

NOTES

GUIDING REGULATORY REFORM IN REPRODUCTION AND GENETICS

Only a few decades ago, doctors and scientists began to understand how to manipulate the fundamental elements of human genetics and human reproduction, raising new hopes but also strong concerns. New reproductive techniques such as in vitro fertilization (IVF) were denounced as heralding a “new holy war against human nature,”¹ and as representing “morally forbidden” techniques that constituted “a disastrous further step toward the evil design of manufacturing our posterity.”² Likewise, the prospect of mixing together DNA from different sources was viewed as “an additional fearful load on generations that are not yet born.”³ Many believed that the specter of drastic consequences arising from such unfettered research necessitated scrutiny and tight regulation.

Despite the similarity of early concerns regarding reproductive medicine and genetic research, the two fields have spawned very different regulatory regimes. Assisted reproduction is now dominated by private firms that provide reproductive services, including fertility treatments, to parents willing to pay, operating under only a minimal set of guidelines with little formal oversight.⁴ In contrast, most genetic research remains tightly regulated by overlapping federal agencies, with funding subject to the approval and oversight of review boards that scrutinize the ethical, safety, and policy concerns of new research.⁵

Some of the most contentious new research and development — from embryonic stem cells (ES cells) to cloning to genetic chimeras — occurs at the intersection of these fields. Largely unregulated fertility clinics, for example, are seeking to offer advanced genetic tests at in-

¹ ROBIN MARANTZ HENIG, PANDORA’S BABY: HOW THE FIRST TEST TUBE BABIES SPARKED THE REPRODUCTIVE REVOLUTION 70 (2004) (quoting Leon Kass, *New Beginnings in Life*, in *THE NEW GENETICS AND THE FUTURE OF MAN* 20–21 (Michael P. Hamilton ed., 1972)) (internal quotation marks omitted).

² *Id.* at 99 (quoting Paul Ramsey, *Shall We “Reproduce”? I. The Medical Ethics of In Vitro Fertilization*, 220 J. AM. MED. ASS’N 1346, 1347 (1972)) (internal quotation marks omitted).

³ SHELDON KRIMSKY, GENETIC ALCHEMY: THE SOCIAL HISTORY OF THE RECOMBINANT DNA CONTROVERSY 267 (1982) (quoting Erwin Chargaff Letter, *On the Dangers of Genetic Meddling*, 192 SCIENCE 938, 938–39 (1976)).

⁴ See DEBORA L. SPAR, THE BABY BUSINESS: HOW MONEY, SCIENCE, AND POLITICS DRIVE THE COMMERCE OF CONCEPTION 31–67 (2006) (describing the structure and mechanics of the modern fertility market).

⁵ See Nancy M.P. King, *RAC Oversight of Gene Transfer Research: A Model Worth Extending?*, 30 J.L. MED. & ETHICS 381 (2002); Thomas F. Kresina, *Federal Oversight of Gene Therapy Research*, in *AN INTRODUCTION TO MOLECULAR MEDICINE AND GENE THERAPY* 303 (Thomas F. Kresina ed., 2001).

creasingly early stages of embryonic development that can help parents shape the traits of their future children by screening embryos.⁶ At the same time, a growing amount of genetic research utilizes the techniques pioneered in reproductive medicine, with the study and use of ES cells being a prime example. The regulatory disparity creates a number of dilemmas, perhaps most prominently the increasing difficulty of determining which regulatory regime to apply when the underlying technologies and procedures span both fields.

It is tempting to dismiss the jumbled state of regulation as an accident of history, and many policy proposals indeed devote little attention to the origins of the divergence.⁷ However, a closer examination of the social, political, and economic forces that produced the modern-day regulatory divergence suggests policy principles relevant to regulatory reform efforts. This Note seeks to draw out some of these lessons. Part I examines the growing technological convergence between reproductive medicine and genetic research, the current state of regulation and its shortcomings, and the challenges to formulating comprehensive and coherent policy principles. Part II traces the development of regulation in these fields, identifying factors that shaped present-day institutions and laws. Part III extracts from this history lessons that current policymakers may wish to heed, focusing on the potential role of expanded governmental funding of ethically problematic research. It also suggests that the willingness of American society to accept new technologies once introduced should motivate policymakers to permit some degree of new development even in the face of initially negative public opinion, but that policymakers should take care that public enthusiasm for new technology does not result in underprotective safety regulations.

⁶ See SPAR, *supra* note 4, at 118–27; Mark S. Frankel & Michele S. Garfinkel, *To Market, To Market: Effects of Commerce on Cross-Generational Genetic Change*, in DESIGNING OUR DESCENDANTS 311 (Audrey R. Chapman & Mark S. Frankel eds., 2003).

⁷ Although explanations for the divergence have been lacking, attempts to fix it have not. See, e.g., FRANCIS FUKUYAMA & FRANCO FURGER, HUMAN BIOTECHNOLOGY GOVERNANCE FORUM, BEYOND BIOETHICS: A PROPOSAL FOR MODERNIZING THE REGULATION OF HUMAN BIOTECHNOLOGIES (2006), available at <http://www.biotechgov.org> (follow link to request final report of forum) (proposing institutions of public consultation to supplement formal rulemaking authority); SPAR, *supra* note 4, at 197 (accepting the existence of a market for babies but seeking to “embed this market in an appropriate political and regulatory context”); Cynthia B. Cohen, *Designing Tomorrow’s Children: The Right to Reproduce and Oversight of Germ-Line Interventions*, in DESIGNING OUR DESCENDANTS, *supra* note 6, at 296 (espousing a strongly precautionary approach to technologies with the capacity to introduce “germ-line interventions into our genetic armamentarium”); Erik Parens & Lori P. Knowles, *Reprogenetics and Public Policy*, HASTINGS CENTER REP. (SPECIAL SUPPLEMENT), July–Aug. 2003, at S1, S18–21 (proposing federal funding of embryo research, a commission to formulate legislative proposals for Congress, and a standing federal entity “to facilitate reasoned and systematic public and policy deliberation about the purposes of reprogenetic research and practice”).

I. REGULATORY CHALLENGES OF CONVERGENCE

A. *Convergence of Reproduction and Genetics*

The convergence of the fields of reproduction and genetics presents new challenges not easily answered by a simple choice between more and less regulation.⁸ Practitioners of reproductive medicine have traditionally focused on problems related to infertility, using genetic material from existing sperm or eggs to replicate the ordinary process of conception. In contrast, most genetic research to date has been concerned with understanding and manipulating the genetic material within plants, simple organisms such as bacteria, and the nonreproductive (somatic) cells of humans. Recent developments in genetics, however, have led reproductive specialists to use new genetic technologies for applications such as screening or sex selection. Similarly, genetic researchers have increasingly turned to advanced techniques of reproductive medicine to provide key components for new research, whether through cell nucleus transfers or the derivation of ES cells. Greater convergence is likely as genetic research offers reproductive-medicine practitioners more ways to screen and manipulate genetic material, and as reproductive research generates more flexible tools with which to study genetic information.

