2003

Choosing the Genetic Makeup of Children: Our Eugenics Past-Present, and Future?

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"God and Nature first made us what we are, and then out of our own created genius we make ourselves what we want to be . . . Let the sky and God be our limit and Eternity our measurement."[1]

"If you want to see God smile, tell him your plans."[2]

"The keenest sorrow is to recognize ourselves as the sole cause of all our adversities."[3]

I. INTRODUCTION

Prior to the advent of amniocentesis in the 1960s, prospective parents' control over the genetic makeup of their children was limited to deciding with whom to procreate. Today, the limits on that control have been reduced to the genes of prospective parents or the donors of ova and sperm they deem acceptable, the number of viable embryos produced, the genetic screening available, and the financial resources necessary to put genetic screening and other assisted reproduction technologies to use.[4] And ongoing biomedical research promises to further minimize these limitations. An

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[1] GREGORY STOCK, REDESIGNING HUMANS 1 (2002) (quoting Marcus Garvey (1887-1940)).

[2] A PRIMER FOR HEALTH CARE ETHICS: ESSAYS FOR A PLURALISTIC SOCIETY 152 (Kevin O'Rourke ed., Georgetown Univ. Press 2d ed. 2000) [hereinafter PRIMER].

[3] THE MOST BRILLIANT THOUGHTS OF ALL TIME 9 (John M. Shanahan ed., 1999) (quoting Sophocles (c. 496-406 B.C.)).

[4] In fact, as observed by Professor Storrow, today a child could have up to eight "parents"—the egg donor, the sperm donor, their spouses, a surrogate and her husband, and the intending mother and father. Richard F. Storrow, *Parenthood by Pure Intention: Assisted Reproduction and the Functional Approach to Parentage*, 53 HASTINGS L.J. 597, 602 (2002).

exponential increase in identified gene and protein functions, the capacity to screen for hundreds—eventually for many thousands—of genetic characteristics in a matter of minutes from a single sample and for a fraction of the present costs of running genetic tests[5] and, ultimately, the advent of

[5] Presently, there are market impediments keeping predictive genetic testing off of the market. *See generally* Michael J. Malinowski, *Separating Predictive Genetic Testing from Snake Oil: Regulation, Liabilities, and Lost Opportunities*, 41 JURIMETRICS J. 23 (2000) [hereinafter *Snake Oil*] (proposing that predictive genetic testing should be introduced on a regulatory framework like other medical technology). Some of the testing that is available is costly and the subject of extensive intellectual property filings, which has been resulting in disputes. For example, Myriad Genetics' test for BRCA1 and BRCA2, genetic alleles associated with breast and ovarian cancers, is priced at $3,850, which has resulted in a dispute between Myriad and the Canadian provinces of Alberta and Ontario. *See Gene-Patent Policy Review Urgently Needed*, EDMONTON J., Jan. 10, 2003, *at* http://lists.essential.org/pipermail/ip-health/2003-January/004055.html (last visited Sept. 24, 2003) (on file with the Connecticut Law Review). While there is ample recognition that intellectual property rights are a prerequisite for research and development ("R&D") to make genetic tests, some commentators assert that intellectual property rights in genotype-phenotype linkages impede access to resulting genetic tests for medical use—an argument substantiated by the Myriad dispute. *See* Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 8 (2003) ("We conclude that patents and licenses have had a significant negative effect on the ability of clinical laboratories to continue to perform already developed genetic tests . . . ."); Sherizaan Minwalla, *A Modest Proposal to Amend the Patent Code 35 U.S.C. § 287(c) to Allow Health Care Providers to Examine Their Patients' DNA*, 26 S. ILL. U. L.J. 471, 473, 503-04 (2002) (proposing to expand the provision in the Patent Act that protects physicians from infringement actions for performing medical procedures to include genetic tests); John A. Robertson, *Extending Preimplantation Genetic Diagnosis: The Ethical Debate*, 18 HUMAN REPRODUCTION 465, 467 (2003) (discussing Myriad Corp's patent on the BRCA1 and 2 genes). However, this awkward period of only a relatively limited number of commercially available genetic tests is giving way to a deluge of genetic screening capabilities based upon the extensive compilations of genetic subtleties and the bioinformatics capabilities—such as cost-effective DNA chip technology—to manage them and to derive medicinal meaning, albeit based upon probabilities, meaning an innate element of speculation. *See* discussion *infra* Part V. *See generally* Michael J. Malinowski, *Law, Policy, and Market Implications of Genetic Profiling in Drug Development*, 2 HOUS. J. HEALTH L. & POL'Y 31 (2002) [hereinafter *Market Implications*] (discussing the use and implications of genetic profiling in drug development and the delivery of health care); Lars Noah, *The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients' Genetic Profiles*, 43 JURIMETRICS J. 1, 7-11 (2002) (analyzing the effects genetic research may have in discovering more refined treatments for disease); *Snake Oil*, *supra*, at 28-31 (examining the definitional meaning of predictive genetic testing and its emerging significance in the field of medicine). This deluge of genetic information is a predictable byproduct of ongoing pharmaceutical R&D. *See Market Implications*, *supra*, at 39-43 (discussing the trends in pharmaceutical R&D that have led to the entrance of genetic testing in the medical setting as an accompaniment to drug delivery); *Snake Oil*, *supra*, at 33 (noting the use of genetic profiling by pharmaceutical and biotechnology industries in all aspects of drug development); Noah, *supra*, at 7 (noting that existing research on the effects of genetic differences involving enzymes that metabolize drugs could potentially be put to use in pharmacology). The biomedical R&D community now is identifying, compiling, and processing a multitude of genetic subtleties through bioinformatics and creating database "commons" to make these subtleties useful. *See, e.g.*, Orchid Biosciences, Inc., *Overview of Orchid*, *at* http://www.orchid.com (last visited Aug. 26, 2003) (on file with the Connecticut Law Review) (claiming to be a "leading provider of services and products for profiling genetic uniqueness"). In October 2003, several companies announced the market availibility of whole-genome DNA chips. Andrew Pollack, Human Genome Placed on Chip; Biotech Rivals Put It Up for Sale, N.Y. TIMES, Oct. 2, 2003, at C1. *See also Market Implications*, *supra*, at 40-41; *Snake Oil*, *supra*, at 32. In fact, "Craig Venter is already offering the very rich the chance to buy a map of their genomes at a staggering $710,000, but even he anticipates selling them for much less—

genetic engineering capabilities will add new dimensions to the concept of "planned pregnancy."[6]

Through the advancement of ongoing science, preimplantation genetic screening ("PGD") will significantly improve existing medical standards for prenatal care by enabling many—ideally all—prospective parents to complete desired families without the trauma of miscarriages and seriously health-impaired children.[7] Moreover, the constitutional right of a woman

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$1,000— in years to come." Tim Radford, *Fear of 'Genetic Apartheid'—Debate Urged on Consequences of Health Predictions*, THE GUARDIAN, Mar. 4, 2003, at P9, LEXIS, News Library, Guardn File; *see also* Jonathan Leake, *Gene Map of Your Life Will Cost Pounds 400,000*, TIMES (London), Sept. 22, 2002, at 5, LEXIS, News Library, Ttimes File. Carry-over of this technology from research to personal health care use is imminent, especially through the ongoing identification of millions of very slight genetic variations (single nucleotide polymorphisms, also known as "SNPs"), that impact responsiveness to pharmaceuticals. *See id.*; *Market Implications*, *supra*, at 52-58; Noah, *supra*, at 7-11. Companies such as Orchid Biosciences, Inc. that sell researchers access to SNPs databases may provide the access to individuals to enable them to monitor the connections made between SNPs, individuals' DNA blueprints, and commercial pharmaceuticals. *See* Radford, *supra*; *Snake Oil*, *supra*, at 32-33.

[6] *See* discussion *infra* Part V; FRANCIS FUKUYAMA, OUR POSTHUMAN FUTURE 72-83 (2002) (discussing "designer babies" in the context of modern genetic technology); Mark A. Hall, foreword, Symposium, *Genetic Technology: Social Values and Personal Autonomy in the 21st Century*, 34 WAKE FOREST L. REV. 557 (1999) ("The genetics revolution has spawned a tremendous amount of thought in recent years on ethical, legal, and social implications . . . ."). *See generally* STOCK, *supra* note 1 (examining the consequences of emerging reproductive technologies used for selecting and altering human embryos); *Making Babies* (PBS television broadcast, June 1, 1999) (questioning how far humans will go to "engineer a baby"); *18 Ways to Make a Baby* (PBS television broadcast, Oct. 9, 2001) ("A new revolution in making babies is underway, one that could allow us to influence and even shape the genetic fate of our children."); *How to Build a Human: Predictor* (BBC television broadcast, 2002) (analyzing the arguments for and against genetically engineering humans).

[7] *See generally* Robertson, *supra* note 5 (providing a framework for ethical evaluation of uses of PGD, and concluding that, with the exception of sex selection of first-born children, most ongoing uses of PGD are ethically acceptable). *See* Carey Goldberg, *Screening of Embryos Helps Avert Miscarriage*, BOSTON GLOBE, June 13, 2003, at A1, LEXIS, News Library, Bglobe File ("[PGD] began more than a decade ago as a form of futuristic baby making . . . . Fertility experts say that preimplantation screening is now becoming common at cutting-edge clinics."). As summarized by Professor John Robertson:

> PGD has been available since 1990 for testing of aneuploidy [(the gain or loss of individual chromosomes)] in low prognosis infertility patients, and for single gene and X-linked diseases in at-risk couples. A report in July, 2001 on worldwide use of PGD since 1990 reported that embryo or polar body biopsy occurred in more than 3000 clinical cycles, with a 24% pregnancy rate, which is comparable with assisted reproductive practices which do not involve biopsy . . . . More than 1000 children have now been born after PGD, and many pregnancies are ongoing . . . .

Robertson, *supra* note 5, at 465. Today, approximately 1,000 PGD screenings presently are done each year in the U.S., and that number is rising rapidly. Goldberg, *supra*. It has been reported that present use of PGD centers on avoiding miscarriages: "In about three out of four cases, it is used not to choose disease-free babies, but to help women who are older or who have had repeated miscarriages to produce viable babies." *Id.* Basic PGD generally adds about $3,500 to the cost of an IVF cycle. *Id.* Illinois and New Jersey have expanded mandatory coverage for infertility to include treatments for recurrent miscarriage, including PGD, and Massachusetts also is considering such legislation. 215 ILL. COMP. STAT. ANN. § 5/356m(c) (2000) (definition of "infertility" includes the "inability to sustain a successful pregnancy"); N.J. STAT. ANN. § 17:48E-35.22(a) (2003) ("'infertility' is defined to include the inability to "carry a pregnancy to live birth"); *see also* Goldberg, *supra*.

has been established law in the United States for three decades.[8] Nevertheless, contemporary biomedical research has raised a question that bears upon this right but, arguably, is increasingly distinguishable:[9] Beyond existing scientific capabilities and personal financial constraints, should there be *any* legal checks placed on the right of prospective parents to choose the genetic makeup of their children through assisted reproduction technology ("ART")? This article answers affirmatively based upon several considerations. First, in the absence of mandatory and comprehensive law and pol-

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[8] This right was established in *Roe v. Wade*, 410 U.S. 113 (1973), and has been affirmed through that case's progeny. *See* Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833 (1992); Stenberg v. Carhart, 530 U.S. 914 (2000). The right has been stated as a freedom from undue state burden, not an entitlement to access the medical procedure. *Stenberg*, 530 U.S. at 921 (holding that a state regulation that places a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus constitutes an undue burden); *accord Casey*, 505 U.S. at 852 ("Though abortion is conduct, it does not follow that the State is entitled to proscribe it in all instances."). In fact, the Court has expressly held that there is no affirmative right to abortion. *See* Harris v. McRae, 448 U.S. 297 (1980) ("[Roe] does not confer an entitlement to such funds as necessary to take advantage of that freedom."). Legislation enacted to ban the partial birth abortion procedure and the prospect of Supreme Court vacancies under the Bush Administration have reinvigorated the abortion debate. *See* Editorial, *'Partial Birth' Mendacity, Again*, N.Y. TIMES, June 4, 2003, at A30. ("Their strategy is to curtail access to abortion further as the inevitable legal challenge wends its way back to the Supreme Court for another showdown. They obviously hope that by that time, there will have been a personnel change that will shift the outcome their way."); Susan Milligan, *House Close to Abortion Procedure Ban: Challenge Against 1st Federal Curb Vowed*, BOSTON GLOBE, June 4, 2003, at A3, LEXIS, News Library, Bglobe File ("Advocates of the bill said the courts should defer to the legislative findings in the bill, which say there are no health reasons to perform such a procedure); Robin Toner & Neil A. Lewis, *Lobbying Starts as Groups Foresee Vacancy on Court*, N.Y. TIMES, June 8, 2003, at A1 ("The expectation of change on the court is based, in part, on its record-breaking stability in recent years; no one has stepped down since President Bill Clinton appointed Stephen G. Breyer in 1994, providing for the longest period without a turnover since the 1820's."); Joan Vennochi, *Abortion Issue Sharpens for '04*, BOSTON GLOBE, June 24, 2003, at A15, LEXIS, News Library, Bglobe File (noting that, when President Bush signed into law a measure prohibiting doctors from performing the partial birth abortion procedure, polls showed that the majority of Americans support a woman's right to an abortion in the first three months of pregnancy). In addition, the Supreme Court decided on June 27, 2003 to not interfere with a nationwide judicial order barring antiabortion forces from publishing identifying information about abortion doctors on "wanted" posters via the Internet. Lyle Denniston, *High Court Rejects Appeal Over Antiabortion Posters*, BOSTON GLOBE, June 28, 2003, at A3, LEXIS, News Library, Bglobe File.

[9] As observed by this author in 1994, given the potential psychological ramifications and social considerations, choosing to terminate an otherwise wanted pregnancy due to a particular genetic characteristic or characteristics may be readily distinguishable from choosing to terminate an unwanted pregnancy. Michael J. Malinowski, *Coming into Being: Law, Ethics, and the Practice of Prenatal Genetic Screening*, 45 HASTINGS L.J. 1435, 1485-86 (1994) [hereinafter *Coming into Being*] (distinguishing the choice to terminate an unwanted pregnancy from the choice to terminate a wanted pregnancy based upon genetic information stemming from differences from the pregnant woman's perspective). Completion of mapping of the human genome, the identification of genotype-phenotype connections through enabling technologies such as bioinformatics, and the general advancement of biomedical research subsequent to 1994 presumably underscores this distinction. *See supra* note 5 and accompanying text. *See generally* discussion *infra* Part V; Noah, *supra* note 5; *Market Implications*, *supra* note 5; *Snake Oil*, *supra* note 5.

Third, unless we choose to block our ears and look away, the United States' haunting eugenics[13] legacy beckons us to remember the consequences of allowing the appeal of genetic improvement and controlling evolution to reach well beyond the limitations of science and to skew the practice of medicine and related law and policy.[14] These lessons suggest that enhanced capability to intervene with and potentially control procreation at the most fundamental level through science will raise the temptation

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ble of reshaping the legal definition of the family"); Janet L. Dolgin, *Choice, Tradition, and the New Genetics: The Fragmentation of the Ideology of Family*, 32 CONN. L. REV. 523, 540 (2000) (stating ART introduces confusion about "the implications of biological parentage"); Janet Dolgin, *The Ideological Context of the Disability Rights Critique: Where Modernity and Tradition Meet*, 30 FLA. ST. U. L. REV. 343 (2003) [hereinafter *Ideological Context*] (exploring the balance between individual choice and the sacrifice of communal responsibility to individual preferences). Consider that, while we grapple with the possibilities of human cloning in the midst of the genetics revolution, the first meaningful population of in-vitro fertilization ("IVF") children and children born to arrangements such as surrogacy is just now reaching adulthood. In conjunction with ART, the practice of surrogacy is steadily increasing. *See* David P. Hamilton, *She's Having Our Baby: Surrogacy Is on the Rise as In-Vitro Improves*, WALL ST. J., Feb. 4, 2003, 2003 WL-WSJ 3958406. "The latest figures from the Centers for Disease Control and Prevention, which [reportedly] tracks roughly 95% of advanced fertility procedures in the U.S., show 1,210 attempted gestational surrogacies in 2000, double the number attempted just three years earlier." *Id.*

[13] *See infra* notes 24-27 and accompanying text. *See generally* EDWIN BLACK, EUGENICS AND AMERICA'S CAMPAIGN TO CREATE A MASTER RACE (2003). "Eugenics" originates from the Greek word "eugenes," which means "good in birth." DIANE B. PAUL, CONTROLLING HUMAN HEREDITY: 1865 TO THE PRESENT 3 (1995). Today, medical geneticists tend to delineate genetics and eugenics by limiting "eugenics" to expressly encompass social coercion. *Id.* at 133. However, a definition that requires coercion leads to seemingly absurd conclusions—e.g., that Francis Galton, a forefather of the eugenics movement, *see infra* Part II.A, was not a eugenicist. *See* PAUL, *supra*, at 133; *infra* note 27 and accompanying text. In fact, "eugenics" is a broad term with a stained past:

> We have come to identify eugenics with the most terrible parts of its history. When we think of eugenics, it is usually not Margaret Sanger or Havelock Ellis who comes to mind but Madison Grant or Adolf Hitler. We do not think of free love and birth control but of compulsory sterilization or euthanasia. Eugenics evokes the image not of Denmark but of Germany. Indeed, over every contemporary discussion of eugenics falls the shadow of the Third Reich. No wonder geneticists resist the label. To call their enterprise "eugenics" is thereby to condemn it.

PAUL, *supra*, at 133-34.

[14] The legacy referred encompasses Nazi medicine and genocide, for the United States' movement was an impetus for an international eugenics movement, which then was carried to this extreme under the Third Reich. For discussion of eugenics movements in the United States and Europe from the late 1800s through the 1930s, see discussion *infra* Part II; JOHN J. MICHALCZYK, NAZI MEDICINE: IN THE SHADOW OF THE REICH (First Run Features 1997) [hereinafter SHADOW OF THE REICH] (discussing the origins of eugenics movements in Germany and the Nazi doctors' experimentation on prisoners in the concentration camps). *See generally* INTERNATIONAL AUSCHWITZ COMMITTEE, NAZI MEDICINE: DOCTORS, VICTIMS AND MEDICINE IN AUSCHWITZ (1986) (documenting the criminal experiments undertaken by the Nazi doctors); ROBERT JAY LIFTON, THE NAZI DOCTORS (1986) (examining the Nazi "biomedical vision" as evidenced by the doctors' cruel medical experiments in the concentration camps); THE NAZI DOCTORS AND THE NUREMBERG CODE (George J. Annas & Michael A Grodin eds., 1992) (discussing the practices of the Nazi doctors that led to the Nuremberg trial and the implications of these practices on present day medical research and experimentation). For discussion of the genetics revolution cautioning that advances in human genetics threaten to dehumanize, see generally BILL MCKIBBEN, ENOUGH: STAYING HUMAN IN AN ENGINEERED AGE (2003) (analyzing the possibility of technology replacing humanity).

to put that capability to use prematurely and to overuse whatever means are available.[15] Temptation never has been greater: The present largely consumer-driven law and policy environment for assisted reproduction[16] simply cannot support jolting, ongoing advances in human genetics through the advent of enabling technologies such as bioinformatics capabilities[17] without threatening to bring us dangerously close to past mistakes. We must pay attention to the pace of advancement of biomedical science over the last two decades, including completion of a map of the human genome years ahead of schedule[18] and the resulting pressures on both the medical community and prospective parents to use this technology prematurely.[19] The medical profession and general public alike are living in the mushrooming, rapidly burgeoning cloud of innovation categorically referred to as the "genetics revolution."[20] Given the dynamism of this science, its in-

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[15] *See generally* discussion *infra* Part II.

[16] As explained *infra* Part VI.A., tremendous reliance is placed on the industry and medical professional participants to self-report and self-police.

[17] *See Market Implications*, *supra* note 5, at 31-32; *Snake Oil*, *supra* note 5, at 30-31; Noah, *supra* note 5, at 7-8, 10; *Predictive Pharmacogenomics: Revolutionizing Health Care*, M2 PRESSWIRE, Dec. 17, 2002, LEXIS, News Library, M2pw file (identifying a range of SNP applications); *Pharmacogenomics—Personalized Approach to Medicine—Companies Leading the Personalized Medicine Revolution*, M2 PRESSWIRE, July 18, 2002, LEXIS, News Library, M2pw file (providing a guide to "the development of personalized medicines with its related research areas and technology that span the biotechnology, diagnostics, bioinformatics, pharmacological and genomic markets"). *See generally* discussion *infra* Part IV.

[18] Completion of a rough map of the human genome was announced on June 26, 2000. *See generally* 291 SCIENCE 1145 (Feb. 16, 2001) (highlighting the near completion of the human genome); 409 NATURE 745 (Feb. 15, 2001) (discussing the release of a draft map of the human genome). Updated information about the Human Genome Project ("HGP") is available at the Internet site of the National Human Genome Research Institute ("NHGRI"), at www.genome.gov (last visited Aug. 26, 2003) (on file with the Connecticut Law Review).

[19] The public is embracing biomedical research as health care, as made evident by the public's demand for information about and access to experimental clinical trials and assisted reproduction technologies, and the U.S. government's efforts to provide access to that information and technologies. *See* Michael J. Malinowski, *Institutional Conflicts and Responsibilities in an Age of Academic-Industry Alliances*, 8 WIDENER L. SYMP. J. 47, 53-56 & n.1 (2001) (discussing the proliferation of information via Internet sites like http://www.clinicaltrials.gov and the Health Care Financing Administration's September 19, 2000 decision to cover the routine costs of qualifying clinical trials) [hereinafter *Institutional Conflicts*]. *See generally Market Implications*, *supra* note 5, at 42-43 (addressing trends associated with pharmaceutical R&D, including the integration of experimentation and treatment).

[20] *See generally* THE GENOMIC REVOLUTION: UNVEILING THE UNITY OF LIFE (Michael Yudell & Robert DeSalle eds., 2002) (concluding that "[t]he knowledge gained [from the Human Genome Project] could cure cancer, prevent heart disease, and feed millions. At the same time, its improper use can discriminate, stigmatize, and cheapen life through frivolous enhancement technologies."); *Climbing the Helical Staircase*, THE ECONOMIST, Mar. 29, 2003 (discussing the biological revolution, which "promises much: more and better drugs, medical treatment tailored to the individual's biological makeup; new crops; new industrial processes; even, whisper it gently, new humans"); GENOMICS AND WORLD HEALTH: REPORT OF THE ADVISORY COMMITTEE ON HEALTH RESEARCH, WORLD HEALTH ORG. (2002) (discussing the positive implications of the genetics revolution on medical research and patient care while also considering the potential risks of such research resulting from various ethical considera-

tense, explosive, and highly complicated nature even for those trained in science and medicine, the emotional nature of human reproduction and societal pressures which can readily skew judgment for those subjecting themselves to related medical procedures, and other human health and related ethical, legal, and social implications, it is irresponsible to assume the luxury of time when contemplating meaningful law and policy assurances for the safe, responsible, and thoughtful practice of medicine in assisted human reproduction.[21]

Part II of this article discusses the origin of eugenics, including the rise of its popularity as a scientific, social, and political movement at the turn of the 20th century through the early 1930s.[22] Part II also explores the codification of eugenics policies into law in both the United States and Europe before Nazi medicine was put on trial in Nuremberg on December 9, 1946.[23] Part III addresses the impact of Nazi medicine and the Nuremberg trials on the eugenics movement and medical ethics, and Part IV chronicles the evolution of informed consent from a principle into law, eventually becoming the cornerstone ethos for medical research and the practice of medicine. Part V provides an overview of ongoing genetic profiling trends in life science R&D. Part VI reviews trends in assisted reproduction and the present state of ART regulation. Part VII sets forth proposals to introduce more meaningful law and policy assurances for the safe, responsible, and thoughtful practice of medicine in assisted human reproduction without unduly burdening the procreative liberty of prospective parents or impeding innovation.

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tions). For a thoughtful, elegant account of the fundamentals of DNA and evolution of the genetics revolution, see JAMES D. WATSON, DNA: THE SECRET OF LIFE (2003).

[21] *See Snake Oil*, *supra* note 5, at 23-26 (discussing that medical community skepticism about biotechnology in the early 1990s has given way to a global sector and aggressive application of the technology in drug development, with more than 100 biotech drugs on the market by the end of the decade, extensive pharmaceutical industry buy-in and reliance upon biotechnology, and a rough map of the human genome in hand at the commencement of the new millennium). Bioinformatics, the technology that enabled the human genome to be mapped years ahead of schedule, continues to advance in jolts and could radically accelerate the development of genetic medicine. *See id.*; *see also* discussion *infra* Part V. *But see* Steven Pinker, *Better Babies? Why Genetic Enhancement is Too Unlikely to Worry About*, BOSTON GLOBE, June 1, 2003, at D1, LEXIS, News Library, Bglobe File (relying upon behavior genetics and observations of human nature as well as unfulfilled expectations "not long ago" that by the turn of the century we would be living in domed cities and commute by jet packs to argue that genetic enhancement is not inevitable nor "particularly likely in our lifetimes" and premising this argument on the assumption that prospective parents will be rational when faced with genetic information and the option to take action based on that information); David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 78 FERTILITY AND STERILITY 932 (Nov. 2002) (analyzing the reasons for the widespread notion that ART is not regulated in the United States).

[22] *See* discussion *infra* Part II.A.

[23] *See* discussion *infra* Part II. In July 2003, the Harvard Law School Library announced that it will digitalize and post original documentation via the Nuremberg Trials Project: A Digital Document Collection at http://www.nuremberg.law.harvard.edu. David Mehegan, *Presenting Evidence for Posterity: Harvard's Nuremberg Site Counters Holocaust Deniers*, N.Y. TIMES, Aug. 5, 2002, at A1.

II. THE ORIGIN AND 20TH CENTURY POPULARITY OF EUGENICS

Within a span of less than fifty years (the 1890s into the 1940s), "eugenics" shifted at the most fundamental level from a term inspiring praise and connotations of social patriotism to one invoking intolerance for human variation, state oppression, and mad science.[24] As discussed below, in the hands of the Nazi state, eugenics was grossly soiled and stained: The term was used to rationalize selective breeding programs, compulsory sterilization, and macabre experimentation on humans including children.[25] Consequentially, contemporary definitions of eugenics are narrower, often embodying a crisp distinction between *eugenics* and *medical genetics* and restricting the scope of "eugenics" to coercive genetic policies.[26]

A. *Eugenics Before Nuremberg: Improving the Human Condition*

"Eugenics" was coined in the 1880s by Francis Galton, a Victorian aristocrat and nephew of Charles Darwin, to mean "well-born" and to capture his concept of using knowledge about genetics to better the human condition.[27] Galton and his contemporaries coupled centuries of success utilizing stockbreeding methods to improve animal species with the persuasive influence of the scientific rage of the time—Mendelian genetics, meaning the embodiment of distinguishable traits attributable to single genetic characteristics.[28] Their work culminated in variations of the con-

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[24] For a definition of "eugenics", see *supra* note 13 and accompanying text; PAUL, *supra* note 13, at 17. Victorian founders of the early eugenics movements sought to raise the human condition closer to perfection. "It is sadly ironic that this noble original objective eventually led to some of the most heinous crimes mankind has ever seen." NANCY L. GALLAGHER, BREEDING BETTER VERMONTERS: THE EUGENICS PROJECT IN THE GREEN MOUNTAIN STATE 2 (1999) (quoting ERNST MAYR, TOWARD A NEW PHILOSOPHY OF BIOLOGY: OBSERVATIONS OF AN EVOLUTIONIST 80 (1988)).

[25] SHADOW OF THE REICH, *supra* note 14; *see also* PAUL, *supra* note 13, at 3-4, 135 (discussing breeding programs and compulsory sterilization). "When the Third Reich translated eugenics into a program of racial purification through genocide, the Holocaust came to epitomize, for many people, the purpose, character, and meaning of eugenics." GALLAGHER, *supra* note 24, at 2.

[26] *See* PAUL *supra* note 13, at 3. "To some, breeding decisions based on genetic tests appear to be eugenics in modern dress. Others insist that if decisions are voluntary, the label is wrongly applied." *Id.* Author Francis Fukuyama has proposed alternative terminology for discussing genetic engineering:

> My own preference is to drop the use of the loaded term eugenics when referring to future genetic engineering and substitute the word breeding in German, Züchtung, the word originally used to translate Darwin's term selection. In the future, we will likely be able to breed human beings much as we breed animals, only far more scientifically and effectively, by selecting which genes we pass on to our children. Breeding has no necessary connotations of state sponsorship, but it is appropriately suggestive of genetic engineering's dehumanizing potential.

FUKUYAMA, *supra* note 6, at 88 (italics omitted).

[27] GALLAGHER, *supra* note 24, at 1; *see also supra* note 13 and accompanying text.

[28] Gregor Mendel, an Austrian monk, bred some 30,000 plants over ten years and published his results in 1866 in the *Proceedings* of the Brünn Natural Sciences Society, a publication distributed to some 134 institutions in various countries. DANIEL J. KEVLES, IN THE NAME OF EUGENICS 41-42 (1995) (1985). Although his work went unrecognized in the Nineteenth Century, it was rediscovered simultaneously in 1900 by three scientists—Carl Correns in Germany, Erich Tschermak in Austria, and

cept of controlled human breeding,[29] which caught on after the turn of the century and inspired organized movements.[30] These movements were founded in Germany in 1904, in Britain in 1907, and in the United States around 1910.[31] In fact, eugenics prospered in approximately thirty countries.[32]

The United States' eugenics movement, headed by Charles Davenport, was financially seeded in 1904 by a $10 million grant from the Carnegie Institute of Washington.[33] This grant, which at the time surpassed the total endowment for research in United States universities, enabled Davenport to establish the Station for Experimental Evolution at Cold Spring Harbor,

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Hugo de Vries in Holland—working independently on problems involving hybridization and, in the case of de Vries, theories of evolution. *Id.* at 43. Soon thereafter, Mendelian genetics triggered international popularity within the scientific community. *See id.*; SHADOW OF THE REICH, *supra* note 14; *infra* notes 41-42 and accompanying text.

[29] *See generally* KEVLES, *supra* note 28, at ix-x (discussing scientific and political programs based on Galton's eugenics work). As explained by author Daniel Kevles, "Human genetics as a program of research originated with the eugenic idea that the physical, mental, and behavioral qualities of the human race could be improved by suitable management and manipulation of its hereditary essence." *Id.* at vii. According to Francis Galton, the forefather of the movement:

> the key to human progress would rest on a national program of better breeding, in which the intelligent and the accomplished, the men and women of demonstrated high moral character—the educated upper classes—would conceive more children, while the shiftless, the chronic poor, the insane and feebleminded, and the "criminal class" would be discouraged, preferably prevented, from breeding at all.

GALLAGHER, *supra* note 24, at 1. Within and beyond eugenics, many living in the midst of the industrial revolution, including Galton and other leaders in the eugenics movement, equated science with progress. KEVLES, *supra* note 28, at 3. Galton and his contemporaries placed complete faith in the science available at the time, which was a matter of observation of husbandry practices and social observation rather than any meaningful scientific understanding of human genetics:

> Francis Galton, innocent of the future, confidently equated science with progress. All around him the technology of the industrial revolution confirmed man's mastery over inanimate nature. To be sure, in the mid-Victorian era, heredity in plants and animals was less a science than a body of lore based on empirical practice. . . . [I]t was well known that by careful selection farmers and flower fanciers could obtain permanent breeds of plants and animals strong in particular characters. "Could not the race of men be similarly improved?" Galton wondered. "Could not the undesirables be got rid of and the desirables multiplied?" Could not man actually take charge of his own evolution?

