

# The Octuplet Case— Why More Regulation Is Not Likely

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**I**n vitro fertilization and assisted reproductive technologies, or ARTs, have always posed a regulatory conundrum. They've been hugely successful (52,000 births from 152,000 IVF cycles in 2005) and are firmly established as the treatment of choice for many kinds of infertility.<sup>1</sup> But over the years there has been a steady drip of ethical lapses, from doctors who oversell their success rates to theft of eggs and embryos. A 1992 federal law arranges for accurate reporting of success rates and encourages accreditation of IVF laboratories, but there is no centralized licensing and control authority to enforce it (as exists, for example, in the United Kingdom) and thus few teeth to it.<sup>2</sup>

The IVF industry argues that there is more regulation in place than meets the eye, citing the many federal and state laws that impinge on IVF practice in some way.<sup>3</sup> It also is active in developing ethical and practice guidelines, though it

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has little muscle to enforce them. Critics of the industry argue that it's like the wild west—anything goes if patients can pay, often to that patient's detriment. Yet these critics are remarkably silent on what specific form more regulation should take. The Bush-appointed President's Council on Bioethics was concerned enough to spend two years examining the field but found no reason to urge major regulatory intervention.

The octuplet case has peeled back the ART industry's claim that everything is fine and dandy. In the end, however, it is unlikely to bring major changes to how IVF is conducted and regulated. This is in part due to the case being such an outlier. If the situation had not arisen in real life, it would have been hard to imagine it: an unemployed, thirty-three-year-old single mother of six IVF children with some evidence of personal instability has her IVF doctor implant six frozen embryos in her uterus. She then ends up giving birth to eight children and touching off a media firestorm.

The "octomom" has been widely reviled as an example of irresponsible reproductive behavior, not just because the octuplets, born at thirty-one weeks, are at high risk for cerebral palsy and learning disabilities, but because she doesn't have the money to pay for their care, nor a husband or partner to help with it. She is partially estranged from her family and depends on the kindness of strangers and Medicaid to pay the enormous medical and rearing costs of an additional eight premature infants.

Nevertheless, the decision to transfer the embryos initially had some defenders. One noted fertility specialist in Los Angeles, Jeffrey Steinberg, was quoted in the *Philadelphia Inquirer* as saying, "Who am I to say that six is the limit. There are people who love big families." Jamie Grifo, who is paid approximately \$2.3 million annually by New York University medical school for his fertility skills, was similarly quoted in the *New York Times*: "I don't think it's our job to tell them how many babies they are allowed to have. I am not a policeman for reproduction in the United States."

However, since the first reports, few other doctors have publicly defended Dr. Michael Kamrava's decision to transfer six embryos. His Web site reportedly proclaimed that he was an "internationally recognized leader in the field of in-vitro fertilization whose work has led to breakthrough technology." Although no law directly regulates who may have IVF procedures or the number of embryos to transfer, Dr. Kamrava appears to have violated the American Society of Reproductive Medicine's guideline to transfer only two embryos for healthy women under thirty-five (one if they have already had an IVF

birth) and has offered no justification for doing so.<sup>4</sup> It is noteworthy that his program—one of many in the Los Angeles area—had a very low success rate.

So what, if anything, should be done about this? Since ART, like most medical procedures, relies heavily on professional self-regulation, let us first examine whether professional self-regulation can prevent such situations, and then turn to the possibility of legal change.

The ASRM has two sets of guidelines that pertain to this situation. Its ethics committee statement on "Child-Rearing Ability and the Provision of Fertility Services" discusses situations in which the patient appears unlikely to be able to provide adequate childrearing.<sup>5</sup> The statement says that programs

may deny services to patients if they have a substantial basis for thinking that any given patient will not be adequate to the task. The statement is careful to say that this judgment is not easy to make and should be arrived at as a group. It also warns against assuming that having a disability alone is enough to support such a judgment.

Based on this guidance, a doctor should have no doubt that he could have refused to provide any services to a woman in Suleman's position, not just her request to transfer six embryos at once. The statement also says, however, that a doctor is still free to treat, except in

cases where clear significant harm to offspring is likely. While that provision might have justified the doctor if he were transferring one or two embryos, the transfer of six crosses that line, since higher-order multifetal gestation clearly poses a threat of harm to offspring.

The second set of ASRM guidelines are those concerning the number of embryos to be transferred that I mentioned above. The ASRM's affiliate group of reproductive endocrinologists, the Society of Assisted Reproductive Technology (SART), developed the practice guidelines. They are quite clear that no more than two embryos should be transferred for women under thirty-five, and only one if the mother has already given birth through IVF. There is no question that transferring six violated the professional guideline.

Critics, however, would argue that even clear professional guidelines are not adequate to deal with such cases. The ethics statement on reproductive services and inadequate childrearing leaves much room for individual judgment and does not explicitly condemn providing services in this kind of case. And like the embryo transfer policy, no sanction exists for violating it beyond expulsion or suspension from those societies and loss of the right to use that affiliation on Web sites and in advertising. Since Dr. Kamrava was a member of SART at the

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time of the embryo transfer, it will be interesting to see what action, if any, SART takes for violation of its guidelines.

