

CENTER FOR
GENETICS AND
SOCIETY

436 14TH STREET, SUITE 700
OAKLAND, CA 94612 USA
TEL (510) 625-0819
FAX (510) 625-0874
WWW.GENETICSANDSOCIETY.ORG

The Baby Business and Public Policy

Regulation Can Ensure Well-being and Protect Reproductive Rights

Marcy Darnovsky

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The recent media storm over the in vitro fertilization-induced birth of octuplets has receded into the tabloids and entertainment pages. A second fertility industry scandal that emerged several weeks later—the announcement by a Los Angeles fertility clinic that it would soon offer a program to select embryos not just for sex but also for hair, eye and skin color—has also veered out of the headlines. But the outcry surrounding these events has revealed mounting disquiet about the multi-billion dollar baby business.

The fertility industry's professional societies offer a potential avenue for self-regulation of the field, but their existing recommendations are too often ignored. Other countries regulate assisted reproduction to protect the well-being of all participants, including the children whom it helps create and the families and society into which they are born. Drawing lessons from their successes could help temper the commercial pressures in the U.S. assisted reproduction sector, without in any way diminishing reproductive rights.

The importance of addressing these issues is readily evident. The octuplets story left a mark even on the English language. Google now reports one and a half million results for the ungainly and unsympathetic neologism OctoMom (and the babies' mother, Nadya Suleman, has now filed a trademark application on it). The outpouring of public hostility toward Suleman that the term bespeaks seemed in part a case of misdirected anger about corporate

excesses and irresponsibility, as Jonathan Moreno has pointed out. But there was more to it than that. News articles and blog posts about the octuplets routinely drew hundreds of comments; many focused on the reckless behavior of the fertility doctor responsible for the octuplets, and raised pointed questions about the adequacy of oversight in the fertility industry. So did editorial writers, bioethicists, and a number of assisted reproduction insiders.

A smaller but no less critical response greeted the unprecedented offer to pre-select future children's cosmetic traits, first reported in mid-February in the Wall Street Journal. Fertility doctor Jeffrey Steinberg initially defended his program, explaining that it was not so different from cosmetic surgery for adults.

But that "designer baby" mentality was precisely what disturbed so many. A father who used embryo screening (the procedure is known technically as pre-implantation diagnosis or PGD) to avoid having a child with a serious genetic disease wrote in a Los Angeles Times op-ed that "Something stinks about reproductive medicine in Southern California, and it doesn't involve eight dirty diapers....Abusing...hard-won knowledge to capriciously choose hair color, eye color and other cosmetic traits in a baby is wrong and repugnant."

Bioethicist Art Caplan articulated the widespread concern that reproductive genetics could contribute to new forms of discrimination and inequality:

Designing your descendents and seeking out perfection is the biggest slippery slope we could go on. Are the rich going

to be able to do it and the poor not? Are we going to create a sort of sub-population of the genetically perfect as against everybody else?

After several weeks of reactions like these, Steinberg decided to “suspend” his program. But the door to what Caplan called our “biggest slippery slope” is hardly bolted shut.

The Limits of Self-regulation

The current problems in the baby business and the prospect of future abuses have persuaded many of the need for effective oversight. But it’s by no means unanimous: Some continue to believe that whatever adjustments are needed can be accomplished through voluntary guidelines and better enforcement of existing rules that govern general medicine. Kavita R. Shah and Frances R. Batzer of Jefferson Medical College-Thomas Jefferson University, for example, wrote in *Science Progress* after the octuplets controversy that:

American medicine already has in place several checkpoints (state licensing boards, professional organizational sanctions, and the National Practitioner’s Databank) to curb this sort of headline-grabbing behavior in the future. Utilizing these mechanisms more fully is the answer.

But both the octuplets and the designer-baby offer suggest that those mechanisms aren’t up to the job.