Id.

[30] SHADOW OF THE REICH, *supra* note 14; *see also* PAUL, *supra* note 13, at 6. As discussed by Robert Proctor:

> Most of the 20-odd university institutes for racial hygiene were established at German universities before the Nazi rise to power, and by 1932 racial hygiene had become an orthodox fixture in the German medical community. The major expansion in this occurred *before* Hitler came to power; most of the 15-odd journals of racial hygiene, for example, were established long before the rise of National Socialism.

Robert N. Proctor, *Nazi Doctors, Racial Medicine, and Human Experimentation, in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 14, at 17, 19-20.

[31] PAUL, *supra* note 13, at 6.

[32] SHADOW OF THE REICH, *supra* note 14.

[33] KEVLES, *supra* note 28, at 45.

New York.[34] In 1910, on land next to Cold Spring Harbor, Davenport also established the Eugenics Record Office through generous support from Ms. Mary Harriman, a philanthropic socialite.[35] The Office's mission was to collect, catalogue, and eventually analyze hereditary information from thousands of individuals.[36] "Able or not, more than two hundred and fifty field workers were sent out by the Eugenics Record Office between 1911 and 1924, when the training program ended."[37]

The "authority" gathered by the Office fueled the perceptions of legitimacy and popularity of the eugenics movement, and the movement surged forward. Regardless of the limitations of the related science,[38] the data gathered by the Office substantiated centuries of observation—however tainted by prejudices. The end product was then coupled with the mantra of improving the human condition in a collective manner[39] and fur-

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[34] *Id.* at 45, 51.

[35] SHADOW OF THE REICH, *supra* note 14. Ms. Harriman gifted the Office to the Carnegie Institution in 1918. KEVLES, *supra* note 28, at 55.

[36] KEVLES, *supra* note 28, at 56.

[37] *Id.* The Office proved an important center for the study of and training in human heredity for three decades, and it inspired a West Coast counterpart—the Human Betterment Foundation in Pasadena, California. *See* GALLAGHER, *supra* note 24, at 4.

[38] *See* PAUL, *supra* note 13, at 115-16. Early in the century, "[m]ainline doctrine presumed that like produced like—that superior or inferior parents spawned, respectively, superior or inferior offspring through the transmission of traits by single Mendelian characters—unit characters as they were known." KEVLES, *supra* note 28, at 145. However, voices of scientific reason arose to argue that one could not predict an organism's phenotype (physical embodiment) simply from knowledge about its genes. These scientists—often geneticists—recognized that a given genotype may be expressed differently in varying environments:

> It was here that the principal disjunction lay between mainline ideas and the advance of genetics. While geneticists knew that many physical characteristics were inherited, and a number of them also thought there might indeed be a biological basis for mental and behavioral traits, they also knew that, even with the simplest version of Mendelism like did not necessarily produce like.

Id. Eventually many geneticists separated themselves from eugenics and even challenged it scientifically:

> Many geneticists held that the biological strength of the human race lay in the vast diversity of its genetic makeup. The diversity allowed for variety of types, and such variety was essential, not only for the endlessly different tasks that man asked himself to perform but also for the variation in environments, both present and possibly to come, to which he had to adapt. J. B. S. Haldane held forth on the matter in 1932, from the steps of a building at Cornell University, where he was attending the Third International Congress of Genetics. A society composed of uniformly perfect men, he said, would be highly imperfect. The essence of perfection among plants, animals, and most certainly man was variety. The ideal society had to have room for all sorts of people, each best at some one thing or other. But would it not be desirable to produce more Leonardo da Vincis? a reporter wondered.

Id. at 147.

[39] *See* GALLAGHER, *supra* note 24, at 3. As stated by Nancy Gallagher, the author of a case study on Vermont's eugenics policies in the 20th century:

> Eugenicists promoted the idea that the *human germplasm* was the most important thing in the world, the source of all human potential in a nation or race. As such, it demanded cultivation and conservation. The handicapped, the mentally incompetent, and the chronic dependents on poor relief compromised, in the

thering what had become the tenets of epidemiology and public health—individual sacrifice, and at times even government imposition of significant personal risk to one's health or the health of one's children, to promote the health and well-being of the masses.[40]

In this packaging, eugenics appealed to leading scientists, health care providers, a range of academics, politicians, and the public, and the movement's supporters persuaded others in missionary fashion.[41] Eugenics inspired the founding of centers and international conferences that drew large, cross-disciplinary audiences:

> Hundreds of colleges and universities in the United States and Europe introduced eugenics into their curricula in the areas of biology, social work, public health and medicine, and "sex hygiene." Eugenics societies enlisted the support of churches, patriotic organizations, private charities, and state welfare agencies to promote research and education in eugenics.[42]

> eugenicists' view, the future of the human race by contributing their genes too liberally to the national germplasm through indiscriminate breeding and having too many "unwanted children." Likewise, the highly educated upper classes and the "old pioneer stocks" in particular were blamed for what Theodore Roosevelt called "race suicide" in their trend toward smaller families.

Id.

[40] Consider that it has become common place to administer several vaccines to all children to protect the masses, knowing that a significant number will suffer adverse effects and, recently, in the face of allegations that the mercury content in many vaccines may be responsible for an increase in autism and/or other childhood ailments. *See* Arthur Allen, *The Not-So-Crackpot Autism Theory*, N.Y. TIMES, Nov. 10, 2002, §6 (Magazine) at 66; Mike Wowk, *Autism Rate Up 1,500% in State*, DETROIT NEWS, Mar. 3, 2003, at 1D, LEXIS, News Library, Detnws File ("The rates of autism in children have risen 700 percent nationally and more than 1,500 percent in Michigan since 1992, according to a recent study, and no one in the medical industry or government knows why."); *Two Class-Action Suits Launched in B.C. Over Vaccines Given to Infants*, CANADIAN PRESS, Feb. 25, 2003, 2003 WL 15019641 (reporting on class action suits filed against Aventis Pasteur Ltd. alleging that thimerosal, an additive containing mercury used to preserve the vaccines, caused autism and other neurological damage). The common good was Davenport's mantra: "Davenport was prepared to curtail other people's rights in order to promote the race—to ensure the common protoplasmic good. He remarked to a prospective patron that 'the most progressive revolution in history' could be achieved if somehow 'human matings could be placed upon the same high plane as that of horse breeding.'" KEVLES, *supra* note 28, at 48.

[41] *See* KEVLES, *supra* note 28, at 56, 61 (discussing popular support of the eugenics movement). Belief in biological determinism became a unifying force that crossed fields of discipline:

> Despite its heterogeneity, the eugenics movement provided a unifying paradigm, common themes, and a new language of biological determinism that gained strong support during the first three decades of the twentieth century, as new research programs in human heredity promised to provide a more scientific approach to ensuring the national health, preventing crime and poverty, and preserving the national character. Eugenics provided intellectuals in many fields with an interdisciplinary forum to apply their research to the common goal of human betterment.

GALLAGHER, *supra* note 24, at 2-3.

[42] GALLAGHER, *supra* note 24, at 4. *See generally* JAMES R. MOORE, THE POST-DARWINIAN CONTROVERSIES: A STUDY OF THE PROTESTANT STRUGGLE TO COME TO TERMS WITH DARWIN IN

In 1926, the American Eugenics Society ("AES") published *A Eugenics Catechism.*[43] This publication "assured readers that eugenics was not a plan for making supermen or for breeding human beings as if they were animals. The catechism did promise that eugenics would 'increase the number of geniuses,' foster 'more selective love-making,' and produce more love in marriage."[44] The AES integrated its philosophy with the religious sentiment prevalent at the time, which provided assurances and appealed to the general public.[45] The AES also sponsored public displays that integrated eugenics with family and patriotic values, such as "fitter families contests" at state fairs across America's heartland.[46]

Without the check of natural science reality,[47] the AES's philosophy proved extraordinarily malleable and realized broad appeal.[48] Ironically, given that the objective was to eliminate genetic variations deemed unde-

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GREAT BRITAIN AND AMERICA, 1870-1900 253-98 (1979) (discussing the relationship between a theory which taught the survival of the fittest in a brutal struggle for existence and a theology which taught God's designing providence in a creation that he saw was "good").

[43] KEVLES, *supra* note 28, at 60.

[44] *Id.* at 61.

[45] Consider this excerpt from the Eugenics Catechism:

> Q: Does eugenics contradict the Bible?
> A: The Bible has much to say for eugenics. It tells us that men ought not gather grapes from thorns and figs from thistles.
>
> . . . .
>
> Q: Does eugenics mean less sympathy for the unfortunate?
> A: It means a much better understanding of them, and a more concerted attempt to alleviate their suffering, by seeing to it that everything possible is done to have fewer hereditary defectives.
>
> . . . .
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> Q: What is the most precious thing in the world?
> A: The human germ plasm.

AMERICAN EUGENICS SOCIETY, INC., A EUGENICS CATECHISM 2, 9 (1926).

[46] PAUL, *supra* note 13, at 11, 13. Families competed to be deemed the embodiment of the most desirable genetic characteristics. *See id.* (quoting a contest organizer's description of the contest held at the Kansas Free Fair). These contests were prevalent in the 1920s. *Id.*

[47] Admittedly, in hindsight and with completion of a map of the human genome in hand, the speculative nature of the underlying science was breathtaking:

> In the last two decades of the nineteenth century and the first three of this century, it was widely assumed that human mental, temperamental, and moral traits were determined by heredity. Shiftlessness, religiosity, courage, patriotism, a sense of humor, love of beauty, taste for philosophy, trustful nature, and a tendency to wander were only a few of the traits ascribed to good or bad blood. . . .
>
> That society ought to foster the breeding of those who possessed favorable traits ("positive" or "constructive" eugenics) and discourage or prevent the breeding of those who did not ("negative eugenics") seemed obviously to follow.

PAUL, *supra* note 13, at 1; *see also infra* note 134 and accompanying text.

[48] *See supra* notes 41-42 and accompanying text.

sirable,[49] the AES represented a diverse membership and headed a movement that encompassed everything from patriotism to Marxism:

> In the 1920s, several Russian geneticists called for a "Bolshevik eugenics" based on Marxist principles. In their view, eugenics was a logical extension of the Marxist commitment to the scientific organization of society.
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> . . . .
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> In the late nineteenth and early twentieth centuries, eugenicists were found on every side of arguments about capitalism, war, and especially the role of women. . . . Most defended capitalism, whereas others argued that only in a classless society would it be possible to separate the genetic wheat from the chaff. Thus eugenicists were united only in their enthusiasm for technocrat solutions to social problems.[50]

Within just a few decades, the United States eugenics movement had grown strong enough to inspire active government involvement. The United States funded research in countries such as Germany and led the world in enacting responsive immigration policy and forced-sterilization laws.[51] Indiana passed the first sterilization law in 1907,[52] and fifteen additional states followed between 1907 and 1917—resulting in such legislation in every region of the country except for the South. Although the scope of the laws varied, ultimately, some form of compulsory sterilization was codified in twenty-seven American states:[53]

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[49] Actually, Galton, Davenport and their contemporaries attempted to distinguish "positive genetics" from "negative genetics," though they supported both. *See* KEVLES, *supra* note 28, at 47. The former consisted of encouraging the proliferation of "good [human] stock," which they identified as intellectuals, artists, musicians, and scientists drawn from the middle class. *Id.* Charles Davenport "[l]ooked forward to the day when a woman would no more accept a man 'without knowing his biologico-genealogical history' than a stockbreeder would take 'a sire for his colts or calves . . . without pedigree.'" *Id.*

[50] PAUL, *supra* note 13, at 20-21. The Victorian founders of the U.S. eugenics movement deliberated extensively about procreation:

> While [Davenport] preferred segregation to sterilization as a means of preventing the reproduction of the unfit, he argued that any sterilization of the unfit should be accomplished by castration instead of vasectomy. Vasectomy, he knew, prevented paternity but not lust, and he believed that physiologically divorcing the sex act from responsibility for its procreative consequences might well encourage rapists. Davenport maintained that castration, unlike vasectomy, "cuts off the hormones and makes the patient docile, tractable and without sex desire."

KEVLES, *supra* note 28, at 53.

[51] *Id.* at 56; SHADOW OF THE REICH, *supra* note 14.

[52] KEVLES, *supra* note 28, at 100 ("Dr. Sharp of the State Reformatory had mounted a campaign for the measure. ('Indiana is working much on sterilization,' a Johns Hopkins physician remarked in 1910. 'Practice hurries ahead of inquiry there.')").

[53] SHADOW OF THE REICH, *supra* note 14.

> Virtually all of the prewar statutes gave the states the power to compel the sterilization of habitual or confirmed criminals, or persons guilty of some particular offense, like rape. Also included within the scope of most of the statutes were epileptics, the insane, and idiots in state institutions. Most wide-ranging was a law passed in Iowa in 1911. It made eligible for sterilization inmates in public institutions who had been incarcerated for a variety of reasons, including drug addiction, sexual offenses, and epilepsy. The Iowa statute compelled the sterilization of twice-convicted sexual offenders, of thrice-convicted other felons, and anyone convicted just once of involvement in white slavery.[54]

Implementation of this legislation, however, was approached with more caution than its enactment. Although there were approximately 300,000 to 400,000 people deemed "feebleminded" in the United States who were capable of procreation, fewer than 9,000 of these candidates were eugenically sterilized from 1907 to 1928.[55] Still, this restraint on implementation in no way reflected misgivings on the part of American eugenicists. "Indeed, they were confident, even enthusiastic about the policy—enthusiastic enough to make one speculate about the psychodynamics of their attitudes."[56] Rather, implementation was tempered by legal challenges:

> In many states, sterilization measures ran afoul of the courts, of legislative opposition, of executive refusal to enforce, and of gubernatorial vetoes.
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> . . . .
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> By the outbreak of the First World War, sterilization laws were in such dispute as to have been de facto suspended in the operation in a number of states. The courts had also declared unconstitutional not only the stringent Iowa statute but less sweeping measures in six other states. Advocates of eugenic sterilization, frustrated at the legal impasse, wanted to take the issue to the Supreme Court.[57]

The eugenicists' vehicle to break through judicial impediments was *Buck v. Bell*,[58] a legal challenge to a Virginia sterilization statute passed in

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[54] KEVLES, *supra* note 28, at 100.

[55] *Id.* at 106-07.

[56] *Id.* at 107.

[57] *Id.* at 109-10.

[58] 274 U.S. 200 (1927).

March 1924.[59] The case proved a victory for eugenicists. In the often quoted opinion written by Justice Oliver Wendell Holmes, the Court concluded that "[t]hree generations of imbeciles are enough."[60]

The fact that eugenicists in the United States were able to influence public education, shape public policy, and even codify eugenics theory through enactment of compulsory sterilization laws[61] made the United States an epicenter for applied eugenics.[62] The United States was the envy of many eugenicists abroad who pointed to United States law and policy as precedent, even paradigms, for their domestic reforms.[63] In addition to becoming an exporter of eugenics, the United States also directly supported foreign eugenics.[64] For example, the Rockefeller Foundation directly funded a project on race variations carried out by the Berlin Institute and the Kaiser Wilhelm Institute that encompassed the infamous twin studies—"one of most serious ethical violations in the history of medicine."[65] Also, U.S. leaders lent their support. Charles Davenport became President of the International Federation of Eugenicists and an active proponent of the work of German eugenicists, as did Harry Laughlin, the Assistant Director of Cold Spring Harbor Laboratory.[66] In fact, as late as 1938, Laughlin pro-

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[59] *Id.* at 205. The Supreme Court has yet to expressly overturn this decision.

[60] *Id.* at 207.

[61] Before practice, in principle and theory eugenics was closely linked with procreation: "In both England and the United States such studies fed anxieties that the population was deteriorating physically and mentally due to the unrestricted reproduction of genetically inferior persons." GALLAGHER, *supra* note 24, at 3. Giving into the temptation to improve society at such personal costs to individuals was tantamount to succumbing to and condoning prejudices. "Marriage restrictions, segregation in institutions, and sterilization laws (negative eugenics measures) dramatically affected the lives of the people who were investigated eugenically. Less tangible, but more powerful perhaps, was the rhetoric of degeneracy that the eugenics studies introduced, which validated long-held prejudices and encouraged discrimination." *Id.* This temptation proved even more persuasive in the 1920s and 1930s: "Aided and abetted by the Depression, sterilization drew diverse support in the United States and Britain which went far beyond eugenicists. . . . Governments in Sweden, Denmark, Finland, and even a canton of Switzerland also enacted eugenic sterilization measures." KEVLES, *supra* note 28, at 115. By 1933, sterilization laws in effect reached perhaps 150 million people. *Id.*

[62] *See* KEVLES, *supra* note 28, at 56, 118 (highlighting the success of American field workers and the "Anglo-American eugenics movement"); SHADOW OF THE REICH, *supra* note 14. In fact, some eugenics leaders in the U.S. became international celebrities. For example:

> In 1936, the University of Heidelberg voted an honorary doctorate of medicine to Harry Laughlin, still a sterilization enthusiast and in charge of the Eugenics Record Office, at Cold Spring Harbor, Long Island. Laughlin, who accepted the degree at the German consulate in downtown Manhattan, wrote to the Heidelberg authorities that he took the award not only as a personal honor, but also as "evidence of the common understanding of German and American scientists of the nature of eugenics."

KEVLES, *supra* note 28, at 118.

[63] *See* KEVLES, *supra* note 28, at 56, 118 ("German eugenicists, flattering to their American counterparts, said that they owed a great debt to American precedent . . . .").

[64] SHADOW OF THE REICH, *supra* note 14.

[65] *Id.*; *see also infra* notes 97-98 and accompanying text.

[66] SHADOW OF THE REICH, *supra* note 14.

moted and distributed a Nazi propaganda film attacking Jews entitled "The Genetically Diseased" to church groups and clubs.[67]

B. *Eugenics Under German Law*

Germany readily imported United States' eugenics.[68] In fact, American programs served as precedent and models for German initiatives to apply eugenics at home:

> As early as 1913, a member of the Berlin eugenics society published a glowing report on the American eugenics movement. Géza von Hoffman's *Racial Hygiene in the United States of North America* made many Germans (and Scandinavians, who closely followed German sources) envious of their American counterparts, who apparently enjoyed much greater popular and legislative support as well as success in attracting financial patrons.
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> . . . .
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> In the aftermath of the First World War, close links were forged between German and American eugenicists. . . .
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> These relationships were not disturbed by the Nazi seizure of power. . . .
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> The Nazis regularly quoted American geneticists who expressed support for their sterilization policies. They also frequently invoked the large-scale California experience with sterilization.[69]

Within just a few years, German caution about eugenics gave way to state-mandated sterilization.[70] During this time, sweeping scientific conclusions were drawn based upon observations, general theories, and some splinters of solid science.[71] When introduced in 1925, Hitler's proclamation in *Mein Kampf* that the state "must declare unfit for propagation all

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[67] *Id.*

[68] *Id.* "[I]t was the United States that provided the most important model for German Sterilization laws. By the late 1920s, some 15,000 individuals had been sterilized in the United States—most while incarcerated in prisons or homes for the mentally ill." Proctor, *supra* note 30, at 21.

[69] PAUL, *supra* note 13, at 84-86 (citations omitted).

[70] *See* DANIEL JONAH GOLDHAGEN, HITLER'S WILLING EXECUTIONERS 456 (Vintage Books 1997) (1996) (explaining that the German people "willingly acquiesced" to the Nazi German revolution).

[71] *See id.* In essence, science was used to justify a social agenda: "The revolution was primarily the transformation of consciousness—the inculcation in the Germans of a new ethos. By and large, it was a peaceful revolution willingly acquiesced to by the German people. Domestically, the Nazi German revolution was, on the whole, consensual." *Id.*

who are in any way visibly sick or who have inherited a disease and can therefore pass it on, and put this into actual practice . . . . Those who are physically and mentally unhealthy and unworthy must not perpetuate their suffering in the body of their children"[72] had been received with skepticism even from ardent eugenicists.[73] However, "most of the 20-odd university institutes for racial hygiene were established at German universities before the Nazi rise to power, and by 1932 racial hygiene had become an orthodox fixture in the German medical community."[74] By the time Hitler came to power, there was support to codify coerced sterilization into German law:

> Before 1933, most German eugenicists had actually been dubious about proposals for compulsory sterilization, regarding them as politically unrealistic and scientifically premature. However, a draft law permitting sterilization with the consent of the person concerned or that person's guardian had been prepared in 1932, during the last days of the Weimar Republic. Before it could be approved, the government was in the hands of Adolf Hitler. . . .
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> The Law for the Prevention of Genetically Diseased Progeny, issued two months after the Nazis came to power, allowed for compulsory sterilization, extended the range of "hereditarily determined" conditions, and required doctors to register cases of genetic disease (except in women past reproductive age). Sterilization was *mandated*, whether or not the person was institutionalized, in cases of congenital feeblemindedness, schizophrenia, manic-depression, severe physical deformity, hereditary epilepsy, Huntington's chorea, hereditary blindness and deafness, and severe alcoholism.[75]

Implementation of forced sterilization was achieved through a collaborative effort by the science and medical communities, the judiciary, and the

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[72] ADOLF HITLER, MEIN KAMPF 404 (Ralph Manheim trans., Houghton Mifflin 1971) (1925).

[73] PAUL, *supra* note 13, at 86 ("Before 1933, most German eugenicists had actually been dubious about proposals for compulsory sterilization, regarding them as politically unrealistic and scientifically premature.") (citations omitted).

[74] Proctor, *supra* note 30, at 19-20. "[M]ost of the 15-odd journals of racial hygiene, for example, were established long before the rise of National Socialism." *Id.*

[75] PAUL, *supra* note 13, at 86 (citations omitted) (emphasis added). Nancy L. Gallagher notes that:

> German eugenics was not a Nazi invention; the rationale, procedures, and medical and psychiatric research institutions for such a program had developed concurrently with the American and British research. The Nazi legislation, however, removed legal impediments to sterilization that had existed in the Weimar Republic and framed its purpose in terms of an urgent fight for survival of the German nation and the "Aryan race."

GALLAGHER, *supra* note 24, at 139.

Nazi regime:[76]

> [F]ar from being passive pawns or a small minority in the Nazi effort, physicians were instrumental in formulating, and took the lead in carrying out, the Nazi racial hygiene program. The Nazi theory, based on a social Darwinist view of genetics and racial purity, meshed perfectly with the Nazi ideology.[77]

Physicians referred cases to "genetic health courts" established to evaluate cases.[78] The role of physicians was expanded in 1935 to encompass cases beyond preventive sterilization: German law was amended to allow women deemed "hereditarily ill" to undergo abortion within the first six months of pregnancy:[79]

> Within three years, German authorities had sterilized some two hundred and twenty-five thousand people, almost ten times the number so treated in the previous thirty years in America. About half were reported to be "feebleminded."

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[76] "[M]edical scientists were the ones who invented racial hygiene in the first place. . . . Scientists, in other words, were not simply pawns in the hands of Nazi officials. But without a strong state to back them, racial hygiene was relatively impotent. It was not until 1933 that the programs of the pre-Nazi era gained the support of officials willing to move aggressively in this area." Proctor, *supra* note 30, at 19-20; *see also* SHADOW OF THE REICH, *supra* note 14.

[77] THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 14, at 15. Robert Proctor points out that:

> The Nazis, in turn, were able to exploit both the intimacy and the authority of the traditional physician-patient relationship. Crudely stated, they could do things with doctors that would have been much harder without them. . . . Medicine also served as a disguise. In Buchenwald 7,000 Russian prisoners of war were executed in the course of supposed "medical exams," using a device disguised as an instrument to measure height.

Proctor, *supra* note 30, at 27.

[78] PAUL, *supra* note 13, at 87. As of 1934, Germany had established 181 Genetic Health Courts and Appellate Genetic Health Courts to adjudicate the Sterilization Law. Proctor, *supra* note 30, at 21.

[79] PAUL, *supra* note 13, at 87. It is important to note that many state laws in the United States that prohibit abortion at viability of the fetus also make exceptions where the health of the fetus is in question based upon medical diagnosis and the health of the mother. *See, e.g.*, KAN. STAT. ANN § 65-6709(a)(4) (2002) (stating that a viable fetus may be aborted if necessary to preserve the life of the pregnant woman "or . . . the fetus is affected by a severe or life-threatening deformity or abnormality"); MD. CODE ANN. HEALTH–GEN. § 20-209(b)(ii) (2003) (explaining that the state may not interfere with a woman's decision to terminate any time during her pregnancy if "[t]he fetus is affected by genetic defect or serious deformity or abnormality") (2002); TEX. HEALTH & SAFETY CODE ANN. § 170.002 (Vernon 2001) (stating that an abortion may be performed at any time provided that "the fetus has a severe and irreversible abnormality, identified by reliable diagnostic procedures"); VA. CODE ANN. § 32.1-92.2 (Michie 2001) (funding abortions if a physician "believes the fetus will be born with a gross and totally incapacitating physical deformity or with a gross and totally incapacitating mental deficiency"). *But see* President George W. Bush, Statement on Banning Partial-Birth Abortion (June 2003) (expressing support for legislation banning partial-birth abortions), *available at* http://www.whitehouse.gov/news/releases/2003/06/20030604-4.html. (last visited Sept. 23, 2003) (on file with the Connecticut Law Review).

. . . .

> For a time, the Nazi sterilization program ran independently of the regime's anti-Semitic policies.[80]

Ultimately, the Germans sterilized 350,000-400,000 persons, with some racial hygienists dissatisfied and arguing that 10-15 percent of the entire population should be sterilized.[81]

Familiarity with forced-sterilization made euthanasia acceptable to many—even palatable as a logical policy progression. "The German sterilization program was followed in 1939 by a euthanasia program designed to rid the nation of its mental patients, now characterized as 'useless eaters.'"[82] Specifically, Hitler issued orders to commission doctors to grant Gnadentod (mercy death) to patients judged "incurably sick by medical examination" and, by August 1941, more than 70,000 patients from German mental hospitals had been killed.[83] This program inspired the development of the infamous Nazi gas chamber technology.[84] In fact, German implementation of coerced sterilization and then euthanasia of the "genetically infirm" based upon health conditions paralleled and then blended into the broader eugenics agenda of the German government—"racial purification" via genocide.[85] The two agendas—eugenics and genocide of the Jewish race—were implemented in unison. On April 1, 1933, in conjunction with codifying forced sterilization, the Nazi regime decreed an anti-Jewish

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[80] KEVLES, *supra* note 28, at 117 (citation omitted).

[81] Proctor, *supra* note 30, at 21.

[82] PAUL, *supra* note 13, at 90.

[83] Proctor, *supra* note 30, at 23.

[84] PAUL, *supra* note 13, at 90; Proctor, *supra* note 30, at 25 ("The ultimate decision to *gas* the Jews emerged from the fact that the technical apparatus already existed for the destruction of the mentally ill.").

[85] The term "genocide" was "coined by the Polish refugee Raphael Lemkin toward the end of World War II and enshrined for the United Nations Genocide Convention . . . ." Christopher Shea, *Critical Faculties*, BOSTON GLOBE, June 15, 2003, at H5, LEXIS, News Library, Bglobe File. For an insightful case study analysis of early 20th-century genocide beyond the geography of Europe, see UWE TIMM, MORENGA (Breon Mitchell trans., New Directions 2003) (1978) (addressing the 20th-century German presence in South West Africa as an illustration of brutal European colonialism and genocide). A review of the novel explains that:

> Doctors in [the South West African colony] formulated theories of racial superiority that anticipated Nazism and the Holocaust. German administrators took the lesson of "concentration camps" (the British general Kitchener's policy for containing Boer noncombatants) and applied it with more terrible vigor to the Herero. Out of some 80,000 people, only about 15,000 survived.

Giles Foden, *Rehearsal for Genocide*, N.Y. TIMES, Apr. 20, 2003 (book review), at 15. Moreover, dozens of cases of genocide have been identified since 1945, ranging from the Sudan in the 1960s to Kosovo in 1999. Shea, *supra* at H5; *cf.* Nicholas D. Kristof, *What Did You Do During the African Holocaust?*, N.Y. TIMES, May 27, 2003, at A25 (commenting on Eritrea and Africa's tailspin).

boycott of Jewish-owned businesses and passed the Enabling Act.[86] Through the Act, the government established restrictive quotas for Jews serving in government positions, professions, and universities and effectively terminated the employment of all state employees and other civil servants half or more Jewish.[87] In 1935, Germany enacted the first Nuremberg law; this law defined who was a Jew, stripped Jews of their citizenship, and forbade them from marrying "citizens of German or related blood."[88] A flurry of similarly-intentioned laws followed: "Other laws and extralegal actions directed against Jews, Gypsies, the offspring of German mothers and black French soldiers, homosexuals, and other social and political 'deviants' followed, culminating in the program of mass extermination known as the Holocaust."[89]

The Third Reich persecuted political dissidents, Communists, Jehovah's Witnesses, and Catholics, but used biology to draw a macabre line between persecution and execution.[90] The Third Reich distinguished and undertook "race hygiene" measures against those deemed biologically inferior by Aryan race theorists. This latter group included Jews, Gypsies, and persons declared genetically diseased—people with visible disabilities and people tagged "asocials", meaning homosexuals, sex offenders, and criminals.[91] By the time Hitler assumed power, the mantra of the German revo-

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[86] GALLAGHER, *supra* note 24, at 138. The Enabling Act is addressed in WHITNEY R. HARRIS, TYRANNY ON TRIAL: THE EVIDENCE AT NUREMBERG 47-48 (1954).

[87] KEVLES, *supra* note 28, at 117-18 (citation omitted); GALLAGHER, *supra* note 24, at 138.

[88] PAUL, *supra* note 13, at 90 (citations omitted); Proctor, *supra* note 30, at 23. "These measures began the formal, government-sanctioned process of exclusion, public humiliation, and persecution of German Jews—policies against groups deemed alien by the German state, which triggered the first wave of Jewish refugees seeking asylum." GALLAGHER, *supra* note 24, at 138. As observed by historian Robert Proctor:

> Sadly, there is yet another area where Nazi physicians were able to draw support from their American colleagues. In 1939, Germany's leading racial hygiene journal reported the refusal of the American Medical Association to admit black physicians to its membership; 5,000 black physicians had petitioned to join the all-white American body were turned down. German physicians only one year before, in 1938, had barred Jews from practicing medicine (except on other Jews); Nazi racial theorists were thereby able to argue that Germany was "not alone" in its efforts to preserve racial purity.

Proctor, *supra* note 30, at 23. Today, some Holocaust survivors and their heirs are bringing legal actions against those who benefited financially from and participated in these actions. For example, an action has been brought against the French National Railroad for delivering more than 75,000 Jews and others to Nazi death camps in World War II. *French Railroad Holocaust Suit Reinstated*, N.Y. TIMES, June 19, 2003, at A4 (reporting on the reinstatement of this three-year law suit by the federal Second Circuit Court of Appeals).

[89] PAUL, *supra* note 13, at 90-91.

[90] GALLAGHER, *supra* note 24, at 138.

