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# A Law-Policy Proposal to Know Where Babies Come From During the Reproductive Revolution

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Creating Life? Examining the Legal, Ethical, and Medical Issues of Assisted Reproductive Technologies

\*549 A LAW-POLICY PROPOSAL TO KNOW WHERE BABIES COME FROM DURING THE REPRODUCTION REVOLUTION

Michael J. Malinowski [FN1]

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## I. Introduction

The awesome capability to intervene at the beginning of human life through medicine--to actually enable the creation of life and choices about human characteristics--has burgeoned in recent years and continues to expand at an ever-quickening pace. [FN1] Assisted reproduction technology (ART) has become an increasingly accessible means for prospective parents to realize parenthood when confronting human health impediments--overcoming infertility, or avoiding an identifiable genetic risk or health impairment. Assisted reproduction (AR), which is carried out in the United States predominantly in hundreds of private, independent clinics, has become a vibrant, highly competitive business that markets itself aggressively and generates billions of dollars annually. [FN2]

The revolution in human reproduction through AR (reproduction \*550 revolution) is broadening parental choice about whether to have children and what genetic characteristics those children will or will not have. [FN3] This reproduction revolution and the genomics revolution, both ongoing and raging, are becoming intertwined through the use of AR technologies. [FN4] Colleagues have termed the nexus "reprogenetics." [FN5] Professor John Robertson, a visionary immersed in the law and policy aspects of AR and genomics, has predicted our society's destiny in reprogenetics. As observed by Professor Robertson, "Ultimately, decisions about how to use or not use genomics in human reproduction will be determined, not by biologic necessity or evolutionary theory, but by how those uses fit into the fabric of rights and interests of individual and social choice and responsibility that particular societies recognize." [FN6]

The objective of this Article is to question the role of regulation in the field of AR at the present time and over the next several years as the genomics and AR revolutions continue to intensify and integrate. Part II discusses the extent to which AR is a distinguishable field of medicine, and does so from the often conflicting perspectives of patient, provider, and payer. Part III probes the United States' unique level of acceptance of AR among industrialized countries, attributable largely to a trilogy of deferences: to human reproduction, to the physician's discretion to practice medicine, and to physician-patient decision making. The Article concludes \*551 that assurance of good medical practices and public accountability through regulation are at least as desirable in AR as in most other areas of medicine. Proposals for regulatory reform include a comprehensive, national licensing requirement for all AR services and the establishment of a federal overseeing authority.

## II. Distinguishing Features of AR as a Field of Medicine

AR is generally performed as a medical clinical service, [FN7] and the Food and Drug Administration's jurisdiction historically has been checked not to interfere with physician discretion to practice medicine. [FN8] In fact, the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA) [FN9] expressly provides: "In developing the certification program, the Secretary [of the Department of Health and Human Services] may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs." [FN10] Consequently, the United States' federal regulation consists almost entirely of self-regulation through a program of voluntary reporting and certification. [FN11] The federal system rests largely upon the FCSRCA, pursuant to which the Centers for Disease Control and Prevention (CDC) developed a model certification program for AR laboratories. [FN12] The CDC has contractually outsourced implementation of its responsibilities \*552 under the FCSRCA to the Society for Assisted Reproductive Technology (SART) and the American Society for Reproductive Medicine (ASRM). [FN13] Most AR providers belong to these organizations and report data to them voluntarily. SART-ASRM then collects, processes, and submits the data to the CDC, which in turn processes that data in a standard format and issues reports annually for public dissemination. [FN14] In addition to the CDC, the Federal Trade Commission (FTC) has jurisdiction to police marketing claims and has used that authority to investigate some AR providers. [FN15] Some states have done the same. [FN16]

This author [FN17] and others, including Professor Lars Noah, [FN18] Erik Parens and Lori Knowles, [FN19] and the Food and Drug Administration (FDA), [FN20] have questioned the sufficiency of this voluntary reporting, self-regulation system in the field of AR. [FN21] The FCSRCA did not even introduce a mandatory mechanism to report adverse events associated with fertility treatments, [FN22] and the CDC performs site visits on fewer than ten percent of AR clinics. [FN23] \*553 Moreover, states "have failed to offer much direct regulation of fertility clinics." [FN24] As summarized by the FDA:

The model certification program for embryo laboratories developed by the Centers for Disease Control and Prevention (CDC) is a voluntary program that States may or may not choose to adopt; its primary

focus is not on preventing the transmission of communicable disease. No State has yet adopted CDC's model certification program. Membership in professional societies is voluntary. Moreover, many establishments do not report to the Society for Assisted Reproductive Technology. [FN25]

#### A. Existing AR Features

Several features of AR support more direct government regulation by the United States. First, the three primary patient groups at issue--prospective parents, pregnant women, and the unborn--are exceptionally vulnerable, and two of these groups (pregnant women and the unborn) have been deemed as such under the Common Rule for the protection of human subjects. [FN26] Second, rapidly emerging technology, experimentation, and the practice of medicine are inherently mixed in AR--much more so than in most other fields of medicine. Novel techniques are often practiced in AR without the prerequisite of sufficient animal studies and human subjects protection oversight. [FN27] Examples include discovery and clinical use of \*554 intracytoplasmic sperm injection (ICSI); [FN28] cytoplasmic transfer; [FN29] in vitro ovum nuclear transplantation (IVONT); [FN30] and administering extraordinarily high doses of hormones to premenopausal women to impregnate them, even while physicians are being warned to administer only mild doses of estrogen to postmenopausal women, and just when most needed. [FN31] Nevertheless, the field of AR largely circumvents the United States' regulations to protect human subjects because the experimentation generally is deemed an extension of clinical service and is not carried out for product review and approval by the FDA. [FN32] "And since [new interventions in the field] are presented as innovative clinical practice rather than as research, oversight of \*555 them is left to the discretion of the individuals or institutions offering them." [FN33]

A third feature necessitating more government regulation is that the majority of AR patients pay out-of-pocket, which means that standard accountability and good medicine checks on clinical practice through third-party payer scrutiny generally do not pertain. [FN34] Fourth, commercial influences, including aggressive direct-to-consumer (DTC) marketing, are intense in AR and carried out regionally, nationally, and even internationally. [FN35] Much of the marketing data equates "success" with live births, regardless of whether those births are seriously premature or suffer serious health problems. [FN36] Fifth, a significant increase in multiple births, associated with premature delivery and health impairments, has already been attributed to AR services. [FN37]

#### B. AR in the Future

When considering the role of regulation in AR at the present time and over the next several years, the distinguishing features of AR must be thought through in the context of ongoing trends in biomedical research and development (R&D). These trends include the mission to make medical sense out of the map of the human genome; the extraordinary and ongoing commercial, governmental, and academic investment to accomplish that mission; and the voluminous and amassing power of bioinformatics. [FN38] The considerable genotype-phenotype connections (connections between genetic characteristics and physical/mental characteristics) being generated by the \*556 "genomics revolution" must be taken

into consideration. [FN39] Although the vast majority of these genotype-phenotype connections are subtle in the context of human health and even negligible for contemporary clinical health application, the capability to test for large numbers of them simultaneously is becoming remarkably easier. [FN40] As clusters of bits of information become larger, cheaper, and collectively more medically meaningful, presumably so will their appeal to patient-consumers. [FN41]