Let’s look first at the guidelines issued by the fertility industry’s professional organization, the American Society for Reproductive Medicine, about how many embryos to transfer into a woman’s body [PDF]. The health risks associated with IVF multiple births came in for a good deal of discussion in the aftermath of the octuplets. While in years past IVF sextuplets and septuplets were celebrated as feel-good miracles, it has become increasingly clear that even IVF triplets and twins pose significant risks to mothers and babies. Evidence is also accumulating that in younger women, transferring more than one or two embryos doesn’t

increase pregnancy success rates, even as it sharply boosts the chances of high-order multiple births.

For these reasons, ASRM guidelines now call for transferring no more than two embryos per cycle for women under 35, and the group has mounted educational efforts that have in fact helped to reduce the rate of IVF multiples. But ASRM’s spokesperson told a reporter that “exceptions to the guidelines are permitted, and the society is not inclined to second-guess decisions made by physicians.”

Michael Kamrava apparently transferred six embryos at 33-year-old Nadya Suleman’s request; two of them twinned. By any measure and at any time, the eight-baby pregnancy thus created would be considered extreme, and a six-embryo transfer into a young woman is, we would all hope, unusual. But notwithstanding the criticisms of Kamrava by other fertility doctors, he is hardly alone in violating ASRM recommendations. In fact, a large majority of assisted reproduction programs—fully 80 percent of them, according to Centers for Disease Control and Prevention data—fail to comply with the guidelines. In California, home to Kamrava’s practice and a disproportionate number of fertility programs, the non-compliance rate is 92 percent.

What about the use of PGD for selecting non-medical traits? ASRM’s Ethics Committee has issued guidelines that discourage using PGD for sex selection except in the rare cases of sex-linked disease. Yet that recommendation too is openly and commonly flouted. A 2006 survey of IVF centers that provide PGD, conducted by the Genetics and Public Policy Center, found that 42 percent acknowledge offering it for social sex selection. A quick online tour shows that many fertility programs advertise [PDF] it openly [PDF].

Professional guidelines, by definition non-binding, can’t be expected to effectively regulate assisted reproduction. But ASRM could put at least some teeth behind its rules: It could, for example, publicly sanction or suspend the memberships of fertility practices that don’t

comply with its guidelines. Unfortunately, it has not exercised even that minimal influence.

Fertility Medicine is Different

What about the argument that assisted reproduction is adequately regulated by the rules governing general medicine? Those rules are of course important, but they don’t account for the important ways in which fertility treatment and the fertility industry differ from most other medical practice.

First, assisted reproduction in the United States is subject to less oversight than most other medical fields. Much of it takes place in private, for-profit clinics that do not receive public funding and therefore are not required to adhere to the human subject protections and research reviews that apply to most experimental medical procedures. Thus, some new IVF techniques like intracytoplasmic sperm injection, which places a single sperm directly inside an egg, have moved from concept to clinic without systematic animal studies or reviews by any independent agency or committee.

Second, the U.S. assisted reproduction sector is subject to more and different kinds of commercial pressures than most other medical fields, largely because most patients pay for fertility treatment out of pocket. Like practices offering cosmetic procedures, fertility programs use a full range of advertising and marketing devices to compete with each other for customers. While assisted reproduction resembles cosmetic medicine in its commercial nature, it’s more like adoption or foster care in that it helps people become parents. Adoption, however, has robust rules to ensure that the well-being of the children involved comes first. That’s not at all true of assisted reproduction. In fact, fertility clinics’ responsibility ends when pregnancy is established; other medical personnel take over the care of both the mothers and children from there.

At the same time, assisted reproduction is unlike adoption, and unlike any other field of medicine, in that it creates new

people. Yet fertility doctors focus entirely on the intended parents, who are, after all, their patients—and their customers. And fertility practitioners are not necessarily thinking about—or should they be solely responsible for—the ways in which some reproductive genetic procedures could wind up changing the society into which those newly created children are born.

Concerns About Abortion Politics and Medical Practice

Those who resist additional regulation and oversight of assisted reproduction often worry about possible harms to reproductive choice and to medical practice. These are serious concerns.