This convergence is illustrated by the increasing potential to provide advanced genetic diagnoses as part of traditional reproductive testing for the purpose of screening. These tests have become more powerful as researchers have established correlations between physical characteristics and particular DNA sequences.⁹ Parallel advances in reproductive medicine now permit extremely early use of these tests. Preimplantation genetic diagnosis (PGD), for example, allows potential parents to identify genetic conditions in embryos even before they are placed in a mother's womb.¹⁰ There is little formal regulation preventing fertility clinics from offering screening of even novel genetic characteristics to prospective parents.¹¹

⁸ See, e.g., Roger Brownsword, *Regulating Human Genetics: New Dilemmas for a New Millennium*, 12 MED. L. REV. 14, 14 (2004) (describing regulators' dilemma in these fields as more complex than "simply one of choosing between 'green light' (permissive) or 'red light' (proscriptive) responses").

⁹ See David Cram & David de Kretser, *Genetic Diagnosis: The Future*, in ASSISTED REPRODUCTIVE TECHNOLOGY 186 (Christopher J. De Jonge & Christopher L.R. Barratt eds., 2002) (discussing the connection between genetics and male infertility).

¹⁰ See SUSANNAH BARUCH ET AL., GENETICS & PUB. POLICY CTR., PREIMPLANTATION GENETIC DIAGNOSIS (2004), available at http://www.dnapolicy.org/images/reportpdfs/PGD_DiscussionChallengesConcerns.pdf.

¹¹ See GENETICS & PUB. POLICY CTR., WHO REGULATES GENETIC TESTS? (2006), available at http://www.dnapolicy.org/images/issuebriefpdfs/Who_Regulates_Genetic_Tests_Issue_Brief.pdf.

Convergence is also apparent in the use of advanced reproductive technologies for genetic research, as is reflected by recent developments in the use of ES cells. ES cells are the product of reproductive medicine; they are generated from embryos created using well-known reproductive techniques. These cells are useful vehicles for genetic research due to their ability to develop into different types of body cells and to replicate indefinitely.¹² They may become most useful as tissue to be transplanted into adult patients suffering from previously “defective” genetic patterns — a kind of gene therapy that has been a long-sought-after goal of many gene researchers. Genetic modifications could also be targeted at reproductive rather than nonreproductive cells, a process that would typically involve the transfer of modified DNA within an ES cell into an egg or sperm, thus creating embryos with the modified DNA.¹³ Procedures utilizing this kind of genetic modification and transfer could have a wide variety of uses, some more ethically problematic than others. A parent who is a carrier of a genetic disease might limit the chances of passing the disease on to his or her descendants by extracting DNA from ES cells produced by the parent, replacing the offending DNA segments with “normal” DNA, and then transferring the DNA from the ES cell’s nucleus into an egg or sperm cell. The egg or sperm containing the new genetic material could then be used in reproductive techniques such as IVF.¹⁴

Cloning presents similar regulatory problems, whether performed for reproductive or therapeutic purposes.¹⁵ As with direct genetic manipulation, cloning has not yet resulted in practical applications. Nonetheless, and again illustrating the regulatory challenges posed by the convergence of genetic and reproductive medicine, some fertility clinics have stated their intention to offer reproductive cloning as part

¹² See Antonio Regalado, *The Troubled Hunt for the Ultimate Cell*, 101 TECH. REV., July–Aug. 1998, at 34.

¹³ See MARK S. FRANKEL & AUDREY R. CHAPMAN, HUMAN INHERITABLE GENETIC MODIFICATIONS 11–13 (2000), available at <http://www.aaas.org/spp/sfrl/projects/germline/report.pdf>.

¹⁴ Although the ability to manipulate genetic material as precisely as described is not yet a practical reality, it is within the realm of possibility and already the subject of considerable debate. See *id.* at 23–46; Bhavani G. Pathak, *Scientific Methodologies To Facilitate Inheritable Genetic Modifications in Humans*, in DESIGNING OUR DESCENDANTS, *supra* note 6, at 55.

¹⁵ At a general level, cloning is straightforward. The DNA from an extracted egg cell is removed and replaced with the DNA of a donor, creating a reconstructed egg with entirely new DNA. The egg is then stimulated to begin cell division. This process would be roughly the same for both reproductive and therapeutic purposes. Many of the elements of this process have been developed and perfected in the context of IVF and other reproductive medicine. Extraction, manipulation, and reinsertion of DNA, on the other hand, have been the focus of much genetic research. See THE PRESIDENT’S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY 57–71 (2002), available at http://bioethics.gov/reports/cloning_report/pcbe_cloning_report.pdf.

of their normal services.¹⁶ The largely unregulated nature of fertility clinics makes it possible for these clinics to market such services quickly and aggressively.¹⁷

B. Current Regulation of Reproduction and Genetics

In light of these rapid developments, the current regulatory arrangements governing these fields may not be sufficient to provide the kind of oversight and guidance necessary to resolve the dilemmas arising from this convergence. Reproductive medicine, for example, has never received close regulatory scrutiny, with reproductive clinicians and researchers instead operating under a loose patchwork of federal, state, and nongovernmental authority. In contrast, nearly all genetic research takes place under the auspices of formal oversight boards, with medical applications undergoing the same detailed approval process required of new pharmaceuticals. Because much new research cannot be classified clearly as reproductive medicine or genetic research, the regulatory boundaries between the fields have been blurring, leading to redundancy, inconsistency, and inefficiency.

1. *Assisted Reproductive Technologies (ARTs)*. — Governmental regulation of reproductive medicine is light, with most fertility clinics operating under some form of self-regulation. Most reproductive procedures are now regarded as sufficiently within the mainstream of medical practice that they are treated only as innovative clinical practices rather than basic or applied research. Because they are not formally classified as engaging in research, clinics are generally free to offer new applications and reproductive options, limited primarily by the discretion of the individual practitioners and their supporting institutions.¹⁸ The parent- and market-driven nature of the fertility market, combined with clinics' broad leeway to develop new reproductive applications, produces strong economic incentives for clinics to offer new services even when those services raise ethical concerns.

States and professional organizations provide the most substantial guidelines for clinics, but these are either non-pervasive (in the case of state regulation) or not legally binding (in the case of professional practice standards). Most clinics are members of the Society for Assisted Reproductive Technologies, which provides some ethical guidelines.¹⁹

¹⁶ See SPAR, *supra* note 4, at 146–48.

¹⁷ See *id.* at 145–58.

¹⁸ See *id.* at 51–60; GENETICS & PUB. POLICY CTR., REGULATORY BRIEF: REGULATORY ENVIRONMENT FOR ASSISTED REPRODUCTIVE TECHNOLOGIES (2004); Parens & Knowles, *supra* note 7, at S11–12.

¹⁹ See Eric Surrey, President, Soc'y for Assisted Reprod. Tech., *What Is SART?*, <http://www.sart.org/WhatIsSART.html> (last visited Nov. 12, 2006).

But such groups are strongly tied to the interests of their industry — working, for example, “diligently to protect [their] patients and the practice of ART from inappropriate external intrusion and regulation” — and they generally act only in the shadow of threatened governmental regulation.²⁰ These industry groups focus primarily on ensuring that reproductive applications are performed properly and not on more fundamental questions concerning the propriety of these applications in the first place.