Many predict that consumer-driven medicine is the emergent post-managed care era in United States medicine. [FN42] Certainly a reasonable amount of faith must be placed in the judgment of the patient-consumer in the United States to make responsible decisions about the use of AR and health care in general. Nevertheless, medicine, and medical technology in particular, cannot be equated with standard commodities like groceries, clothes, and entertainment. [FN43] As explored fully in legal literature--especially comparative health law literature--patients are not typical consumers, and health care is not a typical product or commodity. [FN44] Innovative medical \*557 technologies that require more expertise to assess and are promoted through aggressive DTC marketing exacerbate these differences. A recent illustration is the patients' purchase of billions of dollars worth of prescription Vioxx and other Cox-2 inhibitors through providers as an alternative to ibuprofen--a drug that was familiar and tested through use over time, available over the counter at a fraction of the cost, and now has been proven to be equally or even more effective for most patients and with significantly less risk. [FN45]

When considering the role of regulation in the AR context, one must embrace the health care realities of patient and provider, and with sensitivity for the distinguishing features of the practice of AR addressed above. [FN46] In addition to the capacity to generate genetic information, the genomics revolution encompasses fields such as stem cell research and provides an understanding of cellular differentiation and genetic expression, resulting in immeasurable potential for human health application. [FN47] Given the distinguishing features of AR, AR providers will be at least as tempted and as likely as other physicians to apply emerging technology prematurely, and in a manner that risks deviation from good medicine practices and detract from the quality of care. [FN48]

It is highly likely that the genomics revolution will intensify the appeal of AR as a consumer product by adding considerably more information at nominal additional cost to services presently rendered. From the patient's perspective, imagine being desperate to have a child, [FN49] frustrated and pressured by time, worrying to the point of being willing to spend tens of thousands of dollars, perhaps exhausting savings and mortgaging a home, and undergoing invasive procedures, all for a thirty to thirty-five percent chance of success. [FN50] If extensive multiplex genetic testing for relatively \*558 nominal additional cost means considerably more information about a pregnancy, even if that information is generally hazy at best and of questionable medical utility, the temptation to opt for more information is understandable. AR providers could enhance that appeal by packaging the extra information as an added value. From the patient's perspective, given the element of desperation associated with most AR services, more information about the medical status of embryos and pregnancies is likely to be perceived as preferable, especially in light of limited patient-consumer capabilities to meaningfully assess and process that information. From an AR provider's perspective, offering patients more medical information and, specifically, genetic information [FN51] for a relatively nominal extra cost, even if the

information is of marginal clinical utility, means more market appeal in the highly competitive commercial AR sector--a sector marketing aggressively for patients. [FN52]

### III. A Proposal for Public Accountability in AR

The United States' approach to health care--in essence, heavy dependence on the private sectors and no universal system to ensure a baseline of care for all--is readily distinguishable among developed economies. [FN53] The implications for the roles of payer, provider, and patient are extensive. [FN54] Arguably, especially for areas of medicine with relatively profound social, ethical and legal implications, the United States' privatized approach sometimes necessitates targeted government regulation to ensure collection of information routinely gathered by governments acting as payers and comprehensive health care overseers in universal health care systems. [FN55] Presumably this need is underscored in highly sensitive areas of medicine that also fall into the extreme range of privatization, such as AR in the United States. [FN56]

\*559 Experience with AR elsewhere in the world is extensive enough to, at the very least, provide a means for drawing comparisons--comparisons made with appreciation for the distinguishing features of the United States' health care system that enable thoughtful questioning about the fundamental role of government regulation in AR. Virtually all industrialized nations offer meaningful access to AR but with more direct government regulation and comprehensive oversight, even when considerable AR services are provided through private health care. [FN57] "Increasingly, countries are attempting to create statute-based regulatory schemes that regulate either the entire assisted reproduction technology (ART) enterprise or large portions of it." [FN58] A common denominator is regulation to ensure comprehensive screening of donated sperm and ova to protect against HIV and other diseases. [FN59] In addition to assurance of public safety and good medical practice, most other industrialized nations check the goal of assistance in adult procreation with measures to promote public accountability--for example, conclusive AR licensing requirements for all service providers. [FN60] Perhaps most notably, from 1982 to 1984 the United Kingdom (U.K.) engaged in public debate and deliberation--which, incidentally, expressly recognized the entanglement of human embryonic research and infertility services [FN61]--through the work of the Warnock Committee. [FN62] For the next six years, Parliament considered the Committee's sixty-four recommendations \*560 in deliberations open to the public, and these deliberations resulted in the Human Fertilisation and Embryology Act (hereinafter the Act) of 1990. [FN63] The Act introduced statutory regulations governing donor insemination, in vitro fertilization, and embryonic research, and the United Kingdom established the Human Fertilisation and Embryology Authority (HFEA) to implement it. [FN64] Foremost, the Act requires licensing for all AR services to ensure government oversight and public accountability. [FN65] In 2001, Parliament broadened the HFEA's enabling legislation to allow research that derives human embryonic stem cells (hESC) to explore therapeutic properties. [FN66]

As an extension of regulating AR for accountability, the United States' industrialized counterparts have defined and codified a varied set of principles to govern AR. [FN67] Approaches to AR are intentionally value-laden, and as varied as the cultures of the countries themselves. For example, the U.K. has adopted a primarily child-oriented perspective. [FN68] The country has placed restrictions on the use of AR to protect the interests of the potential child, including checks on parental screening and limitations on prospective parents' access to donor information which could impose expectations on children created with AR. [FN69] In contrast, Canada's perspective has been primarily parent-oriented. [FN70] The country involves the law to protect prospective parents from discrimination based upon family status, marital status, or sexual orientation. [FN71]

Similarly, countries vary immensely in terms of practical access to AR \*561 services. [FN72] For example, the French have imposed stringent standards on access in favor of heterosexual couples seeking to realize a conventional nuclear family structure, but, where those criteria are satisfied, there is meaningful access. [FN73] In comparison with France, the U.K. favors physician discretion rather than prescribed, rigid standards. [FN74] However, U.K. physicians must and do take funding limitations into account, for local health authorities adhere to budgets and generally limit allocation of resources for AR services. [FN75] A common denominator among the U.K., France, and Canada is that both public and private providers of AR services are directly regulated by, and accountable to, government entities through licensing and reporting requirements. [FN76]

What makes the United States so different--so relatively willing to leave AR to self-regulation by the medical profession and largely unrestrained for those with the financial means to procure AR services? The United States' position on AR is as value-laden as those of its industrialized counterparts, and several sociocultural influences are responsible for the United States' unique level of acceptance of AR. The United States' approach is multifaceted and shaped largely by a trilogy of deferences. The approach encompasses the parent perspective through high deference to human reproduction, and then adds additional dimensions of deference to patient-doctor decision making and physicians' discretion to practice medicine.