One sort of reassurance can be found in the dozens of countries that regulate assisted reproduction quite robustly without in any way infringing on abortion rights. In those countries, however, the right to terminate an unwanted pregnancy is better protected than in the United States. Indeed, in this country, there have already been efforts to slip restrictions on abortion rights into proposals to regulate assisted reproduction. In the aftermath of the octuplets case, a Georgia state senator introduced a bill that addressed fertility clinic practices but also contained provisions establishing the legal personhood of human embryos. That language was later stripped from the bill, but similar Trojan horses are possible in the future.

Any policy proposals to regulate assisted reproduction will have to be carefully scrutinized to make sure they don't deliberately or inadvertently undermine women's health or reproductive rights. But that's true of policies in many arenas. And the Georgia experience arguably demonstrates that we're better off taking a proactive approach to regulating assisted reproduction than allowing opponents of abortion rights to capture the high ground and public sentiment. Especially now, with an administration that is friendly to women's rights, we have the chance to establish public policy for the fertility field in a way that fully respects abortion rights.

The other frequent objection to setting

enforceable assisted reproduction rules is that it will put unwarranted limitations on doctors. Shah and Batzer, cited above, warn of “resort[ing] to bulky legislation” and “allowing government's heavy hand to further encroach on medical practice.” But public policy isn't inevitably bulky, and government doesn't always encroach. And as recent financial misadventures demonstrate, the absence of regulation and oversight can itself be a problem: Market mechanisms can and do encourage irresponsible behavior and unacceptable practices.

To be sure, no law should attempt to specify the medical details of fertility treatment. But few would suggest that. There are successful models of public policy on assisted reproduction from which we can learn a great deal. Other countries have adopted regulatory mechanisms that give medical professionals the leeway they need to adjust treatments to individual patients, and that have shown themselves flexible enough to change with scientific and technical developments.

How to Regulate Assisted Reproduction

In most of the industrialized world, comprehensive oversight of assisted reproduction has already been put in place. In many countries, fertility clinics are licensed by a government agency. This arrangement allows for rules to be modified as needed, but provides a mechanism for ensuring that clinics are following them. A few extreme reproductive practices—most commonly efforts to produce a cloned or genetically modified child—are typically prohibited outright. Rules about permitted procedures, guided by consistent principles, are set and enforced by the licensing agency.

Take, for example, the United Kingdom. After the birth of the first baby by in vitro fertilization in 1978, a lengthy process of public input and deliberation led to a detailed report, and then to a law creating the Human Fertilisation and Embryology Authority. The HFEA oversees both assisted reproduction and research with human embryos. By statute, its governing board is diverse, and

not dominated by researchers or clinicians. By requiring and issuing licenses, it is able to maintain standards and prevent abuses. While a few of HFEA's decisions have been controversial, its principles and processes are widely supported both by the public and by practitioners of assisted reproduction and embryo research. Canada is following a track similar to the British one.

Many close observers consider the United Kingdom's HFEA a model for oversight of assisted reproduction in the United States. That was the conclusion, for example, of a multi-year study by fourteen prominent scholars and bioethicists led by Erik Parens and Lori Knowles of the Hastings Center. Importantly, their analysis [PDF]—which was published in 2003—called not only for careful consideration of the safety of repro-genetic procedures and technologies, but also for assessments of their broader social consequences and their effects on personal and societal well-being.

The UK and many other countries that regulate assisted reproduction differ from the United States in another crucial way: They regard health care as a right and provide it to their citizens. Typically public health care systems pay for a limited number of IVF cycles, and even where fertility treatment providers remain largely in the private sector, this changes the commercial dynamics of assisted reproduction significantly.

Obviously, slavish duplication of the UK's assisted reproduction system would be ill-advised. We live, after all, in a larger and more diverse nation that, for better and for worse, is unaccustomed to public regulation of any kind of health care. But continuing to resist oversight of the fertility business would also be unwise, particularly with the possibility of real health care reform on the horizon. The many thousands of families who look to assisted reproduction, and the society into which the children it helps create are born, deserve better.

Marcy Darnovsky, PhD, is associate executive director of the Center for Genetics and Society.