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Editorial

Assisted reproduction and choice in the biotech age: recommendations for a way forward

Over the past several decades, millions of people have used new reproductive technologies in their quest for biologically related children. Access to these technologies has enabled people who suffer from infertility, same-sex couples and single women to form biological families. At the same time, these tools can be used to select the sex of a future child [1] or to "de-select" based on a growing number of genetic markers for disabilities and other conditions [2]. While assisted reproductive technologies have increased parental options for those who can afford them, they pose numerous ethical challenges that the reproductive rights, health and justice communities are only beginning to address.

The assisted reproduction field has so far developed largely outside the realm of public policy and with little public discussion about how new technologies should be used and who should have access to them. Difficult questions have had minimal public airing. Should access to reproductive technologies be limited to those who can pay for them? Should the characteristics of future children be pre-determined? What about efforts to develop extreme technologies such as reproductive cloning or genetic techniques for producing "enhanced" children? How can we safeguard the well-being of everyone involved in assisted reproduction, including children who are produced and third parties who provide gametes or serve as surrogates?

Satisfactory answers to these questions will require robust and nuanced consideration by a full range of stakeholders. We believe that both clear guidelines for providers and enforceable public policies will be needed if we are to make assisted reproduction safer for women, protect the health and rights of all involved, and prevent socially unacceptable uses of the technologies.

1. The challenge of regulation

Supporters and providers of comprehensive reproductive health services have good reasons to be skeptical of government regulation in the area of reproduction. Too often, laws and regulations have been designed to restrict access to reproductive health services, in particular to abortion and especially for the most vulnerable groups of women. Rather than promote health or well-being, regulations promulgated by those seeking to restrict access to abortion have burdened providers with requirements unrelated to health or safety, distorted "informed consent," forced providers to give patients false and misleading information, and placed limits on who can be a parent [3]. Recently, opponents of abortion rights have seized on the use of reproductive technologies as a pretext to curtail abortion access by promoting legislation to ban sex and race selection [4]. Reproductive justice leaders from the SisterSong Women of Color Reproductive Justice Collective, Georgia Spark and Generations Ahead have responded, pointing out that there is no such thing as "race selection" and that we can discourage sex selection without restricting the decision-making agency of women [5,6].

Perhaps because of this history, the debate about regulation of reproductive technologies has been cast as a yes-or-no matter. Depending on how it is crafted and where it is targeted, however, regulation can support the outcomes and values we support. For example, the risks and ethical dilemmas posed by reproductive technologies can often be addressed by in-depth considerations and by clear professional guidelines. Sex-selective abortion is one example. More than 10 years ago, reproductive health champion Felicia Stewart acknowledged the challenge of serving patients who were happily monitoring their pregnancies until they received amniocentesis results that revealed the sex of their child. Suddenly, they were asking for abortions. The pressure on providers to accede to such requests has only increased since Dr. Stewart raised the issue, and the professional community has developed very little guidance for handling it. In Canada, the demand for sex selection is so widespread that a bioethicist and a physician — both supporters of abortion rights — recently recommended that doctors delay imparting information about fetal sex in order to discourage abortions for the purpose of sex selection [7]. Caring and conscientious practitioners have told us they would welcome clear rules and a level playing field on this issue.

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In other cases, regulation and oversight are the most promising strategies we have to ensure that existing and emerging reproductive technologies are used safely and in ways that do not involve abuse and exploitation. Policies regulating sterilization practice in the US provide an example. Voluntary sterilization is an important contraceptive technology and is today one of the most common forms of birth control. However, before regulations were put in place, tens of thousands of people of color, mentally disabled people and poor people — the majority of them women — were sterilized without their consent. Public policies including a requirement for fully informed consent in advance of a sterilization procedure have significantly reduced these abusive practices and ensured that this important tool has remained available to millions.

While we need to continue to be vigilant against laws that police women's bodies, or that make access to assisted reproduction dependent on a person's status or identity, we also need to step up and begin designing public policies that responsibly regulate the application of reproductive technologies and the industry that develops and depends on them.

2. The assisted reproduction industry in the United States

A central point of Barnard College President Debora Spar's 2006 book *The Baby Business* is the widespread American reluctance to acknowledge that assisted reproduction is a commercial enterprise that is subject to the full force of market dynamics [8]. It is now a $3 billion dollar a year industry in the United States [8], with tens of thousands of patients/consumers each year. But unlike other developed countries such as Canada and the UK, the United States has allowed the business of assisted reproduction to develop in a largely unregulated manner. We have neither a public health care system nor many private insurance companies that provide coverage for assisted reproduction, and we have little public oversight of the fertility industry's practices.

By contrast, many other industrialized countries have adopted public policies to protect fertility patients, their children and third parties involved in assisted reproduction, and also to prevent socially unacceptable practices. The UK is the best example of a nation that has established rules for assisted reproduction — with notable success from the perspectives of both patients and practitioners — while supporting both abortion rights and widespread access to assisted reproduction. It and dozens of other countries prohibit extreme reproductive procedures — inheritable genetic modification, reproductive cloning, and embryo screening techniques (known as pre-implantation genetic diagnosis or PGD) for clearly non-medical purposes. Many countries also license fertility clinics and put limits on practices such as commercial surrogacy and egg provision. In many cases, these policies are explicitly intended to protect the health and well-being of women and children [9].