Federal agency regulation leaves similar gaps. The FDA itself has limited the scope of its regulation of fertility clinics, acknowledging that “Congress did not intend the [FDA] to interfere with medical practice . . . [or] to regulate the practice of medicine as between the physician and the patient.”²¹ This statutory restriction on the FDA’s authority leaves the FDA with limited power to regulate the provision of assisted reproductive technologies.²²

Related to the lack of significant federal regulation of reproductive services is the absence of public funding for the kind of embryo research at the core of most reproductive applications and the corresponding absence of the approval and oversight regimes that typically accompany such funding. Although federal funding for embryo research is not available, no legislation has ever precluded private research, which now shapes many of the new advances in reproduction. Accordingly, embryo research conducted using private funds takes place largely free from public oversight, approval, or guidance.

2. *Genetic Research.* — Genetic research operates under a comparatively stringent regulatory regime, administered primarily under the auspices of the National Institutes of Health (NIH) and the FDA. Within the NIH, the Recombinant DNA Advisory Committee (RAC) serves as a deliberative body for considering novel ethical questions raised by new types of gene transfer research, with Institutional Review Boards (IRBs), local to particular research institutions, carrying out the primary oversight role.²³

The FDA regulates the clinical application of gene therapy research.²⁴ FDA review, however, is generally limited to evaluating the

²⁰ *Id.*

²¹ Legal Status of Approved Labeling for Prescription Drugs, 37 Fed. Reg. 16,503 (Aug. 15, 1972).

²² See Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§ 301–97 (West 1999 & Supp. 2006) (addressing many topics, but not ART); Nanette R. Elster, *ARTistic License: Should Assisted Reproductive Technologies Be Regulated?*, in ASSISTED REPRODUCTIVE TECHNOLOGY, *supra* note 9, at 366; Parens & Knowles, *supra* note 7, at S12.

²³ See Joseph M. Rainsbury, *Biotechnology on the RAC—FDA/NIH Regulation of Human Gene Therapy*, 55 FOOD & DRUG L.J. 575, 590–92 (2000).

²⁴ See Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products, 58 Fed. Reg. 53,248 (Oct. 14, 1993); GENETICS & PUB. POLICY

safety and efficacy of medical products; thus, assuming a particular gene therapy application is shown to be both safe and effective, it is unclear whether the FDA could base its approval on the ethics or morality of the underlying research.²⁵ Nonetheless, the FDA has adopted an expansive view of its authority to regulate new genetic technologies based on its authority over medical-product safety.²⁶

Despite FDA and NIH control over genetic research, important gaps remain. The mandate of the NIH's RAC focuses specifically on research involving recombinant DNA (artificially created DNA from more than one source).²⁷ The specificity of this focus ignores a wide range of other processes for producing genetic modifications. For example, neither the NIH nor the FDA currently has clear authority to regulate the kind of implicit genetic selections enabled by early-stage genetic testing and embryo selection because these applications are regarded as occurring within the general practice of reproductive medicine.²⁸ Furthermore, since these applications do not involve recombinant DNA, they would not fall within the RAC's authority.²⁹

C. *New Regulatory Challenges and the Need for Reform*

The current debates surrounding ES cell research and cloning illustrate the limits of existing regulation and the difficulties involved in applying this regulation to research at the intersection of reproduction and genetics. The ES debate has, on the one hand, been driven by the promise of important medical advances and, on the other hand, has been limited by the politics of abortion and a statutory withdrawal of federal funding for research "in which a human embryo or embryos are destroyed."³⁰ The current compromise is a technical one, permitting federally funded "use" of ES cells derived from private sources

CTR., REGULATORY ENVIRONMENT FOR GENE TRANSFER (2004); Kresina, *supra* note 5, at 308-11.

²⁵ See Robert P. Brady et al., *The Food and Drug Administration's Statutory and Regulatory Authority to Regulate Human Pluripotent Stem Cells*, in 2 NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH B-1, B-11 (2000).

²⁶ See Rick Weiss, *Human Clone Research Will Be Regulated*, WASH. POST, Jan. 20, 1998, at A1. Commentators have criticized the FDA's stance on novel reproductive and genetic technology, questioning its statutory authority over the field and its institutional competence to assess the novel ethical questions the procedures raise. See, e.g., Richard A. Merrill & Bryan J. Rose, *FDA Regulation of Human Cloning: Usurpation or Statesmanship?*, 15 HARV. J.L. & TECH. 85, 124-39 (2001).

²⁷ See Rainsbury, *supra* note 23, at 580.

²⁸ See *id.* at 585-90 (reviewing the legislative and institutional history surrounding FDA and NIH regulation).

²⁹ See sources cited *supra* notes 24-25; see also Parens & Knowles, *supra* note 7, at S10-14.

³⁰ Parens & Knowles, *supra* note 7, at S13; see also Heather Boonstra, *Human Embryo and Fetal Research: Medical Support and Political Controversy*, GUTTMACHER REP., Feb. 2001, at 3.

prior to August 9, 2001, but making no distinctions between acceptable and unacceptable use of embryos.³¹ Furthermore, despite the restrictions placed on federally funded research, there are no general restrictions on ES cell research not involving federal money.³²

Similarly, there is currently no federal legislation banning or significantly regulating most cloning technology.³³ Despite numerous calls for a ban on human cloning, disagreement over the application of such a ban to therapeutic cloning has stymied legislative efforts on this front. And although the FDA has asserted jurisdiction over human cloning and has effectively banned its practice by declaring that no existing cloning methods can be deemed safe, its claim of jurisdiction is not particularly strong and has been criticized by commentators.³⁴ Given the uncertainties in the FDA's cloning ban, fertility clinics' use of cloning may fall into a regulatory gap similar to the one inhabited by reproductive services more generally. That some fertility clinics have announced an intention to offer reproductive cloning services speaks to the uncertainties in existing regulatory regimes.

II. PAST PATHS OF REGULATION

These new challenges have their roots in the divergent paths of reproductive and genetic medicine regulation. Both fields faced widespread skepticism early on, but this gave way to a largely deregulated environment for reproduction and a stringent oversight regime for genetic research. A close examination of how and why the regulatory environment governing these fields diverged to such an extent offers clues for structuring future regulation.

A. *Early Concerns Common to Reproductive and Genetic Research*

The debates surrounding alternative insemination foreshadowed the concerns surrounding IVF nearly a century later. The first reported success of alternative insemination in 1884 inspired sharp criticism from the public and the medical profession.³⁵ However, the practice was never banned or criminalized, as some advocated.³⁶ As

³¹ See Parens & Knowles, *supra* note 7, at S13.

³² Relatively unrestricted research continues to take place, utilizing funding from private sources, individual states, and foreign countries. See *id.*

³³ See THE PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY, *supra* note 15, at 28–33. A number of states, however, have banned cloning in some form. *Id.* at 32.

³⁴ See, e.g., Gail H. Javitt & Kathy Hudson, *Regulating (for the Benefit of) Future Persons: A Different Perspective on the FDA's Jurisdiction To Regulate Human Reproductive Cloning*, 2003 UTAH L. REV. 1201; Merrill & Rose, *supra* note 26.

³⁵ See HENIG, *supra* note 1, at 26–27.