For more than a quarter of a century, United States jurisprudence has recognized and protected procreative liberty expansive enough to encompass decisions to terminate pregnancies for any reason prior to viability of the fetus. [FN77] Today, in spite of anxiety over research that destroys embryos and use of cloning in human reproduction, [FN78] procreation, with or without AR, generally is embraced and largely shielded from the intrusion of law to the point of making government accounting and public accountability dependent \*562 upon voluntary reporting. [FN79] As observed by Professor Robertson:

It is not surprising that an interlocking set of laws, norms and practices exist that support reproduction. Deeply engrained social attitudes and practices celebrate the importance of family and children. Laws, ethical norms, and institutions protect and support human desires to have or avoid having offspring, and the rearing that follows. The deep psychological commitment one has to the well-being of one's offspring is reflected in the strong family and constitutional law protections for rearing rights and duties in biologic offspring, in special tort damages for the loss of children and parents, in the law of rape, in the rise of an infertility industry, and in the wide acceptance of prenatal screening programs for the

health of offspring . . . Strong protection of procreative liberty and family autonomy in rearing offspring is yet another way that social recognition of the importance of reproduction is shown. [FN80]

In addition to this psychological, social, and, as many argue, biological drive to embrace human reproduction, [FN81] the United States also has a rich legacy of deferring to individual doctor-patient relationships [FN82] and to doctors' discretion to practice medicine. [FN83] Limitations on the FDA's authority, both under law [FN84] and through FDA self-restraint, [FN85] underscore deference to the medical profession. [FN86] These deferences under the law--\*563 deference to reproduction, doctor-patient decision making, and the discretion to practice medicine without government intrusion--intersect in AR.

Eric Parens, Lori Knowles, and others have emphasized an association between United States oversight of reproductive medicine and the dynamics of the abortion debate. [FN87] According to Parens and Knowles, “[t]hose dynamics make policymakers reluctant to engage in a decision about embryo research.” [FN88] In fact, the more fundamental trilogy of deferences identified above are encompassed in the United States abortion debate and arguably drive Justice Blackmun's *Roe v. Wade* opinion. [FN89] These deferences also transcend the abortion debate and link acceptance of ART with both proponents and opponents of a woman's right to terminate her pregnancy. Opponents of abortion center on deference towards reproduction, while proponents advocate individual choice in reproduction, patient-doctor decision making, and the discretion to practice medicine.

Lori Knowles also attributes the United States' warm embrace of ART to “an embedded tradition of commercialization.” [FN90] According to Professor Knowles:

This [influence] applies to many realms of human reproduction, from sales of ova and commercial surrogacy, to sales of gender selection technologies and parental DNA testing. Restrictions on commercialization in the United States are viewed with suspicion as is much government regulation. Current government restrictions on funding of hESC research continue to be controversial. [FN91]

While faith in market forces and suspicion of government certainly distinguish the United States from Canada and many European counterparts, the United States is becoming increasingly questioning of commercial incentives in the context of the delivery of health care, especially with the proliferation of managed care. [FN92] In fact, managed care and excessive commercialization in the health context, from the delivery of care to the marketing of pharmaceuticals, is pushing the United States into an era of consumer-driven medicine. [FN93] Moreover, in biotechnology R&D, where \*564 commercialization has been most embraced in the context of health care, the United States government has been directly and extensively involved. From the Human Genome Project to the tens of billions of dollars invested in basic research annually through the National Institutes of Health, the United States government has been a presence welcomed by academia, industry, patient groups, and the general public. And from the Federal Technology Transfer Policy introduced in the 1980s to the dramatic expansion of the FDA through user fees in the 1990s, extensive government regulation has been accepted as the means to advance the genomics revolution. [FN94] The trilogy of deferences has shielded ART from more

extensive government regulation in spite of the norms of a looming government presence in biomedical R&D and increasing public discomfort with and suspicion of the commercial sectors in health care.

Proponents of continued reliance on voluntary reporting and self-regulation in AR assert that this approach is working, that AR is effectively regulated, and that more extensive direct government regulation of AR would invite intrusion. [FN95] For example, they caution that more direct government involvement in AR could welcome the codification of subjective values that many of our industrialized counterparts have engaged in--for example, to favor heterosexual couples seeking to realize a conventional nuclear family structure while discouraging others. [FN96] This is a valid concern, but the value our society places on family, and the trilogy of deferences that have proven so influential in the United States' approach to AR regulation thus far suggest the opposite. Rather, as observed by Professor Robertson, our society probably will grow even more comfortable with AR over time with increasing familiarity and expansion of clinical capabilities, especially if there are reliable assurances of good medicine practices and accountability along the way. [FN97]

The distinguishing features of AR as a field of medicine deserve attention, [FN98] as recognized in a March 2004 report issued by the President's Council on Bioethics, entitled *Reproduction and Responsibility: The Regulation of New Biotechnologies*. [FN99] The increase of more direct, reliable government regulation of AR in the United States would, of course, have to \*565 be implemented in a constitutionally sound manner, meaning in a way consistent with recognized rights such as procreative liberty [FN100] and commercial free speech. [FN101] Any expansion of the role of the FDA could not transcend checks on the agency's authority that protect the physician's discretion to practice medicine. [FN102]

An approach proposed by Professors Lori Andrews, Nanette Elster, and others is regulation to raise the quality of consumer information about AR, thereby heightening consumer awareness and meaningful choice. [FN103] States may require physicians to provide information about alternatives to abortion and make women wait days after the delivery of such information before exercising their decision to terminate a pregnancy, as held by the Supreme Court in *Planned Parenthood v. Casey*. [FN104] The ability to require the delivery of sound medical information about AR services should fit cleanly within states' discretion. [FN105] Nevertheless, given the regional, national, and significant international scope of the markets for AR services and the Internet access to those markets that is being exercised by service providers \*566 and patients, a baseline of more meaningful federal oversight is preferable. [FN106] Any United States federal regulatory approach will have to embody sensitivity to governing values in the United States--the deferences influencing current law and policy [FN107]--and comply with constitutional and other restrictions on government involvement. Accordingly, the United States should adopt a regulatory approach to AR centered on assurance of good medicine and, to the extent possible, build upon existing regulatory schemes, such as federal oversight of commercial laboratories under the *Clinical Laboratories Improvement Amendments (CLIA)*. [FN108]

At the very least, the United States should join its industrialized counterparts and adopt a comprehensive, national licensing requirement for all AR services that is an extension of the CDC's model program [FN109] and that draws from the certification of clinical laboratory services under CLIA.

[FN110] As so many other nations have done, and as has been suggested by Erik Parens, Lori Knowles, and others, the United States should draw from the United Kingdom experience, albeit with focus on United States law and policy, and work with the driving trilogy of deferences. [FN111] Responsive to the sensitivities of AR, the United States should establish a committed overseeing authority modeled as a counterpart to--not a substitute for--the Office of Human Research Protection, which centralizes oversight of implementation of human research protections in the United States. [FN112] In crafting this body, the United States also should draw from the HFEA in England and the Reproductive Technology Accreditation Committee (RTAC) in Australia. [FN113] Unlike the HFEA, and in spite of the inevitable practical entanglement of AR and human embryonic stem cell research (HESCR), this body should be focused on AR to avoid commingling the often competing goals of advancing research and patient care, though their innate entanglement must be constantly recognized and addressed. [FN114]

\*567 This approach is responsive to a governing theme of Reproduction and Responsibility. [FN115] While the Council made some recommendations for studies and data collection, self-regulation by professional societies, and targeted legislative measures, the overall theme of the report is that there simply is too much unknown about AR to undertake significant regulatory reform at this time. [FN116] According to the Council, “[w]ithout the answers to such questions, it would be premature at best to recommend dramatic legal or institutional changes. Further research and inquiry, and additional consultations with all those affected, are clearly needed.” [FN117] An alternative conclusion is that, given the maturity of the AR sector over the last several years and the distinguishing features of AR, it is irresponsible for the United States government to further delay regulatory reform necessary to ensure reliable accountability and awareness of what is transpiring in AR in the United States while tens of thousands of people use AR services on an annual basis. [FN118] Reforms such as those proposed in this article should be undertaken to move the United States closer to a position of awareness, accountability, and reliable oversight in AR.

