerce Clause.²⁶⁷ In November 2011, the U.S. Supreme Court granted certiorari in the case hailing from the 11th Circuit striking down the individual mandate. Oral arguments, allocated for an unprecedented six hours, are set to begin on March 26, 2012.²⁶⁸

Assuming that the entire Affordable Care Act survives, or that the individual mandate is severed leaving the essential benefits portion intact, could the inclusion of coverage for infertility care have an impact of multiple birth rates in the U.S.? Yes, definitely. Studies comparing ART outcomes in states that mandate coverage with those in which no coverage is provided consistently show insurance coverage yields lower embryo transfer rates and fewer multiple births.²⁶⁹ A study published in 2011 found "nonmandated states transferred significantly more embryos than mandates states" (2.7 v. 2.4 per cycle) and produced "significantly higher" multiple live-birth rates (29.8% v. 27.3%).²⁷⁰ The coverage-generated 27.3% multiple birthrates compares favorably with the national rate of 32% of all ART live births.²⁷¹ Interestingly, recall that the multiple birthrate in the UK is 27%. This in a jurisdiction where IVF is a covered service and national guidelines restrict embryo transfers to no more than two to three per cycle, depending on patient age. If the U.S. can achieve this same rate without formal embryo transfer laws within the states that provide coverage for IVF, there is little doubt that combining a mandate for coverage with clinical guidelines restricting transfers—even to ASRM limits—would further reduce national multiple birth rates in the U.S.

Now is the time to add infertility care to any essential health benefit package that moves forward. At the same time, coverage can be linked to adherence to contemporary ASRM guidelines, incentivizing both patients and physicians to comply with embryo transfer restrictions. As previously discussed, adopting the ASRM practice guidelines has the benefit of industry buy-in and currentness. Combining both coverage and clinical parameters in one regime simplifies the regulatory regime by eliminating the need for

266 *Thomas More Law Ctr. v. Obama*, 651 F.3d 529, 549 (6th Cir. 2011).

267 *Florida ex rel. Atty. Gen. v. U.S. Dep't Health & Hum. Servs.*, 648 F.3d 1235, 1311 (11th Cir. 2011).

268 *See Adam Liptak, Health Care Act Offers Roberts a Signature Case*, N.Y. TIMES, Mar. 12, 2012, at A1.

269 *See Martin et al.*, *supra* note 231.

270 *Id.* at 967 (noting there may be other factors that explain this differential, including that state mandates encourage patients with a poorer reproductive prognosis to seek treatment, thus lowering the pregnancy and multiple birth rates).

271 *See 2008 ART REPORT*, *supra* note 7, at 75.

a separate enforcement mechanism. Instead of tasking the CDC with probing individual patient charts to discover excess transfers, existing structures in which insurance carriers review submissions for reimbursement could be utilized to enforce clinical guidelines. Physicians who fail to comply with incorporated guidelines will not receive reimbursement from the patient's insurance carrier; patients who "demand" excess embryos be transferred risk being held responsible for the full amount of their treatment. While the problems associated with monitoring compliance with clinical guidelines would remain, a provision that mandated reporting of embryo transfers - combined with a penalty for false reporting - could act as an incentive for adherence. Knowing that ongoing mismatches between embryo transfer and multiple birth rates could trigger provider scrutiny, ART doctors would take care to follow and accurately report clinical practices.

CONCLUSION

Reproductive medicine's ability to shed its moniker as the wild west of medicine is highly questionable given the string of serious and public mishaps that have made the field tabloid fodder. While ART outliers may garner disproportionate attention, the vast majority of families formed through assisted conception are produced safely within the bounds of ethical and sound medical practice. Nevertheless, when the likes of Nadya Suleman undergoes a single round of IVF with twelve embryos and births eight children, ART watchers cannot help but be alarmed that such behavior is more widespread. One response to the Octomom fiasco was the suggestion that Congress enact a law limiting embryo transfers in every IVF cycle, much like is done in a handful of European countries. The proposal had both specific and general appeal: such a law could stave off the next Octomom (and Septamom, and so on), while addressing the persistently high rate of ART-induced multiple births in the U.S. Reducing embryo transfers, clinically speaking, does reduce the number of multiple births that result from each cycle.

Drafting an embryo transfer law is not a particularly difficult task. Existing federal law requiring reporting of ART success rates could be amended to include reporting of embryo transfers, as well as monetary fines for nonreporting. To limit embryo transfers, lawmakers could codify specific standards based on patients' age, or could incorporate by reference industry-generated guidelines that permit some provider discretion to account for a host of clinical factors. The latter approach, arguably, assures that guidelines will remain current and will garner more robust support and compliance from physicians who have a greater say in the regulation of their bedside conduct. Even if an embryo transfer law can effectively set clinical standards and require reporting, the prospects for widespread compliance remain uncertain. Data collected on the effectiveness of civil fines in the

regulatory setting suggest rampant undercollection, casting doubt on fine-based penalties' capacity to deter banned conduct. Still other data suggests that criminal penalties fare no better, as both prosecutors and juries are reluctant to penalize a physician who, in good faith, responds to a patient's plea for help.

Compliance with embryo transfer limits are in doubt not only because traditional penalty structures are ineffective, but also because patients and physicians are incentivized by the high cost and low reimbursement rates for infertility care to prefer more embryos be transferred to maximize the chances for a live birth. When multiple birth, particularly twins, is a preferred outcome based on financial constraints, looking to a stand-alone embryo transfer law to curb the high rate of multiples will have little effect. Instead, now is the time to ease the financial burden by including infertility care in the package of essential health benefits being developed under the Affordable Care Act. Matching the burden of embryo transfer limits with the benefit of coverage will have a real and lasting impact on the public health concerns that legitimately coalesce around multiple births. Using inroads in health care reform to make ART safer and more accessible will go a long way in taming the reputed wild west of reproductive medicine.