³⁶ See *id.* at 28.

alternative insemination became established as a common medical procedure for producing children, public and professional skepticism melted away and the law busied itself with sorting out the legal implications for families created through this process.³⁷ By the late 1970s and early 1980s, when IVF began to emerge as a plausible alternative reproductive technology, some six to ten thousand children were being conceived annually through alternative insemination.³⁸

Many of the fears that initially surrounded alternative insemination were rekindled by IVF. Although confined to nonhuman subjects, early IVF research provoked opposition in many quarters.³⁹ At a debate in 1971, Princeton Professor of Religion Paul Ramsey foresaw “the introduction of unlimited genetic changes into human germinal material while it [was] being cultured by the Conditioners and Predeterminators of the future.”⁴⁰ Critics also focused on the ethical problems inherent in IVF research itself, independent of broader religious or societal concerns. Professor Ramsey argued that “[i]n vitro fertilization constitutes unethical medical experimentation on possible future human beings, and therefore it is subject to absolute moral prohibition.”⁴¹ James Watson adopted a similar line of criticism, characterizing IVF research as accepting “the necessity of infanticide.”⁴² Clearly, a markedly suspicious mood pervaded American sentiment toward IVF in the years leading up to the first IVF treatments, despite broad acceptance of the alternative insemination techniques developed decades earlier.

Further complicating the early debates was the connection made between IVF, other embryo research, and the highly politicized abortion debate. Research involving fetuses and embryos provoked sharp reactions among antiabortion activists who believed that success in these fields would place what they viewed as mass murder in a positive light.⁴³ The federal government settled on an awkward compromise that eliminated federal funding for such research without ban-

³⁷ See Dominick Vetri, *Reproductive Technologies and United States Law*, 37 INT’L & COMP. L.Q. 505, 508–11 (1988).

³⁸ See Martin Curie-Cohen et al., *Artificial Insemination by Donor in the United States*, 300 NEW ENG. J. MED. 585, 588 (1979); Note, *Reproductive Technology and the Procreation Rights of the Unmarried*, 98 HARV. L. REV. 669, 683 n.78 (1985). It should also be noted that the development of alternative insemination did not require large-scale research efforts, and public funding did not play a significant role in shaping its development. See Jean Cohen et al., *The Early Days of IVF Outside the UK*, 5 HUM. REPROD. UPDATE 439, 445–49 (2005). Rather, it was simply considered a new kind of medical procedure, developed and made available by individual medical practitioners and governed by their professional ethical canons. See Parens & Knowles, *supra* note 7, at S11–12.

³⁹ See HENIG, *supra* note 1, at 31.

⁴⁰ *Id.* at 72 (internal quotation marks omitted).

⁴¹ *Id.* (internal quotation marks omitted).

⁴² *Id.* at 76 (internal quotation mark omitted).

⁴³ *Id.* at 79–82.

ning its practice altogether.⁴⁴ This approach even extended to embryo research aimed at improving the safety of potential IVF treatments and limiting the number of embryos required.⁴⁵

These early debates surrounding IVF were also intertwined in the public eye with contemporaneous developments in gene research. During the first stages of genetic research, concerns centered on the potential environmental effects of releasing novel DNA into the wild. These environmental concerns led to the first Asilomar Conference, meant to assess the biological risks of organisms used in this research and to develop recommendations for carrying out future work.⁴⁶ The Asilomar discussions — primarily involving scientists — led to a widely read letter by Dr. Paul Berg in *Science* in 1974, calling for a voluntary moratorium on certain gene-splicing experiments given the seemingly remote benefits of the research and the unknown but potentially dire risks to both researchers and subjects.⁴⁷

The early debates also recognized the potential for technological convergence between genetic research and the burgeoning field of reproductive medicine, and particular attention was paid to the ethical dilemmas posed by genetic engineering of human traits and behavior. The Genetics and Society Group of the Boston area chapter of Science for the People, for example, recognized the potential for combining gene research with technologies such as cell fusion and IVF, which would seemingly lead toward human genetic engineering.⁴⁸ The group called for broad public participation in the Asilomar discussions, skeptical that self-regulation by scientists would be adequate.⁴⁹ Related to these reproduction-oriented concerns was the ability of the fledgling genetic technologies to “breach species barriers” and the corresponding social ramifications.⁵⁰ One prominent critic of DNA research, Dr. Robert Sinsheimer, sought to draw attention to the “natural” products of evolution, warning that “[t]o introduce a sudden discontinuity in the human gene pool might well create a major mismatch between our social order and our individual capacities. Even a minor perturbation

⁴⁴ *Id.* at 134–38.

⁴⁵ *See id.* at 136–37 (noting research that sought to examine the chromosomes of some four hundred IVF embryos to “establish the genetic risk in the obtainment of human preimplantation embryos”). Despite the primarily precautionary nature of this research, federal funding was never made available. *Id.*

⁴⁶ *See* KRIMSKY, *supra* note 3, at 62–69.

⁴⁷ Paul Berg et al., Letter, *Potential Biohazards of Recombinant DNA Molecules*, 185 *SCIENCE* 303 (1974).

⁴⁸ *See* KRIMSKY, *supra* note 3, at 136–37.

⁴⁹ *See id.*

⁵⁰ *See id.* at 264–67.

such as a marked change in the sex ratio . . . could shake our social structures.”⁵¹

Prior to the first successful IVF birth, then, there was a remarkable similarity between the public and professional concerns that surrounded the new reproductive technologies and genetic research, despite their many differences. The central ethical criticisms regarding both fields touched in large part on conceptions of “naturalness” and shared a strong interest in avoiding intervention in areas concerning human nature and humanity as a species. Despite the sharp professional cleavages between the fields, the public and many policymakers viewed reproductive and genetic medicine in very similar ways,⁵² as evidenced by polls, common attention from new bioethics groups, and the intense focus on these fields by politicians and policymakers.⁵³

B. Divergent Development of Oversight and Regulation

One way of understanding the different regulatory paths of reproduction and genetics might be to focus on the interaction between the distinct professional cultures of the practitioners in these fields, the government’s role in both setting the permissible bounds of research and supplementing or supplanting private funding of research, the dramatic shifts in public acceptance of new reproductive services, and the politics of abortion that has remained sharply divisive throughout the history of both fields. These historical threads do not reveal consistently deregulatory impulses with respect to reproductive services. Rather, they suggest that the initially stronger connection between abortion and reproductive services — due to the use of embryos in IVF research — may have created an early regulatory deadlock that unexpectedly accelerated the development and broad availability of IVF. The strong public acceptance of IVF that ensued, coupled with an entrenched economic force in the form of a private fertility industry, may have then solidified the early deadlock into a long-term deregulatory norm that has persisted to this day. In contrast, the deep financial involvement in, and close government oversight of, genetic research limited the influence of private economic actors in shaping the early regulation of the field. One possible result of this stronger public control has been greater attention to the broad ethical and safety concerns raised by new genetic technologies.

1. Distinct Professional Spheres. — Even before research in either IVF or genetics began in earnest, most of the key researchers occupied

⁵¹ Robert Sinsheimer, *Troubled Dawn for Genetic Engineering*, NEW SCIENTIST, Oct. 16, 1975, at 148, 151.

⁵² See HENIG, *supra* note 1, at 132.