#### IV. Conclusion

Deference to human reproduction, to physician discretion to practice medicine, and to physician-patient decision-making have limited direct government regulation of AR in the United States, resulting in considerable reliance upon self-regulation by those providing AR services. [FN119] This article has identified features of AR that support meaningful direct government \*568 regulation. [FN120] The present lack of information about AR recognized by the President's Council on Bioethics is unacceptable, [FN121] especially given the expansive growth of AR over the last several years, the predictability of that growth years before, and the measures to ensure accountability undertaken by the United States' industrialized counterparts, such as the United Kingdom's adoption of the Human Fertilisation and Embryology Act a decade and one-half ago. [FN122]

The United States should join its industrialized counterparts and adopt a comprehensive, national licensing requirement for all AR services that is an extension of the CDC's Model Program [FN123] and

which draws from the certification of clinical laboratory services under CLIA. [FN124] Reliable government oversight and full awareness of what is transpiring in AR is a baseline that must be established now, for the reproduction and genomics revolutions are raging, intensifying, and integrating. The trilogy of deferences must give way to accountability and assurance of good medicine in the clinical practice of AR.

[FNa1]. Ernest R. and Iris M. Eldred Endowed Professor of Law. This article draws heavily from the author's related work, *Choosing the Genetic Makeup of Our Children: Our Eugenics Past--Present, and Future?*, 36 Conn. L. Rev. 125 (2003), and his participation in this Symposium, *Creating Life? Examining the Legal, Ethical and Medical Issues of Assisted Reproductive Technologies* (Oct. 8-9, 2004). The author would like to thank Professors Nanette Elster and Ellen Waldman for their thoughtful suggestions. This article was submitted for publication in summer 2005 and does not necessarily reflect changes thereafter.

[FN1]. See generally President's Council on Bioethics, *Reproduction and Responsibility: The Regulation of New Biotechnologies* (2004), [http://www.bioethics.gov/reports/reproductionandresponsibility/\\_pcbe\\_final\\_reproduction\\_and\\_responsibility.pdf](http://www.bioethics.gov/reports/reproductionandresponsibility/_pcbe_final_reproduction_and_responsibility.pdf); see generally Analytical Sciences, Inc., CDC, *Final Report Survey of Assisted Reproductive Technology: Embryo Laboratory Procedures and Practices* (1999), <http://www.phppo.cdc.gov/dls/pdf/art/ARTsurvey.pdf>; Erik Parens & Lori P. Knowles, *Reprogenetics and Public Policy: Reflections and Recommendations*, 33 *Hastings Ctr. Rep.* S1, S1-S25 (2003); Michael J. Malinowski, *Choosing the Genetic Makeup of Our Children: Our Eugenics Past--Present, and Future?*, 36 Conn. L. Rev. 125, 172-97 (2003). See also Paul Carrick, *Medical Ethics in the Ancient World* 99 (2001) (“[N]ever in human history has reproductive freedom been greater: we are now providing a single person or a couple the leeway to choose not only with whom, but when, and by what means conception will take place.”). Cf. John A. Robertson, *Procreative Liberty in the Era of Genomics*, 29 *Am. J.L. & Med.* 439 (2003).

[FN2]. See Malinowski, *Choosing*, *supra* note 1, at 189-97; see generally Parens & Knowles, *supra* note 1.

[FN3]. See generally Parens & Knowles, *supra* note 1; Malinowski, *Choosing*, *supra* note 1. A frequently referenced illustration of this point is preimplantation genetic diagnosis (PGD), which involves screening embryos for selection prior to implantation. See generally John A. Robertson, *Debate, Extending Preimplantation Genetic Diagnosis: The Ethical Debate*, *Ethical Issues in New Uses of Preimplantation Genetic Diagnosis*, 3 *Hum. Reprod.* 465, 465-71 (2003). Another example is sperm sorting to control the sex of offspring. Parens & Knowles, *supra* note 1, at S4. As of July 2003, at least 430 children had been born in the United States using this technique. *Id.* In addition to applications through genotype-phenotype connections (connections between genetic characteristics and outward physical manifestations), advancement of research with human stem cells, including deeper understanding of genetic expression responsible for cellular differentiation and improvement of existing techniques such as somatic cell nuclear transfer, promises to generate opportunities for AR applications. See generally Parens & Knowles, *supra* note 1; Symposium, *Stem Cell Research and Human Cloning: Where Do We*

Draw the Line?, 39 New Eng. L. Rev. 477, 477-794 (2005). Cf. Nat'l Acad. of Sciences, Proceedings, Guidelines for Human Embryonic Stem Cell Research, <http://www.pnas.org/cgi/search?fulltext=Guidelines+for+Human+Embryonic+Stem+Cell+Research> (last visited Mar. 27, 2006). For the resulting NAS guidelines, see Nat'l Acad. of Sciences, Guidelines for Human Embryonic Stem Cell Research (2005), available at <http://www.nap.edu/books/0309096537/html/>.

[FN4]. See generally Parens & Knowles, *supra* note 1. For discussion of the genomics revolution with a focus on several priority fields of study, see Symposium, Proceedings of "The Genomics Revolution? Science, Law and Policy," 66 La. L. Rev. 1, 1-143 (2005) (live and published symposium sponsored in part by the Department of Energy-Human Genome Project Ethical, Legal and Social Implications Program).

[FN5]. See generally Lee M. Silver, *Remaking Eden: Cloning and Beyond in a Brave New World* 15 (1997); Lori B. Andrews, *The Clone Age: Adventures in the New World of Reproductive Technology* (1999); Parens & Knowles, *supra* note 1.

[FN6]. Robertson, *supra* note 1, at 452.

[FN7]. Malinowski, *Choosing*, *supra* note 1, at 180-87; Parens & Knowles, *supra* note 1, at S11-S12.

[FN8]. See *infra* notes 83-86 and accompanying text. See Practice of Medicine, 21 U.S.C. § 396 (2000) (retaining practitioner's ability to prescribe medical device); Prohibition Against Any Federal Interference, 42 U.S.C. § 1395 (2000) ("Nothing in [Medicare] shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided ...."); Legal Status of Approved Labeling for Prescription Drugs, Prescribing for Uses Unapproved by the Food and Drug Administration, 37 Fed. Reg. 16,503, 16,504 (Aug. 15, 1972) ("[I]t is clear that Congress did not intend the [FDA] to regulate or interfere with the practice of medicine ...."). These limitations reflect the fact that the FDA was introduced and its authority expanded during times when, relative to today, the medical profession was more highly organized, politically influential, and professionally autonomous. See Paul Starr, *The Social Transformation of American Medicine* 79-144 (1982).

[FN9]. Fertility Clinic Success Rate and Certification Act, 42 U.S.C. § 263a-1 et seq. (2000).

[FN10]. 42 U.S.C. § 263a-2(i)(1) (2000).

[FN11]. See Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 Fla. L. Rev. 603, 614-16 (2003); Malinowski, *Choosing*, *supra* note 1, at 180-97. But see Parens & Knowles, *supra* note 1, at S12 (stating that the FCSRCA does require clinics offering AR services to disclose pregnancy success rates to the CDC).

