

FOREWORD: GENETIC EXCEPTIONALISM

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Collected on the occasion of the *Harvard Journal of Law & Technology's* Symposium on "Privacy, Property, and Family in the Age of Genetic Testing," the articles in this issue of the *Journal* sketch the landscape of contemporary genetic and reproductive law and policy. Taken together they form a provocative, if only accidentally harmonic theme: society may not always benefit from special genetic and reproduction regulations, or special "exceptions" to existing policies for genetics. Against the backdrop of dozens of ongoing attempts to craft new policies, amend existing policies, and challenge existing law regarding genetics, analysis of genetic "exceptionalism" is welcome.

Lee Silver and Susan Remis Silver use a provocative thought experiment to illustrate the need to reemphasize the right to reproduce in contemporary policy:¹ a lesbian couple utilizes sperm donation, embryo fusion, gender selection, and mutual gestation to have two children, each borne by one of the partners. This imaginative case study, and subsequent legal analysis of existing policy and recent decisions, points to a future in which determining "who is the parent" will become both more complex and more crucial. Lori Andrews adapts her study of human cloning commissioned by the National Bioethics Advisory Commission, asking whether regulation of human cloning could withstand constitutional scrutiny.² She describes the context and significance of human cloning experiments, and claims that there may be constitutionally acceptable justifications for government interventions and policies to restrict some kinds of human cloning. Her article also illustrates the complexity of separating the need for policy designed to protect "future" human subjects from policies and decisions aimed at

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The opinions expressed in this foreword are those of Dr. McGee and do not necessarily reflect the opinions of other participants in this year's Symposium or of other authors included in this issue.

1. See Lee Silver & Susan Remis Silver, *Confused Heritage and the Absurdity of Genetic "Ownership,"* 11 HARV. J.L. & TECH. 593 (1998).

2. See Lori B. Andrews, *Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning,* 11 HARV. J.L. & TECH. 643 (1998).

protecting scientific and parental liberties. Elizabeth Price explores in detail the question of FDA authority in the area of reproductive science and medicine, concluding that regulatory authority over clinical human cloning at the federal level has little clear precedent and that such authority might be difficult to establish in the FDA.³

Several important dimensions of genetic law and policy that were discussed at the *Journal's* conference receive only limited attention in these articles, but merit discussion in our introduction. Ronald M. Green and A. Mathew Thomas' article, *DNA: Five Distinguishing Features for Policy Analysis*⁴ maps these in a suggestive way. In Green and Thomas' article, five broad tropes of DNA-distinct policy issues are discussed: informational risks; the longevity of DNA; DNA as an identifier; familial risks; and community impacts of DNA analysis. These features of genes distinguish DNA from other kinds of medical information, leading the authors to conclude that special DNA-specific exceptions to existing policy must be carved out. In the conference, other distinct features of DNA were debated as well, including the viability of DNA as property, DNA as invention, and genetic association as a patentable manufacturing or diagnostic process.

Some introduction to the theme of "genetic exceptionalism" is appropriate. At the dawn of the twenty-first century, legislators, lobbyists, industries, and courts struggle to cope with new genetic and reproductive science and medicine. As Lori Andrews notes, the pace of change in reproductive genetics vastly outstrips existing clinical and formal community understanding. The year 1997, for example, saw the identification of many new genes, the birth of septuplets, birth to a sixty-three year-old, cloning of a mammal, births from frozen eggs, and the harvesting of sperm from deceased men. Outcry against human cloning and genetic patenting suggests an American constituency that profoundly distrusts its own and its institutions' ability to deal with new human biotechnology. This mistrust evidences itself in unusual ways, as biotechnological debate is hardly connected to partisan politics. The only barometer for political engagement on many new genetic and reproductive issues seems to be the more or less informed sentiment of a particular representative or her constituency or religious affiliation. Even religious groups have scarcely begun to sort out their positions on modern genetic issues.

3. See Elizabeth Price, *Does the FDA Have Authority to Regulate Human Cloning?*, 11 HARV. J.L. & TECH. 619 (1998).

4. 11 HARV. J.L. & TECH. 571 (1998).

This overt distrust of human wisdom in biotechnological policy evidences itself in two contradictory ways. One dates to the American history of eugenics. As Daniel Kevles,⁵ Diane Paul⁶ and others have demonstrated, the eugenics movement eventually resulted in widespread fear of reproductive policy. In these pages, the juridical debate over procreative liberty is sketched by Lori Andrews, Lee Silver, and Susan Remis Silver, with an emphasis on the increasing problem of defining the scope of the community's interest in monitoring the making of children.

The emerging sense that parents and social institutions have a responsibility to the future, and particularly to future generations, bears little resemblance to the comprehensive eugenic planning of the early twentieth century. New tools open an unprecedented window to the womb, allowing not only mothers but a large and growing set of individuals and institutions to peer into the possible futures of unborn or frozen future offspring. The advent of neonatal intensive care and changing economic and cultural standards of care in pediatrics and obstetrics are everywhere evident. The upshot is that parents can now think of planning for fetal and infant health in very personal and intimate terms and at an ever earlier stage. Parents throw their financial livelihoods into care for an imperiled fetus or newborn, and include ultrasound pictures of their fetus in photo albums. The standards for care in pediatrics are being applied to ever-younger humans, so that it is now thought of as a moral, if not legal, responsibility to provide comprehensive prenatal care for any wanted pregnancy. This is the analysis used by the President's Bioethics Advisory Commission in its report on the cloning of humans. The Commission determined that, despite the legal and moral problems with protecting possible future persons, there is a compelling state interest in preventing the creation of individuals whose future would be imperiled by the very act intended to create them.⁷

5. See Daniel J. Kevles, *Out of Eugenics: The Historical Politics of the Human Genome*, in *THE CODE OF CODES: SCIENTIFIC AND SOCIAL ISSUES IN THE HUMAN GENOME PROJECT 3*, 11 (Daniel J. Kevles & Leroy Hood eds., 1992) [hereinafter *THE CODE OF CODES*]; Daniel J. Kevles & Leroy Hood, *Reflections*, in *THE CODE OF CODES*, *supra*, at 300, 326 ("In its ongoing fascination with questions of behavior, human genetics will undoubtedly yield information that may be wrong, or socially volatile, or, if the history of eugenics is a guide, both.").