⁵³ See *id.* at 66–77.

distinct professional spheres with different cultures and approaches to their work. Those involved in the early development of IVF were generally medical doctors with ties to individual patients seeking treatment for various infertility “diseases.” IVF was simply one medical tool, like alternative insemination, for approaching this particular kind of affliction.⁵⁴ In drawing primarily from a “medical” as opposed to “scientific” tradition, IVF researchers naturally worked under the auspices of the medical establishment, regulated primarily by state medical bodies.

In contrast, given the high costs and uncertain payoff of their work, genetic researchers were far more dependent on public funding and expected that the government would play a role in shaping their work through both approval of research grant proposals and ongoing oversight mechanisms. Scientists working in public laboratories had less contact with prospective patients, unlike medical doctors, and were perhaps more likely to view their government funders or the public at large as the primary beneficiary of their work and loyalty.

The basic organizational needs of working within a large cooperative enterprise also shaped the professional culture of genetic research. Many of the early researchers saw their work in the same vein as other large-scale, government-funded scientific initiatives, more along the lines of the major atomic energy projects than the small-scale experimentation that dominated work leading to IVF treatments.⁵⁵ Top-down managerial control has been the norm for such projects, with a great deal of specialization among both researchers and support staff. Managers seeking greater efficiency in monitoring and controlling the work of the enterprise naturally impose a more rules-based environment, with adherence to particular procedures and enterprise-wide social norms considered an acceptable and necessary practice.⁵⁶

⁵⁴ Most doctors developing IVF techniques simply sought to provide potential parents with the same ability to conceive children enjoyed by other parents. Indeed, nearly all of the early figures in IVF research were medical doctors by training, including most notably Dr. Landrum Shettles, a gynecologist well known for an early attempt to perform IVF for a Florida couple seeking to conceive; Dr. William J. Sweeney III, Dr. Shettles’s collaborator in IVF research; and Drs. Howard and Georgeanna Jones, who opened the first American fertility clinic. See HENIG, *supra* note 1, at 56–60, 160–61, 175–76. The “medical” culture of fertility clinics endures today. Many doctors also have financial stakes in their fertility clinics, and prominent clinics have formal affiliations with medical schools. See SPAR, *supra* note 4, at 49.

⁵⁵ Indeed, the cultural divide instilled by the larger sense of scale has continued to this day, as evidenced by the “big science” treatment accorded to the Human Genome Project, a natural outgrowth of the early genetic research. For a detailed history of the politics and political economy that drove the Human Genome Project and related research, see IRA H. CARMEN, *POLITICS IN THE LABORATORY: THE CONSTITUTION OF HUMAN GENOMICS* (2004).

⁵⁶ See, e.g., *id.*; PETER GALISON, *IMAGE & LOGIC: A MATERIAL CULTURE OF MICROPHYSICS* (1997).

Although it is unlikely that professional culture alone was substantially determinative of the different regulatory paths that the fields have followed, professional culture likely had some effect in shaping the direction of regulation, magnifying, for example, the effects of early policy decisions made in both fields.

2. *Public Funding, Public Oversight, and the Politics of Abortion.*

— One important and early policy distinction was the level of government involvement in research. Motivated primarily by ethical concerns about research involving embryos, legislators moved to forbid federal funding for such research. However, this drive to restrict funding did not extend to a blanket ban on embryo research. The tight restrictions on federal funding, coupled with the small scale of most reproductive medicine, drove nearly all IVF research out of the purview of governmental funding and regulation. But this banishment to the private sector might have had the unintended effect of accelerating IVF's development. For genetic research, conversely, the strong presence of governmental funding provided both a forum and a means for shaping the course of research and for addressing the thorny ethical and policy issues. The scale of funding required for most genetic research, and the high level of government funding, prevented private enterprise from becoming a significant early force.

Although there have been some governmental efforts to strike a compromise balancing the scientific benefits of research utilizing reproductive material with the important social and religious concerns attached to embryos, Congress has largely avoided the trickier policy questions.⁵⁷ Indeed, the durability of the regulatory stalemate in embryo research has largely mirrored the endurance of the divisive abortion debate. With Congress locked in a decades-long stalemate over embryo research, researchers turned to private sources of funding, and, at least for the development of IVF, such funds were not lacking.⁵⁸ As

⁵⁷ See HENIG, *supra* note 1, at 81. Congress attempted to address these issues in 1974 by passing the National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974), which imposed a moratorium on federally funded fetal research. See Boonstra, *supra* note 30, at 3. This moratorium was formally lifted in 1975 but was replaced with a de facto prohibition requiring all federally funded fetal research to be approved by a nonexistent Ethics Advisory Board (EAB). See HENIG, *supra* note 1, at 134-38. Although an EAB was established for a brief period between 1977 and 1980, it never approved any research proposals. See *id.* Since 1995, Congress has prohibited federal funding for any research that places human embryos at risk, which effectively prohibits funding of IVF-related research. Boonstra, *supra* note 30, at 3.

⁵⁸ Drs. Howard and Georgeanna Jones, who would go on to produce the first successful IVF-conceived birth in the United States, had little trouble raising money for a new fertility clinic in Norfolk, Virginia. See HENIG, *supra* note 1, at 176. They amassed seed money from private sources with the aim of quickly producing IVF treatments for American couples, and they overcame opposition from antiabortion groups through the strength of private demand for IVF. The clinic's lack of federal funding limited the ability of national policymakers to interfere with the clinic's operations. See *id.* at 208-12.

a result, clinics utilizing exclusively private money were largely free to develop their own rules and procedures governing embryo use. The fertility clinic that would ultimately produce the first successful IVF-conceived birth in the United States, for example, actively sought out publicity associated with the controversial aspects of IVF.⁵⁹ In this environment, caution was not a foremost concern, and few external forces existed to slow the work of the clinic.

Governmental involvement in genetic research was very different. In its infancy, relatively little genetic research involved reproductive or embryonic material, and thus it generally avoided the political quagmires created by the ongoing abortion debate. Furthermore, much of the research leading to genetic research had occurred in government laboratories or with government funding, so it was natural to extend the relationship to the new field of study.

The deep involvement of federal agencies in genetic research permitted more rapid and consistent responses to public concerns. Researchers and laboratories dependent on governmental largesse could be expected to obey the agencies responsible for approving and funding their work. In addition, procedures and safeguards could be made broadly applicable to all recipients of federal funding for genetic research, ensuring that the field as a whole would follow a consistent set of guidelines devised through debate and the deliberative process.⁶⁰

Other factors magnified the divergent effects of the federal government's absence from reproductive research as contrasted with its funding and support of genetic research. The small scale of IVF research, for example, made it feasible for private groups to serve as the sole source of funding for reproductive research.⁶¹ Meanwhile, the government's active funding of genetic research provided a disincentive for firms to engage in duplicative or even complementary work, given the possibility that the value of their efforts would be diluted or preempted by the publicly funded work.⁶² Finally, as discussed in the

⁵⁹ See *id.* at 203 (suggesting that medical administrators at the clinic "relished the opportunity to earn a national reputation, serve a desperate and growing market niche, and make a good deal of money, all in a single grand gesture").