[FN12]. The model program is available at the Centers for Disease Control's website, <http://www.cdc.gov/reproductivehealth/ART/index.htm> (last visited Mar. 15, 2006). Supplemental

sources of regulation include state regulation, practice standards set by professional organizations, and the FDA's assertion of jurisdiction over human cloning and ooplasm transplantation. Parens & Knowles, *supra* note 1, at S12.

[FN13]. For information about these organizations, visit Society for Assisted Reproductive Technology, <http://www.sart.org> (last visited Mar. 15, 2006) and The American Society for Reproductive Medicine, <http://www.asrm.org> (last visited Mar. 15, 2006).

[FN14]. See, e.g., CDC Report, *supra* note 1. These reports are issued annually, but presently are running two years behind the governing calendar year. See *id.* at 1.

[FN15]. Noah, *supra* note 11, at 615 n.49.

[FN16]. See Noah, *supra* note 11, at 615-16 (acknowledging that some states have enacted legislation, and that there is at least some precedent for AR patients to seek redress under general consumer protection laws). Several commentators have called for increased consumer protection in the field of AR. See, e.g., Lori B. Andrews & Nanette Elster, *Regulating Reproductive Technologies*, 21 *J. Legal Med.* 35, 50 (2000). But see Judith F. Daar, *Regulating Reproductive Technology: Panacea or Paper Tiger?*, 34 *Hous. L. Rev.* 609 (1997).

[FN17]. See generally Malinowski, *Choosing*, *supra* note 1.

[FN18]. See Noah, *supra* note 11, at 606 nn.10-11. See also Philip G. Peters, Jr., *Protecting the Unconceived: Nonexistence, Avoidability, and Reproductive Technology*, 31 *Ariz. L. Rev.* 487, 491 (1989).

[FN19]. See generally Parens & Knowles, *supra* note 1.

[FN20]. Dep't of Health and Human Serv., Food and Drug Admin., *Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing*, 66 *Fed. Reg.* 5447, 5452 (Jan. 19, 2001) (codified at 21 C.F.R. pts. 207, 807).

[FN21]. But see generally David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 78 *Fertility & Sterility* 932, 938 (2002) (asserting that existing professional self-regulation and federal and state regulation are, with patient judgment, sufficient oversight of AR).

[FN22]. See Lori B. Andrews, *Human Cloning: Assessing the Ethical and Legal Quandaries*, *Chron. Higher Educ.*, Feb. 13, 1998, at B4 (“[T]he United States does not require clinics to report when children created as a result of reproductive technologies are born with abnormalities.”); Noah, *supra* note 11, at 615.

[FN23]. CDC, 2002 Assisted Reproductive Technology (ART) Report, *Commonly Asked Questions #7*, <http://www.cdc.gov/ART/ART02/faq.htm#7> (last visited Mar. 27, 2006). In 2002, only 30 of 391 reporting clinics were selected for site visits. *Id.*

[FN24]. Noah, *supra* note 11, at 615. But see Parens & Knowles, *supra* note 1, at S12 (observing comprehensive regulation of AR by New Hampshire and Virginia, and that “many states have laws regulating some aspects of, or techniques used in, embryo research”).

[FN25]. Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. 5447, 5452-53 (Jan. 19, 2001) (codified at 21 CFR §§ 207, 807 (2001)). At the time the Agency issued this notice of rulemaking, the FDA had not introduced regulations to address the infectious disease risk of donating, processing, and storing reproductive cells and tissue. *Id.* at 5452. However, the FDA finalized responsive regulations on May 25, 2004, which went into effect on May 25, 2005. See Suitability Determination for Donors of Human Cellular and Tissue-Based Products, 69 Fed. Reg. 29786 (May 25, 2004) (addresses donor screening and testing measures to prevent the unwitting use of contaminated tissues with potential to transmit infectious diseases, and applies to all such products, including reproductive cells and tissues). The FDA also has introduced two additional rules to make the nation's tissue supply safer. See generally Press Release, U.S. Food and Drug Admin., FDA Improves the Safety of Human Cells and Tissues by Finalizing New Rules for Good Tissue Practice (Nov. 18, 2004), <http://www.fda.gov/bbs/topics/news/2004/NEW01137.html>. For more information, visit U.S. Food and Drug Admin., Tissue Related Documents, <http://www.fda.gov/cber/tissue/docs.htm> (last visited Mar. 15, 2006).

[FN26]. See Criteria for IRB Approval of Research, 45 C.F.R. § 46.111(b) (Common Rule); Criteria for IRB Approval of Research, 21 C.F.R. § 56.111(b).

[FN27]. Parens & Knowles, *supra* note 1, at S11; Noah, *supra* note 11, at 607-12, 617-19.

[FN28]. This technique, which involves directly injecting a sperm cell into an egg cell with a pipette, was developed by Professor Andre van Steirteghem, a Belgian gynecologist, and Dr. Ng, a Vietnamese physician, following an accidental injection and then implantation of an embryo. See Andreas Voss, *The Right to Privacy & Assisted Reproductive Technologies: A Comparative Study of the Law of Germany and the U.S.*, 21 N.Y.L. Sch. J. Int'l & Comp. L. 229, 232 (2002); *Nova: 18 Ways to Make a Baby* (PBS television broadcast Oct. 9, 2001).

[FN29]. This technique involves removing cytoplasm from a donor egg and inserting it into a patient's egg before fertilization to add vibrant mitochondria, the “batteries” or energy sources. See *Nova: 18 Ways*, *supra* note 28. For more information about cytoplasmic transfer, see Human Genome Project Information, Gene Therapy, <http://www.ornl.gov/TechResources/HumanGenome/medicine/genetherapy.html> (last visited Mar. 15, 2006). See also R.G. Gosden, *The Role of Cytoplasmic Transfer*, OBGYN.net, <http://www.obgyn.net/displayarticle.asp?page=firstcontroversies/prague1999gosden> (last visited Sept. 22, 2005); see also David B. Sable, *Cytoplasmic Transfer*, <http://www.inciid.org/article.php?cat=femaleinfertility&id=323> (last visited Mar. 27, 2006).

[FN30]. This technique involves removing the nucleus from a donor egg and replacing it with a nucleus taken from a patient's egg before fertilization. See Noah, *supra* note 11, at 610. For broader discussion of IVF techniques, see John A. Robertson, Oocyte Cytoplasm Transfers and the Ethics of Germ-Line Intervention, 26 *J.L. Med. & Ethics* 211, 212-13 (1998).

[FN31]. See Linda Bren, *The Estrogen and Progestin Dilemma: New Advice, Labeling Guidelines* (Mar.-Apr. 2003), available at [http://www.fda.gov/fdac/features/2003/203\\_estrogen.html](http://www.fda.gov/fdac/features/2003/203_estrogen.html). (concerning and summarizing the findings of a Women's Health Initiative (WHI) study, sponsored by the National Institutes of Health, of 16,000 postmenopausal women who still had a uterus and were taking either a combination estrogen-progestin drug or a placebo. The study found that, "after one year of treatment with estrogen and progestin, for every 10,000 women, there were seven more cases of heart disease, eight more strokes, eight more instances of blood clots in the lungs, thirteen more cases of blood clots in the limbs, and eight more cases of breast cancer." The FDA has responded by issuing revised guidances to manufacturers of these products and making labeling changes to clarify risks, benefits, and appropriate indications for these products. Specifically: "The FDA is requiring the physician's labeling to include a boxed warning--the highest level of warning information in labeling--that highlights the increased risks found in the WHI study and emphasizes that estrogen and estrogen-progestin products are not approved for heart disease prevention." Writing Group for the Women's Health Initiative Investigators, *Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women: Principal Results from the Women's Health Initiative Randomized Controlled Trial*, 288 *J. Am. Med. Ass'n* 321 (2002).

