

## Preventing the Next Fertility Clinic Scandal

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### Sperm fertilizing an egg

Given the U.S. fertility industry's long-standing resistance to effective oversight, the field's two recent controversies - first octuplets, then an offer of embryo screening for cosmetic traits - shouldn't really come as a surprise. What was remarkable about the reaction they evoked from knowledgeable observers, in fact, was the chorus of agreement that it's time to leave the "Wild West" days of assisted reproduction behind.

The octuplets story turned many of us into reluctant voyeurs, fascinated by the daily dribble of details. Fortunately, at least some of the media attention soon turned away from the unsettling details about the babies' mother and focused instead on the fertility doctor involved. We soon learned that Michael Kamrava had not only transferred six embryos — two of which divided into twins — into the octuplets' mother, but had also recently put seven embryos into another woman who wanted only one child, leaving her pregnant with quadruplets.

The industry that had tolerated such irresponsible medical conduct also came under much-needed scrutiny. Many people were surprised to learn that the multibillion dollar American fertility industry operates largely without oversight. It is subject only to the typical standards of general medical practice and the voluntary guidelines of the American Society for Reproductive Medicine (ASRM), the dominant industry group. The

only federal requirement is for clinics to report their success rates to the Centers for Disease Control and Prevention (CDC).

How well does self-regulation work? Take the one guideline that has come under the most scrutiny: the number of embryos a fertility doctor should implant. The ASRM asks its members to transfer only one into women with a favorable prognosis who are under age 35 (as was the mother of octuplets). Yet CDC data reveal that the average number of embryos transferred is higher than the guideline. Media analysis of the CDC data shows that 80 percent of clinics do not follow the guidelines.

Although these guidelines are nonbinding, the ASRM and its sister organization, the Society for Assisted Reproductive Technology, could sanction members by expelling them. But that doesn't appear to be occurring. Our brief analysis found no correlation between whether a clinic meets the guideline and whether it is a member.

Condemnation of Kamrava came from all quarters: bioethicists, fertility doctors, users of assisted reproductive technologies, newspaper editorial boards, and "person on the street" interviews. And calls for regulation were unequivocal and frequent. An editorial in the Los Angeles Times said, "Clearly, the field of fertility treatment needs more than guidelines."

Bioethicist Art Caplan wrote in the Philadelphia Inquirer:

If the medical profession is unwilling or unable to police its own, then government needs to get involved. We already have rules governing who can get involved with adoption and foster

care. Shouldn't these minimal requirements be extended to fertility treatment? And shouldn't some limit be set on how many embryos can be implanted at one time, along with some rules about what to do with embryos that no one wants to use?

Other nations, such as Britain, keep a regulatory eye on reproductive technologies and those who wish to use them, knowing their use can put kids at risk in ways that nature never envisioned. We owe the same to children born here.

A rare public defender of Kamrava was Dr. Jeffrey Steinberg, who said, "Who am I to say that six is the limit? There are people who like to have big families." In fact, he is at the center of the second recent controversy in the fertility industry.

For years, Steinberg has vocally supported broadening the use of genetic selection during IVF, or preimplantation genetic diagnosis (PGD), to any potential trait. He believes that "the ability of PGD should go as far as the science allows us to take it." Last December, his clinic's Web site began to advertise the "pending availability" of PGD for selection of the hair color, eye color, and skin color of future children. He dismissed criticism, noting that what he's offering is little different from existing procedures for adults: "I live in L.A. and everyone here wants to have a straight nose and high cheekbones and are perfectly happy to pay for cosmetic surgery."

Steinberg's offer was a realization of previous concerns about PGD. Predictions previously considered alarmist - "What's next...hair and eye color?"--were suddenly coming true. And the inclusion of skin complexion among the selectable traits holds the risk of reinvigorating our worst prejudices. As my colleague Osagie Obasogie wrote on the potential to scientifically influence skin color in *New Scientist* in 2007:

As the science advances, however, policy-makers must develop a regulatory framework that does not allow innovations to exploit the deep-rooted bias that society has towards certain groups.

It would surely be a pity for any aspect of biotechnology research to develop in ways that help people to profit from racial prejudice.

After Steinberg's offer was reported in the *Wall Street Journal*, media coverage gradually grew. Three weeks after the *Journal* article, the story made it to the major television broadcast networks and cable news programs. Steinberg remained dismissive of concerns, and was the beneficiary of publicity via the controversy.

As with Kamrava's octuplets, criticism was widespread. Mark Hughes, a pioneer of PGD, said, "It's ridiculous and irresponsible... no legitimate lab would get into it and, if they did, they'd be ostracized." William Kearns, the medical geneticist on whose work Steinberg's procedure is based, was clear where he stood: "I won't sell my soul for any amount. Steinberg has jumped on my research but I'm totally against this." A father of one of the first children born via PGD, for a medical reason, wrote in a *Los Angeles Times* op-ed that, "Abusing that hard-won knowledge to capriciously choose hair color, eye color and other cosmetic traits in a baby is wrong and repugnant."

Art Caplan captured the concerns of many when he said, "Designing your descendants 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 subpopulation of the genetically perfect as against everybody else?" And Pamela Madsen, founder of the American Fertility Association, admitted:

As a leading fertility advocate for close to 20 years, I have actively fought against federal legislation of Reproductive Technologies. But if the doctors in our field cannot employ common sense — and harness in their own — the time has never been riper for the federal government to step in.

Last week, Steinberg announced that he was suspending his program of trait selection, citing "apparent negative societal impacts." However, his statement was worded in a way that leaves the door open

for later resumption.

If Steinberg does not resume offering so-called "designer babies," in the absence of clear lines, someone else will. As long as the baby business remains free of oversight, competitive pressures will push clinics into a race to the bottom, and social pressures will push parents to demand "only the best children."

However, achieving good legislation governing the fertility industry is a hazardous process. Some will try slipping Trojan horses that infringe on reproductive rights into proposals to regulate assisted reproduction. This is already occurring in Georgia, where legislators opposed to abortion rights introduced a bill that establishes the embryo as a person and likely prohibits the derivation of embryonic stem cell lines.

In contrast, in Missouri, a very brief bill simply limits the number of transferred embryos to what's specified in the ASRM guidelines. In fact, the industry group is supporting the measure. While it is a limited start, it demonstrates the principle that such proposals need not get entangled in abortion politics.

Yet state-level action can only go so far, and can actually be counterproductive. At their best, state laws will produce a cumbersome patchwork while encouraging fertility practitioners and patients to travel to the most favorable jurisdiction.

Responsible federal oversight of the fertility industry, in ways that protect reproductive rights and actually improve appropriate access to fertility treatment, is not only possible but long overdue. Most of the industrialized world has put such regulation and oversight in place. Comprehensive policies have been adopted in Canada, the United Kingdom, and elsewhere. It's time for the United States to catch up and move beyond its reputation as the "Wild West" of assisted reproduction.

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