⁶⁰ For example, the environmental fears that dominated early discussion of genetic and recombinant DNA studies resulted in the NIH's creation of the RAC to study and approve federally funded research in these fields and to set binding procedural guidelines for funding recipients. CARMEN, *supra* note 55, at 134. The swiftness and enthusiasm with which the government met the emerging environmental concerns of the public resulted in regulations that were, in one commentator's view, "at the least very strict and at the most unprecedented." *Id.*

⁶¹ The Joneses' seed money for the first Norfolk clinic, for example, totaled only \$25,000, an amount sufficient to begin substantial work toward successful IVF treatments but unlikely to produce any significant work in the more expensive and laboratory-oriented realm of genetic research. See HENIG, *supra* note 1, at 203.

⁶² Although private firms have the ability to engage in large-scale scientific endeavors — witness, for example, the healthy competition spurred by Celera, Inc., in the race to map the human

previous section, the different professional cultures in reproductive medicine and genetic research may have influenced the ultimate effects of the government's stance on research funding.

3. *Public Acceptance and the New Reproductive Industry.* — The first successful IVF births abroad and in the United States represented a key inflection point in the regulation of reproductive services. These early successes in reproductive medicine provided fuel for a fledgling industry of fertility clinics in fending off government regulation, magnifying the deregulatory forces already in place. In contrast, gene research has seen few successes and fewer widespread applications. Whether a cause or an effect of the slower pace of practical advances in gene research, governmental regulation of the field is stringent, and the public remains wary of the potential harms of such research.

Public attention to the first IVF births was intense. A few days after the birth of Louise Brown in 1978, a Gallup poll found that ninety-eight percent of Americans had heard of IVF, with sixty percent able to describe the basics of its operation.⁶³ Although some skepticism remained,⁶⁴ most fears surrounding IVF disappeared shortly after the first successful births. A poll just one year after Louise Brown's birth showed that half of Americans, including two-thirds of young adults, would be willing to use IVF if confronted with infertility.⁶⁵

The strong acceptance of IVF may have initiated a long-term entrenchment by a new fertility industry and established a new deregulatory norm. The initial IVF successes sparked a flurry of private funding for reproductive clinics from investors.⁶⁶ Although it is plausible that substantial restrictions might have been placed on IVF prior to its early successes, such restrictions soon became untenable,⁶⁷ despite important safety concerns lurking in the background, such as increased chances of multiple births and certain chromosomal abnormalities.⁶⁸

genome, or the long-term research efforts of large pharmaceutical companies — the risks in the early days of genetic research may have been too high and the benefits of such research too uncertain to justify the aggregation of vast sums of capital. See J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCIENCE 1304, 1304 (2001).

⁶³ See HENIG, *supra* note 1, at 190.

⁶⁴ Some insisted that it was too early to assess the “normality” of Ms. Brown, not to mention the normality of those babies that might still be conceived through IVF. *Id.* at 174. Religious thinkers, too, continued to disagree about the implications of the apparent IVF success. Some applauded the expansion of knowledge and the enhancements to procreative life provided by IVF, while others criticized the separation of love and procreation. *Id.*

⁶⁵ *Id.* at 201.

⁶⁶ See SPAR, *supra* note 4, at 28–35.

⁶⁷ See THE PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH 245–48 (2004).

⁶⁸ See Raymond D. Lambert, *Safety Issues in Assisted Reproduction Technology: The Children of Assisted Reproduction Confront the Responsible Conduct of Assisted Reproductive Technologies*, 17 HUM. REPROD. 3011, 3011 (2002).

Within just a few years, the clamor for access to the new procedure controlled the debate.⁶⁹ The quick acceptance of IVF, therefore, began to entrench a deregulatory norm that may have originated with the exclusively private funding of the field, magnified by a strong medical culture of local and professional self-regulation.⁷⁰

In contrast, no major medical applications based on gene therapy research have been made widely available to date, and public opinion has favored caution and avoidance.⁷¹ Although efforts have been made to streamline the approval of new genetic research and to reduce the overlap of authority between the NIH and FDA, there have not been significant changes to the regulatory structure of the field compared with the early days of genetic research.⁷²

III. LESSONS AND SUGGESTIONS FOR REGULATORY REFORM

A. *Early Public Funding and Public Oversight*

The political stalemate that resulted in the elimination of federal funding for embryo research while permitting the same research to be conducted unfettered in the absence of federal funds has reappeared in areas of convergence, such as ES cell research and arguably even cloning. In some ways, this kind of regulatory inaction generates a politically appealing compromise: scientists conducting the affected research are free to continue their work with nonfederal money, while opponents are comforted by the knowledge that they are not supporting through their tax dollars practices they find morally abhorrent.

However, this compromise may produce unexpected dynamics for new research while eliminating a valuable means of imposing safeguards to ameliorate many key ethical concerns. Counterintuitively, extending public funding to problematic areas of research in their early stages — particularly when the economic rewards remain uncertain — might provide a more politically tractable means of slowing the pace of development to ensure greater deliberation over the consequences of a new technology. Public funding may, in some instances, also limit

⁶⁹ See The Bertarelli Found. Scientific Bd., *Public Perception on Infertility and Its Treatment*, 15 HUM. REPROD. 330, 330 (2000); see also HENIG, *supra* note 1, at 226, 229.

⁷⁰ It should be noted that some view the establishment of a deregulatory norm as a positive development in the history of IVF. One analysis, James P. Toner, *Progress We Can Be Proud of: U.S. Trends in Assisted Reproduction over the First 20 Years*, 78 FERTILITY & STERILITY 943 (2002), points out that in comparison with European clinics, U.S. fertility clinics have been able to offer a greater variety of therapies, more streamlined treatments, and higher pregnancy rates. *Id.* at 949. However, these successes have come at the cost of higher incidences of multiple deliveries. *Id.*

⁷¹ See Human Genome Project Information, Gene Therapy, http://www.ornl.gov/sci/tech/resources/Human_Genome/medicine/genetherapy.shtml#status (last visited Nov. 12, 2006).

⁷² Rainsbury, *supra* note 23, at 591.

the influence and eventual entrenchment of private market forces, which would help preserve a greater range of regulatory options once a new technology matures. Although a scheme of early public funding will not always be the most effective way to regulate a new technology, such an option ought to be considered by advocates on all sides as a potentially more productive compromise that could ensure continued scientific progress while giving added voice to broadly held ethical concerns.

The current compromise governing ES cell research permits limited federal funding for research on ES cells derived from previously developed cell lines, and thus could be considered partially consistent with this proposed model of early funding and oversight.⁷³ An analysis of this model may offer useful guidance for shaping future schemes of regulation through funding. Although the federal government now funds a substantial level of ES cell research, it excludes a large amount of research dependent on ES cell lines derived after 2001.⁷⁴ Funding and oversight of ES cell research, then, resembles a kind of middle ground between the paths followed by IVF and genetic research, permitting some federal funding subject to approval and oversight processes similar to those in place for genetic research, but denying funding for a large swath of research as with IVF.