[FN32]. The applicability of human subject protection regulations is driven largely by the definitions of "human subject" under the Common Rule and relevant FDA regulations. See *General Requirements for Informed Consent*, 21 C.F.R. § 50.20 (2005); *Institutional Review Boards*, 21 C.F.R. § 56 (2005); *Investigational New Drug Application*, 21 C.F.R. § 312 (2005); *Biological Products: General*, 21 C.F.R. § 600 (2005); *Investigational Device Exemptions*, 21 C.F.R. § 812 (2005).

[FN33]. Parens & Knowles, *supra* note 1, at S11-S12.

[FN34]. See generally *Analytical Sciences, Inc., CDC*, *supra* note 1; *Frontline: Making Babies* (PBS Home Video 1999); *Nova: 18 Ways*, *supra* note 28.

[FN35]. Some providers even offer financial guarantees. See, e.g., *Dominion Fertility, Shared Risk*, <http://www.dominionfertility.com/insurance.html> (last visited Mar. 15, 2006) ("Should a qualifying couple not achieve a live birth, after receiving all of the indicated services (four IVF cycles and the transfer of all frozen embryos obtained from each of four fresh cycles), 100% of the program fee will be returned."). See *Frontline: Making Babies*, *supra* note 34; Gina Kolata, *Fertility Inc.: Clinics Race to Lure Clients*, *N.Y. Times*, Jan. 1, 2002, at D1 (addressing marketing practices of clinics, including money-back guarantees that pressure clinics to transfer more embryos and otherwise be more aggressive in practice).

[FN36]. See Analytical Sciences, Inc., CDC, *supra* note 1; Frontline: Making Babies, *supra* note 34; Nova: 18 Ways, *supra* note 28.

[FN37]. According to the CDC, thirty-five percent of ART deliveries result in multiple births compared with less than three percent in the general population. See CDC, Final Report, Survey of Assisted Reproductive Technology: Embryo Laboratory Procedures and Practices (Jan. 29, 1999), <http://www.phppo.cdc.gov/dls/pdf/art/ARTsurvey.pdf>. Michèle Hansen et al., The Risk of Major Birth Defects After Intracytoplasmic Sperm Injection and In Vitro Fertilization, 346 *New Eng. J. Med.* 725 (2002); Parens & Knowles, *supra* note 1, at S6.

[FN38]. See generally Proceedings, *supra* note 4.

[FN39]. See Parens & Knowles, *supra* note 1, at S11. See generally Proceedings, *supra* note 4.

[FN40]. See generally Proceedings, *supra* note 4.

[FN41]. Malinowski, *Choosing*, *supra* note 1, at 194.

[FN42]. See, e.g., James C. Robinson, Reinvention of Health Insurance in the Consumer Era, 291 *J. Am. Med. Ass'n* 1880 (2004).

[FN43]. Congressional Budget Office, *Economic Implications of Rising Health Care Costs* (1992), in Barry R. Furrow et al., *The Law of Health Care Organization and Finance* 127-30 (5th ed. 2004).

[FN44]. *Id.* As recognized by the Congressional Budget Office (CBO) more than a decade ago, health care consumers tend to lack significant information about the quality and prices of medical services, alternative treatments, and prices of the medical care they buy. *Id.* at 128. “The presence of third-party payers dulls the incentives for consumers to pay much attention to costs at the point of service.” *Id.* at 129. Even when information is available, consumers may lack the expertise necessary to interpret it. *Id.* at 128. Moreover, consumers delegate considerable decision making about health care to their physicians. *Id.* In many instances they have no choice, for physicians are gatekeepers to medical services and prescriptions, especially for innovative drugs. *Id.* at 129. Moreover, both consumers and the medical profession often depend upon the pharmaceutical industry for information about the pharmaceutical pipeline and new products. This point has been illustrated all too vividly by the belated release of clinical data on Cox-2 inhibitors and use of Prozac in pediatric patients. See Tamsin Waghorn, *Rattled Drug Giants Act Over Safety Concerns*, *Express Daily*, Jan. 7, 2005. To preempt a Congressional mandate, several pharmaceutical companies have volunteered to make all clinical data available via the Internet. Ted Agres, *Congress Wants Data to Be Free*, *Drug Discovery & Dev.*, Nov. 1, 2004, at 14 (facing a Congressional mandate, “Eli Lilly and a handful of major drug companies have agreed to voluntarily make public their clinical trials results either on their own Internet sites or through an industry database maintained by the Pharmaceutical Research and Manufacturers of America ...”); Waghorn, *Rattled*, *supra* (“Leading pharma players, including the UK’s GlaxoSmithKline and AstraZeneca, have backed plans

for companies to [voluntarily] publish on the Internet details and results of all clinical trials on new prescription-only drugs.”). But see Editorial, Hiding the Data on Drug Trials, N.Y. Times, June 1, 2005, at A22 (commenting on a government survey that “determined three of the largest drug companies [Merck, GlaxoSmithKline, and Pfizer] have effectively reneged on their pledges to list trials in a federal database”). Even if the data is made available, the burden will fall on the medical profession to interpret and apply it and, increasingly in an age of genomics and the associated precision, often on a patient-by-patient basis. See generally Proceedings, *supra* note 4; Lars Noah, The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients' Genetic Profiles, 43 *Jurimetrics J.* 1 (2002).

[FN45]. Bitter Medicine: Pills, Profit and the Public Health, CBS News, May 29, 2002, <http://www.dklevine.com/archive/bitter-medicine.htm>.

[FN46]. See *supra* notes 26-37 and accompanying text.

[FN47]. See generally Nat'l Acad. of Science, Guidelines for Human Embryonic Stem Cell Research (2005), <http://fermat.nap.edu/books/0309096537/html/> (last visited Mar. 27, 2006) [hereinafter NAS Guidelines].

[FN48]. See *supra* notes 26-37 and accompanying text.

[FN49]. As noted by Professor Nanette Elster, the notion that the vast majority of patients using AR services flatly reject adoption as an option is a fallacy. In fact, many patients who use AR are receptive to adoption as an option but are discouraged by the associated costs, waiting periods, screening processes, and by concerns that a biological parent will change his or her mind. Nanette Elster, Disentangling Fact from Fiction: The Realities of Unequal Health Care Treatment, Presentation at the DePaul University School of Law conference (Mar. 5, 2005).

[FN50]. According to the most recent report issued by the CDC, based upon information submitted voluntarily by 383 fertility clinics around the country, more than 35,000 babies (25,228 live births, including many multiple pregnancies) were born as a result of 99,639 ART cycles carried out in 2000, meaning a delivery rate of 35%. CDC, Assisted Reproductive Technology Success Rates, 2000 National Report (2000), <http://www.cdc.gov/ART/ARTReports.htm#2000>. This rate fluctuates immensely in conjunction with variables such as age. See generally *id.* Nevertheless, the chance of conception for a perfectly healthy, fertile couple without any intervention is only about 25% in any given cycle. See *id.* at 1.