[91] *Id.* As observed by author Daniel Goldhagen:

> The notion, for example, that an individual's defining characteristics were derived from his race and that the world was divided into distinct races—whose respective capacities and moral worth were biologically determined and widely variable—was, if not quite an axiom of German society during the Nazi period, then an extremely

lution was no less than to:

> reconstitute and reshape the European social landscape according to its racial biological principles, by killing millions of people deemed, according to its racial fantasies, dangerous or expendable, and thereby to increase the proportion of the "superior races" and strengthen the overall biological stock of humanity and, complementing this, to reduce the danger to the "superior races" by the more numerous "inferior" ones. . . . Eastern Europe would become a German colony populated by German settlers and Slavic slaves.[92]

Germany would build itself into a biological super-state through genetic perfectionism and govern a Brave New World.[93] However, as this extreme position actually was implemented, seams appeared in the broader eugenics science community and those gave way to divisions:

> The shift in the meaning of eugenics was brought into sharper relief with the publication of scientific commentaries on eugenic sterilization and racial biology in the mid-1930s. . . .
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> . . . .
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> Political developments in Europe also forced eugenicists to take a position on the issue of race. In 1935, several influential and widely publicized scientific critiques of eugenics race research were published in response to Nazi implementation of their race hygiene policies. Repeated citation to these works as evidence of the scientific defeat of eugenics has fostered a myth that knowledgeable biologists in the 1930s had abandoned any serious consideration of reproductive selection for the purpose of population improvement.[94]

Scientific critiques certainly did not temper German policy. Rather, the German science and medical communities engaged in unchecked human experimentation to perfect their sterilization procedures and to build a

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> widespread belief. That the world ought to be organized and reorganized according to this conception of an immutable hierarch of races was an accepted norm.

GOLDHAGEN, *supra* note 70, at 460.

[92] GOLDHAGEN, *supra* note 71, at 458.

[93] *Cf.* Charles J. Rolo, *Introduction* to ALDOUS HUXLEY, BRAVE NEW WORLD & BRAVE NEW WORLD REVISITED, at vii, xiii (Harper & Row 1960) (1932) (describing Huxley's novels as books depicting a world in which "mass production has been applied even to biology."). *See generally* SHADOW OF THE REICH, *supra* note 14.

[94] GALLAGHER, *supra* note 24, at 142-43. *See generally discussion infra* Part III.B.

stronger scientific base for their positions.[95] Experimentation to improve sterilization procedures gave way to so-called war studies to measure human endurance, including germ warfare studies, and crude attempts at genetic manipulation.[96] Some of the more notorious of these involved 1,500 pairs of twins culled from the masses on their way to concentration camps.[97] The common pattern was for one twin to be injected with a germ, get sick, and die, and then to immediately execute the healthy twin to perform an autopsy to compare their organs.[98] The range of studies included some to measure human endurance in water conditions inflicting hypothermia and manipulation of atmospheric pressure, death being the target endpoint, and gruesome genetics experiments. The genetic experiments included attempts to change eye color through the injection of chemicals, generally resulting in blindness,[99] to change sex.[100] In the words of eye

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[95] The Nazis supported but also grossly skewed the course of research. They commingled excellent, innovative science with result-oriented experimentation. As explained by historian Robert Proctor:

> The Nazis suppressed some areas and encouraged others. They supported extensive research on ecology, public health, cancer, behavioral genetics, and (of course) race and sociobiology. The Nazi government funded research on the effects of exposure to X-rays and heavy metals; some of the first reliable studies on the health effects of asbestos were done in this period. The Nazis were among the first to initiate bans on smoking in public buildings; Nazi leaders organized unprecedented support for midwifery, homeopathy, and a number of other areas of heterodox medicine. Nazi physicians recognized the importance of a diet high in fruit and fiber, and in the early war years managed to have enacted a law requiring every German bakery to produce whole-grain bread. Nazi physicians restricted the use of DDT and denied women tobacco rationing coupons on the grounds that nicotine could harm the fetus. Racial hygiene itself was supposed to provide "long-run," preventive care for the German germ plasm, complementing shorter-term social and individual hygiene.

Proctor, *supra* note 30, at 28.

[96] *See* Eva Mozes-Kor, *The Mengele Twins and Human Experimentation: A Personal Account*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 14, at 55 ("One set of [Mengele's] experiments dealt with genetics and the other with germ warfare.").

[97] *See generally* SHADOW OF THE REICH, *supra* note 14 ("[T]he most notorious experiments were the twin studies.").

[98] *See* Mozes-Kor, *supra* note 96, at 53, 55 ("To look back on my childhood is to remember my experience as a human guinea pig . . . . [W]e were there . . . to be used as experimental objects and then to be killed."); SHADOW OF THE REICH, *supra* note 14 (giving Eva Mozes-Kor's personal account of the twin experimentations).

[99] SHADOW OF THE REICH, *supra* note 14 (describing experiments that were conducted to convert brown eyes to blue eyes).

[100] Telford Taylor, *Opening Statement of the Prosecution December 9, 1946*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 14, at 71-84 (discussing the following: high-altitude experiments; freezing experiments; malaria experiments; mustard gas experiments; Ravensbrueck experiments concerning sulfanilamide and other drugs; bone, muscle, and nerve regeneration and bone transplantation; sea-water experiments; epidemic jaundice; sterilization experiments; typhus and related experiments; poison experiments; and incendiary bomb experiments); Proctor, *supra* note 30, at 25-26 (documenting experiments including: forcing people to drink seawater to assess longevity without fresh water; immersing prisoners of war in ice water to test gear and treatment techniques; vacuum chamber experiments to assess the impact of high-altitude bailouts; infecting prisoners with pathogens to test homeopathic preparations and to cope with exotic diseases; exposure to phosgene gas to test possible antidotes; sterilization and castration experiments; limb and bone transplants in the absence of medical

witness and survivor Eva Mozes-Kor:

> One of the twins, who was 19 years old, told of experiments involving a set of teenage boys and a set of teenage girls. Cross-transfusions were carried out in an attempt to "make boys into girls and girls into boys." Some of the boys were castrated. Transfusion reactions were similarly studied in the adolescent twins.
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> . . . .
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> A set of Gypsy twins was brought back from Mengele's lab after they were sewn back to back. Mengele had attempted to create a Siamese twin by connecting blood vessels and organs. The twins screamed day and night until gangrene set in, and after 3 days they died. Mengele also attempted to connect the urinary tract of a 7-year-old girl to her own colon. Many experiments were performed on the male and female genitals.[101]

III. THE IMPACT OF NAZI MEDICINE ON EUGENICS, RESEARCH, AND MEDICAL ETHICS PRIOR TO NUREMBERG

Close to fifty percent of German physicians were members of the Nazi Party, and thousands of doctors, nurses and other health care providers were directly involved in the genocide and human experimentation practices put on trial at Nuremberg.[102] Many more witnessed these actions and the resulting suffering and did nothing. Confrontation of Nazi medicine through the Nuremberg doctor trials (the "Doctors' trial") had a fundamental impact on the eugenics movement, research on human subjects, and, ultimately, general medical ethics.[103] Most notably, informed consent

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need; and, attempts to permanently change eye color); SHADOW OF THE REICH, *supra* note 14 (describing various types of human experimentation).

[101] Mozes-Kor, *supra* note 96, at 57.

[102] Proctor, *supra* note 30, at 19 ("By 1942, more than 38,000 doctors had joined the Nazi Party, representing about half of all doctors in the country."); SHADOW OF THE REICH, *supra* note 14 (thousands of healthcare providers helped conduct experiments on humans); *see also infra* notes 108-09 and accompanying text. *See generally* LIFTON, *supra* note 14, at 5 ("Part 1 examines the sequence from forcible sterilization to direct medical killing . . . made possible by the Nazification of the German medical profession . . . .").

[103] *See* Proctor, *supra* note 30, at 29 ("Today one hopes that . . . professional honor will always be understood to include a requirement that professionals act in an ethical and socially responsible manner. Elaborating on this ethic has become the painful task of physicians ever since Nuremberg . . . ."); LIFTON, *supra* note 14, at xii ("[N]azi doctors are distinguishable from . . . other ['doctors in evil'], not so much in their human experimentation but in their central role in genocidal projects—projects based on . . . genocide as a means of national and racial healing. . . . For this, Nazi doctors require a study of their own . . . ."). Lifton also concludes that "[d]octors in general, it would

evolved from a principle into law, eventually becoming the cornerstone ethos for contemporary medical research and the practice of medicine.[104]

A. *The Role and Prosecution of German Physicians*

In the early 20th century through post-WWI, the Weimar Republic's medical profession was revered by the world and often cited as the absolute pinnacle of medicine.[105] Germans routinely captured global attention for their pioneer contributions in science and technology, and the German medical profession was renowned for its scientific sophistication and eagerness to incorporate the latest advances into practice. Some American medical scholars who went to Germany for training were later accepted for admission at schools such as Harvard and John Hopkins.[106]

Serious consideration must be given to the fact that German doctors, though medical professionals, also were citizens of a proud nation rich in culture that had been humbled in WWI and thereafter, as a means of recovery, prioritized the status of the nation state over all else.[107] They were a politically conservative and active group.[108] As explained by historian Robert Proctor:

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seem, can all too readily take part in the efforts of fanatical, demagogic, or surreptitious groups to control matters of thought and feeling, and of living and dying." *Id.* Lifton cites the following examples in support of this conclusion:

> One need only look at the role of Soviet psychiatrists in diagnosing dissenters as mentally ill and incarcerating them in mental hospitals; of doctors in Chile (as documented by Amnesty International) serving as torturers; of Japanese doctors performing medical experiments and vivisection on prisoners during the Second World War; of white South African doctors falsifying medical reports of blacks tortured or killed in prison; of American physicians and psychologists employed by the Central Intelligence Agency in the recent past for unethical medical and psychological experiments involving drugs and mind manipulation; and of the "idealistic" young physician-member of the People's Temple cult in Guyana preparing the poison (a mixture of cyanide and Kool-Aid) for the combined murder-suicide in 1978 of almost a thousand people.

Id. *See generally* SHADOW OF THE REICH, *supra* note 14 (explaining that the Nuremberg trials fundamentally impacted medical ethics).

[104] *See* discussion *infra* Part III.B (exploring the development of eugenics after WWII). *See* KENNETH GETZ & DEBORAH BORFITZ, INFORMED CONSENT: THE CONSUMER'S GUIDE TO THE RISKS AND BENEFITS OF VOLUNTEERING FOR CLINICAL TRIALS 17 (2002) (providing a pragmatic treatment of informed consent written for the general public).

[105] SHADOW OF THE REICH, *supra* note 14 (explaining that the medical profession of the Weimar Republic was "of an extremely high quality").

[106] *Id.*

[107] *See* LIFTON, *supra* note 14, at 30-44 ("[T]he physician could carry out what Gerhard Wagner identified as the task of his Public Health Office: 'the promotion and perfection of the health of the German people . . . to ensure that the people realize the full potential of their racial and genetic endowment.'"); SHADOW OF THE REICH, *supra* note 14 (explaining that many German doctors, like other German citizens, prioritized the status of their nation state over all else).

[108] *See generally* LIFTON, *supra* note 14, at 110 (discussing how one member of the medical faculty of the University of Berlin "favored abandoning the old 'liberal-materialistic spirit' . . . and acquiring instead 'the idealistic *Weltanschauung* of National Socialism'").

> Before 1933, the leadership of the profession was dominated by the *Deutschnationalen*—a German nationalist party that subsequently threw its support to Hitler. . . . The profession was politicized and polarized after the economic collapse in the late 1920s and early 1930s . . . . By the end of 1932, the National Socialist Physicians' League was twice as large as the Association of Socialist Physicians (3,000 vs. 1,500 members). In the Reichstag elections leading to the Nazi seizure of power, nine physicians were elected to represent the Nazi Party; only one physician was elected to represent the socialists.[109]

Germany's stumble as a nation in WWI fit well within the lifetimes of a generation of active, senior medical professionals post-WWI who until that point had relished in both the esteem of their international peers and the position of global leadership their nation enjoyed.[110] In fact, for these individuals, the two were largely intertwined: Membership in the German medical and science professions innately encompassed striving to become recipients of the prestige and government support enjoyed by the nation's top research-scientists who, again, generally were recognized by competing nations as among the best in the world.[111] Post World War I, as citizens and participants in German politics and culture, doctors and scientists readily embraced the spirit of reborn nationalism that invigorated the life of their deflated nation.

The Third Reich was able to ready members of the German medical profession by effectively combining the roles of patriotic citizen and medical professional.[112] Foreign eugenics movements and the support they embodied enabled the Third Reich to package their political, social and economic agenda in recognized science and to present the medical and scientific communities with a national mission encompassing notions of health, welfare, service, and acceptance of individual sacrifice as a necessary means to realize the former.[113] Medicine, science and nationalism were integrated in social Darwinism—the promise of achieving a vibrant German society through a rising population of full-blooded Aryans, the cul-

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[109] Proctor, *supra* note 30, at 26-27.

[110] *Id.* at 17-29; *see supra* notes 105-06 and accompanying text.

[111] SHADOW OF THE REICH, *supra* note 14 (explaining that many German doctors wanted government support to help their professional reputation).

[112] *See* Proctor, *supra* note 30, at 27 ("[I]t is possible to argue that there was a certain ideological affinity between medicine and Nazism at this time. Many physicians were attracted by the importance given to *race* in the Nazi view of the world . . . .").

[113] *See id.* at 21-22 ("German racial hygienists throughout the Weimar period expressed their envy of American achievements in this area [of sterilization], warning that unless Germans made progress in this field, America would become the world's racial leader."); SHADOW OF THE REICH, *supra* note 14.

ture-based "fitter family"[114] ideal shared by the majority of the German population. The principles were familiar and fundamental: achieve sound health and other desirable qualities in the German population through practices developed, tried, and proven true through centuries of animal and plant husbandry. The objective of sound health and a reinvigorated Germany resonated well; and, after all, social Darwinism simply was a German national application of prevalent theories in eugenics—theories that already had shaped policy and law and had been implemented in nations such as the United States.[115] The link between medicine and anti-Semitism then became a matter of extending this philosophy: "The most important theoretical link was what might be called the 'medicalization of anti-Semitism,' part of a broader effort to reduce a host of social problems—unemployment, homosexuality, crime, 'antisocial behavior,' and others—to medical or, ideally, *surgical problems*."[116]

So the Third Reich called upon those responsible for Germany's renowned international strengths in technology, science, and medicine to enable their nation to "treat" societal ills deemed causative of overwhelming social, political and economic burdens.[117] Those called upon responded:[118]

> Contrary to postwar apologies, doctors were never forced to perform [medical] experiments. Physicians volunteered—and in several cases, Nazi officials actually had to restrain overzealous physicians from pursuing even more ambitious experiments. . . . Doctors acting in this situation were not without values. Their values were clear (Nordic supremacy, total war demands extreme measures, Jews are vermin, etc.), and they acted in accordance with those values.[119]

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[114] *See supra* note 48 and accompanying text. *See generally* SHADOW OF THE REICH, *supra* note 14 (explaining that medicine was used to eliminate "inferior" traits).

[115] As stated by author Nancy Gallagher:

> After World War II the Nazi radicalization of eugenics into genocide would demonstrate the potential for evil in eugenics ideology and would make prophets of its early critics, but the implications of the German sterilization program were not so obvious in 1934. Some found the German program enviable; campaigns for sterilization laws were launched in the United States and many nations abroad, including the Scandinavian countries, the Baltic states, Japan, and the Netherlands.

GALLAGHER, *supra* note 24, at 139-40.

[116] Proctor, *supra* note 30, at 25.

[117] SHADOW OF THE REICH, *supra* note 14 (explaining that doctors were called upon to "treat" or "heal" societal ills).

[118] LIFTON, *supra* note 14, at 43-44 ("[W]hile a few doctors resisted [committing medical crimes], and large numbers had little sympathy for the Nazis, *as a profession* German physicians offered themselves to the regime."); SHADOW OF THE REICH, *supra* note 14 (explaining that doctors were "ready and willing to offer their assistance"); *see also supra* note 72 and accompanying text.

[119] Proctor, *supra* note 30, at 26 (internal citation omitted).

Commitment to healing and strengthening the German state and belief in social Darwinism certainly were not the only inspirations for medical community participation in Nazi medicine. A much more sober and perhaps decisive influence was professional self-interest and advancement.[120] Another related influence was government coercion and survival, which later became the primary defense of Nazi doctors put on trial at Nuremberg.[121] So, how influential was professional self-interest and advancement relative to these other influences? First, within the professions of medicine and science, ardent eugenicists had an especially strong incentive to collaborate, for the Nazis were the only party to wholly support their proposed sterilization policies and vice versa.[122] Ultimately, the research community supportive of eugenics was given virtually carte blanche discretion to experiment on human beings and state support for doing so.[123] The end result, in addition to immense human suffering and murder, was "nothing which civilized medicine can use":[124]

> Even if [Nazi clinical researchers] had merely been forced to pay as little as two dollars for human experimental subjects, such as American investigators may have to pay for a cat, they might have thought twice before wasting unnecessary numbers, and thought of simpler and better ways to solve their problems. The fact that these investigators had free and unrestricted access to human beings to be experimented upon misled them to the dangerous and fallacious conclusion that the results would thus be better and more quickly obtainable

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[120] SHADOW OF THE REICH, *supra* note 14 (explaining that many German doctors conducted experiments to gain professional advancement); *see also* Proctor, *supra* note 30, at 27 ("[I]n a certain sense, the medical profession might even be said to have prospered under the Nazis. . . . It may even be true that physicians achieved a higher status in the Nazi period than at any time before or since."); GOLDHAGEN, *supra* note 70, at 384 (stating that "the perpetrators [of the Holocaust] . . . pursued their self-interest (conceptualized of as career advancement or personal enrichment) in total disregard of other considerations").

[121] SHADOW OF THE REICH, *supra* note 14 (explaining that many doctors, nurses, and other healthcare providers defended their actions by alleging government coercion); *see infra* notes 149-50 and accompanying text.

[122] SHADOW OF THE REICH, *supra* note 14 (stating that involvement of doctors legitimized implementation of racial theories).

[123] *See* Proctor, *supra* note 30, at 25 ("Given the effort to destroy entire peoples, and given the medical complicity in Nazi racial crime, it is hardly surprising that physicians attempted to exploit concentration camp inmates as subjects in human experimentation."); SHADOW OF THE REICH, *supra* note 14; *supra* note 100 and accompanying text (identifying documented Nazi experiments); LIFTON, *supra* note 14, at 5-6 ("Part I examines . . . the Nazification of the German medical profession . . . . Part II . . . [examines] the socialization of Nazi doctors to the killing project . . . . [P]art III [examines] more general principles of Nazi genocide . . . .").

[124] Taylor, *supra* note 100, at 91; *see also id.* at 70-85 (referring to ghastly experiments including, *inter alia*, administering poison to prisoners of war, forcing subjects to drink seawater, and performing medicinal sterilizations on persons imprisoned in concentration camps).

> than if they had gone through the labor of preparation, thinking, and meticulous preinvestigation.[125]

Second, in accordance with Nazi eugenics, Jewish doctors were gradually barred from participating in the medical system. The immediate practical effect of pushing Jews out of the practice of medicine was to make room for other German doctors whose careers had been impeded during the Great Depression.[126] Therefore, for non-Jewish doctors struggling to establish themselves in a zero-sum profession during difficult economic times, nationalism and bolstering the health of the German people certainly were convenient rationales for personal advancement, and personal advancement proved a powerful influence from the outset with this group. In fact:

> The medical community grew substantially under the Nazis despite the banishment of the Jews and Communists. It may even be true that physicians achieved a higher status in the Nazi period than at any time before or since. During the 12 years of Nazi rule, for example, the office of *Rektor* (president) at German universities was occupied by physicians 59 percent of the time; this contrasts with 36 percent for the decade prior to the rise of the Nazis and 18 percent for the two decades following the Nazi period. Doctors also prospered financially under the Nazis. In 1926, lawyers earned an average annual salary of 18,000 RM compared with only 12,000 RM for physicians. By 1936 doctors had reversed this trend and were earning 2,000 RM more than lawyers.[127]

Third, once the Third Reich put Nazi medicine into motion, presumably professional self-interest grew much more persuasive and more of a pervasive influence on the medical profession. Medicine and party politics became interchangeable; there was no viable opportunity to succeed in the German medical profession without actively participating in Nazi medicine. Ultimately, as Nazi medicine spread from forced sterilization of targeted groups to genocide and experimentation on those destined for genocide,[128] the entire German medical profession—thousands of nurses and orderlies as well as doctors—participated.[129] Under these circumstances (terminating rather than saving lives), nurses were shown heightened pro-

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[125] *Id.* at 91-92.

[126] Proctor, *supra* note 30, at 27-28; SHADOW OF THE REICH, *supra* note 14.

[127] Proctor, *supra* note 30, at 27-28; *see also* SHADOW OF THE REICH, *supra* note 14.

[128] *See supra* notes 82-86 and accompanying text.

[129] *See generally* SHADOW OF THE REICH, *supra* note 14. The few doctors with some Jewish heritage who were allowed to practice were placed in the worst of all situations. *Id.* They often were assigned to assist in carrying out the mass executions, which they did with the knowledge that resistance would result in their own executions. *See id.* One rationale was that, occasionally, some good could be done. *Id.*

fessional discretion that included administering thousands of lethal injections.[130] However, the Third Reich issued rules to ensure that doctors assisted in every step of the process, especially gassing.[131] The rules of the Third Reich mandated that at least one doctor be present when executing by gas, and doctors were recruited expressly to supervise mass extermination. After gassing, these doctors were responsible for certifying death.[132]

Beyond the context of genetics-premised forced sterilization and execution, the conduct of members of the German medical profession raises an additional dimension of considerations. In the Third Reich, complying physicians assumed the ultimate position of power over life and death; those engaged in eugenics and war-driven research enjoyed unprecedented freedom. Members of the medical profession actually decided who among those destined to die at their hands—concentration camp inmates and those destined for the camps—should first be subjected to experimentation for the benefit of science in the name of the German government, meaning to advance a German war effort so intertwined with German science.[133] Typically, death was the target endpoint of these studies, and in fact, surviving research subjects were sent to gas chambers as soon as studies were deemed complete—meaning there was absolutely no medical benefit earned by people for having been subjected to experimentation on behalf of the German government.[134]

Much of the most controversial experimentation began with the objective of perfecting sterilization techniques—for example, sterilization experimentation in Barracks Ten at Auschwitz to eliminate hereditary blindness.[135] In fact, "[a]s a consequence of the Sterilization Law, sterilization research and engineering rapidly became one of the largest medical industries. Medical supply companies designed new and improved sterilization equipment; medical students wrote more than 180 doctoral theses explor-

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[130] *Id.*

[131] SHADOW OF THE REICH, *supra* note 14.

[132] *Id.*

[133] *See supra* notes 95-96 and accompanying text; SHADOW OF THE REICH, *supra* note 14.

[134] SHADOW OF THE REICH, *supra* note 14; *see also supra* note 98 and accompanying text; Mozes-Kor, *supra* note 96, at 53-59.

[135] SHADOW OF THE REICH, *supra* note 14. As relayed by historian Daniel Kevles:

> During the war, news reports trickling back to the United States indicated that the Nazis were deploying eugenic sterilization on an even broader scale. When the full horrors of the death camps were revealed at the Nuremberg trials just after the war, witnesses testified that Nazi doctors had established centers for experimental sterilization. Men were used to test castration procedures; women, to assess sterilization by X rays, injections, and electrical destruction of their reproductive organs. Marie Claude Valliant-Couturier, a former inmate at Auschwitz, reported: "The Germans said they were looking for the best method of sterilization so they could repopulate all western European countries with Germans within one generation after the war."

KEVLES, *supra* note 28, at 169 (citations omitted).

ing new methods and consequences of sterilization."[136] But then a range of studies were introduced, the very nature of which typically involved unimaginable human suffering. For example, studies were undertaken on starvation and on high altitude to benefit German aviation (subjects were "tested" in pressure chambers).[137] Physicians also conducted "sea water tests" (subjects were to struggle to stay afloat in a tank of frigid water until death) to determine how long a downed pilot could endure the frigid North Atlantic.[138] Children, rather than being spared, were sought out. For example, Dr. Mengele engaged in research on some 1,500 pairs of twins at Auschwitz from 1942-1944. These experiments, which generally were not based on any meaningful scientific foundation and contributed little scientific knowledge, encompassed a gruesome range of applications including attempts to convert brown eyes to blue by injecting methalyn blue[139] and exposing children to a range of toxic injections.[140] Dr. Mengele also had contemporaries, including Dr. Kurt Heissmeyer who conducted a study on tuberculosis in which he and his associates removed the lymph glands from twenty Jewish children ages five through twelve and then infected them with the disease.[141]

Nazi medicine was put on trial on December 9, 1946 at the Doctors' trial following a major international trial of the political leaders.[142] Ultimately twenty-four defendants were charged with performing medical experiments on concentration camp inmates and other living human subjects.[143] Twenty-three defendants were brought before an American military tribunal; fifteen were found guilty, seven were acquitted, and one was convicted of other crimes.[144] Of those convicted, seven were executed by hanging and five were sentenced to life imprisonment. The remaining four

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[136] Proctor, *supra* note 30, at 21.

[137] *Id.* at 25-26; SHADOW OF THE REICH, *supra* note 14.

[138] Proctor, *supra* note 30, at 25; SHADOW OF THE REICH, *supra* note 14.

[139] SHADOW OF THE REICH, *supra* note 14. Similar eye color experiments were performed on adult Jews and gypsies. *See id.*; Proctor, *supra* note 30, at 26.

[140] Proctor, *supra* note 30, at 26; Mozes-Kor, *supra* note 96, at 53-59.

[141] SHADOW OF THE REICH, *supra* note 14. In order to eliminate all witnesses, Dr. Heissmeyer ordered the execution of these children, along with two French doctors, two Dutch orderlies, and twenty-four Russian prisoners of war. LIFTON, *supra* note 14, at 457. "After the war, Heissmeyer returned to his home in Magdeburg, now in East Germany, where he was highly regarded as a lung and tuberculosis specialist." *Id.*

[142] George J. Annas & Michael A. Grodin, *Judgment and Aftermath*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 14, at 94, 94 [hereinafter *Judgment and Aftermath*]; SHADOW OF THE REICH, *supra* note 14. For a list of the twenty-three trial defendants with identification summaries, see George J. Annas & Michael A. Grodin, *The Doctor's Trial and the Nuremberg Code*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 14, at 63, 63-65.

[143] *Judgment and Aftermath*, *supra* note 142, at 120; SHADOW OF THE REICH, *supra* note 14.

[144] SHADOW OF THE REICH, *supra* note 14; Alexander Mitscherlich & Fred Mielke, *Epilogue: Seven Were Hanged*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 14, at 105.

were sentenced to extended prison terms, and all were free by 1967.[145] Some of the most notorious Nazi doctors, including Dr. Mengele, escaped capture and prosecution.[146] In fact, "[e]ven Nazi doctors who had been directly involved in murder could initiate or resume medical practice in their home areas and become conscientious, much-admired physicians. Hence, the strange three-part odyssey from pre-Nazi physician-healer, to Nazi-physician-killer, to post-Nazi physician-healer."[147] The United States directly contributed to this outcome via a program called "Paperclip," which encompassed employing 765 German and Austrian scientists, engineers, and technicians with the objective of exploiting their expertise and preventing remilitarization of post-war Germany.[148]

It is important to note that, given the thousands of doctors and many more thousands of medical professionals who engaged in the intentional mutilation and infliction of grave harm, refusal to treat, and murder of thousands of human beings under the auspices of research,[149] the defenses raised proved highly persuasive. The gist of these defenses was that involved medical professionals were simply following government orders during a time of war and at the hand of direct government coercion. Many of the medical professionals actually left the experience expressing belief that, on the whole, they were apolitical and simply did their jobs.[150] However, there remains much evidence to the contrary:

> Among physicians, there were as many volunteers as victims; no one had to *force* physicians to support the regime. Hans Hefelmann testified to this effect in the euthanasia trial at Limburg in 1946: "no doctor was ever ordered to participate in the euthanasia program; they came of their own volition."[151]

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[145] Mitscherlich & Mielke, *supra* note 144, at 105-07; SHADOW OF THE REICH, *supra* note 14.

[146] SHADOW OF THE REICH, *supra* note 14.

[147] LIFTON, *supra* note 14, at 457; *see also supra* note 141 and accompanying text (discussing Dr. Kurt Heissmeyer).

[148] Mitscherlich & Mielke, *supra* note 144, at 106-07; LINDA HUNT, SECRET AGENDA: THE UNITED STATES GOVERNMENT, AND THE PROJECT PAPERCLIP, 1945-1990 78-93 (1991). *See generally* TOM BOWER, THE PAPERCLIP CONSPIRACY: THE HUNT FOR NAZI SCIENTISTS (1987) (exploring the history and consequences of the Paperclip Conspiracy). Some participants in this program subsequently were prosecuted for war crimes. Mitscherlich & Mielke, *supra* note 144, at 106-07.

[149] *See* Proctor, *supra* note 30, at 27-29.

[150] SHADOW OF THE REICH, *supra* note 14.

[151] Proctor, *supra* note 30, at 28. Nevertheless, presumably the circumstances caused some to believe that the choice they faced was, rather than a professional one, a choice of life or death—especially for Jewish health care providers. Although readily distinguishable, consider the story of Dr. Gisella Perl, a Jewish gynecologist who performed more than 1,000 abortions in Auschwitz in order to save the lives of women, many of whom were destined for the gas chamber because guards impregnated them. GISELLA PERL, I WAS A DOCTOR IN AUSCHWITZ (1948); *Out of The Ashes* (Showtime television broad-

Although the number of prosecutions and convictions was small, the tone and implications of the doctors' trial extended far beyond prosecution of the culprits charged. The world's medical profession, largely via founders of the World Medical Association which came into being during the process, was asked how doctors, recognized as healers, could have engaged in some of the most immoral antihuman crimes ever imagined. There was strong international consensus that measures had to be taken to ensure that these pages from history were never duplicated.[152] The trial put in motion codification of basic principles that, over the following decades, became codified as international professional standards, then domestic professional standards and, ultimately, the domestic rule of law in countries such as the United States.[153]

B. *Post-WWII "New Eugenics"*

In the aftermath of WWII, German *geneticists* like their medical profession counterparts claimed that they were victims of the regime, not willing participants in Nazi medicine. "They knew nothing of the mass murders of mental patients and Jews. Even if they had joined the party, none had been Nazis 'at heart.' They found Nazi racism abhorrent. There were no traces of anti-Semitism in their work. Some of their best friends were Jews."[154] However, they were not able to erase memories of their actions through denial, for those were too plentiful, public, and recent:

> Most of Germany's leading geneticists—including those who prior to 1933 had criticized anti-Semitism—actively helped construct the racial state. They served on important commissions, provided opinions on individuals' racial ancestry, gave courses on genetics for SS doctors, participated in the drafting of racial laws. More than half of all academic biologists joined the Nazi Party, the highest membership rate of any professional group. That so many joined the Party (and also the SS and SA) is not explained by pressure; in fact, there was remarkably little. For example, party members and nonmembers had equal success in obtaining grants for their research. It rather reflects their enthusiasm for a regime that finally gave biologists, and geneticists in particular, the support they thought was their due. Far from being repressed, genetics—which was considered to be of great ideological,

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cast, Apr. 13, 2003); Robin Pogrebin, *Entering the Gray Areas of Survivalist Morality*, N.Y. TIMES, Apr. 13, 2003 § 13 (Television), at 4.