6. See Diane B. Paul, *Eugenic Anxieties, Social Realities, and Political Choices*, 59 *SOC. RES.* 663, 670-71 (1992).

7. See Glenn McGee & Ian Wilmut, *Cloning and the Adoption Metaphor*, in *THE HUMAN CLONING DEBATE 192* (Glenn McGee ed., 1998).

As the debate concerning the overall scope of genetic and reproductive policy has proceeded during the past fifteen years, very little progress has been made in developing institutions whose role will be to address these areas or to alleviate public suspicions that genetic policy is ultimately aimed at eugenic ends. Genetic counseling is provided to only a small fraction of those using genetic tests, and there are fewer than 2,000 certified genetic counselors in the United States.⁸ Genetic education of clinicians and others in positions of social responsibility is woefully inadequate. In fact, much of the move to define specifically "genetic" kinds of privacy or discrimination is no doubt precipitated by the apparent lack of any rubric within which genetic questions can be comprehensively addressed by existing institutions. Both the parents who hope to use new genetic technologies to plan for making a baby, and the parents who fear state interventions aimed at genetic screening are confused about where to turn and about the meaning of existing policies and laws.

The second manifestation of the odd political debate over genetic policy is the problem of prioritizing reproductive health services. New therapies for sexual and reproductive dysfunction force us to define the role of sex and reproduction in health services more generally. In particular, it has become a matter of some urgency to define heretofore fuzzy assumptions about what sort of family, sex life, parenthood, and reproductive activity is normal, so that decisions can be made about which techniques are therapeutic, and which therapies are important.

Would-be fathers with testicular abnormalities may not be able to use their sperm in a "normal" way to secure pregnancy. What therapy is available for these men and their partners? Adoption? Donor insemination? Counseling and life adjustment to infertility? Intra-cytoplasmic sperm injection? Foster parenting? The parameters of these choices will be set by wholly new kinds of debate about the meaning of genes and their role in reproductive flourishing and health. A physiologically impotent man who wants to use Viagra in Alabama or California must wait for his managed care company to define "sexual restoration." Will he receive five pills or ten pills each month, and what will he be required to pay? In the aggregate, our decisions about sexual and reproductive health will increase the burden imposed by reproductive medicine on scarce medical resources.

8. See Kevin Lamb, *Trouble Helix*, DAYTON DAILY NEWS, Feb. 3, 1998, at 1C (fewer than 2,000, according to Anne Veght, a genetic counselor at The Children's Medical Center in Dayton, Ohio); Rick Weiss, *Defect Tied to Doubling Of Risk for Colon Cancer*, WASH. POST, Aug. 26, 1997, at A1 (approximately 1,200, according to Francis Collins, chief of the National Human Genome Research Institute).

In genetic medicine, the debate over how to provide genetic services is most immediately and intimately linked to the present and future situation of adults who want to know about their genes. Patenting of genes and banking of family genetic history will change the way one learns about one's own DNA. The banking of tissue samples is critical for the genetic analysis that will, over the long term, validate many new genetic tests for "susceptibility" to diseases. Over ten or fifteen years, subjects will be examined and re-examined alongside their genetic blueprint, in an attempt to determine the sensitivity of new genetic tests. Patients frequently do not want to wait for the tests to be validated in such a manner, however. As a result, there is enormous pressure to provide genetic testing before tests have been carefully validated by long-term clinical research.

In addition, research subjects may claim a right to profits obtained by companies who patent information associated with the genetic mutation identified in their tissues. Companies already claim that genetic information is not a commons, nor is it contributed by a research subject. Instead, companies argue that there is genuine, patentable innovation involved in associating genes with traits in humans and animals.⁹

Do research subjects whose tissues have been banked and analyzed have a right to profits derived from analysis of their heredity? Do corporations making claims to patent protection for hereditary information have any business claiming that genetic information is an invention, a process, or a tool? Those preparing to litigate existing claims to human gene patents have before them a significant new challenge: developing jurisprudence that either incorporates genetic information and processes into other conventional matters, or holds that genes are not patentable subject matter. Here too, the question is at once difficult and urgent: do we need new and activist genetic policy, or can traditional norms be shaped in the courts to accommodate new problems?

With every passing month another headline announces a watershed event in biotechnology policy: cloning, septuplets, gene patenting, a private genome project, sexual restoration, germ-line gene therapy. We can be confident that the next century will see even more dramatic developments. If the collected articles of this issue tell us anything, it is

9. Cf. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 699 (1998) (noting that private firms are filing patent applications for gene fragments, even before identifying corresponding biological functions); Glenn McGee, *Gene Patents Can Be Ethical*, 7 CAMBRIDGE Q. HEALTHCARE ETHICS 342 (1998).

that whether we write new genetic policy or rely on adapted precedent, the key to responsible genetic stewardship is education and trust in social institutions. The time has come for comprehensive reproductive and genetic education and policy to rise to the top of the agenda in statehouses, churches, medical and nursing schools, and the media.