The United States, often called the "Wild West" of assisted reproduction [10], asks only that doctors and fertility clinics be licensed and that clinics report their success rates to the Centers for Disease Control and Prevention [11]. Other than that, it relies on voluntary guidelines issued by the American Society for Reproductive Medicine (ASRM), the fertility industry's professional organization. Although many of these guidelines are reasonable, they are not binding and are routinely flouted. For example, ASRM recommends that when treating women under the age of 35 years with a favorable prognosis, only one embryo be transferred at a time [12]. Yet, data published by the Centers for Disease Control and Prevention show that fully 80% of fertility clinics fail to abide by this guideline [13]. ASRM also discourages screening of embryos for sex selection [14] and sets $10,000 as the maximum compensation appropriate for third parties who provide eggs for other people's fertility treatments [15]. Nonetheless, many clinics are actively marketing sex selection, and many ads recruiting women to provide eggs offer far higher sums [16].

The US status quo of voluntary self-regulation has left us with an array of unanswered ethical questions and a litany of quality-of-care concerns, including widespread use of off-label drugs, a tendency to gloss over and minimize risks and a marked lack of follow-up studies and data to ensure safety. The commercial dynamics in the fertility business, coupled with the often desperate desires of people seeking to create biologically connected families, too often allow market forces to override health, safety and informed consent concerns. Many people are unaware of the significant safety concerns raised by various aspects of high-tech reproduction as practiced today. For example, how many people know that obtaining eggs for in vitro fertilization requires women (whether undergoing fertility treatment themselves or providing eggs for others) to take a heavy load of hormones; that some of these drugs have not been approved by the FDA for this use; that there have been thousands of reported adverse reactions to the most commonly used of these drugs, including hundreds of hospitalizations; and that no one is systematically collecting data on the long-term effects on women and their offspring? [17] The lack of robust health and safety research and data is a global concern. Even the UK, which has a strong regulatory system, has yet to effectively address the long-term impact of fertility treatments. Given this lack of adequate safety data, can women truly provide informed consent?

In addition, our failure to regulate has contributed to an international market, with people coming to the US to avoid policies in their home countries and Americans going to lesser developed countries where assisted reproduction is cheaper — in part because women there can be paid far less for providing eggs or for surrogacy.

3. Ethical dilemmas and public policies

In essence, by allowing the fertility industry to experiment with new techniques and protocols with little oversight, and by uncritically embracing these new technologies, we have put women and children at risk and crossed numerous moral and ethical lines. Moreover, these lines have been crossed with little public acknowledgment. We believe that it is time for our community to undertake a pro-active, in-depth, critical analysis of the safety concerns and ethical dilemmas posed by new reproductive and genetic technologies. Here we suggest some of the key ethical questions to be addressed:

- Is there an essential difference between a woman's right to terminate an unwanted pregnancy and the decision to pre-select the traits of her children?
- What will be the effects of trait de-selection on people living with disabilities and on society in general?
- Should fertility clinics be permitted to market procedures that allow the selection of future children's eye, hair and skin color, as one did in 2009?
- Is it politically acceptable to condemn sex selection in countries where it is used to avoid girl children, yet accept a burgeoning and lucrative sex selection business in the US and Canada for "family balancing?"
- Do payments to poor women in India for surrogacy services or to young women for eggs benefit these women more than exploit them? How do we create an ethical framework that accounts both for people's desire to have a biologically related child and concerns about risks to egg donors or surrogates?
- Do selection and de-selection technologies serve as a gateway to extreme procedures such as reproductive cloning and inheritable genetic modification?

A thorough discussion of these questions — a discussion that we frame and place in the context of our commitments to women's health, reproductive justice and human rights — should be accompanied by initiatives to craft effective and responsible public policies for assisted reproduction. Women's health, reproductive justice and other public interest organizations in the US have begun this conversation and are inviting broader participation to hear and respect a range of views. Key U.S. organizations engaged in these efforts include Alliance for Humane Biotechnology, Center for Genetics and Society, Generations Ahead, Reproductive Health Technologies Project, Our Bodies Ourselves and the Pro-Choice Alliance for Responsible Research [18]. At the recent Tarrytown Meeting, initiated by the Center for Genetics and Society, advocates, scientists and academics engaged in multidisciplinary discussions about the roles of government and civil society in regulating human genetic and reproductive technologies.

Public regulation and oversight of the assisted reproduction industry are long overdue and much needed. Continuing to allow the market to dictate how assisted reproduction is developed and used, and continuing to insist that voluntary guidelines are all that are needed, leaves us ethically ill-served and politically vulnerable. Taking the policy initiative is far more likely to result in the outcomes we want. Reasonable rules and oversight will make assisted reproduction safer for women, protect the health and rights of all involved, prevent unacceptable uses of the technologies and bolster public trust both in their appropriate uses and in the leadership of the women's health and provider communities.

Francine Coeytaux
Pro-Choice Alliance for Responsible Research
Los Angeles, CA 90035, USA
E-mail address: fcoeytaux@earthlink.net

Marcy Darnovsky
Center for Genetics and Society
Pro-Choice Alliance for Responsible Research
Berkeley, CA 94704, USA

Susan Berke Fogel
Pro-Choice Alliance for Responsible Research
Van Nuys, CA 91401, USA

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