[152] SHADOW OF THE REICH, *supra* note 14.

[153] *See* discussion *infra* Part IV (examining the effect of the Nuremberg trials on the evolution of medical ethical standards).

[154] PAUL, *supra* note 13, at 91 (citations omitted).

> military, and economic importance to the regime—flourished in the Third Reich. Basic research was generously funded, career chances were expanded, and restrictions on experimental work were minimized.[155]

Given the Germans' reliance on eugenics as a "scientific" rationale for genocide, the eugenics movement was immediately criticized sharply (both externally and internally) in reaction to dissemination about the details of Nazi medicine and the Holocaust.[156] Even prior to the full Nuremberg disclosure, the movement had swelled and had begun to show fraying seams, especially between geneticists who valued biodiversity and eugenicists who sought to direct human evolution.[157] Growth of the movement during the 1920s encompassed differences of opinion that tested unity, as was readily apparent by the 1930s, and from the fray arose a smaller, contained, and more scientifically sound movement known as "new eugenics":

> The 1930s represent a period of dissension and reform within the eugenics movement in Britain and the United States. Advances in genetics and medicine, criticism of eugenics research and propagandist campaigns, and a sensitivity to the race and class prejudices, heightened by Hitler's translation of eugenics into a national race hygiene program, all contributed to reforms within the movement. Proponents of the "new eugenics" of the 1930s stressed the role of environment in shaping intellect and behavior, eliminated the rhetoric of racial inequality, condemned anti-Semitism, and abandoned analogies between animal breeding and human betterment. While some eugenicists adhered to the old, or "mainline," eugenics, the new eugenics enjoyed the support of scientists and maintained a notable constituency after World War II.[158]

Geneticists worked to draw an even darker delineation between genetics and eugenics, equating the latter with soft social science.[159] The new

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[155] *Id.* (citations omitted).

[156] GALLAGHER, *supra* note 24, at 4-6; *see also infra* note 159. "After World War II, however, biologists in the United States and Britain fought—by and large successfully—to emancipate human genetics from such biases in order to establish it as a solid field of science that would explain the complexities of human hereditary and assist medicine by illuminating the relationship of genetics to disease." KEVLES, *supra* note 28, at vii.

[157] "The eugenics movement was international, politically diverse, and wrought with internal tensions as its moral and scientific ambiguities became apparent." GALLAGHER, *supra* note 24, at 2.

[158] *Id.* at 4-6.

[159] *See generally* KEVLES, *supra* note 28 (stating that criticisms of the "science" underlying eugenics were valid). *See* discussion *supra* notes 38, 47 and accompanying text. As explained by author Daniel Kevles:

> During the heyday of eugenics—much of the first half of the twentieth century—social prejudice often overwhelmed scientific objectivity in the investigation of hu-

eugenics movement had a difficult time recapturing a meaningful concentration of its pre-Nuremberg popularity:

> The American Eugenics Society continued to revise its eugenic mission in response to scientific and political developments through the 1960s, as it supported research on world population problems, birthrates, and birth control; genetics counseling; and "social biology." Still, the "old eugenics" cast a long shadow on enterprises concerning the quality of the human gene pool, and the term was finally abandoned after 1970.[160]

In addition to the searing wounds associated with the release of details of Nazi medicine and the lingering stigma on eugenics, the movement was been hampered by another trend that the Holocaust and Nuremberg put into motion—a fundamental shift in medical ethos from provider to patient-determined decision-making, culminating with the present emphasis placed on informed consent and patient autonomy.[161]

IV. NUREMBERG TO THE PRESENT: EVOLUTION OF REGULATIONS TO PROTECT HUMAN SUBJECTS AND MEDICAL ETHICS

Although the prosecutions and convictions of Nazi doctors were largely symbolic, Nuremberg has had a penetrating sociological, professional, and legal impact during the decades that have followed. The facts disclosed leading into and during the Doctors' trial shocked civilized society.[162] Even more shocking was the realization that, before the trial, determinative, fundamental bioethical and medical standards were not enforced by the authorities and, rather, were largely entrusted to the practice of the medical profession.[163] Prior to and at the time of Nuremburg, the medical

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> man genetics. Social distinctions of race and class were commonly attributed to differences in biological merit. After World War II, however, biologists in the United States and Britain fought—by and large successfully—to emancipate human genetics from such biases in order to establish it as a solid field of science that would explain the complexities of human hereditary and assist medicine by illuminating the relationship of genetics to disease.

KEVLES, *supra* note 28, at vii.

[160] GALLAGHER, *supra* note 24, at 6.

[161] *See infra* Part IV.

[162] PRICEWATERHOUSECOOPERS LLP, PROTECTING THE PEOPLE WHO VOLUNTEER TO PARTICIPATE IN RESEARCH 11 (Thomas Publisi & Michele K. Russell-Einhorn eds., 2001) [hereinafter PROTECTING THE PEOPLE]; *see also* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 14, at 61-120 (providing a summary of the aftermath of the trial; a discussion of the origin of the Nuremberg Code; and photographs of the judges, the courtroom, counsel, defendants, and exhibits).

[163] SHADOW OF THE REICH, *supra* note 14; *see also* Sharon Perley et al., *The Nuremberg Code: An International Overview*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 14, at 151-52. "[T]he Nuremberg Code was enumerated as part of the judgment against Karl Brandt and his co-defendants. The Code was based on the testimony of two U.S. physicians, Drs. Leo Alexander and

profession throughout the world generally was left to self-regulate,[164] and one of the challenges of the Nuremberg Doctors' trial was to develop and articulate guiding, objective principles against which the actions of the medical profession could be judged objectively.[165] The medical profession's embarrassment and threatened loss of trust and authority prompted a strong reaction, primarily through founding the World Medical Association ("WMA") in 1947.[166] Many principals of the WMA were actively involved in the Nuremberg proceedings, and the founding of the WMA may be interpreted as a self-declaration by the international medical community that measures had to be taken to ensure that Nazi medicine would never be repeated.[167]

The immediate work product of the Doctors' trial was the Nuremberg Code—ten principles developed to judge the actions of the Nazi doctors in the absence of preexisting codified guidance.[168] The Code emphasized that there must be no research on human subjects without their voluntary, informed consent.[169] Under the Code, the advancement of knowledge for the

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Andrew Ivy, who served as expert medical witnesses for the prosecution." *Id.* at 151-52. At its core, the Code constitutes criteria formulated during the course of a trial for war crimes to be used to judge the acts of physicians. *Id.* at 152 (internal citations omitted).

[164] *See* PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 79-144 (1982) ("The Consolidation of Professional Authority, 1850-1920"). Illustrative of this point, consider that Rudolf Ramm, a Nazi medical ethicist, "noted in his 1942 book on medical ethics that physicians will often encounter patients who complain of the treatment they have received from another doctor. Ramm advised that physicians should *always take the side of the other doctor*, turning a blind eye to whatever incompetence or malpractice their colleagues may be accused of." Proctor, *supra* note 30, at 29 (citation omitted).

[165] *See* PAUL CARRICK, MEDICAL ETHICS IN THE ANCIENT WORLD 214-15 (2001); Michael A. Grodin, *Historical Origins of the Nuremberg Code*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 14, at 137 (concluding that "[i]t is not surprising that, in the context of criminal judgment, the judges found the need to go beyond the guilty verdict and to speak to the broader norms of medical ethics. The Nuremberg Code is an attempt to provide a natural law based universal set of ethical principles.").

[166] *See* CARRICK, *supra* note 165, at 217; Perley et al., *supra* note 163, at 154 (stating in an article in the first issue of WMA's journal, "that among the most important of the actions taken by the WMA in its assembly in Geneva in September 1948 was the adoption of a form of dedication by the physician to his profession of medicine") (internal citations omitted).

[167] *See* CARRICK, *supra* note 165, at 219 ("Nor need we consider in detail all the possible personal injuries or deaths that would be visited on innocent persons if individual doctors, or the societies to which they belonged, ever lost their moral footing. The medical agenda of Nazi Germany immediately comes to mind . . . ."); PROTECTING THE PEOPLE, *supra* note 162, at 11.

[168] *See* Grodin, *supra* note 165, at 137; PROTECTING THE PEOPLE, *supra* note 162, at 11.

[169] 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, 181 (William S. Hein & Co., Inc. 1997) (1949). The first principle of the Nuremberg Code, which underscores that the psychological integrity of research subjects must be protected absolutely, provides:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent, should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching or other ulterior form of constraint

benefit of mankind always must be secondary to the well-being of human subjects.[170] As explained by humanities professor Elie Wiesel:

> I once read a dissertation—from the University of California, I think—by a psychiatrist who maintains that the sense of morality was not impaired in these killers. They knew how to differentiate between good and evil. Their sense of *reality* was impaired. Human beings were not human beings in their eyes. They were abstractions. This is the legacy of the Nuremberg Tribunal and the Nuremberg Code. The respect for human rights in human experimentation demands that we see persons as unique, as ends in themselves.[171]

The Code put into motion efforts by the global and then national medical societies to interpret and codify the principles recognized into professional standards.[172] This effort started with establishment of the WMA in 1947 and the WMA's Declaration of Helsinki in 1964,[173] which in turn inspired the American Medical Association ("AMA") and sister organizations in other nations to take similar measures domestically.[174] Ultimately,

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> or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.

Id.

[170] *See id.* at 181-82; Jay Katz, *The Consent Principle of the Nuremberg Code: Its Significance Then and Now*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 14, at 236 (explaining that the code "commanded that the principle of the advancement of science bow to a higher principle: protection of individual inviolability").

[171] Elie Wiesel, *Foreword* to THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 14, at ix.

[172] *See* Perley et al., *supra* note 163, at 154 (explaining that Nuremberg and the resulting Nuremberg Code were an impetus for the founding of the WMA, which was established in 1947); PROTECTING THE PEOPLE, *supra* note 162, at 11.

[173] *See* Figure 2; World Medical Association, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* (1964, revised 1975, 1983, 1989, 1996, 2000, 2002), *available at* http://www.wma.net/e/policy/pdf/17c/.pdf (last visited Aug. 25, 2003) (on file with the Connecticut Law Review); COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES, INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS 8 (1993) ("The purpose of the Guidelines was to indicate how the fundamental ethical principles that guide the conduct of biomedical research involving human subjects, as set forth in the World Medical Association's Declaration of Helsinki, could be applied effectively, particularly in developing countries, taking into account culture, socioeconomic circumstances, national laws, and executive and administrative arrangements."); Perley et al., *supra* note 163, at 157-60 ("The draft code went through a number of revisions and was finally adopted by the 18th World Medical Assembly in Helsinki in 1964.").

[174] *See* AMERICAN MEDICAL ASSOCATION, COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS CODE OF MEDICAL ETHICS (2000-01 ed.) x-xi; Michael J. Malinowski & Eric Rose, *Regulation of Human Subjects Research*, *in* MICHAEL J. MALINOWSKI ET AL., BIOTECHNOLOGY: LAW, BUSINESS AND REGULATION 9-16 (1999) (explaining that the AMA's code has been increasingly supplemented to complement related government initiatives and actions).

the governments of the United States and many other nations codified interpretations of the fundamental principles and standards into their rules of law.[175]

FIGURE 1: HUMAN SUBJECTS' PROTECTION TIMELINE—FROM PRINCIPLES TO LAW

1949.....*Nuremberg Code*

1964.....*Declaration of Helsinki (World Medical Association)*

1966.....*U.S. Public Health Service Order 129 (precursor to IRBs)*

1932-72.....*U.S. Public Health Service Syphilis Study at Tuskegee*

1974.....*National Research Act (establishes the National Commission for the Protection of Human Subjects). The Office for Protection from Research Risks ("OPRR"), also established under the Act and situated in NIH, oversees compliance with human subject protection regulations*

1979.....*The Belmont Report (issued by the National Commission)*

1981.....*DHHS (45 C.F.R. Part 46) and FDA (21 C.F.R. pts. 50 and 56) issue parallel regulations on informed consent and IRB review*

1991.....*Subpart A of the DHHS Regulations (45 C.F.R. pt. 46) are adopted by 15 other federal agencies as "The Common Rule"*

2000.....*The Office for Human Research Protections ("OHRP"), situated in the Office of the Secretary, DHHS, replaces OPRR*

Domestic interpretation, meaning the weaving of these principles into domestic R&D funding, regulatory schemes, and health care systems, has proven somewhat idiosyncratic and reactive to ugly controversies that capture public and political attention.[176] For example, through the early 1970s,

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[175] *See* Malinowski & Rose, *supra* note 174, at 9-16 to 9-17 ("Many of the Belmont Report recommendations have been implemented by federal agencies, including the FDA and HHS.").

[176] *See* George J. Annas, *The Nuremberg Code in U.S. Courts: Ethics versus Expediency*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 14, at 217-19 (explaining that, after Nurem-

the United States government continued with a research agenda, that grinded against the Nuremberg Code and Declaration of Helsinki.[177] Most notably, during the 1950s and 1960s, disclosure of a string of incidents raised public concern: radiation and other experimentation on enlisted military men and patients, including children, institutionalized for mental health, "the dubious transplantation of an animal kidney into a human patient, the 'bugging' by social scientists of jury deliberations in Kansas, the injection of live cancer cells into patients at the Jewish Chronic Disease Hospital, and scientist Henry Beecher's publications (1959, 1966) discussing examples of ethically questionable research."[178]

For the United States, public disclosure of the Tuskegee study, a syphilis study funded by the Public Health Service ("PHS") over four decades, captured the attention of the American public and became a profound turning point:

> The infamous "Tuskegee Study of Untreated Syphilis in the Negro Male" was a 40-year research study conducted in Macon County, Alabama, by PHS physicians. Initiated in 1932, the research targeted poor African-American sharecroppers suffering from syphilis, but was presented to subjects as a study of "bad blood." The study continued until a July 26, 1972 *New York Times* story, "Syphilis Victims in U.S. Study Went Untreated for 40 Years" exposed it as "the longest non-therapeutic experiment on human beings in medical history."[179]

Details of the study, which decades later compelled an apology from the United States government under the Clinton Administration,[180] constitute textbook violations of the fundamental requirements of bioethics. The study encompassed 600 men, 399 men with latent syphilis and a control group of 201 men without the disease,[181] who were "encouraged" to participate through free meals, free medical examinations, and free burial in-

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berg, human experimentation became a mainstream and valued activity, but the courts have fumbled with the Code, troubling experimentation has taken place in the U.S. post-Nazi era, and promise of the Nuremberg Code has not been fulfilled in the United States); FUKUYAMA, *supra* note 6, at 201 (domestically, "[r]ules regarding human experimentation evolved in tandem with regulation of the drug industry in the United States, and were driven forward in each instance by the revelation of scandal or atrocity.").

[177] *See* PROTECTING THE PEOPLE, *supra* note 162, at 12-13.

[178] *Id.* at 12; *see also* Henry K. Beecher, ETHICS AND CLINICAL RESEARCH, 274 NEW ENG. J. MED. 1354, 1354 (1966) (discussing troubling practices in medicine involving human experiments); FUKUYAMA, *supra* note 6, at 201 (detailing medical experiments that raised public unease).

[179] PROTECTING THE PEOPLE, *supra* note 162, at 12.

[180] *Id.* at 13.

[181] *Id.* at 12.

surance.[182] "In a reprehensible breach of ethics, investigators took specific steps to ensure that subjects were denied access to effective treatment, even after penicillin became widely available, to preserve the integrity of the research."[183]

Tuskegee inspired Senate hearings and legislation, Title II of the National Research Act of 1974,[184] which mandated regulation to protect human subjects and the formation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research ("National Commission").[185] This Commission issued *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*,[186] a guideline for distinguishing biomedical research and the practice of medicine that centers on identification and elucidation of three touchstone ethical principles: (1) respect for persons, implemented through realization of informed consent; (2) beneficence, implemented by assessing and comparing risks and benefits from the perspective of the person(s) involved in the study; and (3) justice, implemented through an objective assessment of the fair selection of subjects.[187]

In conjunction with the establishment and operations of the National Commission, in May 1974, the Department of Health Education and Welfare, predecessor of the Department of Health and Human Services ("DHHS"), codified its policy on protection of human subjects.[188] In response to the Commission's recommendations, DHHS greatly enhanced its human subject regulations and implemented a significant revision in January 1981.[189] Simultaneously, the Food and Drug Administration ("FDA") issued parallel regulations[190] and additional product-specific regulations pertaining to the protection of human subjects.[191] In 1981, another commission, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, recommended that the United States adopt uniform regulations for all federally supported human

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[182] *Id.*

[183] *Id.* at 12-13.

[184] National Research Service Award Act of 1974, Pub. L. No. 93-348, § 211, 88 Stat. 342 (repealed 1978).

[185] PROTECTING THE PEOPLE, *supra* note 162, at 13.

[186] NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROT. OF HUMAN SUBJECTS OF RESEARCH (1978).

[187] PROTECTING THE PEOPLE, *supra* note 162, at 13.

[188] 45 C.F.R. §§ 46.1-.22 (1974).

[189] 45 C.F.R. §§ 46.101, 46.109-.111 (1981).

[190] *See* Protection of Human Subjects, 21 C.F.R. §§ 50.1-.56 (2003) (providing guidelines for informed consent of human subjects); 21 C.F.R. §§ 56.101-.124 (2003).

[191] *See* Investigational New Drug Application, 21 C.F.R. §§ 312.1-.160 (2003); Biological Products, 21 C.F.R. §§ 600.3-.90 (2003); Investigational Device Exemptions, 21 C.F.R. §§ 812.1-.150 (2003).

subject research.[192] A decade later, the United States largely realized this recommendation through codification of the Common Rule,[193] which currently is implemented by seventeen federal agencies: the Department of Agriculture;[194] Department of Energy;[195] National Aeronautics and Space Administration;[196] Department of Commerce;[197] Consumer Product Safety Commission;[198] International Development Cooperation Agency, Agency for International Development;[199] Department of Housing and Urban Development;[200] Department of Justice;[201] Department of Defense;[202] Department of Education;[203] Department of Veterans Affairs;[204] Environmental Protection Agency;[205] Department of Health and Human Services;[206] National Science Foundation;[207] Department of Transportation;[208] Central Intelligence Agency;[209] and Social Security Administration.[210] The Common Rule and FDA regulations require institutions engaging in covered human subjects research to establish Institutional Review Boards ("IRBs") to preapprove and oversee human subjects research.[211] In fact, all grant *applications* for federal funding that encompass research on human subjects must include a pre-approved protocol that specifies measures to ensure that voluntary informed consent is obtained from subjects prior to their participa-

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[192] Protection of Human Subjects; First Biennial Report on the Adequacy and Uniformity of Federal Rules and Policies, and their Implementation for the Protection of Human Subjects in Biomedical and Behavioral Research; Report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 47 Fed. Reg. 13,272, 13,274 (March 29, 1982).

[193] Federal Policy for the Protection of Human Subjects, 45 C.F.R. §§ 46.101–.124 (2003).

[194] 7 C.F.R. §§ 1c.101–.124 (2003).

[195] 10 C.F.R. §§ 745.101–.124 (2003).

[196] 14 C.F.R. §§ 1230.101–.124 (2003).

[197] 15 C.F.R. §§ 27.101–.124 (2003).

[198] 16 C.F.R. §§ 1028.101–.124 (2003).

[199] 22 C.F.R. §§ 225.101–.124 (2003).

[200] 24 C.F.R. § 60.101 (2003).

[201] 28 C.F.R. §§ 46.101–.124 (2003).

[202] 32 C.F.R. §§ 219.101–.124 (2002).

[203] 34 C.F.R. §§ 97.101–.124 (2002).

[204] 38 C.F.R. §§ 16.101–.124 (2002).

[205] 40 C.F.R. §§ 26.101–.124 (2002).

[206] 45 C.F.R. §§ 46.101–.124 (2002).

[207] 45 C.F.R. §§ 690.101–.124 (2002).

[208] 49 C.F.R. §§ 11.101–.124 (2002).

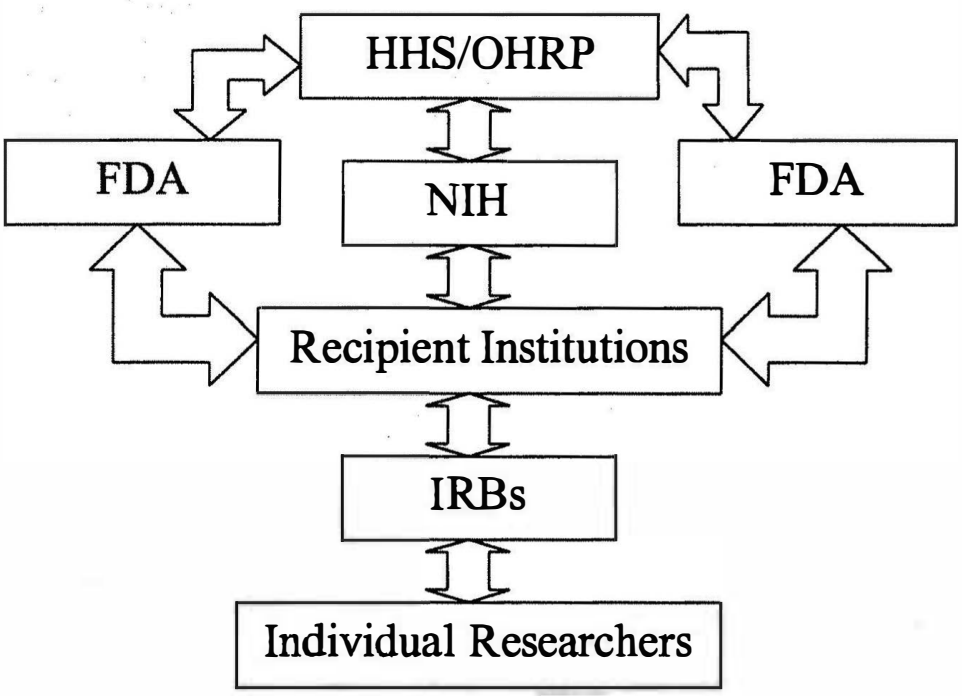
[209] Jeffrey Cohen, Ph.D., Associate Director of Education, Office for Protection from Research Risks, Department of Health and Human Services National Institutes of Health, Presentation at Fordham University School of Law (Feb. 16, 2000) (stating that FDA has regulations that are distinct from those adopted by all other research-oriented agencies in the United States Government).

[210] *See id.*

[211] *See* 45 C.F.R. §§ 46.102(g), 46.103(b)(4), 46.103(b)(5), 46.108(a) (2003); 21 C.F.R. 50.3(i)(2003). *See generally* Malinowski & Rose, *supra* note 174 (explaining the general framework for human subject research regulation in the United States); PROTECTING THE PEOPLE, *supra* note 162.

tion.[212] The Office for Human Research Protections ("OHRP") within the Office of the Secretary of Health and Human Services ("HHS") reviews IRB performance and policies.[213] All institutions, both domestic and international, must file an Assurance with OHRP before enrolling subjects in research.[214] Figure 2 illustrates the resulting regulatory regime.

FIGURE 2: HUMAN SUBJECT PROTECTION REGULATIONS—REPORTING AND ACCOUNTABILITY



The net effect of the Common Rule and FDA regulations is that direct U.S. federal jurisdiction over human subject research encompasses research conducted or supported by the federal government and research regulated under a specific federal statute—i.e., most notably research regu-

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[212] *See* Federal Policy for the Protection of Human Subjects, 45 C.F.R.§§ 46.109(c), 46.116-.117 (2002).

[213] Office for Human Research Protection, OHRP Homepage, *at* http://ohrp.osophs.dhhs.gov (last visited Aug. 21, 2003) (on file with the Connecticut Law Review).

[214] *See* Malinowski & Rose, *supra* note 174, at 9-17, 9-23 (explaining that "many biomedical research institutions and academic medical centers file general assurances with OPRR" and discussing the guidelines in place for experimental drug and genetic research); PROTECTING THE PEOPLE, *supra* note 162, at 340 ("An institution that receives funding from a Federal Policy (Common Rule) department or agency to conduct research . . . must ensure that all collaborating institutions file an Assurance before enrolling human subjects. This Assurance requirement applies to both domestic and international institutions."). Registration information is available on OHRP's Web Office for Human Research Protection's website. Office for Human Research Protection, Assurances and IRB Registration, *at* http://ohrp.osophs.dhhs.gov (last visited Aug. 21, 2003) (on file with the Connecticut Law Review).

lated under the FDA's enabling legislation.[215] No medicinal product within the FDA's jurisdiction can be introduced into the market for human use without pre-approval by the agency, which includes limited market access to engage in research on human subjects to establish safety and/or efficacy. The latter requires an FDA-approved investigational new drug ("IND") or investigational device exemption ("IDE") application.[216] However, the U.S. protection of human subjects has its limitations: "At this time, human subject research neither regulated by the FDA (meaning not involving an investigational drug) nor supported by the federal government is not subject to direct federal oversight."[217] Also, limitations on the FDA's ability to interfere with the practice of medicine has left the delivery of clinical services, including many arguably experimental services, largely to the discretion of the medical profession[218]—even though the contemporary physician's objective discretion has been pruned immensely by managed care and other financial influences.[219] Even when the regulations are applied, their reliability has been called into question.[220] Moreover, there are in-

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[215] Most notable are the Federal Food, Drug, and Cosmetic Act, as amended by the Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (codified in scattered sections of 21 U.S.C.); the Medical Device Amendments of 1992, Pub. L. No. 102-300, 106 Stat. 238; and the Public Health Services Act, 42 U.S.C. § 262 (2000).

[216] *See* 21 C.F.R. §§ 312.3(b), 312.20 (2003) (outlining the requirement for an Investigational New Drug Application); 21 C.F.R. §§ 50.3(b)(15), 50.24(d), 56.102(b)(12) (2003) (outlining the requirement for an Investigational Device Exemption).

[217] *Institutional Conflicts*, *supra* note 19, at 60.

[218] *See* discussion *infra* Part V.

[219] *See* Timothy S. Hall, *Bargaining with Hippocrates: Managed Care and the Doctor-Patient Relationship*, 54 S.C. L. REV. 689, 740 (2003) ("One of the most telling criticisms of managed care is that it has allowed its cost-control function to override, at least in some ways and for some consumers, the fundamental truth of the physician-patient relationship—that the physician's ultimate responsibility must be to the individual patient."); Aaron Seth Kesselheim, Comment, *What's the Appeal? Trying to Control Managed Care Medical Necessity Decisionmaking Through a System of External Appeals*, 149 U. PA. L. REV. 873, 880-81 (2000) (discussing how in the late eighties managed care organizations began restraining the way physicians provide care "either directly through rules and organizational controls limiting the options available to health care providers or indirectly by modifying health care providers' behavior through financial incentives"); Michael J. Malinowski, *Capitation, Advances in Medical Technology, and the Advent of a New Era in Medical Ethics*, 22 AM. J. L. & MED. 331, 338 (1996) [hereinafter *New Era*] (stating that "care managers are assuming direct control over patient care decision-making, thereby shrinking the discretion to which physicians have grown accustomed").

[220] For example, in June 2003 a task force of the Association of American Medical Colleges introduced a set of guidelines for research using human subjects that proposed more intensive review before trials begin and monitoring where researchers hold more than a minimal financial interest. Draft "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection," 68 Fed. Reg. 15456 (March 31, 2003); *see also* Editorial, *Keeping Research Clean*, BOSTON GLOBE, June 15, 2003 at H10; LEXIS, News Library, Bglobe file ("[A] task force of the Association of American Medical Colleges has come up with a set of guidelines for research using human subjects, calling for more intensive review before trials begin and monitoring of any studies in which a researcher has more than a minimal financial interest"); *Protecting Subjects, Preserving Trust, Promoting Progress II—Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research*, TASK FORCE ON FINANCIAL CONFLICTS OF INTEREST IN CLINICAL RE-

stances in which the FDA has demonstrated regulatory passivity—including its regulation of human tissue products, which was the focus of a Senate Investigative Committee inquiry and public testimony in May 2003 following the death of a young man who received contaminated cartilage.[221]

Whether consistently realized in practice, informed consent has evolved from the guiding principle recognized at Nuremberg to a codified standard that constitutes the cornerstone of the United States' human subject protections regime.[222] Legally sound informed consent must be obtained from subjects before they are exposed to experimentation,[223] meaning consent under conditions that provide "sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."[224] Moreover, federal regulations constitute a floor, not a ceiling, for they expressly provide that "[t]he informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be

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SEARCH 2 (Association of American Medical Colleges, Oct. 2002) ("[T]he report offers a conceptual framework for assessing institutional conflicts of interest and a set of specific recommendations for the oversight of certain financial interests in human subjects research that, in the view of the AAM's Task Force, are especially problematic and must therefore receive close scrutiny), *available at* http://www.aamc.org/members/coitf/2002coireport.pdf (last visited on Aug. 21, 2003) (on file with the Connecticut Law Review); *Protecting Subjects, Preserving Trust, Promoting Progress – Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research*, TASK FORCE ON FINANCIAL CONFLICTS OF INTEREST IN CLINICAL RESEARCH (Association of American Medical Colleges, Dec. 2001) (offering "guidance to institutions in their efforts to provide responsible and effective oversight of financial interests in human subject research"), *available at* http://www.aamc.org/members/coitf/firstreport.pdf (last visited on Aug. 21, 2003) (on file with the Connecticut Law Review).

[221] *See infra* note 486 and accompanying text. *But see* Adamson, *supra* note 21, at 936-37 (anticipating FDA assertion of regulatory authority and enforcement with reliance on instances of FDA cease and desist letters to six ART programs engaging in cytoplasmic transfer on a research basis and a statement that lympohocyte immune therapy for recurrent pregnancy loss cannot be performed without an IND).

[222] *See* Malinowski & Rose, *supra* note 174, at 9-18 (describing "[t]he doctrine of informed consent [as] the bedrock of international and domestic codified standards that address the protection of human subjects in research").

[223] 21 C.F.R. § 50.20 (2003); 45 C.F.R. § 46.116 (2002).

[224] 21 C.F.R .§ 50.20 (2003); 45 C.F.R. § 46.116 (2002). Some commentators argue that:

> The use of human subjects for medical research without their informed consent—forbidden by the Nuremberg Code almost fifty years ago—is an instance of a misuse of medicine for goals otherwise acceptable. The ban against such research is almost absolute, applicable even if the research would save lives or provide other great benefits. Only in the case of children and the incompetent can exceptions be made, and then only for the direct benefit of the patient.