[FN51]. See Dorothy Nelkin and M. Susan Lindee, *The DNA Mystique: The Gene as a Cultural Icon* (W.H. Freeman Pub. 1995).

[FN52]. See *supra* note 35 and accompanying text.

[FN53]. Timothy Stoltzfus Jost, Readings in Comparative Health Law & Bioethics 29-48 (Gary J. Simson

ed., Carolina Academic Press 2001).

[FN54]. See *id.*

[FN55]. Cf. *id.*

[FN56]. See generally Lori P. Knowles, *Stem Cell Policy: Where Do We Draw the Lines?*, 39 *New Eng. L. Rev.* 623 (2005); Parens & Knowles, *supra* note 1; Noah, *supra* note 11; Malinowski, *Choosing*, *supra* note 1.

[FN57]. See generally Knowles, *supra* note 56; Parens & Knowles, *supra* note 1. See also Jost, *supra* note 53, at 272-98.

[FN58]. Knowles, *supra* note 56, at 626.

[FN59]. While the United States has been rigorously regulating blood in this manner for years, the FDA did not put into effect regulations to address the infectious disease risk of donating, processing, and storing reproductive cells and tissues until May 25, 2005. See *supra* note 25 (addressing tissue product regulations). See also U.S. Food and Drug Admin., Center for Biologics Evaluation and Research, *Blood Action Plan*, <http://www.fda.gov/cber/blood/bap.htm> (last visited Sept. 7, 2005).

[FN60]. See generally Jost, *supra* note 53, at 272-98. See also Parens & Knowles, *supra* note 1, at S15-S17.

[FN61]. This entanglement has been recognized by Parens and Knowles. See generally Parens & Knowles, *supra* note 1. For discussion of the failure of the United States to fully recognize this entanglement and provide regulatory assurances that advances in embryonic research will not be too readily applied by the private AR sector for reproduction, see generally Michael J. Malinowski, *The Impact of Current Policy and Regulation on Future Stem Cell Human Health Applications*, 39 *New Eng. L. Rev.* 647 (2005).

[FN62]. See Lori P. Knowles, *International Perspectives on Human Embryo and Fetal Tissue Research*, in National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research: Commissioned Papers*, H-1, H-3 (Jan. 2000), <http://www.georgetown.edu/research/nrcbl/nbac/stemcell2.pdf>. Although this entanglement is obvious, the United States has not as readily acknowledged it, arguably resulting in contemporary negative consequences for stem cell research. See generally Malinowski, *Impact*, *supra* note 61; Knowles, *supra* note 56.

[FN63]. *Human Fertilisation and Embryology Act, 1990* (Eng.), available at [http://www.hmsa.gov.uk/acts/acts1990/ukpga\\_19900037\\_en\\_1.htm](http://www.hmsa.gov.uk/acts/acts1990/ukpga_19900037_en_1.htm).

[FN64]. *Id.* at §§ 5, 11.

[FN65]. See Knowles, *supra* note 56, at 626-27; Jessica J. Monachello, *The Cloning for Biomedical Research Debate: Do the Promises of Medical Advances Outweigh the Ethical Concerns?*, 10 *Tulsa J. Int'l. & Comp. L.* 591, 606 (2003); Allison C. Ayer, *Stem Cell Research: The Laws of Nations and a Proposal for International Guidelines*, 17 *Conn. J. Int'l L.* 393, 407 (2002); Parens & Knowles, *supra* note 1, at S11.

[FN66]. Statutory Instrument 2001 No. 188, *The Human Fertilisation and Embryology (Research Purposes) Regulations 2001*, available at <http://www.opsi.gov.uk/si/si2001/20010188.htm>. See NAS Guidelines, *supra* note 47, at 62-65.

[FN67]. See generally Jost, *supra* note 53, at 272-98.

[FN68]. See *id.* at 273-87.

[FN69]. See *id.*

[FN70]. See *id.* at 274. It is important to note, however, that this area of the law is in great flux in Canada. In 2004, Canada enacted Bill C-6, *Assisted Human Reproduction Act*, 37th Parliament, 3d Sess. (Can. 2004), available at <http://laws.justice.gc.ca/en/A-13.4/2389.html>, which is modeled on U.K. legislation and allows hESC research. See Knowles, *supra* note 56, at 627.

[FN71]. See Bill C-6, *Assisted Human Reproduction Act*, 37th Parliament, 3d Sess. (Can. 2004), available at <http://laws.justice.gc.ca/en/A-13.4/2389.html>.

[FN72]. See Jost, *supra* note 53, at 272-87.

[FN73]. See *id.* at 280.

[FN74]. See *id.* at 276-87.

[FN75]. See *id.*

[FN76]. See *id.* at 272-87. Many countries have modeled regulatory schemes on the U.K.'s *Human Fertilisation and Embryology Act, 1990*, which encompasses this approach. *Human Fertilisation and Embryology Act, 1990* (Eng.), available at [http://www.hmsa.gov.uk/acts/acts1990/ukpga\\_19900037\\_en\\_1.htm](http://www.hmsa.gov.uk/acts/acts1990/ukpga_19900037_en_1.htm). See Knowles, *supra* note 56, at 626.

[FN77]. *Stenberg v. Carhart*, 530 U.S. 914 (2000); see *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833 (1992); *Roe v. Wade*, 410 U.S. 113 (1973); *Griswold v. Connecticut*, 381 U.S. 479 (1965). See *The Pill* (PBS television broadcast 2002).

[FN78]. See generally Malinowski, *Impact*, supra note 61.

[FN79]. See supra notes 17-21 and accompanying text; Malinowski, *Choosing*, supra note 1, at 180-89; John A. Robertson, *Oocyte Cytoplasm Transfers and the Ethics of Germ-Line Intervention*, 26 *J.L. Med. & Ethics* 211, 212-13 (1998).

[FN80]. Robertson, supra note 1, at 450-51.

[FN81]. See generally *id.*

[FN82]. The Supreme Court deferred to the doctor-patient relationship and the practice of medicine in *Roe*, 410 U.S. at 140-44, 148-50, and in *Stenberg*, 530 U.S. at 930-38, in which the Court struck down a prohibition on late-term abortion.

[FN83]. See generally Starr, supra note 8.

[FN84]. See supra note 8.

[FN85]. One illustration is the FDA's delay in issuing notice about data suggesting that Cox-2 inhibitors may contribute to higher incidence of heart attacks and strokes. See supra note 44. Another is the FDA's delay issuing tissue product regulations. See supra note 25. A third is the FDA's lack of interference with off-label use of the medicines it puts on the market, and a fourth is the Agency's refraining from calls to regulate "homebrew" predictive genetic tests--for example, through the introduction of regulations for this purpose, or by increasing regulation of the agents used to perform those tests under existing law. See Michael J. Malinowski, *Separating Predictive Genetic Testing from Snake Oil: Regulation, Liabilities, and Lost Opportunities*, 41 *Jurimetrics J.* 23, 23-52 (2001).

[FN86]. "For example, the FDA regulates the market entry of drugs and devices and scrutinizes all label details, but the medical profession engages in considerable off-label use of these products and the pharmaceutical sector promotes such use through aggressive marketing." Malinowski, *Choosing*, supra note 1, at 180-82 (internal citations omitted); John A. Robertson, *Oocyte Cytoplasm Transfers and the Ethics of Germ-Line Intervention*, 26 *J.L. Med. & Ethics* 211, 212-13 (1998).