The ASRM guidelines do, however, have some bite if taken as an indicator of the standard of care for doctors practicing reproductive medicine. The California state medical licensing board will probably take them into account in determining whether to renew Dr. Kamrava's license to practice in California, which expires on November 30, 2009. The guidelines could also be used in tort actions against doctors by patients or offspring, though litigation in this case appears unlikely.

What, then, about legislation to curb such incidents in the future? There are some theoretic possibilities here, but all have problems. First is the question of providing IVF to a person who already has six children by IVF. While small families are now in vogue, it wasn't so long ago that large families were both desired and praised. Indeed, the UN Convention Against Elimination of All Forms of Discrimination Against Women gives women the same rights as men "to decide freely and responsibly on the number and spacing of their children." While India and China have had social policies against large families, we in the United States do not. I suspect that the courts would look with deep constitutional suspicion on laws that limit the number of children one may have.<sup>6</sup> Even Supreme Court Justice Antonin Scalia, who has nine children, might agree that there are constitutional problems with number limits on reproduction. The mode of conception of previous or next children—coital or ART—should not change this conclusion.

So what about laws that restrict reproduction when parents lack the means to care for the child? Such a law would penalize the poor and smack of classism. Limiting public assistance is not a good remedy, since it's the children who are penalized. Nor would compulsory reversible contraception fly. At best, one might be able to restrict ART for persons who already have children they are unable to care for by penalizing the doctors who provide the service, but such a law would interfere with the right of such persons to have additional children. In addition, it would require more screening of IVF patients than is now done. Most of these patients would not be in the doctor's office in the first place unless they were able to afford the treatment (which is quite pricey), and most would presumably then be able to pay the costs of rearing the resulting child.

Perhaps the best that the law can do here is to give greater legal effect to ASRM guidelines, as Missouri recently proposed. But this then shifts the focus to the development of those guidelines. Medical guidelines are never ethically neutral: normative choices are always hidden in the factual specifications. 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 interests of doctors.

I believe that we'll have to stick with professional guidelines to prevent future higher-order multiple cases despite their limited bite because, as Yeats put it, "nothing better can

be had." Guidelines do have some effect—professional shame and reputational standing matter, even if coercive sanctions matter more.

More importantly, though, we should put outliers like the Suleman case to the side and focus on the more important question of how best to reduce the continuing high rate of twin and triplet births in ARTs. In 2005, 35 percent of ART births were multiple, the vast majority being twins.<sup>7</sup> The ASRM has been successful in bringing the triplet-plus rate down from 6 percent in 2001 to 2 percent in 2007, and that rate is expected to drop even further.<sup>8</sup> But reducing the number of twins is much harder. Infertile patients view twins as a good outcome, overlooking the higher risks of twin pregnancies to both the mother and offspring. Also, with little insurance coverage for IVF, many parents like the idea of "getting two for the price of one." The rate of twins is lower in Europe but is still around 22 percent, which is considerably higher than the background rate from coital conception of 5 percent.<sup>9</sup> The best solution here would be single embryo transfer in patients under thirty-five, backed by repeated transfer of single frozen embryos if a fresh cycle fails to produce a pregnancy. Reaching such a goal will require a concerted effort comprised of patient education, insurance coverage, and changes in professional practice standards. Like much else in reproductive medicine, the law is usually too blunt an instrument to do the job.

1. [https://www.sartcorsonline.com/rptCSR\\_PublicMultYear.aspx?ClinicPKID=0](https://www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?ClinicPKID=0); see also V.L. Wright et al., "Assisted Reproductive Technology Surveillance—United States, 2005," *Mortality and Morbidity Weekly Report* 57, Surveillance Summary no. 5 (2008): 1-23.

2. Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146.

3. D. Adamson, "Regulation of Assisted Reproductive Technologies in the United States," *Fertility and Sterility* 78, no. 5 (2002): 932-42.

4. The Practice Committee of the Society for Assisted Reproductive Technology, The American Society for Reproductive Medicine, "Guidelines on the Number of Embryos Transferred," *Fertility and Sterility* 82, Suppl. 1 (2004): 1-2.

5. The Ethics Committee of the American Society for Reproductive Medicine, "Child-Rearing Ability and the Provision of Fertility Services," *Fertility and Sterility* 82 (2004): 564.

6. See, e.g., *Skinner v. Oklahoma*, 316 U.S. 535 (1942).

7. [https://www.sartcorsonline.com/rptCSR\\_PublicMultYear.aspx?ClinicPKID=0](https://www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?ClinicPKID=0).

8. R.W. Rebar and A.H. DeCherney, "Assisted Reproduction in the United States," *New England Journal of Medicine* 350 (2004): 1603-5.

9. A. Andersen et al., The European IVF-Monitoring (EIM) Consortium, for the European Society of Human Reproduction and Embryology (ESHRE), "Assisted Reproductive Technology in Europe, 2004: Results Generated from European Registers by ESHRE," *Human Reproduction* 23, no. 4 (2008): 756.