THE GOALS OF MEDICINE: THE FORGOTTEN ISSUE IN HEALTH CARE REFORM 31 (Mark J. Hanson & Daniel Callahan eds., 1999) [hereinafter GOALS]; *see also* Malinowski & Rose, *supra* note 174, at 9-33, Fig. 9-5 (identifying the fundamental elements of informed consent). *See generally* KENNETH GETZ & DEBORAH BORFITZ, INFORMED CONSENT: A GUIDE TO THE RISKS AND BENEFITS OF VOLUNTEERING FOR CLINICAL TRIALS (2002) [hereinafter INFORMED CONSENT] (analyzing informed consent from a potential subject's perspective).

disclosed for informed consent to be legally effective."[225] The federal regulations also identify and further protect vulnerable populations, including pregnant women,[226] fetuses, and children, and these regulations apply to psychological as well as pharmaceutical research.[227]

The trilogy of informed consent, patient self-determination, and patient autonomy also has become the cornerstone ethos for the practice of medicine in the United States and many other countries.[228] Over the last several decades, the reasonable physician standard (applied from the provider's perspective and resting on medical community judgment) has given way to the material-risks/informed patient standard (the boundaries of disclosure are established by the patient's need to know).[229] The roles of physician and patient have realigned to assure greater patient access to and control over information about their health care options. Perhaps most notably, the prevalence of managed care restrictions on physician discretion[230] and a

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[225] 21 C.F.R.§ 50.20 (2003); 45 C.F.R. § 46.116 (2002).

[226] 45 C.F.R. pt. 46, subparts B, D (2002) (Common Rule); 21 C.F.R. § 56.111(b) (FDA regulations).

[227] 45 C.F.R. pt. 46, subparts B, D (2002).

[228] "An important development in contemporary medicine in many countries, articulated in most international declarations, is increased recognition of the respect due persons. This has been most commonly understood most broadly to entail a right of self-determination, sometimes called autonomy, in medicine and health care." GOALS, *supra* note 224, at 34.

[229] Malinowski & Rose, *supra* note 174, at 9-35. "Physicians are obligated to disclose the risks of the treatment and the risks of foregoing it. . . . The ultimate decision rests on an assessment of what a reasonable patient in the same particular circumstances as the individual patient would consider material in formulating a decision." *Id.* at 9-21. This shift is very visible in professional standards for self-regulation, including those of the American Hospital Association. The American Hospital Association's original 1973 version of A Patient's Bill of Rights was open to withholding medical information from the patient to avoid harm over complete disclosure when the two were in conflict. However, the revised 1992 version promotes full disclosure—presumably a reflection of influences such as heightened appreciation of patient self-determination, the infusion of managed care, a deluge of medical innovation and care options, liability considerations, and economic influences. GOALS, *supra* note 224, at 34.

[230] *See* STARR, *supra* note 164, at 420-49 (indicating competitive pressures in medicine may increase patient access to health care professionals); *Market Implications*, *supra* note 5, at 42 ("The research community, medical community, and even the general public should anticipate access to more pharmacogenomic testing capabilities in the foreseeable future."); KENNETH M. LUDMERER, TIME TO HEAL: AMERICAN MEDICAL EDUCATION FROM THE TURN OF THE CENTURY TO THE ERA OF MANAGED CARE 349-69 (1999) (discussing the rise of managed care in the context of the development of American medical education); *New Era*, *supra* note 219, at 335 (1996). The United States' shift from small practices affiliated with hospitals to consolidation and the domination of large managed care organizations has forced out considerable long-standing inefficiencies and reaped some short-term windfalls. Robin Toner & Sheryl Gay Stolberg, *Decade After Health Care Crisis, Soaring Costs Bring New Strains*, N.Y. TIMES, Aug. 11, 2002, at A1. However, although managed care stabilized the cost of health care in the mid-90s, a new period of turmoil is in sight. The combination of economic troubles and rising costs are pricing working Americans out of health care. "Health insurance premiums rose an average of 11 percent last year and are expected to rise an additional 13 percent this year after several years of very modest growth." *Id.* Premiums for small businesses are expected to rise even higher. *Id.* Prescription drugs rose at an average annual rate of 19.7 percent in the last two years, *id.*, and the

deluge of technological advances attributable to the genetics revolution have overwhelmed members of the medical profession and encouraged patients to demand and seek out information from their doctors, each other, and a range of Internet resources.[231] Today, patients and their physicians routinely look into the drug development pipeline for health care options, thereby commingling clinical research and clinical care.[232] In addition, the prevalence of academic-industry collaborations and general integration of academia and industry in contemporary biomedical research and development necessitate higher standards of disclosure to prevent and manage conflicts of interest that threaten research integrity and patient safety.[233] Unfortunately, the majority of the nation's research institutions have failed to implement policies to meet the threshold of reasonable disclosure,[234] and the reliability of the United States regulatory regime to protect human subjects has fallen into question. These insufficiencies were well documented under the Clinton Administration following several national controversies,[235] and now the Bush Administration too has declared enhancement of

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relative precision of the genomics revolution in drug development will trigger unprecedented drug costs. "Politicians in both parties are beginning to respond, but they are profoundly divided on the issue . . . ." *Id.*

[231] Clinical care and clinical research are integrating through a range of sites compiling and making available data on clinical trials, including the U.S. government's www.clinicaltrials.gov. *See Institutional Conflicts, supra* note 19, at 53-56, 66-68. "The public is seeking access, and the advent of information technology is helping to make access possible." *Id.* at 54; *see also* GOALS, *supra* note 224, at 42 (citing the market's role in patient access).

[232] *See Institutional Conflicts, supra* note 19, at 53-56, 66-68 (exploring the growing relationship between clinical research and patient care).

[233] *See* Janet Fleetwood, *Conflicts of Interest in Clinical Research: Advocating for Patient-Subjects*, 8 WIDENER L. SYMP. J. 105 (2001) (indicating that disclosure may alleviate conflict of interest concerns). *Cf.* Lita Nelson, *The Rise of Intellectual Property Protection in The American University*, SCIENCE, 279, *available at* http://www.sciencemag.org/cgi/content/full/279/5356/1460 (last visited Sept. 2, 2003) (on file with the Connecticut Law Review) (citing benefits of industrial support of clinical research, especially for students); Mark G. Edwards et al., *Value Creation and Sharing Among Universities, Biotechnology and Pharma*, 21 NATURE BIOTECHNOLOGY 618-24 (June 2003) (finding universities play a pivotal role in the biotechnology revolution through collaborations with industry).

[234] *See* Mildred K. Cho et al., *Policies on Faculty Conflicts of Interest at US Universities*, 284 JAMA 2203 (2000) ("Most policies on conflict of interest at major US research institutions lack specificity about the kinds of relationships with industry that are permitted or prohibited."); Patricia Baird et al., *Clinical Trials and Industry*, SCIENCE, Sept. 27, 2002, at 2211 (addressing disputes between clinical researchers and pharmaceutical manufacturers, and asserting that these disputes highlight the critical importance of protecting the right of trial subjects to disclosure of risks and the academic freedom of investigators).

[235] The most notable controversy was the death of Jesse Gelsinger, an 18-year-old gene-therapy subject in a protocol approved by the University of Pennsylvania. *See* Univ. of Pa. Health Sys., Inst. For Human Gene Therapy, Preliminary Findings Reported on the Death of Jesse Gelsinger, *at* http://www.med.upenn.edu/ihgt/findings.html (last visited Aug. 23, 2001) (on file with author); Gelsinger v. Trustees of the Univ. of Pa., Case No. 000901885 (Pa. Ct. Com. Pl., filed Sept. 18, 2000), http://www.sskrplaw.com/links/healthcare2.html (last visited Aug. 23, 2001). For Paul Gelsinger's (the father of Jesse Gelsinger) thoughts about informed consent and more insight regarding this controversy, see *Foreword to* INFORMED CONSENT, *supra* note 224, at 11-12; *see also Institutional Conflicts, supra*

human subject protections and strengthening of conflicts of interest regulations national priorities and has established a Secretary's Advisory Committee on Human Research Protection ("SACHRP").[236]

V. CONTEMPORARY GENETICS: EXPANDING SCIENTIFIC CAPABILITIES

Completion of a draft map of the human genome in February 2002[237] demonstrated the potential of coupling biology and information technology ("bioinformatics"); advances in this and related enabling technologies propelled the project to completion from 1997 through 2001.[238] The resulting map constitutes identification of a digital code that contains three billion base pairs and approximately 30,000 genes.[239] This code, which is ninety nine point nine percent consistent among human beings, translates into a set of instructions that, combined with individual contributions to the tenth

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note 19, at 70-73 (addressing the Clinton Administration's response); Press Release, Department of Health and Human Services, Secretary Shalala Bolsters Protections for Human Research Subjects (May 23, 2000), *available at* http://www.hhs.gov/news/press/2000pres/20000523.html (last visited Sept. 2, 2003) (on file with the Connecticut Law Review) (citing initiatives to bolster protection of human research subjects); Donna Shalala, *Protecting Research Subjects—What Must Be Done*, 343 NEW ENG. J. MED. 808, 809 (2000) (proposing new disclosure guidelines for the protection of human research subjects).

[236] *See* M. Alexander Otto, *New Bush Research Advisory Committee Has Industry Ties, One Patient Advocate*, MED. RES. LAW & POL'Y, vol. 2, no. 2, ISSN 1539-4530 (Jan. 15, 2003); W. Randy Kubetin, *Outlook 2003: HIPAA, Human Subject Protection, Fraud, Among Year's Top Research Policy Concerns*, MED. RES. LAW & POL'Y REP. vol. 2 no.1, ISSN 1539 4530 (Jan. 1. 2003) *available at* http://pubs.bna.com/ip/BNA/mrl.nsf/is/a-a6g7d3w6.

[237] *See Market Implications*, *supra* note 5, at 31 n.1 (announcing completion of a "rough draft" on June 26, 2000, with the release of a "true," complete map due in 2003); Ed Regis, *Other People's Molecules*, N.Y. TIMES, Mar. 16, 2003 (Book Review), at 27 (reviewing JOHN SULSTON AND GEORGIA PERRY, THE COMMON THREAD: A STORY OF SCIENCE, POLITICS, AND ETHICS (2003)). The Human Genome Project was commenced in 1990 with an expected completion date of 2005. *Id.*

[238] *See The Human Genome*, ECONOMIST 3-14 (July 1, 2000) (stating that exponential progress in biotechnology parallels advances in computing); GOALS, *supra* note 224, at 7 (emphasizing advances in medicine and technology). In 1997, the Human Genome Project had exhausted half of its fifteen-year duration and ninety percent of its funding just to sequence approximately 2.68 percent of the human genome. Juan Enriquez & Ray Goldberg, *Transforming Life, Transforming Business: The Life-Science Revolution*, HARV. BUS. REV., Mar.-Apr. 2000, at 96. Advances in enabling technologies such as DNA chips and other bioinformatics capabilities propelled the mapping project to completion. *Id. See generally* NOVA, *Cracking the Code of Life* (PBS television broadcast, Apr. 17, 2001) [hereinafter *Cracking the Code*] (tracing the decoding of the Human Genome); *Snake Oil*, *supra* note 5 (discussing bioinformatics). Information about the Human Genome Project may be obtained from the National Human Genome Research Institute ("NHGRI"), available at www.nhgri.nih.gov (last visited Sept. 2, 2002) (on file with the Connecticut Law Review).

[239] FUKUYAMA, *supra* note 6, at 73-74. For information about the code, visit the Internet site of the National Institutes of Health's National Center for Biotechnology Information at http://www.ncbi.nlm.nih.gov/Genbank/GenbankOverview.html (last visited Sept. 2, 2003) (on file with the Connecticut Law Review). However, in June 2003, a group of scientists concluded that the genes in the human genome total just 21,000. *See* Nicholas Wade, *Gene Sweepstakes Ends, But Winner May Well be Wrong*, N.Y. TIMES, June 3, 2003, at F1.

of a percent variation and environmental factors, makes each of us the person that we are.[240] This translation, beginning with the identification of genes and gene and protein function (the fields of genomics and proteomics, respectively), is an ongoing effort that envelopes the forefront of drug research and development and the future of medicine:

> Beyond genomics lies the burgeoning field of proteomics, which seeks to understand how genes code for proteins and how the proteins themselves fold into the exquisitely complex shapes required by cells. And beyond proteomics there lies the unbelievably complex task of understanding how these molecules develop into tissues, organs, and complete human beings.[241]

There are approximately 30,000 genes and exponentially more proteins in the human body.[242] This composition suggests intense multitasking by genes, extraordinary interaction and complexity, and the need for voluminous data to make medical meaning out of the resulting genetic information—with the end product being mere probabilities, not medical certainties, in most instances.[243]

Nevertheless, the code is being translated.[244] In fact, the rate of transla-

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[240] *See* FUKUYAMA, *supra* note 6, at 73 (stating that a large percentage of the human genome consists of noncoding DNA, while the remainder constitutes genes that contain the actual blueprint for human life). For an insightful discussion of the journey humans have taken as a species and the practical influence of DNA on individuality, see SPENCER WELLS, THE JOURNEY OF MAN: A GENETIC ODYSSEY (2002); *Cracking the Code*, *supra* note 238 (tracing the decoding of the Human Genome); *How to Build a Human: Predictor* (BBC television broadcast, Jan. 2, 2002) (exploring gene connection to human behavior). Moving from base pairs to the level of genes and genetic expression, differences are multiplied however. For example, according to a discovery reported on June 16, 2003, the genomes of men and women differ by a full one to two percent—a difference equivalent to that between a man and a male chimpanzee, and between a woman and a female chimpanzee. Nicholas Wade, *Y Chromosome Depends on Itself to Survive*, N.Y. TIMES, June 19, 2003, at A20; *see also* Helen Skaletsky et al., *The Male-Specific Region of the Human Y Chromosome is a Mosaic of Discrete Sequence Classes*, 423 NATURE 825-837 (June 19, 2003) (presenting data regarding genetic differences between males and females and other mammals).

[241] FUKUYAMA, *supra* note 6, at 74 (internal citations omitted); *see also The Human Genome*, *supra* note 238, at 4 ("Proteins are the workhorses of biology. Almost every molecule in the body is either a protein or the result of a protein's activity."). James Watson refers to DNA as "the script" and proteins as "the actors." *See* Editorial, *A Cast of Thousands*, 21 NATURE BIOTECHNOLOGY 213 (Mar. 2003) (describing proteins as actors). *See generally Supplement: Proteomics*, 422 NATURE INSIGHT 191, 191-237 (Mar. 13, 2003) (discussing the forefront of proteomics research).

[242] *See* Nancy Gibbs, *The Secret of Life*, TIME, Feb. 17, 2003, at 42-45 (explaining that the typical gene may yield 20,500 different proteins).

[243] FUKUYAMA, *supra* note 6, at 73 (describing scientists' partial understanding and uncertainty about the number of genes in the Human Genome).

[244] For a thoughtful, elegant account of the fundamentals of DNA and evolution of the genetics revolution, see WATSON, *supra* note 20; *see also* GENOMICS AND WORLD HEALTH: REPORT OF THE ADVISORY COMMITTEE ON HEALTH RESEARCH, *supra* note 20 (reporting on health care developments since the completion of the Human Genome Project).

tion is escalating with the ongoing advancement of bioinformatics and other enabling technologies attributable largely to the pharmaceutical and biotechnology sectors' aggressive investment in the advancement and application of these tools.[245] This nexus between biology and information technology also is meaningful enough to work in the inverse, meaning that researchers are turning living cells into computers.[246] The pharmaceutical sector, confronted by a plethora of domestic and international market challenges juxtaposed against investor expectations inflated by decades of extraordinary profitability,[247] has embraced biotechnology in drug development.[248] The drug development industry has been dramatically increasing the percentage of revenue allocated to R&D in an attempt to replenish its pipeline and future revenue streams.[249] "The overall revenue allocated to R&D has risen from 11% to 18.5% over the last twenty years, and overall pharmaceutical investment in R&D has risen from approximately $2 billion in 1991 to $30.5 billion in 2001."[250] Through several fields that bridge

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[245] *See Market Implications*, *supra* note 5, at 31 ("Completion of a map of the human genome and the explosive emergence of a multitude of complementary technologies ranging from DNA chips . . . to sophisticated software have transformed great expectations for genetic medicine into goals potentially obtainable in the foreseeable future."); *Snake Oil*, *supra* note 5, at 28-33 (describing the accomplishments in the field of genetic research and health care); *The Human Genome*, *supra* note 238, at 4 (citing computers' contribution to the advancemet of genomics). *See generally* Robertson et al., *Pharmacogenetic Challenges for the Health Care System*, 21 HEALTH AFF. 155-67 (July–Aug. 2002) (defining and analyzing the development of pharmacogenetics).

[246] Jascha Hoffman, *Microbe-Processors*, BOSTON GLOBE, July 1, 2003, at C1, LEXIS, News Library, Bglobe File. Scientists are using knowledge of biology and information technology to actually program cells. These applications include using proteins and DNA within cells to create living circuits (the work of Ron Weiss at Princeton University), creating a working toggle (on/off) switch in which exposure to a particular protein makes a cell glow and heat makes it stop (Prof. Timothy Gardner, Boston University), and designing a bacterium that slowly glows red and green, "like Christmas lights in a Petri dish" (Professors Michael Elowitz and Stanislas LIebler, Rockefeller University). *Id.*

[247] *See* Michael J. Malinowski, *FDA Regulation of Biotechnology Products for Human Use*, *in* 1 ENCYCLOPEDIA OF ETHICAL, LEGAL, AND POLICY ISSUES IN BIOTECHNOLOGY 215, 224-25 (Thomas J. Murray & Maxwell J. Mehlman eds., 2000) (citing market challenges after decades of high revenues); *Market Implications*, *supra* note 5, at 34-35 ("After decades of solid profitability, pharmaceutical business plans to meet shareholder expectations based upon traditional rates of return have become uncertain if not wholly unrealistic.").

[248] *Market Implications*, *supra* note 5, at 39-43 (stating that advances in biotechnology are fueling R&D for patent applications). *See generally* Robertson et al., *supra* note 245 (describing advances in biotechnology as decreasing health costs and sparking new drug development).

[249] *See generally* Robertson et al., *supra* note 248; PHRMA, PHARMACEUTICAL INDUSTRY PROFILE 2003: NEW MEDICINES. NEW HOPE. (2003) [hereinafter PROFILE 2003], *available at* http://www.phrma.org/publications/publications/profile02/index.cfm; PHRMA, PHARMACEUTICAL INDUSTRY PROFILE 2001: A CENTURY OF PROGRESS 14 (2001) [hereinafter PROFILE 2001], *available at* www.phrma.org; PHRMA, PHARMACEUTICAL INDUSTRY PROFILE 2000 (2000) [hereinafter PROFILE 2000] *available at* www.phrma.org.

[250] *Market Implications*, *supra* note 5, at 38 (citing PROFILE 2001, *supra* note 249, at ch. 2). According to the latest data from the Tufts Center for the Study of Drug Development, an industry-funded Center, developing an innovative drug, including studies required after regulatory approval, costs $897 million—a significant jump from the $802 million estimated in November 2001. Joseph A. DiMasi et

science and information technology, the industry anticipates identifying as many as 10,000 drug targets over the next several years—a jolting shift from decades of dependence on approximately 3,000 commercial pharmaceuticals derived from just 483 drug targets.[251]

The alliance-based nature of biotechnology R&D, reflected in the extraordinary integration of biotechnology and pharmaceutical companies, and industry and academia through entanglements of alliance and collaboration agreements, has contributed to the pace of collective advancement in the field of biotechnology and its progeny fields—e.g., bioinformatics, genomics, and proteomics.[252] Although DNA chip[253] and other bioinformatics capabilities have been internalized by major pharmaceuticals such as AstraZeneca, that technology was pioneered by biotech companies such as Affymetrix which sold access to their capabilities as a service available to an array of paying customers.[254] Moreover, HGP and biotechnology collaboration experiences have led commercial players to recognize the shared benefits of creating "biomedical R&D commons."[255] The most notable example to date is the SNP Consortium—a consortium among pharmaceutical, biotech, and academic participants to identify connections between variations of single letters in the genetic code and human health characteristics, such as adverse drug reactions.[256] Other notable examples

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al., *The Price of Innovation: New Estimates of Drug Development* Costs, 22 J. HEALTH ECON. 151, 180 (Mar. 2003); Jeffrey Krasner, *Study by Tufts Group Says Average Cost of a Drug's Development is $897m*, BOSTON GLOBE, May 14, 2003, at C4, LEXIS, News Library, Bglobe File.

[251] *Market Implications*, *supra* note 5, at 33; *see also* PROFILE 2001, *supra* note 249, at 5, 14; Ronald Rosenberg, *Data Bottleneck Slowing Drug Discovery*, BOSTON GLOBE, June 20, 2001, at D4, LEXIS, News Library, Bglobe File (implying future drug development based on the expanding number of targeted genes). *See generally* ERNST & YOUNG, CONVERGENCE: THE BIOTECHNOLOGY INDUSTRY REPORT (2000) [hereinafter CONVERGENCE] (exploring the emergence of biotechnological tools and the increase in targets and drugs in the pipeline).

[252] *See generally Snake Oil*, *supra* note 5 (providing relevant definitions and a discussion of these terms). On September 30, 2003, NIH announced a $2.1 billion, five-year plan to help researchers, physicians, and drug companies apply scientific findings and develop new therapies. M. Alexander Otto, *NIH Streamlining Plan Stresses Cooperation Between Scientists, Others in Research Areas*, MED. RES. LAW & POL'Y, vol. 8, no. 190, ISSN 1091-4021 (Oct. 1, 2003) *available at* http://healthcenter.bna.com/pic2/hc.nsf/id/BNAP-5RXRS5?OpenDocument.

[253] *Market Implications*, *supra* note 5, at 40 ("Utilization of DNA chips, which are silicon chips embedded with multiple, distinguishable bits of DNA, has made large-scale screening possible."); *see also* David Stipp, *Gene Chip Breakthrough*, FORTUNE, Mar. 31, 1997, at 56 ("Taking shape there are biochips whose impact will far outreach that of any clone, helping to transform the practice of medicine and the quality of our lives."). In October 2003, Commercial Suppliers announced the market availability of DNA chips containing the entire human genome. *See* Pollack, *supra* note 5, at C1.

[254] CYNTHIA ROBBINS-ROTH, FROM ALCHEMY TO IPO: THE BUSINESS OF BIOTECHNOLOGY 76-81 (2000); *Snake Oil*, *supra* note 5, at 32; *Market Implications*, *supra* note 5, at 40-41 n.59; Stipp, *supra* note 253, at 56.

[255] *See supra* note 5 and accompanying text.

[256] *See* The SNP Consortium Ltd., *Single Nucleotide Polymorphisms for Biomedical Research*, *at* http://snp.cshl.org (last visited Sept. 24, 2003) (on file with the Connecticut Law Review). *See also supra* note 5. The entity at the center of the SNP Consortium is Orchid Biosciences, Inc., and informa-

are the ongoing initiative to establish a collaboration to develop cancer drugs[257] and a proposed international stem cell project.[258] Historically ruthless academic competitors also are collaborating. The most notable example to date is the collaboration reported on June 20, 2003 between Harvard University and the Massachusetts Institute of Technology to apply knowledge of the human genome to the practice of medicine through the establishment of a $300 million Genome Institute.[259] Other examples include collaborations among various compilations of governments, commercial entities, and academic institutions around sometimes voluminous repositories of human biological samples and medical histories. Following the country of Iceland, whose citizenry's DNA and medical records are being made commercially available through deCODE genetics, Inc.,[260] at least eight other countries have announced or launched similar initiatives—including an ambitious effort announced in 2003 by the United Kingdom.[261] Commercial entities have emerged and continue to emerge to cre-

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tion about the effort is available at http://www.orchid.com (last visited Sept. 24, 2003) (on file with the Connecticut Law Review). Correlations already have been made between variations in genes and enzymes that metabolize drugs, including liver enzymes, and impact the pharmacokinetics (drug absorbtion, metabolization, and excretion) of some commercial pharmaceuticals in identified ways. *See* Noah, *supra* note 5, at 7-8; *Market Implications*, *supra* note 5, at 41 (discussing the compilation of data on the impact of variations of single nucleotide polymorphism on susceptibilities to disease and responsiveness to prescription drugs). As explained by Lars Noah:

> For each gene, individuals have a pair of copies called alleles, and one or both of these may vary from the norm. Over numerous generations, certain variant alleles may become relatively common, and they are designated as "polymorphisms" when they occur in at least one percent of the population. In many instances, only one in the thousands of base-pairs that make up a gene differs from the norm, resulting in a single nucleotide polymorphism (SNP). For some genes, scientists have identified more than half a dozen such variations.

Noah, *supra* note 5, at 7 (internal citation omitted). "The companies involved considered [such variations] important basic information that they wanted placed in the public domain, so that others could not patent them." Andrew Pollack, *An Early Step on Collaboration on Cancer Drugs*, N.Y. TIMES, May 13, 2003, at A1.

[257] Pollack, *supra* note 256, at A1 ("Pharmaceutical companies are beginning to contemplate new collaborative efforts to lower the cost and speed the development of drugs for cancer, according to executives involved in the effort."). A task force has been culled from within industry to put this collaboration together. *Id.*

[258] *Business and Regulatory News: International Stem Cell Project*, 21 NATURE BIOTECHNOLOGY 220 (Mar. 2003).

[259] Andrew Pollack, *$100 Million Donation Helps to Establish a Genome Institute*, N.Y. TIMES, June 20, 2003, at A21.

[260] Information about this company and its endeavor is available at http://www.decode.com (describing deCODE also as having established deCODE to commercialize diagnostics and therapeutics) (last visited Sept. 24, 2003) (on file with the Connecticut Law Review).

[261] Bertha Maria Knoppers, Presentation to the LSU Law Faculty on Populations, DNA Banking, and Ethics (Mar. 13, 2003) (discussing deCODE, DNA Sciences, Uman Genomics AB, RMGA, SignalGene, Eesti Geenikeskus: Estonian Genome Foundation, and Newfound Genomics). *See deCODE and IBM Form Strategic Alliance*, M2 PRESSWIRE, Jan. 23, 2003, LEXIS, News Library, M2pw file (reporting collaboration between deCODE and IBM Global Services to offer joint consulting, implementation and integrations services); Simon King, *Genome Project in Estonia Shows Rapid Progress*,

ate and manage such biocommons, meaning collective accomplishments that make broad contributions to science, sometimes through the public domain and other times through licenses.[262] Academic institutions, such as Howard University, also are participating.[263]

Working on such an intricate level with such multitudes of data would be impossible without DNA chip and other bioinformatics capabilities.[264] The enormity of the information being processed has even necessitated invention of new numbers to measure it.[265] Nevertheless in spite of the enormity of the task, bioinformatics has made fields such as genomics and proteomics at least theoretically feasible, and the genetic code is being translated into human health meaning. For example, "DNA chips can be used to test the samples of individuals for the presence of thousands of identified genetic variations and, alternatively, to screen hundreds of thousands of individuals with a shared phenotype characteristic to isolate and identify shared genetic expressions."[266] In fact, this technology already has been used to engage in voluminous gene expression comparisons with

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WMRC DAILY ANALYSIS, Dec. 20, 2002, *available at* 2002 WL 104096346 (reporting that the project is expected to encompass 70% of the Estonian population, take five years to complete, and be used to develop a number of targeted treatments, including anti-depressant drugs). The U.K. project's backers have pledged $65.6 million (45 million British Pounds) to build a biobank with samples from 500,000 Britons, thereby establishing the world's largest genetic database. *Genetic Database Receives Funding*, WALL. ST. J., Apr. 30, 2002, 2002 WL-WSJ 3393326 (stating that samples are to be gathered from volunteers age 45 to 69 and held in public ownership); *UK Genetic Database to Rival Iceland's Set Up*, MARKETLETTER, May 6, 2002, 2002 WL 7179539. A related scientific endeavor is to engage in haplotype mapping, the International HapMap Project, which involves identifying genetic variations that travel with populations. *See* Paul Recer, *International Project to Map Genome Called a Step Toward Finding Genes that Trigger Diseases*, TORONTO STAR, Nov. 3, 2002, LEXIS, News Library, Tstar File (explaining that the project is premised on the observation that SNPs are organized into DNA neighborhoods called haplotype blocks comprising about 10,000 or more base pairs, and that many people share the same haplotype blocks and common variations).

[262] Knoppers, *supra* note 261 (identifying major commercial efforts). *See generally supra* note 261. An emerging leader in the field is the First Genetic Trust, information about which is available at http://www.firstgenetic.net (last visited Sept. 24, 2003) (on file with the Connecticut Law Review). The author is working on a series of articles that explore biocommons and collaborations among competitors as fundamental to biotechnology, and address biobanking as the latest extension of this phenomenon.

[263] On May 27, 2003, Howard University announced plans to create the nation's largest repository of DNA from African-Americans, "[s]aying black people are in danger of being left behind at the newest frontier of medical research." Andrew Pollack, *DNA of Blacks to Be Gathered to Fight Illness*, N.Y. TIMES, May 27, 2003, at A1. This plan consists of gathering DNA samples from 25,000 people over five years by drawing mainly from patients at hospitals affiliated with Howard College of Medicine and to also use alumni to solicit donors globally. *Id.*

[264] *See Market Implications*, *supra* note 5, at 40-41.

[265] Beyond terabytes (a trillion bits of genetic data), these measurements include "petabytes (equivalent to half the contents of all the academic libraries in America), exabytes, yottabytes and zettabytes. All the words ever uttered by everyone who ever lived would amount to five exabytes." Gibbs, *supra* note 242, at 42, 45.

[266] *Market Implications*, *supra* note 5, at 40-43 (identifying corporate examples) (citations provided).

meaningful results.[267] "What will be possible in the future will depend heavily on the ability of computers to interpret the mind-boggling amounts of data generated by genomics and proteomics and to build reliable models of phenomena such as protein folding."[268]

These advances in biotechnology "have transformed great expectations for genetic medicine into goals potentially obtainable in the foreseeable future."[269] As acknowledged recently by the World Health Organization in an ambitious report, *Genomics and World Health*, increased understanding of gene and protein function will revolutionize the practice of medicine.[270] In fact, that revolution already is underway. Clinical trials are being designed with genetic precision ("pharmacogenomics," also known as "PGx") and those are resulting in pharmaceuticals tied to genetic characteristics.[271] Some of these drugs are entering the market with genetic profiling as an accompaniment, and there are instances of genetic profiling being utilized by physicians to make prescription and other treatment choices for individual patients. An illustration of the former is Herceptin, a drug to treat an aggressive form of breast cancer associated with over-expression of Her-2 neu,[272] and an example of the latter is HIV genotyping.[273] The ability to decode an individual's genome and then screen for a condition or susceptibility for a few hundred dollars has become a realistic and foresee-

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[267] Consider the following disease case study, as reported through interviews with scientists working at the new joint Harvard-MIT genome institute:

> "[N]ew research into the cause of diabetes exemplifies how the new style of research will probably unfold . . . . [A] group of genes involved in producing energy for cells are less active in diabetic patients. If this effect can be counteracted, then it may offer a new way to treat the disease . . ."

Gareth Cook, *$300m Genome Institute Launched; Harvard, MIT Join in Medical Effort*, BOSTON GLOBE, June 20, 2003, LEXIS, News Library, Bglobe File.

[268] FUKUYAMA, *supra* note 6, at 74.

[269] *Market Implications*, *supra* note 5, at 31. *See generally* Robertson et al., *supra* note 245.

[270] Genomics and World Health, *supra* note 20. "The trend, as the WHO has noted, is toward more expensive treatment for diseases affecting fewer people." GOALS, *supra* note 224, at 7.