[FN87]. See Parens & Knowles, supra note 1, at S11.

[FN88]. *Id.*

[FN89]. See generally *Roe v. Wade*, 410 U.S. 113 (1973).

[FN90]. Knowles, supra note 56, at 628.

[FN91]. *Id.* at 628-29.

[FN92]. See generally Timothy S. Hall, *Bargaining With Hippocrates: Managed Care and the Doctor-Patient Relationship*, 54 S.C. L. Rev. 689 (2003).

[FN93]. See *supra* note 42 and accompanying text. The Cox-2 controversy has made Congress and the public appreciate the extent to which the FDA is shackled from fully disclosing clinical research data generated by commercial sponsors of new drugs. See Malinowski, *Impact*, *supra* note 61, at 659 n.55.

[FN94]. See generally Michael J. Malinowski, *Biotechnology: Law, Business, and Regulation* (Aspen Publishers 2003) (1999).

[FN95]. See generally Adamson, *supra* note 21.

[FN96]. See Jost, *supra* note 53, at 280-81 (referencing France).

[FN97]. See Robertson, *supra* note 1, at 452.

[FN98]. See *supra* notes 7-37 and accompanying text.

[FN99]. See President's Council on Bioethics, *supra* note 1.

[FN100]. See *supra* note 77 and accompanying text.

[FN101]. See *Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000) (declaring the marketing of pharmaceutical products commercial free speech and limiting restrictions); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) (recognizing the marketing of dietary supplements as commercial free speech and checking restrictions, and finding that the FDA may not prohibit health claims on dietary supplement labels); *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 359 (2002) (striking down a FDAMA provision that prohibited pharmacies from advertising compounded products). This is highly evident in physicians' discretion to prescribe pharmaceuticals off-label. "In fact, Congress recognized the realities of off-label prescribing when it authorized Medicaid reimbursement of pharmaceuticals for uses that appear in certain medical compendia, even if the FDA has not approved that use for inclusion in labeling." Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 *Am. J.L. & Med.* 361, 398 (2002), citing *Definitions, Drugs and Biologicals*, 42 U.S.C. § 1395x(t)(2)(B), and *Payment for Covered Outpatient Drugs, Definitions, Medically Accepted Indication*, 42 U.S.C. § 1396r-8(k)(6) (2000); John A. Robertson, *Oocyte Cytoplasm Transfers and the Ethics of Germ-Line Intervention*, 26 *J.L. Med. & Ethics* 211, 212-13 (1998). Nevertheless, direct promotion of off-label use is illegal. *Wash. Legal Found.*, 202 F.3d at 337.

[FN102]. See *supra* note 8 and accompanying text. See 21 U.S.C. § 396 (2000) (medical device regulation); 42 U.S.C. § 1395 (2000) ("Nothing in [Medicare] shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner

in which medical services are provided.”); 37 Fed. Reg. 16,503, 16,504 (1972) (“[I]t is clear that Congress did not intend the [FDA] to regulate or interfere with the practice of medicine ....”). These limitations reflect the fact that the FDA was introduced and its authority expanded during a time when the medical profession was organized, politically influential, and enjoyed significant professional autonomy. See generally Starr, *supra* note 8.

[FN103]. See generally Andrews & Elster, *supra* note 16. Professors Andrews and Elster have proposed that patients be told how experimental a procedure is, which includes discussion of how often and widespread the technique has been used and associated rates of successful outcomes. *Id.* at 50-51.

[FN104]. See *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 883 (1992).

[FN105]. See *id.* Cf. Cass R. Sunstein, *Is There a Constitutional Right to Clone?*, 53 *Hastings L.J.* 987, 1002 (2002) (“[N]othing in *Roe v. Wade* supports the right to choose medical treatments.”).

[FN106]. Cf. Noah, *supra* note 11 (proposing that the FDA consider restricting or withdrawing pharmaceutical products used to induce ovulation as a means to introduce federal oversight of AR not susceptible to constitutional challenge as an imposition on procreative liberty).

[FN107]. See *supra* notes 77-86 and accompanying text.

[FN108]. Clinical Laboratory Improvement Amendments of 1988 (CLIA), Pub. L. No. 100-578, 102 Stat. 2903 (1988) (codified at 42 U.S.C. §§ 201 note, 263a, 263a note) (1994)).

[FN109]. See *Analytical Sciences, Inc., CDC*, *supra* note 1.

[FN110]. See CLIA, 42 U.S.C. § 201 (2004).

[FN111]. See generally *Parens & Knowles*, *supra* note 1.

[FN112]. See *id.* at 518.

[FN113]. See *id.* at 518. Human Fertilisation and Embryology Act, §§ 5, 11, 1990 (Eng.), available at [http://www.opsi.gov.uk/acts/acts1990/Ukpga\\_19900037\\_en\\_1.htm](http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm).

[FN114]. This author credits the observation to a dialogue with Professor George Annas at a symposium on stem cell research hosted by the New England School of Law in Fall 2004. See *Symposium, Stem Cell Research and Human Cloning: Where Do We Draw the Line?*, 39 *New Eng. L. Rev.* 479, 479-960 (2005). Professor Annas persuasively emphasized the need for the proposed division. See *supra* notes 4-5 and accompanying text (addressing this entanglement). The NAS has proposed creation of a national independent body for oversight of hESC research in conjunction with the issuance of guidelines. See *NAS Guidelines*, *supra* note 47. Although the National Academies proposes voluntary compliance, these

guidelines call for the formation of a national independent body to periodically review and update them in response to advances in the field and changes in public attitudes. See generally *id.*

[FN115]. John A. Robertson, *Oocyte Cytoplasm Transfers and the Ethics of Germ-Line Intervention*, 26 *J.L. Med. & Ethics* 211, 212-13 (1998).

[FN116]. Points of ignorance identified by the President's Council include: actual incidence and severity of identified possible risks and harms; the impact of how the technologies and practices affect the health of children conceived with their aid; how widely preimplantation genetic diagnosis and preconception (and preimplantation) sex selection are practiced; and actual costs and benefits of overhauling existing regulatory institutions and practices, or of creating new regulatory authorities. President's Council on Bioethics, *supra* note 1, at 205-06.

[FN117]. *Id.* at 257.

[FN118]. See *supra* notes 2, 26-37 and accompanying text.

[FN119]. See *supra* notes 7-25 and accompanying text.

[FN120]. See John A. Robertson, *Oocyte Cytoplasm Transfers and the Ethics of Germ-Line Intervention*, 26 *J.L. Med. & Ethics* 211, 212-13 (1998); *supra* notes 26-37 and accompanying text.

[FN121]. See *supra* notes 99, 115-18 and accompanying text.

[FN122]. Human Fertilisation and Embryology Act, 1990 (Eng.), available at [http://www.hms0.gov.uk/acts/acts1990/ukpga\\_19900037\\_en\\_1.htm](http://www.hms0.gov.uk/acts/acts1990/ukpga_19900037_en_1.htm).

[FN123]. See Analytical Sciences, Inc., CDC, *supra* note 1. See generally Knowles, *supra* note 56.

[FN124]. See *supra* note 108.

9 JGRJ 549

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