The early results of this funding compromise are more similar to IVF's development than to that of genetic research. Most strikingly, a large amount of ES cell research has been driven into the private sector, with few guidelines or procedural protections. Large and small firms have already raised funds devoted to stem cell-based treatments, and the potential market for these treatments could be enormous — "larger, most likely, than those arising from any other modern medical breakthrough."⁷⁵ This similarity to the history of IVF regulation is troubling, for it suggests that despite the important ethical concerns, the opportunity may soon be lost to shape and regulate the use of ES cells before broad use of the technology becomes entrenched and before a deregulatory norm becomes established.

One approach to ES cell research, then, might include an expansion of federal funding, conditioned on adherence to guidelines setting forth acceptable uses of embryos in research. The NIH has already promulgated guidelines for research that is currently eligible for federal fund-

⁷³ See *supra* note 57 and accompanying text; see also THE PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH, *supra* note 67, at 25–29; Parens & Knowles, *supra* note 7, at S13.

⁷⁴ See THE PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH, *supra* note 67, at 41–47.

⁷⁵ SPAR, *supra* note 4, at 149; see also Ken Howard Wilan, *Chasing a Cellular Fountain of Youth*, 23 NATURE BIOTECHNOLOGY 807, 809 (2005).

ing,⁷⁶ and an expansion of federal funding would bring a far greater volume of research — most of which already takes place in the absence of substantial guidance — within the scope of current and future guidelines. Furthermore, the greater influence of NIH guidelines could help focus public attention on their content and generate more effective debate regarding the proper use of embryos. The option to utilize private funds for research might still be available, and such research might not be subject to any NIH guidelines, but, as with early genetic studies, the broad availability of public funding would likely reduce the incentives for researchers to utilize private funding, particularly if the benefits of reduced oversight and regulation are attenuated and thus likely outweighed by the greater relative costs of obtaining private funds.⁷⁷

This model could be applied to a variety of other problems at the convergence of reproduction and genetics. Studies of cloning and inheritable genetic modifications might be particularly good candidates for funding-oriented regulation because both involve relatively high operational costs and are still in early stages of research.⁷⁸ There is also sufficient disagreement about the social value of these projects that a precautionary approach balancing scientific progress with ethical and religious concerns might be ideal. Such an approach would accept the value of new research in these fields but impose procedural restrictions to minimize ethical concerns.

At some point in a technology's development, conditional funding becomes ineffective as a regulatory tool, and direct legislation becomes the preferred and most effective approach. For example, this stage might occur once a technology becomes sufficiently established for private industry to invest in commercialization, or once the costs and risks of such research to private firms become sufficiently low and its commercial promise much greater. But the historical examples provided by genetic research and IVF suggest that a great deal of early-stage research is not easily susceptible to direct legislation, whether due to political forces such as those surrounding abortion or to a lack of information about how popular preferences will evolve. The view of federal research funding as a kind of public gratuity may also make it more politically feasible to attach conditions to funding of nascent research than to legislate new restrictions outright.

⁷⁶ See National Institutes of Health, Stem Cell Information, Policy & Guidelines, <http://stemcells.nih.gov/policy/guidelines.asp> (last visited Nov. 12, 2006).

⁷⁷ Even if federal guidelines were made mandatory for all ES cell research — whether federally funded or not — a comprehensive funding regime could still serve a useful precautionary role by favoring certain forms of research and by limiting the role of private industry in the early stages of this research.

⁷⁸ See FRANKEL & CHAPMAN, *supra* note 13, at 15–25.

Another weakness of funding-oriented regulation is the political difficulty involved in favoring ethically problematic research over other pressing needs. Early critics of federal funding of IVF research, for example, suggested that such funding ought to be shifted to conditions such as pelvic inflammatory disease or blocked fallopian tubes that often lead to infertility and create demand for IVF.⁷⁹ This is an appealing approach, achieving the same goal with fewer political costs.

In many cases, however, the political problem arises in the first place because the ethically problematic option is the most technically sound. If alternative approaches have the same technical characteristics, supporting the more politically palatable one is an easy decision. But technical equivalence is often lacking, and limiting public funding to politically expedient but technically suboptimal alternatives might not produce acceptable compromises in many cases. When private research remains unrestricted, public funding of impractical alternatives may simply drive ethically problematic research to an unregulated private sector. The large sums of private money now devoted to ES cell research focused on profit-generating treatments provide one case study of how an awkward regulatory distinction can thwart the regulatory aims of public funding and oversight.⁸⁰ So although exclusive funding of palatable alternatives is an important option to consider, it should be applied with close attention to the economic motivations of private actors and the relative technical feasibility of all alternatives.

*B. Wariness and Acceptance of New Reproductive
and Genetic Technologies*

The degree to which an initially suspect technology can be established as an ordinary part of modern culture is another important consideration in regulating the development of these technologies. On the one hand, regulators ought to respect and alleviate the deeply held concerns and fears related to new technologies, particularly when they affect such fundamental aspects of the social fabric as reproduction and genetic identity. On the other hand, if a society can be expected to embrace most new technologies despite its initial misgivings, regulators may not wish to constrain research to such a degree that the development of new technologies will be completely foreclosed. Regulators may wish to be cautious of overdetering new research, even when current public opinion indicates strong skepticism about the value and concern about the risks stemming from such research.

⁷⁹ See HENIG, *supra* note 1, at 213.

⁸⁰ In this case, the technical advantages of utilizing ES cells rather than adult stem cells provide clear incentives for private industry to fund development on its own, rather than risk high opportunity costs awaiting the uncertain outcomes of publicly funded research limited to impractical alternatives.

The current debates surrounding cloning provide a useful modern platform for examining the phenomenon of technology acceptance. Nearly all policy proposals for comprehensive regulation include an outright ban on cloning for reproduction and an outright ban, open-ended moratorium, or strict regulation of therapeutic cloning.⁸¹ This approach is informed in large part by strong public skepticism of cloning generally, as well as by more specific concerns such as the societal treatment of children that might be conceived through cloning techniques.⁸² The cautious approach to cloning taken by these proposals also reflects strong concerns about the inability to obtain consent from future generations — who may be most affected by current decisions by parents and policymakers — and the prospect of genetic defects and low success rates for cloned mammals produced through existing reproductive and genetic technologies.⁸³

The natural regulatory response to these issues is exemplified by current policy proposals, which closely track public concerns by imposing strong restrictions on cloning research. The regulatory experiences in the areas of IVF and genetic research, however, may counsel in favor of relaxing many of these proposed restrictions. By linking the regulation of cloning so closely to current public opinion, leading to outright bans on most cloning applications, these proposals might overdeter the development of new cloning-based technology with respect to which public acceptance might actually be quite malleable.

To take one example, many of the concerns motivating total bans on reproductive cloning evoke the same kinds of societal and familial acceptance themes expressed in the years preceding widespread use of IVF.⁸⁴ But predictive policymaking based on these kinds of themes is

⁸¹ See, e.g., FUKUYAMA & FURGER, *supra* note 7, at 5–6 (“Human reproductive cloning is not today something that can be done safely, and for that reason alone should be banned We believe that research cloning should be permitted but tightly regulated.”); THE PRESIDENT’S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY, *supra* note 15, at 223–24 (“Permitting cloning-for-biomedical-research now, while governing it through a prudent and sensible regulatory regime, is the most appropriate way to allow this important research to proceed while ensuring that abuses are prevented. Combined with a firm ban on the transfer of cloned embryos . . . such a policy would provide the balance of freedom and protection, medical progress and respect for moral standards . . .”).