[271] *See generally Market Implications*, *supra* note 5; Noah, *supra* note 5; Robertson et al, *supra* note 245. *See also* Jim Kling, *US FDA Contemplates Collection of Pharmacogenomic Data*, 21 NATURE BIOTECHNOLOGY 590 (June 2003) (reporting FDA contemplation of a draft proposal to incorporate pharmacogenomic data into the regulatory process). For more information, see FORETELLING OUR PHARMACOGENOMIC FUTURE (Mark A. Rothstein ed., 2003) (anthology addressing the science but with a focus on law, ethics, and other policy issues).

[272] Similarly, Gleevec, a drug for the treatment of a form of leukemia, blocks a chemical that signals cancer cells to grow. *See* Gibbs, *supra* note 242, at 42, 44.

[273] *See Market Implications*, *supra* note 5, at 42. Herceptin is manufactured by Genentech, Inc. (South San Francisco, CA), and HIV genotyping services are provided by Visible Genetics Inc. (Toronto, CA) and Virologic (South San Francisco, CA). *See id.* *See also* Andrew Pollack, *When Gene Sequencing Becomes a Fact of Life: Test Helps Doctors Find Best AIDS Drugs*, N.Y. TIMES, Jan. 17, 2001, at C1 (discussing the development of HIV genotyping and noting that it will help doctors choose which of the available drugs will work best with particular patients).

able possibility.[274] Recent history dictates that we not assume the luxury of time when gauging the evolution from science fiction to fact.

In the late 1980s there was a firm consensus among geneticists that it was impossible to clone a mammal from adult somatic cells, a view that came to an end with Dolly in 1997.[275] As recently as the mid-1990s, geneticists were predicting that the HGP would be completed sometime between 2010 and 2020; the actual date by which the new, highly automated sequencing machines completed the work was July 2000. "There is no way of predicting what kinds of shortcuts may appear in future years to reduce the complexity of the task ahead."[276]

VI. REGULATION OF AND TRENDS IN ASSISTED REPRODUCTION TECHNOLOGY ("ART")

George Annas, a noted bioethicist and law professor at the Boston University School of Public Health who serves on the Ethics Advisory Board of the Society for Assisted Reproductive Technology ("SART") and the American Society for Reproductive Medicine ("ASRM"), refers to assisted reproduction as "the wild West" of American medicine.[277] ART is poised at the intersection of a highly vulnerable and growing patient group willing to pay directly and expend considerable personal wealth for these services,[278] and a sophisticated, highly competitive commercial sector engaged in aggressive DTC marketing.[279] ART also provides an opportunity for medical professionals to enjoy professional autonomy and reap signifi-

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[274] *See 60 Minutes* (CBS television broadcast, Apr. 17, 2002) (providing an overview of HGP and stating that hundreds of companies are making tests available so, ultimately, persons will be able to decode and screen their entire genome for a few thousand dollars) (tape on file with author).

[275] *The Start of Something Big? Dolly Has Become a New Icon for Science*, SCI. AM., May 1997, at 15.

[276] FUKUYAMA, *supra* note 6, at 79. *See also Snake Oil*, *supra* note 5, at 23-26 (discussing how the medical community underestimated the promise of biotechnology during the early 1990s). In May 2003, scientists announced that they had cloned a mule, meaning the first clone of an equine animal, and that typically sterile animals now may be able to reproduce. Andrew Pollack, *Another Milestone of Cloning is Reached as a Mule is Born in Idaho*, N.Y. TIMES, May 30, 2003, at A21.

[277] *Making Babies*, *supra* note 6. *But see generally* Adamson, *supra* note 21 (arguing that there exists meaningful, comprehensive, and largely sufficient regulation and placing great trust in patients and the medical profession). *See generally* Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603 (2003).

[278] *See, e.g.*, Maggie Jones, *The Mystery of My Eggs*, N.Y. TIMES, Mar. 16, 2003, § 6 (Magazine), at 44-46. Demographic trends in the U.S. include delaying reproduction and, consequentially, increased difficulty with reproduction. *Making Babies*, *supra* note 6; *18 Ways to Make a Baby*, *supra* note 6; *see also* CDC, Final Report, *supra* note 11; Press Release, *supra* note 11; Kolata, *supra* note 10 (addressing marketing practices of clinics, including money-back guarantees that pressure clinics to transfer more embryos and otherwise be more aggressive in practice). For more information, visit the Internet site of RESOLVE at http://www.resolve.org/main/national/index.jsp?name=home (consumer organization that assists people considering ART treatment) (last visited Sept. 24, 2003) (on file with the Connecticut Law Review).

[279] Kolata, *supra* note 10; *Making Babies*, *supra* note 6.

cant financial returns[280] at a time when physician income and discretion are generally being checked by managed care.[281] In spite of this tension, the sector is subject to insufficient mandatory, consistently enforced, and reliable regulation and oversight.[282]

A. *Regulation of ART*

The practice of assisted reproduction generally is performed as a *medical service* in a clinical laboratory setting, and in recent years, hundreds of independent ART clinics have been established across the country.[283] Historically, the jurisdiction of the FDA, shaped largely by enabling legislation consisting of the Federal Food Drug and Cosmetic Act ("FDCA")[284] and the Public Health Services Act ("PHSA"),[285] has been checked to minimize interference with the practice of medicine.[286] For example, the

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[280] *See generally* proceedings, American Bar Association, Administrative Law Section, New Frontiers: Policy Considerations and Options for Regulation of Assisted Reproduction Technology (ART), Feb. 7, 2003 (Seattle, WA) [hereinafter New Frontiers]. *But see generally* Jeffrey R. Botkin, *Prenatal Diagnosis and the Selection of Children*, 30 FLA. ST. U. L. REV. 265, 287-92 (2003) (proposing professional standards as a desired alternative to regulation or other law).

[281] A contemporary phenomenon is a strong (perverse) financial incentive to refuse treatment to the very sick. *See* Sandeep Jauhar, *When Doctors Slam the Door*, N.Y. TIMES, Mar. 16, 2003, § 6 (Magazine), at 32-33. "For the past 30 years, the profession has been in economic and social decline. Doctors' incomes and professional judgment have been squeezed by managed care." James M. Hirschhorn, *The Doctors' Strike in Context*, 171 N.J.L.J. 589, Feb. 17, 2003; *see also* Jennifer Silverman, *Medicare Pay Cuts Likely to Crimp Salaries*, 5/01/02 INTERNAL MED. NEWS 46, May 1, 2002, *available at* 2002 WL 14305793 ("The Medicare pay cuts expected over the next 3 years could have a whopping impact on internists' yearly salaries."). Therefore, today, we should be even less inclined to entrust medical ethics to the medical profession. "To paraphrase the famous proverb concerning the responsibility for decisions about war, health care ethics is too important to be left in the hands of scientists and health care professionals." PRIMER, *supra* note 2, at xi.

[282] Admittedly, there are several professional initiatives and regulatory measures worth noting, which are summarized in Figures 3 and 4. *See generally* Adamson, *supra* note 21. However, the insufficiency of professional self-regulation is discussed *infra* at Part VI.

[283] *See* Final Report, *supra* note 11. *But see* Adamson, *supra* note 21, at 933 (asserting that regulations for clinical research and ethics at the university level constitute a reliable regulatory check on ART).

[284] *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (2000); Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (codified in scattered sections of 21 U.S.C. and 42 U.S.C.), and Medical Device Amendments of 1992, Pub. L. No. 102-300, 106 Stat. 239 (codified in scattered sections of 21 U.S.C.).

[285] Public Health Service Act, 42 U.S.C. § 262 (2000).

[286] *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."); Legal Status of Approved Labeling for Prescription Drugs: Prescribing Uses Unapproved by the Food and Drug Administration, 37 Fed. Reg. 16,503, 16,504 (Aug. 15, 1972) (to be codified at 21 CFR pt. 130) ("[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 164 (discussing the evolution of the structure of the American medical profession).

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.[287] Much reliance has been placed on self-

[287] *See* Thompson v. W. States Med. Ctr., 535 U.S. 357, 359 (2002) (striking down a FDAMA provision that prohibited pharmacies from advertising compounded products); Wash. Legal Found. v. Henney, 202 F.3d 331, 333-34 (D.C. Cir. 2000) (discussing the hands off approach that Congress and the FDA have taken in regard to off-label use); Pearson v. Shalala, 164 F.3d. 650, 655 (D.C. Cir. 1999) (recognizing the marketing of dietary supplements as commercial free speech and checking restrictions; FDA may not require disclaimers for misleading health claims on dietary supplement labels). 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 42 U.S.C. § 1396r-8(k)(6) (2000)); 42 U.S.C. § 1395x(t)(2)(B) (authorizing Medicare reimbursement for off-label uses of oncology drugs if consistent with medical compendia or the peer-reviewed literature). Nevertheless, direct promotion of off-label use is illegal. *Wash. Legal Found.*, 202 F.3d at 332-33. Recently, the government has prosecuted numerous alleged violations and many pharmaceutical companies accused of marketing improprieties have been settling. *See, e.g.*, Alice Dembner, *Drug Firm Agrees to Big Penalty Astrazeneca Will Pay $355M to Settle Drug Fraud Charges*, BOSTON GLOBE, June 21, 2003, at C1, LEXIS, News Library, Bglobe File; Milt Freudenheim, *U.S. Accuses Merck Unit of Cheating Health Plan*, N.Y. TIMES, June 24, 2003, at C5 (reporting that the Justice Dept. accused Medco Health Solutions, a pharmacy benefit manager ("PBM"), of cheating the federal employees' health plan); Gardiner Harris, *Abbott to Pay $622 Million to End Inquiry into Marketing*, N.Y. TIMES, June 27, 2003, at C1 (reporting that Abbott Laboratories agreed to pay $622 million to settle investigation into sales practices for liquids used to feed the seriously ill); Liz Kowalczyk, *Hospital, Drug Firm Relations Probed*, BOSTON SUNDAY GLOBE, at A1, June 29, 2003, LEXIS, News Library, Bglobe File ("Federal investigators are sending subpoenas to top academic medical centers in Boston and elsewhere in the country for records about their relationships with drug makers as part of a widespread crackdown on pharmaceutical company marketing practices . . . ."); Liz Kowalczyk, *U.S. Filing Backs Suit Against Drug Firm Federal Prosecutors: Epilepsy Medication was Illegally Marked*, BOSTON GLOBE, May 28, 2003, at D1, LEXIS, News Library, Bglobe File (reporting accusations that Pfizer engaged in a fraudulent scheme to persuade doctors to prescribe the country's top-selling anticonvulsant, Neurontin); Melody Petersen, *Court Papers Suggest Scale of Drug's Use*, N.Y. TIMES, May 30, 2003, at C1 ("Documents released yesterday in the case of a drug company whistle-blower shed light on how extensively doctors were involved in promoting unapproved uses of a Warner-Lambert drug, Neurontin."); Melody Petersen, *Indictment Seen by Drug Maker Over Marketing*, N.Y. TIMES, May 31, 2003, at A1 ("The Schering-Plough Corporation said yesterday that it could soon be indicted in a federal investigation into its prescription drug marketing practices . . . ."); Melody Petersen, *U.S. Warns Botox Maker About Its Ads*, N.Y. TIMES, June 24, 2003, at C2 (reporting that FDA warned manufacturer that its ads promoted uses beyond those government approved and, therefore, were illegal); Christopher Rowland, *U.S. Widens Drug Firm Inquiry: Schering-Plough Faces Criminal Investigation*, BOSTON GLOBE, May 31, 2003, at C1, LEXIS, News Library, Bglobe File (reporting that the Boston U.S. attorney is investigating a "broad array of allegedly illegal sales and marketing practices by drug companies across the country," including a criminal investigation of Schering-Plough). *But see* Melody Peterson, *Who's Minding the Drugstore*, N.Y. TIMES, June 29, 2003, § 3, at 1 [hereinafter *Drugstore*] (reporting that FDA's issuance of warning letters for overly-aggressive marketing is down considerably). According to a Harvard University-MIT study released February 14, 2002, drug companies tripled their advertising budgets in recent years to directly reach consumers. *See* Press Release, Harvard. Sch. Pub. Health, Direct-to-Consumer Advertising of Prescription Drugs Grows Rapidly (Feb. 13, 2002), *available at* http://www.hsph.harvard.edu/pressreleases/press02132002.html (last visited Sept. 24, 2003) (on file with the Connecticut Law Review). "Overall, direct-to-consumer advertising spending by the drug

regulation by the medical profession—for example via licensing and board certification requirements—to ensure good medical practice.[288] Tort liability, including medical malpractice, offers another assurance.[289]

The United States federal regulatory scheme for ART clinics can be summarized as voluntary certification. This program was established in accordance with the Fertility Clinic Success Rate and Certification Act of 1992 ("Fertility Act").[290] In accordance with this Act, the CDC developed a model certification program for ART laboratories.[291] The end result is a template program which states have the *option* of implementing, either directly or by certifying independent accrediting organizations. No state has fully adopted the model program,[292] and the CDC has contractually outsourced implementation to SART, meaning that the sector has been left to self-police.[293]

Although ART at times encompasses aggressive integration of emerging technology with the delivery of care, the field also largely circumvents

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industry rose to $2.7 billion in 2001 from $800 million in 1996 . . . . For every $1 spent on direct-to-consumer ads, they reaped $4.20 in sales." Christopher Rowland, *Drug Ads Deliver a Few Side Effects Firms Reap Rewards, but so Do Their Rivals, and Patients Take Data to the Doc, Study Finds*, BOSTON GLOBE, June 12, 2003, at E1, LEXIS, News Library, Bglobe File.

[288] *See* STARR, *supra* note 164, at 102-12; *Drugstore*, supra note 287, at 1 (reporting that FDA under the Bush Administration has relaxed enforcement of prohibitions on direct promotion of off-label use and other advertising practices: "[F]rom 1999 to 2001, the F.D.A. sent one warning letter for every 2.8 complaints about false advertising. But in the first six months of 2002 . . . it sent one letter for every 13.5 complaints"). *But see* Adamson, *supra* note 21, at 932-33 (suggesting that marketing by ART providers is sufficiently regulated by FTC and FDA and referring to anecdotal incidents of FTC investigations of ART programs for exaggerated claims of pregnancy success rates).

[289] *See* Larry I. Palmer, *Genetic Health and Eugenics Precedents: A Voice of Caution*, 30 FLA. ST. U. L. REV. 237, 263 (2003) (proposing reliance on the judiciary and theories of liability rather than regulation).

[290] Pub. L. 102-493, 106 Stat. 3146 (1992).

[291] *See* CDC, Notice, Implementation of the Fertility Clinic Success Rate and Certification Act of 1992—A Model Program for the Certification of Embryo Laboratories, 64 Fed. Reg. 39373 (July 21, 1999); CDC Final Report, *supra* note 11.

[292] *See generally* Final Report, *supra* note 11. *But see* Adamson, *supra* note 21, at 937 (discussing the atypical initiative taken by a New York State task force, which recommended medical advancement policies).

[293] *But see* Adamson, *supra* note 21, at 933. This proponent of self-regulation asserts that "[t]he law has been enacted and over 95% of ART programs in the country annually report their results to the CDC through [SART], which has a contract with CDC to collect these data." *Id.* However, this statement is based upon practices in 1997, and the highly commercial (private companies with patients usually paying directly) and explosive nature of the sector make the reliability of this self-reported data suspect, as addressed *infra* in Part VI. *See id.* The author also places great importance on the observation that "[t]hirty clinics of the approximately 370 in the United States had an on-site validation inspection," meaning 340 of the identified clinics were not inspected. *Id.* The lax enforcement of CLIA for commercial laboratories due to lack of CDC resources for the endeavor even prior to 9/11, the anthrax murders, and recent epidemiological outbreaks such as West Nile Virus, SARS and monkeypox is well established. *See Snake Oil*, *supra* note 5, at 42. *See also infra* note 491 and accompanying text (describing questions about CLIA).

United States regulations to protect human subjects.[294] The applicability of these human subject regulations presently is limited to instances where research is supported at least in part with federal funding,[295] is carried out at least in part by institutions that receive federal funding,[296] or is conducted pursuant to FDA oversight[297]—including research conducted in conjunction with an IND[298] or IDE application.[299] As a clinical service, ART escapes the FDA's product groupings,[300] and the federal government

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[294] *See supra* Part IV. *See generally* Malinowski & Rose, *supra* note 174; PROTECTING THE PEOPLE, *supra* note 162. The failure to appreciate this gap in human subject protection regulations has led to instances of false assurance, such as the following:

> [T]he United States government has also required that Institutional Review Boards (IRBs) be impaneled to monitor any organizations receiving federal funds for genetic research. Nonscientists, including lawyers and philosophers, as well as citizens from other professions, serve on these boards. These nonscientist members will help ensure even-handed scrutiny, candor, and fairness in the administration of this cutting-edge technology.

CARRICK, *supra* note 165, at 210.

[295] Federal funding triggers Common Rule regulations, 45 C.F.R. §§ 46.101-.124 (2002). *See* discussion *supra* Part IV; *supra* note 217 and accompanying text; *see also* Malinowski & Rose, *supra* note 174; PROTECTING THE PEOPLE, *supra* note 162.

[296] Such institutions must file assurances of compliance with human subject protection regulations with the Office for Human Research Protections ("OHRP") in the Office of the Secretary of Health and Human Services. *See* www.hhs.gov (general HHS) (last visited Sept. 24, 2003) (on file with the Connecticut Law Review); http://ohrp.osophs.dhhs.gov (general OHRP) (last visited Sept. 24, 2003) (on file with the Connecticut Law Review); Memorandum from Director, OHRP, to OHRP Staff, Compliance Oversight Procedures (Dec. 4, 2000), *available at* http://www.ohrp.osophs.dhhs.gov/compovr.htm (last visited Sept. 24, 2003) (on file with the Connecticut Law Review). Many of these institutions must adopt policies and procedures for compliance—i.e. establish IRBs and operational procedures—that they apply uniformly to all of their research activities, including research that is conducted without federal funding. 45 C.F.R. §46.103 (2002). *See* Malinowski & Rose, *supra* note 174, at 9-9 to 9-10.

[297] 21 C.F.R. § 56.101 (2003); *see also* 21 C.F.R. § 56.102(e) (2003) (definition of "human subject"). The FDA's human subject protection regulations complement the Common Rule, but the definition of human subject that triggers their applicability rests on FDA's control over market access rather than federal funding. *See* Malinowski & Rose, *supra* note 174, at 9-11 to 9-12.

[298] 21 C.F.R. § 50.23 (2003).

[299] 21 C.F.R. §§ 50.25, 50.3, 56.102 (2003).

[300] *See supra* notes 277, 282 and accompanying text. Although the FDA arguably has authority to regulate agents used in genetic testing, to date the agency has not exercised and tested that authority. *See* Genetic Testing Under the Clinical Laboratory Improvement Amendments, 65 Fed. Reg. 25,928 (May 4, 2000); NAT'L INST. HEALTH, SECRETARY'S ADVISORY COMMITTEE ON GENETIC TESTING (SACGT), ENHANCING OVERSIGHT OF GENETIC TESTS: RECOMMENDATIONS OF THE SACGT (2000), [hereinafter SAGCT RECOMMENDATIONS] *available at* http://www4.od.nih.gov/oba/sacgt.htm (last visited Sept. 24, 2003) (on file with the Connecticut Law Review); PROMOTING SAFE AND EFFECTIVE GENETIC TESTING IN THE UNITED STATES: FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING, 29 n.f (Neil A. Holtzman & Michael S. Watson, eds. 1988); Anny Huang, *FDA Regulation of Genetic Testing: Institutional Reluctance and Public Guardianship*, 53 FOOD & DRUG L.J. 555, 557 n.15 (1998). *But see* Andrew Pollack, *F.D.A. Asks if a Genetic Test Is Sold Without Approval*, N.Y. TIMES, July 18, 2003, at C2. Also, the U.S. regime to protect human subjects has been called into question by both the Clinton and Bush Administrations and many others. *See supra* notes 235-36 and accompanying text. *But see* Adamson, *supra* note 21, at 935 (suggesting that regulations to protect human subjects and university oversight are reliable regulatory mechanisms for ART).

has long abstained from funding embryonic research—thereby further castigating ART to the private sector.[301]

Additional regulation is provided under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") to the FDCA,[302] which generally apply to clinical laboratories.[303] However, these regulations set standards for laboratory proficiency, personnel, and so forth (assurances that laboratory test results are accurate and reliable), but they do not provide any assurance of utility or clinical soundness from a medical point of view.[304] CLIA also is marred by reporting and enforcement deficiencies:[305] CLIA regulations encompass monitoring more than 150,000 laboratory facilities on an ongoing basis.[306] In order to satisfy this responsibility, the CDC has delegated considerable certification authority and responsibility to several professional societies including the Joint Commission on Accreditation of Health Organizations ("JACHO") and the College of American Pathologists ("CAP").[307]

SART-ASRM dominates self-regulation of ART, but its regulation is not exclusive.[308] The professional societies most influential in ART and

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[301] "President Clinton barred federal funding for research on embryos. Yet he allowed federal funding for research on embryos 'left over' from IVF procedures. Congress has refused to allow funds to be allotted by the NIH for research on living fetuses." PRIMER, *supra* note 2, at 198. This ban on federal funding of stem cell research was enacted in 2000 in an amendment to the 1999 Labor, Health & Human Services Appropriations Act. Consolidated Appropriations Act, 2001, Pub. L. No. 106-554, 114 Stat. 2763 (2000). In response to tremendous biomedical advances attributable to research on human stem cells, President Bush has permitted federal funding for research involving stem cells already extracted from human embryos as of August 9, 2001. The White House, President George Bush, Fact Sheet—Embryonic Stem Cell Research, *available at* http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html (last visited Sept. 24, 2003) (on file with the Connecticut Law Review); Sheryl Gay Stolberg, *Ruling by U.S. Widens Study of Stem Cells*, N.Y. TIMES, Aug. 7, 2002, at A1. Subsequently, researchers have claimed that many of these existing lines are of poor quality, the collection lacks necessary genetic diversity, and the availability of the lines is seriously checked by intellectual property rights in the hands of commercial entities. *Id.* In March 2002, the Administration clarified this position, stating that researchers receiving federal funding may study new stem cell lines–and even derive them from embryos–in their university laboratories, provided that they do not commingle their federal and private funds, meaning that they must engage in careful bookkeeping. *Id.* For a concise commentary on the research use of embryos that surveys science applications and ethical and policy aspects, see Louis M. Guenin, *The Set of Embryo Subjects*, 21 NATURE BIOTECHNOLOGY 482-483 (May 2003).

[302] Pub. L. No. 100-578, 102 Stat. 2903 (1994).

[303] Michael J. Malinowski & Erica Rose, *Clinical Laboratory Regulations*, *in* BIOTECHNOLOGY: LAW, BUSINESS AND REGULATION, *supra* note 174, at 10-4 (1999).

[304] *See id. See also Snake Oil*, *supra* note 5, at 42.

[305] *Snake Oil*, *supra* note 5, at 42.

[306] *Id.* (citations omitted).

[307] Malinowski & Rose, *supra* note 303, at 10-1. *See also id.* at 10-11 to 10-12 (addressing JACHO and CAP accreditation).

[308] Visit the Internet sites for SART, *at* http://www.sart.org (last visited Sept. 24, 2003) (on file with the Connecticut Law Review) and ASRM *at* http://www.infertilityprofessionals.com/clinical/asrm.html (last visited Sept. 24, 2003) (on file with the Connecticut Law Review). SART has

their major guidelines are summarized in Figure 3. ASRM and SART guidelines and practice standards are identified in Figure 4.

FIGURE 3: PROFESSIONAL SOCIETY ETHICAL GUIDELINES[309]

ASRM and SART: Ethical considerations of the assisted reproductive technologies (1986, 1988, 1990, 1994, 1997)

- 1994 report with complete statements on over 29 topics
- 1997 report with statements on:
  - disposition of abandoned embryos
  - oocyte donations to postmenopausal women
  - embryo splitting for infertility treatment
  - the use of fetal oocytes in assisted reproduction
  - posthumous reproduction
  - ASRM and SART: Ethical issues with respect to specific ART practices including IVF, GIFT, ZIFT, gamete donation, surrogacy, cryopreservation of embryos, and research

ASRM and SART: Guidelines addressing quality assurance and formation of public policy

- Definition of 'experimental' (1993)
- Definition of 'infertility' (1993)

American College of Obstetricians and Gynecologists (ACOG) committee on ethics and opinions on IVF (1986), surrogacy (1990) and research on preimplantation embryos (1993)

The National Advisory Board on Ethics in Reproduction (NABER) [Originally organized through the cooperative efforts of ACOG and ASRM in 1991, then became independently incorporated and funded and had broad representation before disbanding in 1998 because of lack of funding]: Informed consent and the use of gametes and em-

established a National Coalition for Oversight of the Assisted Reproductive Technologies ("NCO-ART"). In its 1994 edition of its Ethical Considerations, ASRM adopted the position that the preembryo deserves greater respect than other human tissue because of its potential to become a person, but not the respect we give human persons because "the preembryo does not have differentiated organs, much less the developed brain, nervous system, and capacity for sentience that legal subjects ordinarily have." THE ETHICS COMMITTEE OF THE AMERICAN FERTILITY SOCIETY, ETHICAL CONSIDERATIONS OF ASSISTED REPRODUCTIVE TECHNOLOGIES 33S (Nov. 1994); *see also* Richard A. McCormick, S.J., *Reproductive Technologies: Where Are We Headed?*, *in* THE HEALTH CARE PROFESSIONAL AS FRIEND AND HEALER 165, 168 (David C. Thomasma & Judith Lee Kissell eds., 2000).

[309] Adamson, *supra* note 21, at 937.

bryos for research (1997)

- ASRM and SART: Shared-risk or refund programs in assisted reproduction (1998)
- Guidelines for advertising by ART programs (1998, 1999)
- Sex selection and preimplantation genetic diagnosis (1999)
- Financial incentives in recruitment of oocyte donors (2000)
- Human somatic cell nuclear transfer—cloning (2000)
- Preconception gender selection for nonmedical reasons (2001)

FIGURE 4: ASRM AND SART GUIDELINES AND PRACTICE STANDARDS[310]

- Minimum standards for IVF (1984)
- Minimum standards for GIFT (1988)
- Revised minimum standards for IVF, GIFT, and related procedures (1990)
- Guidelines for human embryology and andrology laboratories (1992)
- Guidelines for practice, including gamete donation (1993)
- Statement of intracytoplasmic sperm injection (1994)
- Guidelines for the provision of infertility services (1996)
- Elements to be considered in obtaining informed consent for ART (1997)
- Introduction of ovarian follicle development and ovulation with exogenous gonadotropins (1998)
- Guidelines for number of embryos transferred (1998)
- Guidelines for gamete and embryo donation (1998)
- Revised minimum standards for in vitro fertilization, game intrafallopian transfer, and related procedures ((1998)
- Position statement on nurses performing limited ultrasound in a gynecology/infertility setting (1997)
- Intravenous immunoglobulin (IVIG) and recurrent spontaneous pregnancy loss (1998)
- Guidelines on number of embryos to transfer (1999)
- Antiphospholipid antibodies do not affect IVF success (1999)
- Who is to report ART cycles (1999)
- Optimal evaluation of the infertile female (2000)
- The role of assisted hatching in IVF: a review of the literature (2000)
- Repetitive oocyte donation (2000)
- Does intracytoplasmic sperm injection (ICSI) carry inherent

[310] *Id.* at 936.

genetic risks? (2000)
- Blastocyst production and transfer in clinical assisted reproduction (2001)
- Salpingectomy for hydrosalpinx prior to IVF (2001)
- Preimplantation genetic diagnosis (2001)

However, these efforts at self-policing are undermined by several considerations[311]—the most fundamental of which is that participation in these organizations is voluntary, and certification/licensing by them generally is not required to practice ART in the United States. To summarize, "the reproductive technology industry is completely unregulated at present. True, we do have the ASRM's Ethical Considerations of Assisted Reproductive Technologies. These directives have no legal clout, however; compliance is voluntary."[312] Moreover, ART is further shielded from legislative interference through *Roe v. Wade* and its progeny, which prohibit legislatures from unduly burdening a woman's choice to terminate a pregnancy.[313] Meaningful regulation of ART that impacts its accessibility presumably could be construed as an undue burden on a woman's right to make procreative choices and challenged as such legally.[314]

In February 1998, at a conference co-sponsored by CDC, RESOLVE, and NABER, fundamental questions about the regulation of ART were defined and answered,[315] as summarized in Figure 5.

FIGURE 5: HIGHLIGHTS—CDC-RESOLVE-NABER Q&A ON REGULATION OF ART[316]

"What are the critical gaps in approaches to ART oversight in the United States?"

"The answers were a lack of sanctions in the current system, problems with lack of funding for embryo research, incomplete and non-uniform documentation and reporting, inadequate quality assurance requirements, incomplete and non-uniform informed consent, lack of mandatory availability of counseling, lack of consumer input, inadequate donor

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[311] *See generally* discussion *infra* Part VII.

[312] McCormick, *supra* note 308, at 165 (citing ASRM, Ethics Committee, Ethical Considerations of Assisted Reproductive Medicine (American Fertility Society, 1994)). *But see* Adamson, *supra* note 21, at 932-33 (describing the medical regulations affecting ART).

[313] *See supra* note 8; *infra* notes 413-14 and accompanying text.

[314] *See supra* note 8. *But see infra* notes 435-38 and accompanying text.

[315] *See* Adamson, *supra* note 21, at 939-40.

[316] This dialogue has been rearranged for purposes of this Article. The dialogue is taken from Adamson, *supra* note 21, at 939-40.

screening and standards, lack of insurance, and lack of mandatory universal standards or a code of practice."

"Does the current system protect the consumers, and if not, what should be done?"

"[T]he current approach to ART oversight in the United States is inadequate."

"Does the current system protect providers, and if not, what could be done?"

"It was also concluded that the current system had inadequate protection for providers and that it is important to identify a recognized body that can set standards, provide better coverage and cooperation from insurance companies, provide medical-legal protection for physicians practicing ART, better availability of research institutional review boards, and a code of practice to protect against unreasonable requests."

"Is there fair and equitable access to ART in the United States, and if not, what [are] the barriers to access?"

"It was felt that there is not fair and equitable access because of individual financial constraints and insurance companies' failure to provide adequate coverage for ART, exacerbated by the lack of education and information regarding ART; lack of counseling especially with respect to moral, religious, and cultural views; misperceptions and uninformed social attitudes that are negative toward ART; media sensationalization of ART both good and bad; state mandates; lack of oversight of vendors in the industry; the Employee Retirement Income Security Act ("ERISA"), which places limitations on health insurance liability for employers; nonaccommodating employers and provider attitudes; and geography, race, and quality of care."

"How could new technical issues and [other] new issues be addressed by additional oversight?"

"The following were identified: an oversight committee, SART research committee, local institutional review boards, national funding, nongovernmental committees, and improved guidelines for research innovations and standards of

care."

"How should the increased oversight be financed?"

"It was felt that a number of possibilities existed, including through insurance coverage, through a combination of public and private funding, or a combination of patients, infertility centers, and insurance and the public."

"Is there an international model or attributes of one that could be adopted in the United States?"

"It was concluded by all that the U.S. situation is unique, and that none of the international models are entirely adaptable to this country. However, in general, those at the meeting felt that accreditation [is] superior to licensing, that oversight should show a flexibility of language so that the oversight authority will not be unduly constrained as future unknown developments occur, and that there should be significant consumer participation."

"Are there other forms of oversight in the United States that might be applied to ART?"

"[I]t was felt that none of these organizational models would be able to provide, by themselves, the appropriate oversight of ART in the United States."

B. *Trends in ART*

The field of ART often literally is measured in human lives—those of Louise Brown and Elizabeth Carr, the first IVF child and the first IVF child born in the United States, respectively.[317] Louise Brown now is a twenty-five-year-old woman, and she is leading the first generation of IVF children into adulthood. Tens of thousands of children have been conceived and delivered through IVF and embryo transfer ("ET"),[318] with more than 35,000 ART babies in 2000 alone.[319]

The announcements of these first IVF-ET births caused animated responses from medical professionals and the general public with an intensity

[317] Louise Brown was born on July 25, 1978 in Oldham, England. McCormick, *supra* note 308, at 165; KEVLES, *supra* note 28, at 297. Elizabeth Jordan Carr was born three years later in the United States. *18 Ways to Make a Baby*, *supra* note 6. On July 26, 2003, 1000 IVF children gathered to celebrate Louise Brown's twenty-fifth birthday. Patricia Reaney, *In-Vitro Children Celebrate Milestone*, BOSTON GLOBE, Mar. 20, 2003, at A7, LEXIS, News Library, Bglobe File.

[318] McCormick, *supra* note 308, at 165.

[319] Technology Report, *supra* note 11, at 11.

echoed by reaction to claims of successful human cloning.[320] Concerns raised about IVF and ET when introduced included the possibility that these processes would endanger the health of resulting pregnancies, perhaps not in readily ascertainable ways.[321] There also were concerns that these procedures would negatively impact the family and society—for example, by encouraging abortions and the delay of childrearing through perhaps inflated promises of opportunities later. Most of these concerns were put to rest over time in conjunction with the healthy development of Louise, Elizabeth, and the many thousands of IVF children who followed.[322] Consequentially, the commercial ART sector developed slowly at first but then grew and matured immensely during the 1990s, especially with the introduction of intracytoplasmic sperm injection ("ICSI").[323] This IVF method, which consists of injecting a single sperm cell directly into an egg cell with a pipette (an extremely thin glass needle), alleviates the standard need for 50,000 to 100,000 sperm cells to achieve conception, thereby making conception a possibility for perhaps nine out of ten men previously

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[320] *See* Symposium, *Conceiving a Code for Creation: The Legal Debate Surrounding Human Cloning*, 53 HASTINGS L.J. 987, 987-1204 (2001-02); Carolyn Wilson, Statement in the Ad Hoc Committee on the International Convention Against the Reproductive Cloning of Human Beings, Feb. 26, 2002, *in* ISSUES L. & MED., Fall 2002, at 187-90; President George W. Bush, Remarks on Human Cloning Legislation (Apr. 10, 2002), *available at* http://www.whitehouse.gov/news/releases/2002/04/20020410-4.html (last visited Sept. 24, 2003) (on file with the Connecticut Law Review); THE PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY (2002), *available at* http://www.bioethics.gov/cloningreport/fullreport.html (last visited Sept. 24, 2003) (on file with the Connecticut Law Review); Fox News, *House Passes Cloning Ban* (Feb. 28, 2003) ("The bill, sponsored by Reps. Bart Stupak, D-Mich., and Dave Weldon, R-Fla., and backed by President Bush, passed 241-255. The measure prohibits any form of cloning, including therapeutic cloning used for research of Alzheimer's, Parkinson's, diabetes and other diseases."), *available at* http://www.foxnews.com/story/0,2933,79770,00.html (last visited Sept. 24, 2003) (on file with the Connecticut Law Review). In contrast with the House, the U.S. Senate has proposed banning cloning for reproduction but allowing therapeutic cloning to continue. *See* Human Cloning Prohibition Act of 2002, S. 2439, 107th Cong. (2002); Human Cloning Prohibition Act, S. 2076, 107th Cong. (2002); Human Cloning Prohibition Act of 2001, S. 1899, 107th Cong. (2002); *see also* Jonathan S. Swartz, *The Human Cloning Prohibition Act of 2001: Vagueness and Federalism*, 43 JURIMETRICS J. 79 (2002) (discussing the House version of this bill); Helen Dewar, *Human Cloning Ban Sidetracked*, WASH. POST, June 19, 2002, at A4, LEXIS, News Library, Wpost File. Similarly, in June 2003, the American Medical Association endorsed cloning for research purposes. For information about this statement, visit the Internet site of the AMA at http://www.ama-assn.org/ama/pub/article/8833-7788.html; *see also Research Cloning Backed by AMA*, BOSTON GLOBE, June 18, 2003, at A2.

[321] *See 18 Ways to Make a Baby*, *supra* note 6. According to a report issued from the United Kingdom in July 2003, IVF babies are at least as healthy as babies conceived through the traditional method. *Embryology Conference: Longest-Running Study Finds Little Evidence of Ill-Health*, INDEPENDENT, July 3, 2003, at 10, LEXIS, News Library, Indpnt File.

[322] *See 18 Ways to Make a Baby*, *supra* note 6.

[323] ICSI was developed by Professor Andre van Steirteghem, a Belgian gynecologist, and Dr. Ng, a Vietnamese physician. Andrea S. 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); *see also infra* note 384 and accompanying text.

deemed infertile.[324]

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.[325] These numbers may be conservative. Other reports have placed the number of babies born with ART at 60,000 as early as 1998.[326] Moreover, the sector, already a multi-billion dollar business annually,[327] is growing exponentially due to cultural trends that include delay of childbearing,[328] the rising popularity of medical innovation in general and intervention in reproduction especially in the midst of the genetic revolution,[329] and the placement of a premium on autonomy in medicine,[330] procreation,[331] and procreative liberty.[332] According to one report, as of May 2001, one in six American couples experienced difficulties conceiving a child, and ART constituted a $4 billion industry—a somewhat astonishing number given the youth of the sector.[333] Where limits on reimbursement are tempering

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[324] Voss, *supra* note 323, at 232.

[325] Technology Report, *supra* note 11, at 11.

[326] ISLAT Working Group, *ART into Science: Regulation of Fertility Techniques*, SCIENCE, July 31, 1998, at 651, *available at* http://www.sciencemag.org/cgi/content/full/281/5377/651 (last visited Sept. 24, 2003) (on file with the Connecticut Law Review).

[327] *See* discussion *supra* note 10. ART is at the extreme side of a general trend of shifting health care deeper into the private, for-profit market:

> There can be little doubt that the greatest economic force now sweeping through health care systems worldwide is that of the market. The "market" may be understood in a variety of ways, but it is perhaps best interpreted in theory as a way of allowing individuals, not government, to make their own choices; as a way of promoting the most efficient distribution of goods, to be brought about by open and private competition; and as a means of devising incentives and disincentives for modifying supply and demand behavior. For a growing number of countries a market orientation combines a desire on the part of patients for more choice and a desire on the part of governments to relieve their economic burdens and thus to force onto patients and/or employers a greater share of health care costs.

GOALS, *supra* note 224, at 42.

[328] *See 18 Ways to Make a Baby*, *supra* note 6; discussion *supra* note 10.

[329] *See generally The Human Genome*, *supra* note 238; discussion *supra* Part V. For example, the public is increasingly seeking out information about and demanding access to clinical trials to meet health care needs. *See supra* notes 231-32 and accompanying text.

[330] *See supra* notes 169-70, 228-29 and accompanying text; GOALS, *supra* note 224, at 34 (discussing autonomy as a medical goal).

[331] The "pro-choice" and "pro-life" (or "anti-abortion") movements are both strong, perhaps invigorated by a challenge to the status of *Roe* made by a Republican-dominated government. *See, e.g.*, Marilyn Rauber, *Abortion Foes Hope Vote Signals Shift*, RICHMOND TIMES DISPATCH, Mar. 16, 2003, at A-6, LEXIS, News Library, Rchtmd File; Joan Vennochi, *That Other War: Abortion Rights*, BOSTON GLOBE, Mar. 20, 2003, at A17, LEXIS, News Library, Bglobe File.

[332] *See* discussion *supra* note 313.

[333] *See 18 Ways to Make a Baby*, *supra* note 6; *Making Babies*, *supra* note 6. It is very likely that assessments of the sector are conservative given reliance on self-reporting for available data, institutional differences among the entities offering ART (according to the CDC), and the fact that most are

the financial profitability of most areas of medicine and reducing physician income, patients usually pay for ART directly and at an average cost of $8,000-$10,000 per IVF cycle,[334] even though the average rate of conception is only about twenty-five percent.[335]

The vast majority of ART clinics are highly competitive, for-profit commercial companies.[336] These entities measure their success rates based upon live births and usually without considering the health of the children.[337] Market competition is exacerbated by the mobility of the patient group responsible for market demand. Given the fact that these patients usually are paying for ART directly and making a considerable financial investment in addition to subjecting themselves to invasive procedures and a regimen of high dosages of potent fertility drugs,[338] a significant part of this patient population is willing to travel to obtain the best service—as reflected in the national and even international DTC marketing of many ART service providers.[339] Moreover, with a meaningfully greater likelihood of failure than success, given the cost and invasiveness factors and with time being of the essence,[340] prospective parents usually are eager to maximize the likelihood of a positive outcome by implanting multiple em-

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private commercial entities and profitability and demand suggest that more are being established on an ongoing basis. *See generally* Kolata, *supra* note 10; *Making Babies*, *supra* note 6; ANALYTICAL SCIENCES, INC., CDC, FINAL REPORT SURVEY OF ASSISTED REPRODUCTIVE TECHNOLOGY: EMBRYO LABORATORY PROCEDURES AND PRACTICES 1, 13 (1999), *available at* http://www.phppo.cdc.gov/dls/pdf/art/ARTsurvey.pdf [hereinafter EMBRYO PROCEDURES AND PRACTICES].

[334] Jones, *supra* note 278, at 44-45.

[335] *See* Technology Report, *supra* note 11, at 1.

[336] *See* EMBRYO PROCEDURES AND PRACTICES, *supra* note 333, at 13; *Making Babies*, *supra* note 6; *18 Ways to Make a Baby*, *supra* note 6. Of the clinics included in the CDC survey (which was based heavily on voluntary reporting through SART and ASRT), 182 of the facilities identified as eligible for the survey were categorized "Independent ART programs." Sixty-seven were deemed "University-based ART programs" and fifty-one were categorized as "Hospital-based ART programs." EMBRYO PROCEDURES AND PRACTICES, *supra* note 333, at 1, 13.

[337] *See* Technology Report, *supra* note 11; *Making Babies*, *supra* note 6; *18 Ways to Make a Baby*, *supra* note 6.

[338] *See Making Babies*, *supra* note 6.

[339] *See* Kolata, *supra* note 10; Centres for Assisted Reproduction ("CARE"), *at* http://www.care-ivf.com/welcome.htm (last visited Sept. 24, 2003) (on file with the Connecticut Law Review); The Fertility Center, LLC, *at* http://www.thefertilitycenter.com (last visited Aug. 23, 2003) (on file with the Connecticut Law Review); The Law Office of Sue A. Moravec, A Family Law Practice, *at* http://www.familylawpractice.net/html/assistedreproduction.htm (last visited Sept. 24, 2003) (on file with the Connecticut Law Review).

[340] It has been established that fertility decreases significantly with advancing age. Women experience a significant drop at 35 and men at age 40. *See* Technology Report, *supra* note 11; Michele Norris, *Infertile Ground Study: Fertility Chances Drop Sooner than Expected* (May 1, 2002), *at* http://abcnews.go.com/sections/wnt/DailyNews/fertility020430.html (last visited Sept. 24, 2003) (on file with the Connecticut Law Review).

bryos.[341] ART providers generally are receptive, for rises in success rates increase the persuasiveness of marketing.[342] In fact, some ART clinics even offer money-back guarantees.[343] Consequentially, the popularity of ART has coincided with a substantial increase in the number of multiple pregnancies, which has resulted in more premature births and more children with often debilitating health problems.[344] Also, receptiveness to ART by both providers and patients demonstrates a propensity for applying medical innovation and, in many instances, originating medical innovation in the context of clinical service. The invention and application of ICSI constitutes a noted example.[345] That technique originated as a laboratory mistake: the doctor mistakenly perforated the outer membrane of an egg cell and directly introduced a sperm cell.[346] Then, that embryo grew while the patient's other embryos did not.[347] Without the benefit of comprehensive animal studies, a staple prerequisite for human subject experimentation,[348] or the oversight of an IRB and comprehensive information exchange to obtain informed consent, this researcher then took the liberty of implanting the controversial embryo—which resulted in a successful delivery.[349] Consider that now some ART physicians are taking even greater liberties that involve genetic manipulation without the prerequisite of comprehensive animal studies and compliance with standard human subject protection mechanisms, such as cytoplasmic transfer to help women who conceive but cannot carry a pregnancy past a few months.[350] The procedure involves transferring cytoplasm from a donor egg into a patient's egg in the hopes that the transferred mitochondrial DNA will give the patient's egg and resulting embryo a needed boost of energy.[351] Another evolving,

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[341] *See Making Babies*, *supra* note 6; *supra* note 11 and accompanying text. It also is common practice to create many more embryos than are actually used. *See* discussion *supra* note 11 (reporting nearly 400,000 frozen embryos in the U.S.).

[342] *See* Kolata, *supra* note 10.

[343] *Id.*

[344] *Preemies*, *supra* note 11; *Making Babies*, *supra* note 6.

[345] *See supra* notes 323-24 and accompanying text.

[346] *18 Ways to Make a Baby*, *supra* note 6.

[347] *Id.*

[348] *See* Malinowski & Rose, *supra* note 174, at 9-4 to 9-5.

[349] *See 18 Ways to Make a Baby*, *supra* note 6.

[350] *See id.* For more information about cytoplasmic transfer, visit The Reproductive Sciences Center at http://www.fertile.com/cytoplasmic_transfer.htm (last visited Sept. 24, 2003) (on file with the Connecticut Law Review).

[351] *18 Ways to Make a Baby*, *supra* note 6. The premise for the technique is that the healthier cytoplasm has more or more vibrant mitochondria, which are analogous to batteries, and thus gives the recipient an energy boost. *See id*; *see also* The Reproductive Sciences Center, *supra* note 350. "Mitochondria are the powerhouses of the cell, little 'organelles'—1,000 per cell—that, in the presence of oxygen, convert the energy stored in the hydrogen bonds in fat and sugar into the kind of energy the body can use, a substance called adenosine triphosphate, or ATP." Judy Foreman, *Diseases Can Affect the Power in our Cells*, BOSTON GLOBE, June 17, 2003, at C3, LEXIS, News Library, Bglobe File.

experimental procedure is in vitro maturation, which as of July 2003 was estimated to create about 250 babies worldwide.[352] This method consists of maturing ova in a laboratory dish, thereby allowing fertile women partnered with men who have sperm problems to avoid taking high levels of risk hormone injections.[353]

If the future of ART remains wholly market-driven,[354] companies in the sector will continue to apply advances in genetic medicine as soon as it is financially feasible to do so—for example, to increase their success rates (a powerful marketing factor) and to offer potential clients more options than the competition. From the perspective of a consumer who decides to embrace this technology and to make a tremendous personal and financial investment, having more options to influence the outcome of a pregnancy for marginally more money holds appeal.[355] ART options, which presently include sperm selection to influence the sex of the child and limited genetic screening of embryos prior to their implantation, will expand exponentially in conjunction with the advancement of genetic medicine.[356] While traditional prenatal genetic testing has depended upon the sometimes speculative endeavor of detecting a protein associated with a gene connected to the subject disease,[357] DNA can be analyzed directly through recombinant DNA technology—giving rise to a multitude of application possibilities.[358]

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[352] *Children from Eggs Matured in Lab Normal*, BOSTON GLOBE, July 1, 2003, at A6, LEXIS, News Library, Bglobe File.

[353] *Id.* ("Danish researchers told scientists at a European fertility conference yesterday that a study of 33 babies born using the technique . . . indicat[ed] they are normal, at least up to age 2.").

[354] *See* discussion *supra* Part VI.A.

[355] *But see* Pinker, *supra* note 21 (stating, based largely upon observations of human nature, that the public will not embrace PGD in this manner). In fact, according to a survey of public responsiveness to choosing traits for offspring completed in 1999, sixty percent of respondents indicated that they would do so to rule out fatal illness, thirty-three percent indicated they would to ensure greater intelligence, twelve percent would to influence height or weight, and eleven percent would to determine sex. *What People Think*, TIME, Jan. 11, 1999, at 48, LEXIS, News Library, Time File.

[356] *See* Jason Christopher Roberts, *Customizing Conception: A Survey of Preimplantation Genetic Diagnosis and the Resulting Social, Ethical, and Legal Dilemmas*, 2002 DUKE L. & TECH. REV. 12, ¶¶ 26-27 (July 23, 2002), *at* http://www.law.duke.edu/journals/dltr/articles/2002dltr0012.html (last visited Sept. 24, 2003) (on file with the Connecticut Law Review). *See generally* discussion *infra* Part VI. PGD received much attention with the announcement that Chicago researchers used the technology to enable a woman with a family history of Alzheimer's to deliver a child born free of identified genetic susceptibility to the disease. *See* Roberts, *supra*, at ¶ 3; Jones, *supra* note 278, at 44-45 (discussing the PGD procedure from a patient's perspective). As stated by Leon Kass, "to produce . . . healthy and well-endowed babies, let alone babies with the benefits of genetic enhancement, a new scientific obstetrics will be necessary, one that will come very close to turning human procreation into manufacture." LEON R. KASS, LIFE LIBERTY AND THE DEFENSE OF DIGNITY: THE CHALLENGE FOR BIOETHICS 130 (2002).

[357] "The protein, however, cannot be easily or safely detected in numerous cases—notably sickle-cell anemia. (The telltale hemoglobin can be obtained only by direct extraction of fetal blood—a procedure extremely hazardous to the fetus.)." KEVLES, *supra* note 28, at 294.

[358] "The trick relies on choosing a restriction enzyme that will cut from the DNA chain a strand containing or adjoining the gene of interest." *Id.*

For example, in May 2003, a British woman gave birth to Jamie, a child genetically matched to an older brother, Charlie, suffering from a rare form of anemia so that stem cells from Jamie's umbilical cord could be used to treat Charlie.[359]

Bioinformatics is making it possible to bundle thousands of genetic characteristics into a single and increasingly affordable test. While small bits of genetic information that amount to a cluster of probabilities may not hold much appeal on an individual basis, together, thousands of individual notes may hold the market appeal of a symphony of information, especially when there are embryos from which to choose.[360] Also, some screening tests for specific genetic characteristics—for example, those associated with cystic fibrosis—do deliver meaningful genetic information. When choices must be made among embryos, certainly there is market appeal in testing for these and, for a slightly higher price, screening for hundreds or even thousands more characteristics at the same time. Depending on the prospective parents and their circumstances (for example, an older couple that approaches ART as a single opportunity to have the perfect child), broad genetic screening may hold market appeal even at a significantly higher price.[361]

Arguments can be made that, at least for a number of years, the availability of broad PGD screening will be checked by control over the technology by commercial interests with a focus on drug development rather than patient services and otherwise prevent access through high prices. There certainly are instances now where commercial entities hold patent rights over genetic tests and make them available only at a prohibitive price or not at all.[362] However, these situations reflect limited developed genetic

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[359] The mother obtained ART services at the Reproductive Genetics Institute in Chicago after Britain's regulatory body that oversees ART, the Human Fertilization and Embryology Authority, vetoed the treatment because Charlie did not have a hereditary illness. Warren Hoge, *Britain: Baby Born to Couple Who Want Stem Cells*, N.Y. TIMES, June 20, 2003, at A8. The same authority approved this technique for use by another British couple to save a terminally ill son who suffered from a hereditary disease. *Id.* It is important to note, however, that Britain, in contrast with the United States, allows the creation of embryos for research purposes under the oversight of authorities like the Human Fertilization and Embryology Authority. Nicholas Wade, *Clinics Hold More Embryos Than Had Been Thought*, N.Y. TIMES, May 9, 2003, at A20. *See generally* John A. Robertson et al., *Conception to Obtain Hematopoietic Stem Cells*, HASTINGS CENTER REP., May-June 2002, at 34, 40 (concluding, "[s]uch practices may be controversial, but they will often reflect deep concern for both children, and should be available for parents who have no other good therapeutic alternatives."); Robertson, *supra* note 5, at 468 (addressing case-specific uses of PGD in this context).

[360] *But see* Pinker, *supra* note 21 (measuring the basic appeal of PGD upon the predictive limitations of individual genetic screens rather than the potential appeal of bundles of such genetic screens through bioinformatics and DNA chips). The trend in the U.S. is to create many more embryos than are actually used, resulting in approximately 400,000 human embryos in frozen storage. *See 400,000 Embryos and Counting*, *supra* note 11, at A24.

[361] *See infra* note 409 and accompanying text (competition for "Baby Ivies").

[362] A noted example is Myriad's BRCA test, which is discussed *supra* note 5. *See generally* Allen C. Nunnally, Note, *Commercialized Genetic Testing: The Role of Corporate Biotechnology in the*

testing capabilities in the hands of an also limited number of commercial entities engaged in commercial genetic testing which, incidentally, face tremendous market impediments due to the legal environment surrounding this technology.[363] Limitations on market availability may hold true for genetic tests that generate big pieces of genetic information that carry independent commercial value, but the deluge of subtle genetic-medical connections being made in conjunction with drug development will provide a means for broad PGD.[364] Compilation of SNPs into massive databases is a prerequisite for drug development and certainly should make SNPs medically useful.[365] Even multinational competing commercial interests such as AstraZeneca and Merck have been collaborating to create these commons, and the commons are being created.[366] Consider that, from a commercial perspective,[367] use of these commons in ART constitutes a potentially meaningful windfall return—an additional source of revenue and also a means for generating yet more data to better clarify some genotype-phenotype connections in the broad human population. We live in an age when the DNA and medical histories of entire populations are being organized and made commercially available.[368] Ultimately, the same advances in bioinformatics that make this knowledge useful for drug development will make it useful for PGD and on a cost-effective basis:

> In the future it should be routinely possible for parents to have their embryos automatically screened for a wide variety of disorders, and those with the "right" genes implanted in the mother's womb. . . . Geneticist Lee Silver paints a future scenario in which a woman produces a hundred or so embryos, has them automatically analyzed for a "genetic profile," and then with a few clicks of the mouse selects the one that not only lacks alleles for single-gene disorders like cystic fibrosis, but also has enhanced characteristics, such as height,

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New Genetic Age, 8 B.U. J. SCI. & TECH. L. 306, 322 (2002) (discussing the high costs of genetic tests for breast cancer and Canavan disease resulting from the monopoly rights awarded to the patent holders); James Donahue, Note, *Patenting of Human DNA Sequences—Implications for Prenatal Genetic Testing*, 36 BRANDEIS J. FAM. L. 267, 282 (1997-1998) ("Nevertheless, the patenting of human DNA sequences will have a profound effect on the lives of nearly every American.").

[363] *See* Nunnally, *supra* note 362, at 324; *Snake Oil*, *supra* note 5, at 38-39 (stating "Legal liability is simply too crude an instrument for responsible integration of predictive genetic testing into health care. . . .").

[364] *See* discussion *supra* note 5 and accompanying text.

[365] *See* discussion *supra* note 5 and accompanying text.

[366] *See* discussion *supra* note 5 and accompanying text.

[367] It is important to note that there likely will be varying commercial interests and commercial controls over this information, as reflected in the interests of AstraZeneca, Merck, Orchid Pharmaceuticals, and other entities in the SNP Consortium. *See* discussion *supra* note 5 and accompanying text.

[368] *See supra* note 261 and accompanying text (addressing biobanking).

hair color, and intelligence.[369]

"Ultimately" may prove to be years rather than decades. The pace of advancement of biotechnology over the last decade and of genomics over the last few years loudly cautions one to not assume the luxury of time.[370]

VII. A PROPOSED ROLE FOR MORE MEANINGFUL REGULATION OF ART

There are ample reasons to embrace ART and to rejoice at the vitality of this sector, especially now as technology such as bioinformatics opens entirely new dimensions for science—namely the orchestrated intricacies of gene and protein function—and introduces potential to improve human health.[371] ART already must be attributed with a dramatic increase in procreative liberty: Annually, thousands of children who would not otherwise exist are being delivered to wanting parents.[372] Also, through ART, many miscarried pregnancies and the associated trauma have been avoided.[373]

Nevertheless, there are compelling arguments that support immediate infusion of comprehensive regulation into the field of ART. First, experimentation on human subjects must be recognized as such and regulated accordingly.[374] Controversies reported over the last several years have caused many to question the soundness of the United States' regulatory

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[369] FUKUYAMA, *supra* note 6, at 75. Professor Silver "[e]ven contemplates a scenario in which society splits into two camps, the 'gen-rich' and the 'gen-poor,' those with and those without a designer genome." Michael Lemonick, *Designer Babies*, TIME, Jan. 11, 1999, at 66, LEXIS, News Library, Time File; *see also* LEE SILVER, REMAKING EDEN 199-203 (1997) (discussing the potential for PGD to allow parents to screen virtual children in order to choose desired genetic characteristics). For further discussion on this, see MCKIBBEN, *supra* note 14, at 226-227.

[370] *See supra* notes 18, 275-76 and accompanying text.

[371] *See generally* discussion *supra* Part V. Genetic disorders occur in three to five percent of all live births. KEVLES, *supra* note 28, at 291. This technology, if mainstreamed and used with a focus on human health certainly could make a meaningful difference, especially as genetic testing capabilities unfold:

> The percentages may be small, but the absolute annual numbers suggest a wrenching magnitude of individual afflictions—in the United States, up to one hundred and sixty-five thousand abnormal infants, including from six to eight thousand with neural-tube defects like spina bifida, five thousand cases of Down's syndrome, fifteen hundred of cystic fibrosis, at least a thousand of sickle-cell anemia.

Id.

[372] According to data reported voluntarily and processed by the CDC, more than 35,000 babies were born as a result of ART procedures carried out in 2000. Technology Report, *supra* note 11.

[373] *See, e.g.*, Goldberg, *supra* note 7.

[374] *See generally* discussion *supra* Part IV. One might argue that experimentation on humans involving genetics should trigger extra scrutiny given how the quest for understanding and controlling genes and the mission of improving the human condition have proven intoxicating rationales for the science and medical communities. *See generally supra* Parts II and III; *cf.* PAUL, *supra* note 13, at 2 ("Some people have recently questioned whether the reaction to Nazi crimes produced more than a temporary hiatus in eugenic theory and practice. . . . They fear that eugenics is back—in the benevolent guise of medical genetics.") (citation omitted).

regime to protect human subjects[375] and prompted first the Clinton Administration[376] and then the Bush Administration to declare their intentions to make the regime more reliable.[377] Nevertheless, a baseline of regulations to protect human subjects through regulatory oversight of human experimentation does exist.[378] Ironically, this law, which evolved over time in response to Nazi eugenics and subsequent domestic human subject abuses such as the Tuskegee experiments,[379] which expressly recognizes pregnant women, fetuses, and children as vulnerable groups in need of added protections,[380] and which expressly imposes added protections for human in vitro fertilization, has not been meaningfully applied to ART.[381] In the absence of application of these baseline safeguards, experimentation such as the early applications of ICSI and now aggressive drug therapy, cytoplasmic transfer, and perhaps even attempts at human cloning for reproduction[382] are being carried out on an immensely vulnerable patient group[383] and at their significant personal financial expense and with great profitability to

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[375] One of the most publicized controversies was the death of Jesse Gelsinger. *See supra* note 235 and accompanying text; Jeffrey Brainard, *Could Better Reports by Researchers Have Prevented a Clinical-Trial Death?*, CHRON. HIGHER EDUC., Apr. 14, 2000, *available at* http://chronicle.com/prm/weekly/v46/i32/32a04501.htm. Controversies in human subjects research continue to arise. *See, e.g.*, Alexander Otto, *Researchers Under Criminal Investigation for VA Drug Study Deaths in N.Y.*, BNA, INC., *available at* http://www.researchprotection.org/infomail/0203/06.html (last visited Sept. 18, 2003) (on file with the Connecticut Law Review) (reporting that two medical researchers are under criminal investigation for the deaths of at least five patients in drug studies at the Stratton Veterans Affairs Medical Center in Albany, NY).

[376] *See* Press Release, Department of Health and Human Services, Secretary Shalala Bolster Protections for Human Research Subjects (May 23, 2000) [hereinafter DHHS Press Release], *available at* http://www.hhs.gov/news/press/2000pres/20000523.html (last visited Sept. 18, 2003) (on file with the Connecticut Law Review); Shalala, *supra* note 235, at 809; Erica Rose, *Financial Conflicts of Interest: How are we managing?*, 8 WIDENER L. SYMP. J. 1, 8 (2001) (discussing the expectation that NIH and FDA would develop joint conflicts of interest policies).

[377] *See* discussion *supra* notes 235-36; Jeffrey Brainard, *New Human Subjects Chief Will Face Challenges and Controversies; Agenda May Include Protections for Embryos, Self-Regulation, and Unfinished Business*, CHRON. HIGHER EDUC., Nov. 22, 2002, at A25 (mentioning that the Bush administration is likely to expand human-subject protection).

[378] *See generally* Malinowski & Rose, *supra* note 174, at 9-4 (stating that "regulatory schemes . . . include safeguards to ensure that the rights and interests of individual patients are not sacrificed for the advancement of medicine."); PROTECTING THE PEOPLE, *supra* note 162, at 20 (explaining that federal jurisdiction over human subject research extends to research that is conducted or supported by the federal government, and to research that is regulated under a federal statute).

[379] *See generally* discussion *supra* Part IV.

[380] 45 C.F.R. §§ 46.111(b), 46.201-.207 (2002); 21 C.F.R. 56.111(b) (2003).

[381] *See generally* discussion *supra* Part VI.

[382] *See Today: Panos Zavos Discusses the Controversial Cloning for the First Human Baby* (NBC television broadcast, Aug. 13, 2002); *Sunday Morning: French Chemist Claims to Have Produced the First Human Clone* (CBS television broadcast, Dec. 29, 2002). *See generally* CLONE, *supra* note 12 ("A highly controversial effort is underway to produce children by cloning.").

[383] *See supra* notes 226-27 and accompanying text (added protections for pregnant women and embryos under the Common Rule).

those engaged in providing ART services.[384]

Second, action must be taken to ensure good medicine practices are developed and adhered to especially given the vulnerability of this patient group,[385] commercial influences,[386] and the temptations to overuse emerging science prematurely.[387] The well-documented trend of multiple ART births—the CDC estimates thirty-five percent of ART deliveries[388] and some estimates exceed forty percent of ART pregnancies[389]—and, consequentially, tens of thousands of premature deliveries resulting in often seriously unhealthy babies[390] is ample reason to take this action. In addition, known experience to date with ART includes the unchecked introduction of techniques such as ICSI,[391] ongoing experimentation with cytoplasmic transfer,[392] and the brazen declarations of Dr. Panos Zavos and the Raelians of their intentions to clone humans.[393] Moreover, ART is a field that has expanded explosively during the last decade, and especially in recent years. Its detonation synchronized with the launch of the genetics revolution and a jolting shift of biomedical research into commercialization and privatization of even basic research through academic-industry collaborations and the proliferation of hundreds of private biotechnology companies.[394] This

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[384] *See supra* notes 278-80 and accompanying text.