⁸² See, e.g., THE PRESIDENT’S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY, *supra* note 15, at 32 (“[A] Gallup poll from May 2002 . . . showed opposition to cloning to produce a child at 90 percent, and opposition to ‘cloning of human embryos for use in medical research’ at 61 percent.”).

⁸³ See ROSLIN INSTITUTE, SOMATIC CELL NUCLEAR TRANSFER (CLONING) EFFICIENCY (2001), available at <http://www.reproductivecloning.net/hosting/waite/efficiency.pdf>.

⁸⁴ Consider the President’s Council on Bioethics report, *Human Cloning and Human Dignity*, which asks: “What harms might be inflicted on the cloned child as a consequence of having been made a clone? . . . How might cloning-to-produce-children affect relationships within the cloning families? . . . [H]ow might it affect the relationship between the generations?” THE PRESI-

difficult. Modern acceptance of IVF, for example, indicates that children conceived through novel processes suffer few abnormal social or familial consequences due to the circumstances of their conception. The identical genetic makeup of cloned children is a marked difference from IVF, of course, but this difference may not be significant because even genetically identical mammals may emerge from the womb with markedly different characteristics.⁸⁵ The nature of family relationships between parents and cloned children might turn on the initial motivations of parents in utilizing cloning technologies, but this issue turns even more strongly on the question of whether parent-child relationships are defined primarily through genetics or through environment or attachment.⁸⁶

Given the demonstrated capacity of American families and society at large to assimilate even deeply transformative technologies such as IVF, policymakers may not wish to foreclose so quickly consideration of new technologies through preemptive bans. There may be, for example, legitimate demand for applications based on reproductive cloning, whether to permit parents who are carriers of a disease to guarantee that their children will not suffer from the disease or to enable infertile men and women to parent biologically related children. Although some of these potential applications are more politically acceptable than others, it might be best to defer heavy-handed regulation until there is better information about the specific harms and benefits of these new technologies.

One concern regarding this permissive approach is the danger that a new technology might become so quickly and deeply entrenched that it will be difficult to regulate effectively. The history of IVF, after all, illustrates this very kind of entrenchment as a side effect of the rapid public acceptance of the technology. Also, minimizing what might be considered values-based regulation might inflict social harms on children born in the absence of beneficial regulation who have no ability to affect the decisions made on their behalf. These concerns are valid, but they ought to be weighed against the costs of preventing a beneficial technology from coming to fruition. Furthermore, the problem of

DENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY, *supra* note 15, at 76.

⁸⁵ See Press Release, Tex. A&M Univ., Texas A&M Clones First Cat (Feb. 14, 2002), available at <http://www.tamu.edu/aggedaily/press/020214cc.html> ("The pattern of pigmentation in multi-colored animals is the result of genetic factors as well as developmental factors that are not controlled by genotype." (quoting Dr. Mark Westhusin) (internal quotation marks omitted)). Furthermore, genetically identical children develop within distinct environments that can be expected to create distinct social and cultural identities.

⁸⁶ See Elizabeth Bartholet, *Guiding Principles for Picking Parents*, 27 HARV. WOMEN'S L.J. 323, 325-29 (2004).

premature entrenchment of a new technology might be lessened by tailoring regulation to minimize the most difficult ethical problems.⁸⁷

C. Safety and Public Pressure

Although safety ought to be one of the foremost concerns with any new research, research in reproduction and genetics generates particularly complex safety issues both because these fields have the capability of rendering fundamental changes to human biology and because the effects of these changes can extend to future generations that have no way of consenting to current medical decisions. Despite these heightened concerns, attention to safety has often been lacking over the course of the development of IVF and genetic research. The regulatory history of IVF and genetics highlights the phenomenon that strong public acceptance and entrenched market forces surrounding new technologies often result in suboptimal safety standards. Thus, it may be wise for policymakers to dictate a level of protection substantially higher than that called for by public opinion once a technology becomes broadly accepted.

Strict attention to safety has often faltered in the face of strong public demand for new or even undeveloped technologies. For example, the strong public acceptance of IVF may have masked important, yet subtle, safety concerns for children conceived through IVF. Complications arising from multiple pregnancies were well known even when the first babies conceived through IVF were born.⁸⁸ Yet the transfer of multiple IVF embryos, long identified as the cause of increased multiple pregnancies, has remained a commonly accepted medical practice.⁸⁹ The persistence of this practice is likely influenced by the strong desire to perform IVF in the first place and to produce a pregnancy with a minimum of discrete procedures. Indeed, despite a string of studies hinting at basic medical risks associated with IVF, demand for the technology has increased.⁹⁰ The lure and availability of IVF may alter affected parents' overall perception of the risks, making the existing level of safety regulation suboptimal.

A similar pattern can be discerned in the regulation of safety in genetic research. Although no genetic treatments have become widely available, even in the case of highly experimental genetic therapies

⁸⁷ New therapeutic applications might be sharply curtailed, but not completely precluded, by permitting or even funding research for only the most compelling cases and reevaluating the scope of regulation once the relevant social and safety considerations are better understood.

⁸⁸ See Lambert, *supra* note 68, at 3013.

⁸⁹ See HENIG, *supra* note 1, at 236–37.

⁹⁰ Early studies in the late 1980s and early 1990s, for example, found higher rates of miscarriages, stillbirths, and ectopic pregnancies among users of IVF. See *id.* at 236–42 (reviewing recent analyses of safety and birth defects in children conceived through IVF).

strong demand has often limited attention to safety.⁹¹ Indeed, as gene therapy's promise has extended beyond rare genetic diseases to more common afflictions, advocacy groups for patients have generally sought to reduce the regulatory hurdles imposed by even the purely safety-oriented regulations governing experimentation. Although the terminal nature of many of these diseases, and the dearth of options for their victims, greatly reduces the perceived costs of weakening safety provisions, the lack of attention to safety illustrates the power of demand for even unproven treatments to shape regulation.

The regulatory experience with IVF safety and the strong pressures from patients and activist groups to loosen safety requirements for human gene therapy experiments all point to the need for higher levels of safety regulation than popular sentiment would appear to require. In order to develop effective and optimal safety regulation, then, policymakers should consciously correct for the strongly deregulatory forces of market demand.

CONCLUSION

The recent convergence between reproductive medicine and genetic research creates new dilemmas for current regulation, but it also presents an opportunity to develop a regulatory framework that is guided by fundamental public sentiments rather than by technical formalities and that is the result of reasoned deliberation. Any reform ought to consider the past forces that have contributed to today's regulatory divide, even if they simply inform rather than dictate the future direction of regulation. The lessons presented in this Note — that funding-oriented regulation may be effective for early-stage research, that there may be a large cultural capacity to absorb new technologies, and that safety concerns ought to be heightened in the face of strong market forces — suggest potential tools for reform. More work is needed to establish an effective regulatory framework, but these insights, drawn from the hard experience of history, should offer useful guidance as today's speculative ethical debates develop into concrete realities.

⁹¹ See Rainsbury, *supra* note 23, at 586 & n.95 (describing political pressure to bypass ordinary processes to expedite particular gene therapy treatments).