[385] This vulnerability has been recognized and codified under United States law. 46 C.F.R. §§ 46.201-.207; *see also supra* notes 226-27 and accompanying text.

[386] *See* Kolata, *supra* note 10 (discussing the competitive fertility clinic market and the strategies some clinics are using to attract clients).

[387] *See generally* Botkin, *supra* note 280, at 288 (proposing professional standards, but as opposed to regulation or other law). *But see* David Wasserman, *A Choice of Evils in Prenatal Testing*, 30 FLA. ST. U. L. REV. 295, 313 (2003) (preferring unrestricted parental choice rather than making medical choices about testing options); *Making Babies*, *supra* note 6 (mentioning that the ART industry has consistently resisted regulation).

[388] This estimate is based upon data submitted voluntarily by ART clinics. *See supra* note 11 and accompanying text.

[389] *See Making Babies*, *supra* note 6 ("In many leading fertility clinics, nearly 50 percent of all in vitro treatments of women under 35 result in multiple births . . . .")

[390] *Id.*; *see also Preemies*, *supra* note 11 (discussing the health problems premature infants face due to their underdeveloped organs and immune systems).

[391] *See supra* notes 323-24, 345-39 and accompanying text.

[392] *See supra* note 350 and accompanying text.

[393] *See supra* notes 320, 382 and accompanying text.

[394] *See generally Market Implications*, *supra* note 5, at 33 (predicting that the increased pressure the biotechnology industry faces will lead to increased risks for human subjects). In September 2003, NIH announced a multi-billion-dollar commitment to integrate academia and commercial application yet further. *See supra* note 252. For information about these companies and the commercial application of biotechnology by multinational sectors such as pharmaceuticals and agriculture, visit the sites of the Biotechnology Industry Organization ("BIO"), the major biotechnology trade association, at http://www.bio.org (last visited Sept. 24, 2003) (on file with the Connecticut Law Review), and the site of the Pharmaceutical Research and Manufacturers Association ("PhRMA"), the multinational pharmaceutical trade association, at http://www.phrma.org (last visited Sept. 24, 2003) (on file with the Connecticut Law Review). *See also Genomics Players: From Discovery to Integration—Business and Technology Assessment, 2002*, M2 PRESSWIRE, Feb. 19, 2003, LEXIS, News Library, M2pw file (dis-

emergence was recent enough to escape meaningful self-regulation by the medical profession, the mechanism traditionally relied upon heavily to ensure quality medical care, for the spread of managed care and the consolidation and for-profit conversions of health care institutions throughout the 1990s has weakened that mechanism immensely.[395] Also, managed care has grown in conjunction with ART, but as an accompaniment rather than as a mechanism for control, for ART draws patients willing to pay out of pocket.[396] As stated previously, no state has fully implemented the CDC's Model Legislation for regulation of ART, and professional certification and licensing are not prerequisites to provide ART in the direct-pay, private market that is driving these services. In addition, ART introduces complicated patient care issues, especially for a generation of health care providers grappling with the novelty of contemporary, dynamic genetic medicine.[397] Advances in genetics are permeating throughout the practice of medicine.[398] At least according to the perception of a significant portion of the general population, standard of care has expanded to encompass

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cussing new business models and profiling key bioinformatics companies and estimating that the bioinformatics market, valued at $360 million in 1999, will surpass $2 billion by 2007); FUKUYAMA, *supra* note 6, at 214 ("The U.S. biotech industry by itself spent nearly $11 billion on research in 2000, employs over 150,000 people, and has doubled" over the last decade).

[395] In fact, the control held by care managers has inspired a flurry of legislative initiatives, state and federal, ranging from prohibitions on "gag rules" to review of coverage denials by independent third party bodies and a range of "patient bill of rights" protections. For example, California has created a Department of Managed Health Care to oversee private managed care organizations, including HMOs. *See* Department of Managed Health Care, *at* http://www.hmohelp.ca.gov (last visited Mar. 23, 2003) (on file with the Connecticut Law Review). As observed by Daniel Callaghan and Mark Hanson:

> [w]hile medicine still has the capacity from within significantly to determine its own course, it is highly influenced by the mores, values, economics, and politics of the societies of which it is a part. The border between the realm of medicine and the realm of society is increasingly porous. Medicine is fed by the large amounts of money spent by government and private industry, and no less by the power of advertising and the media, as well as popular tastes, fantasies, and desires.

GOALS, *supra* note 224, at 13.

[396] *But see* Adamson, *supra* note 21, at 934 (stating "[o]ther mandatory nonmedical regulations include insurance company, HMO, and other healthcare organization requirements" and then relying on examples drawn from Massachusetts, one of the few states that legislatively require IVF coverage by insurers).

[397] *See generally* MARY B. MAHOWALD ET AL., GENETICS IN THE CLINIC: CLINICAL, ETHICAL, AND SOCIAL IMPLICATIONS FOR PRIMARY CARE (Liz Fathman ed., 2001) [hereinafter GENETICS IN THE CLINIC] (aiming to assist primary caregivers with the needed integration of genetics into their routine practice). "Specialists in genetics are needed for the education of primary care physicians, who will be responsible for providing established medical genetics practice." *Id.* at xi; *see also Snake Oil*, *supra* note 5, at 45 ("Ultimately, application of [predictive genetic testing] is patient-specific.").

[398] FUKUYAMA, *supra* note 6, at 72-83 (discussing existing and potential medical advances involving genetics); GENOMICS AND WORLD HEALTH: REPORT OF THE ADVISORY COMMITTEE ON HEALTH RESEARCH 5 (World Health Organization 2002), *available at* http://www.who.int ("It is now believed that the information generated by genomics will . . . have major benefits for the prevention, diagnosis and management of many diseases which hitherto have been difficult or impossible to control.") (last visited Sept. 24, 2003) (on file with the Connecticut Law Review).

advanced clinical trials,[399] and the probabilities introduced by the results of genetic screening pose an interpretation challenge for providers and patients accustomed to the definitive results of traditional diagnostics.[400] Realizing informed consent under such circumstances poses an ominous challenge in many cases,[401] which has proven a chronic focus of ongoing multidisciplinary debate.[402]

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[399] *Institutional Conflicts*, *supra* note 19, at 53-54 (discussing the public's perception of clinical research as offering the most innovative treatment options). For identification of ongoing clinical trials, visit http://clinicaltrials.gov (providing details on approximately 8,400 mostly government-funded clinical trials) (last visited Sept. 24, 2003) (on file with the Connecticut Law Review); http://cancer.gov/clinicaltrials (giving the National Cancer Institute's clinical trial listing) (last visited Sept. 24, 2003) (on file with the Connecticut Law Review); http://aidsinfo.nih.gov (the AIDS clinical trials information service ("ACTIS")) (last visited Sept. 24, 2003) (on file with the Connecticut Law Review); http://www.veritasmedicine.com (discussing trials and standard treatments for numerous diseases) (last visited Sept. 24, 2003) (on file with the Connecticut Law Review); http://www.americasdoctor.com (trials in seven disease categories, excluding cancer) (last visited Sept. 24, 2003) (on file with the Connecticut Law Review); and http://www.acurian.com/patient (developing lists of trials in various disease categories) (last visited Sept. 24, 2003) (on file with the Connecticut Law Review).

[400] MAHOWALD, *supra* note 397, at 2 (discussing the difficulties facing clinicians with regard to communicating genetic diagnoses, "[g]ood news does not preclude a bad outcome and vice versa"). As stated by author Daniel Kevles:

> The advance of genetic knowledge has already increased the range of medical and procreative opportunities, and the choices raised by their advent can be discomfiting. Genetic screeners worry that the publicity given screening programs may cause needless apprehension among people whom the roll of the genetic dice has favored, and that the genetic information obtained may lead to unreliable anxiety among those whom it has not. Many more genetic diseases can now be identified than can be cured or even treated. . . . The revelation of genetic hazard has been observed to result not only in repression but in anxiety, depression, and a sense of stigmatization.
>
> Some genetic counselors report that their patients show no difficulty in comprehending the information they are given, but various studies by psychologists and psychiatrists have concluded that a large fraction of counselees are likely not to understand, assimilate, or remember analyses relevant to their own genetic constitutions.

KEVLES, *supra* note 28, at 297-98 (citations omitted); *see also* PRIMER, *supra* note 2, at 151 ("At present, however, there are only about one thousand genetic counselors in the United States, most within university centers. The general population will seek help in interpreting genetic tests from their primary care physicians. . . . Is there hope that physicians will be able to achieve this knowledge?").

[401] *See generally* Fleetwood, *supra* note 233 (arguing that patients are rarely informed of or protected against a doctor's conflict of interest); MAHOWALD, *supra* note 397 (analyzing the issue of informed consent in a variety of circumstances).

[402] *See, e.g.*, Ruth Chadwick, THE ETHICS OF GENETIC SCREENING at xv (Ruth Chadwick et al. eds., 1999) (highlighting projects to raise public awareness of genetic screening); Ruth Chadwick et al., *Genetic Screening and Ethics: European Perspectives*, 23 J. MED. & PHIL. 255 (1998) (highlighting projects to raise public awareness of genetic screening); Mark A. Rothstein & Sharona Hoffman, *Genetic Testing, Genetic Medicine, and Managed Care*, 34 WAKE FOREST L. REV. 849 (1999) (maintaining that increased patient education is necessary); Sonia M. Souter, *The Routinization of Prenatal Testing*, 28 AM. J.L. & MED. 233 (2002); NUFFIELD COUNCIL ON BIOETHICS, GENETIC SCREENING ETHICAL ISSUES at i-ii (1993) *available at* http://www.nufieldbioethics.org/filelibrary/pdf/genetic_screening.pdf (arguing for increased patient consideration of moral implications of prenatal testing) (last visited Sept. 18, 2003) (on file with the Connecticut Law Review).

Third, additional regulatory safeguards must be introduced to effectively regulate ART as an alternative to categorically prohibiting ongoing stem cell and other tissue research—for example, through express prohibitions on therapeutic cloning or protections for embryos that accomplish the same.[403] According to NIH, one in three Americans have health conditions, many life-threatening and highly debilitating, that could be improved through this research, and others have reported that number to be as high as one in two Americans.[404] Regulatory oversight and control over assisted reproduction with perhaps criminal penalties for violations would provide some assurance that techniques perfected through therapeutic cloning would not have immediate carryover into the "wild, wild West" of medicine.[405]

Fourth, meaningful regulation is a prerequisite for full observation, accountability, societal reflection, and collective, democratic decision-making.[406] Genetic manipulation in procreation, even at the level of genetic screening and embryo selection, is something that we as a society should know about and contemplate at least as it is transpiring, and preferably beforehand. This is especially true in our aggressively competitive, Darwinian society with its premium on perfection[407] and its difficulties accepting people with observable health care challenges.[408] The potential social ramifications of doing otherwise are well documented and all too vivid in our past.[409] The opportunity to proactively consider social implica-

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[403] *See* Brainard, *supra* note 377, at A25 ("Any new director of [OHRP] will almost certainly have to be comfortable with extending regulations to protect embryos and fetuses, say several university officials involved in human-subjects protection."). *But see generally* KASS, *supra* note 356 (suggesting non-technological ideas and practices are needed to prevent tragedy from biotechnology). For discussion of stem cell research and an overview of related moral and ethical problems, see generally THE NATIONAL RESEARCH COUNCIL, INSTITUTE OF MEDICINE, STEM CELLS AND THE FUTURE OF REGENERATIVE MEDICINE (2002) *available at* http://www.nap.edu/books/0309076307/html.

[404] *See How to Build a Human: Predictor* (BBC television broadcast, 2002). The potential of this area of science has inspired Stanford University to establish a new center for stem cell research. Arguably, the mission of the center includes perfecting cloning techniques. William Kristol & Eric Cohen, *A Clone by Any Other Name*, WKLY. STANDARD, Dec. 16, 2002, at 9, LEXIS, News Library, Wklyst File.

[405] *See supra* note 277 and accompanying text (George Annas quote).

[406] For discussion of the importance of this, see generally MCKIBBEN, *supra* note 14 (arguing debate is needed regarding societal controls on genetic technology).

[407] *See Coming into Being*, *supra* note 9, at 1517 ("The availability of prenatal genetic screening technology is likely to reinforce insecurities arising from our survival-of-the-fittest norms, and those same norms may compel prospective parents to act on the insecurity.") (citations omitted).

[408] *Cf.* Harriet McBryde Johnson, *Unspeakable Conversations Or How I Spent One Day as a Token Cripple at Princeton University*, N.Y. TIMES, Feb. 16, 2003, § 6 (Magazine) at 50 (providing the first-person narrative of attorney Harriet McBryde Johnson discussing Professor Peter Singer's support of infanticide and her visit to Princeton as his guest).

[409] *See* discussion *supra* Parts II and III.

tions and legalities including family law considerations[410] accompanying use of this technology in a non-speculative manner will remain marginalized unless use of ART is observed and fully reported.

Fifth, and overshadowing each of the preceding reasons, we have a moral obligation to reflect on our not-too-distant eugenics past and our present tendency to make value judgments about the quality of the lives of people with visible differences.[411] As stated by Nancy Gallagher, author of *Breeding Better Vermonters*:

> The boundary between private rights and the public interest is a negotiable one. . . . As eugenics sentiments emerge, as they frequently do, our best safeguard against the injustices of the past rests with our willingness to confront our connection to this history prior to disowning it and with our recognition of the enduring power of research findings and the consensus of experts over perceptions of other people's problems.[412]

Through ART, procreative liberty is at a historical high.[413] In the United States, procreative liberty generally is recognized as a valued principle and often as a hard-earned right,[414] which is at least a partial explana-

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[410] *See supra* note 12 and accompanying text (addressing the Buzzaca case and referencing the work of Janet Dolgin). For example, there has been a marked increase in surrogacy arrangements in conjunction with use of ART. *See supra* note 12 and accompanying text.

[411] *See generally* Adrienne Asch, *Reproductive Technology and Disability, in* REPRODUCTIVE LAWS FOR THE 1990S (Sherrill Cohen & Nadine Taub eds., 1989) (arguing that women and people with disabilities have a common interest in ensuring biology is not controlling of life opportunities); Adrienne Asch, *Disability, Equality, and Prenatal Testing: Contradictory or Compatible?*, 30 FLA. ST. U. L. REV. 315 (2003) (concluding change is needed to make the climate in which prenatal testing takes place consistent with a society inclusive of the disabled); Johnson, *supra* note 408. "Human genetic engineering raises most directly the prospect of a new kind of eugenics, with all the moral implications with which that word is fraught, and ultimately the ability to change human nature." FUKUYAMA, *supra* note 6, at 72.

[412] GALLAGHER, *supra* note 24, at 8.

[413] *See* CARRICK, *supra* note 165, at 199 ("[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.").

[414] As explained by Daniel Kevles, although amniocentesis was developed in the 1960s, there was little demand for it until the Supreme Court legalized abortion. Since *Roe v. Wade* in 1973, the number of women undergoing prenatal diagnosis had continually grown, as have the kinds of fetal anomalies detected. KEVLES, *supra* note 28, at 257. Similarly, Daniel Callahan and Mark Hanson have observed that:

> modern contraceptives have brought about a striking change in the role of women and of procreation as a part of life. Genetic enhancements will add to those developments the prospect of manipulating fundamental human traits—improvements in intelligence and memory, and a reduction in violence, are among the speculative dreams—just as human growth hormone can already increase the height of those who, not abnormally short in the first place, want to be taller for personal or social reasons.

tion for the present dearth of regulatory oversight in the field of ART.[415] Another partial explanation is the premium placed on autonomy in health care decision-making, which also is rooted in libertarian ideals.

Contemporary genetic medicine promises to add scientific substance and practicality to what eugenicists set out to accomplish at the outset of the 20th century—improve the human condition through genetic selection.[416] Given the now dominant ethos of autonomy and self-determination in medicine,[417] which is underscored by the libertarian elements of United States culture, there is meaningful assurance that eugenics will not be imposed by a government body in the United States.[418] However, we must at least recognize the danger that through ART, the genetics revolution, and carte blanche procreative liberty we could do unto ourselves via the collective impact of individual decision-making what governments have imposed in the past in the name of bettering the human condition.[419] In the context of ART, our libertarian culture and the premium we place on procreative liberty must be tempered by social reflection.[420] "Traditional medical eth-

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GOALS, *supra* note 224, at 12. *See generally* THE CHOICES WE MADE, TWENTY-FIVE WOMEN AND MEN SPEAK OUT ABOUT ABORTION (Angela Bonavoglia ed., 2001) (discussing the increasing power of women resulting from reproductive freedom).

[415] Some commentators, including Daniel Kevles, believe that the role for law in procreation will remain minimal:

> The willingness of individuals to use rapidly developing genetic and reproductive knowledge may have more subtle effects. Genetic screening and counseling, amniocentesis and abortion, and attempts at genetic therapy will probably long remain matters of private, voluntary choice, to be arrived at by consultation between individual families and their physicians.

KEVLES, *supra* note 28, at 300 (addressing the private-public tension over the introduction of advances in human genetics).

[416] *See generally* discussion *supra* Part II.

[417] *See supra* note 228 and accompanying text (the ethos trilogy).

[418] *See* KEVLES, *supra* note 28, at 300; discussion *supra* Part IV.

[419] *See* PAUL, *supra* note 13, at 135 (discussing past projects in compulsory sterilization and Nazi breeding programs).

[420] *See* FUKUYAMA, *supra* note 6, at 99-100, 102 ("What is ultimately at stake with biotechnology is . . . the very grounding of human moral sense. . . .if so, we need to accept the consequences of the abandonment of natural standards for right and wrong."). *See generally* MCKIBBEN, *supra* note 14 (arguing that debate is needed regarding societal controls on genetic technology); Suzanne Holland, *Selecting Against Difference: Assisted Reproduction, Disability and Regulation*, 30 FLA. ST. U. L. REV. 401 (2003) (arguing that social obligations, including obligations to vulnerable populations, check the right to reproduction); Mary B. Mahowald, *Aren't We All Eugenicists? Commentary on Paul Lombardo's "Taking Eugenics Seriously"*, 30 FLA. ST. U. L. REV. 219, 224 n. 22 (2003) ("our ongoing relationships to others are inseparable from our autonomous decisions"); Dolgin, *supra* note 12, (concluding that prospective parents should understand the moral complications that go with prenatal genetic testing).

> As even proponents acknowledge, the line between repair and enhancement is too murky to be meaningful. Soon you're headed toward a world where Kathy's lungs work fine [even though she has cystic fibrosis], but where her goodness, her kindness, don't mean what they did. Where someone's souping up her brains or regulating her temper, not just clearing up her mucus.

Nicholas D. Kristof, *The New Eugenics*, N.Y. TIMES, July 4, 2003, at A21.

ics . . . has relied on principles other than utility in determining what is and is not ethically appropriate in the practice of medicine in the research and therapeutic settings," and such must be the case with ART.[421] The eugenics implications of ART underscore the proposals made above to protect patients who participate in experimental procedures and to ensure the practice of good medicine in the field. At the very least, eugenics considerations prioritize the need to ensure that ART, now a largely private endeavor, is practiced within full view of the general public and subject to related scrutiny.[422]

The social impact of combining ART and broad genetic screening could prove profound, especially if that happens quickly. Arguably, there is a moral imperative to not assume the luxury of time.[423] Given experience with assisted reproduction over the last several decades,[424] we should anticipate that, assuming availability, prospective parents will utilize PGD to the fullest extent their financial means allow. Present cultural and scientific trends support this assumption. For example, consider the competition among upper and even middle-class families to get their children into the "right" preschools—the "Baby Ivies"—and elementary schools in order to give them early advantages in life, resulting in waiting lists for some of these schools nearly reaching back to the child's conception and regardless of the extraordinary tuitions they charge.[425] Now consider that, with dis-

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[421] PRIMER, *supra* note 2, at 193. *But see* Palmer, *supra* note 289, at 263 (concluding that legislatures and liability doctrine development should guide genetic research).

[422] CARRICK, *supra* note 165, at 211 (emphasizing the need for an informed public).

[423] *Cf. Snake Oil*, *supra* note 5, at 39-41 (describing parents need to camp-out to enroll their children in preschool).

[424] GOALS, *supra* note 224, at 31 ("The use of medical skills for family planning purposes (which may, but also may not, have direct health purposes), including contraception and sterilization as well as abortion, is now well accepted throughout much of the world.").

[425] *See* Anne Marie Owens, *A Child's Future is Set by Nursery School: Forget the Rich and Famous. In Manhattan, the Directors of Pre-Schools Have Become the New Power Brokers*, NAT'L POST, Mar. 8, 2003, *available at* 2003 WL 14864604 (describing competition to get into preschools in Manhattan, including planning at birth); Elaine Rivera, *An Eye-Opening Experience for Parents; In Competition for Preschool Slots, Restless Camp-Out Ends with Handful of Victors*, WASH. POST, Feb. 3, 2003, at B03, 2003, LEXIS, News Library, Wpost File (describing parents need to camp-out to entoll their children in preschool); Marco R. della Cava, *Parents and Preschool: Schmooze or Lose*, USA TODAY, Aug. 28, 2002, at 1D, LEXIS, News Library, Usatdy File (noting that demand for expensive preschools has increased across the country); Mary McNamara, *Southern California Living: Learn, Baby, Learn as More Kids than Ever are Identified as "Gifted" the Programs Designed to Teach Them are Becoming Ever More Complex*, L.A. TIMES, Apr. 1, 2001, at E1, LEXIS, News Library, Lat File (describing parents efforts to get their children into nursery school); Claire Martin, *A Tense Time for Parents Has Implications for Their Children That May Last a Lifetime*, DENVER POST, Jan. 21, 2001, at F-01, LEXIS, News Library, Dpost File (describing the lengths that parents go to enroll children during Denver's open school enrollment); Maureen Freely, *Creche Course*, TIMES (London), May 28, 2000, LEXIS, News Library, Ttimes File. Some parents even are paying thousands of dollars (hourly rates of $300 an hour and $3,000 package services) to private school advisors. Jane Gross, *Right School for 4-Year-Old? Find an Adviser*, N.Y. TIMES, May 28, 2003, at A1. *But see* Pinker, *supra* note 21

covery that there are only about 30,000 genes in the human genome and with bioinformatics capabilities in hand, the research community is working on a more intricate level, which includes identifying and valuing even slight genetic variations such as SNPs.[426] Given the human complexity and variation attributable to such a small number of genes, it appears likely that genes multitask exponentially more and are much more responsive to environmental stimuli than previously appreciated. It also is likely, therefore, that the result of genomics and proteomics will be a multitude of identified genetic factors that will generate an exponentially greater magnitude of individually minute probabilities made manageable for extensive PGD and other health care use through bioinformatics.[427] Experience with genetic testing to date suggests that these PGD results, in spite of their intricacy and lack of definitiveness, may translate into parental expectations.[428] If difficult choices have to be made among embryos, why not make them with this added information? So now (or yesterday) is the time to ponder questions such as how broad PGD may impact the best interests of children.[429] Prospective parents and their resulting children may get what the parents wish for, but one commentator warns, "Recall the mouse whose intelligence was genetically boosted . . . but which seems also to have felt greater pain as a result."[430] Also, presumably market forces will drive competing parents to utilize the same technology even though many of the prizes sought—for example, the limited admission tickets into the most prestigious schools—will remain the same regardless of PGD, meaning

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(suggesting that genetic enhancement is not likely in our lifetimes because people will be rational about limitations of the technology and will not be as receptive to it as some anticipate).

[426] *See supra* note 256 and accompanying text (SNPs references); PRIMER, *supra* note 2, at 149-50 ("More and more information is available concerning our genetic makeup and the diseases that result from genetic malfunction. . . . Not only will testing for diseases that may occur later change the practice of medicine; predictive pre-symptomatic testing is expected to become 'a boom industry.'").

[427] *See supra* notes 17, 238, 245, 253, 254, 264, 360, 369 and accompanying text (bioinformatics references).

[428] "Genetic modification is more like giving your child a tattoo that she can never subsequently remove and will have to hand down not just to her own children but to all subsequent descendants." FUKUYAMA, *supra* note 6, at 94; *see also* ROBERT J. MOSS ET AL., *Genetic Testing as a Family Affair*, *in* GENETICS IN THE CLINIC, *supra* note 397, at 197 (warning that prenatal genetic testing may distort parent-child or sibling-sibling relationships).

[429] Professor Winslade and Judith Ross observe that the best interest of the child is seldom considered by those providing ART services:

> Born into a society that is already fragmented by divorce and confused about alternative life styles, morals and sexual choices, the child may well have serious identity problems at a later time. Does such a possibility have to be seriously considered by those who want to undertake unusual reproductive methods. . . ?
>
> The interests and well-being of the baby-to-be-made seem to be the last issues considered, and sometimes (when physicians promise anonymity to the donor or parents require it of the surrogate) seem not to be considered at all.

MCCORMICK, *supra* note 308, at 171.

[430] FUKUYAMA, *supra* note 6, at 92.

more tension for all.[431] Alternatively, will prospective parents who condition procreation on aggressive control over the genes of their offspring prove less inclined to assume and exercise responsibility for the resulting child when characteristics they do not desire materialize, or when characteristics they invested in prove missing?[432] Again, in the vast majority of instances, it is likely that PGD will offer lots of probabilities and very few medical certainties. How will parental choices based on PGD impact other children, perhaps including preexisting children in the same family who possess characteristics the parents choose to avoid in subsequent progeny? When the price of PGD drops low enough to make the technology standard care—and the pace of advancement of bioinformatics suggests it will and perhaps more quickly than many estimate[433]—will the pressure to have a baby as healthy and desirable as medically possible actually compel prospective parents to use PGD even beyond their levels of comfort—meaning, ironically, could PGD become an imposition and reduce the freedom of parents to choose?[434]

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[431] "Another important type of negative externality is related to the competitive, zero-sum nature of many human activities and characteristics. . . . People want smarter kids so that they will get into Harvard, for example, but competition for places at Harvard is zero sum." *Id.* at 97.

[432] *See In re* Marriage of Buzzanca, 72 Cal. Rptr. 2d 280, 293 (Ct. App. 1998). As Francis Fukuyama observes, the decision recognized that:

> Children who are the subjects of genetic modification, obviously without consent, are the most clear class of potentially injured third parties. . . . Libertarians argue that since the vast majority of parents would want only what is best for their children, there is a kind of implied consent on the part of children who are the beneficiaries of greater intelligence, good looks, or other desirable genetic characteristics.

FUKUYAMA, *supra* note 6, at 93. As explained by Diane Paul, "A spate of recent books and articles has warned of eugenics as the unintended result of individual choices. On this view, the greatest danger arises not from coercion but its reverse: our enhanced ability to *choose* the kind of children we want." PAUL, *supra* note 13, at 4. *See generally* TROY DUSTER, BACKDOOR TO EUGENICS (1990) (warning of serious social consequences arising from eugenics). Parental choice may prove disparate from the interests of children and society as experience to date substantiates:

> Cultural norms may also lead parents to make choices that harm their children. One example was alluded to earlier, the use in Asia of sonograms and abortion to select the sex of offspring. In many Asian cultures, having a son confers clear cut advantages to the parents in terms of social prestige and security for old age.

FUKUYAMA, *supra* note 6, at 96. *But see* Wasserman, *supra* note 387, at 313 (stating that "the tendency to treat children as commodities will be largely offset by the transformative effect of actually raising them").

[433] "Designer babies will be expensive at first and an option only for the well-to-do. Whether having a designer baby will ever become cheap and relatively popular will depend on how rapidly technologies like preimplantation diagnosis come down the cost curve." FUKUYAMA, *supra* note 6, at 80. *But see* PRIMER, *supra* note 2, at 152 ("Will genetic testing and the ability to combat some future genetic anomaly be available to uninsured persons? Underlying every advance in health care technology should be the realization that more than forty million people in the United States have limited access to health care.").

[434] It is misguided to assume that parental interests and the best interests of their offspring will be harmonious:

> Policy makers generally assume that individual and social interests are congruent, that families will act 'rationally.' . . . As we have seen, the assumption that normal

Deference to practice of medicine is very vivid in *Roe v. Wade*[435] and the recent late-term abortion case, *Stenberg v. Carhart*.[436] That said, women would have a right to terminate and procreate independent of ART and to utilize ART. Introduction of a reliable regulatory baseline in the practice of ART with the express objectives of ensuring good medicine, the safety of women, and public accountability of those who perform ART and their practices would not constitute an undue burden. While an early term abortion is safer for women than carrying the child and delivery, aggressive ART is not safer for women than no ART for it encompasses often intense use of fertility drugs and often results in multiple pregnancies and unhealthy children.[437] In addition to protecting the health of women, the state certainly has a recognizable interest in the latter.[438]

Moreover, the social implications of PGD extend beyond the prospective parents who choose to utilize this technology and their families. The combination of genetics and ART will affect us economically, politically, and culturally.[439] At the commencement of HGP, Nobel Laureate James Watson, co-discoverer of the double-helix structure of DNA and HGP's first director, raised this caution:

> The power of the information to be gained from mapping and sequencing projects raises concerns about how it will be

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> people will do what they can to avoid the birth of children with disabilities has a long history. . . . Subtle pressures to make the 'right' choice are what many people have in mind when they characterize contemporary genetic medicine as a form of eugenics. Of course many women welcome the opportunities to learn more about their fetus and to act on the results. But some women also feel that they have no realistic alternatives to the decision to be tested or to abort a genetically imperfect fetus. Of course they are under no legal coercion. But they may nevertheless feel pressured to be tested and avoid having children with disabilities—by their doctors, who fear being sued if the child is born with a genetic disorder, by anxiety over the potential loss of health or life insurance, by their inability to bear the enormous financial costs of caring for a severely disabled child, or by the lack of social services (even with national health insurance) for handicapped children.

PAUL, *supra* note 13, at 132-33 (citations omitted); *cf.* KASS, *supra* note 356, at 130.

[435] 410 U.S. 113, 140-44, 148-50 (1973) (relying on medical procedures and the position of the AMA).

[436] 530 U.S. 914, 930-38 (2000) (discussing the amici curae brief by the American College of Obstetricians and Gynecologists).

[437] *See, e.g., supra* notes 341 (implantation of multiple embryos), 344 (multiple pregnancies), 353 (hormone injections) and accompanying text. Clinical studies have raised concerns about consumption of hormones to offset effects of menopause. National Cancer Institute, *Cancer Facts: Menopausal Hormone Use: Questions and Answers, at* http://www.cancer.gov/newscenter/estrogenplus (last visited Oct. 27, 2003) (on file with the Connecticut Law Review). The maturation of the first critical mass generation of ART mothers could trigger significant, yet undiagnosed, human health problems.

[438] *Roe*, 410 U.S. at 150. *See generally supra* note 8 and accompanying text.

[439] FUKUYAMA, *supra* note 6, at 83 ("[H]uman nature is fundamental to our notions of justice, morality, and the good life, and all of these will undergo change if this technology becomes widespread."). *See generally* Symposium, *Genes and Disability: Defining Health and the Goals of Medicine*, 30 FLA. ST. U. L. REV. 191 (2003) (examining the ethical and social considerations of genetic medicine).

> used. There is no avoiding the fact that arguments drawn in part from eugenics have been politically misused in the past, most egregiously by the Nazis but also elsewhere in Europe and North America. Indeed the specter of coercive government eugenics programs persists even today in the statutes still on the books in several nations . . . . The only way to ensure that history does not repeat itself is for the scientific and medical communities to remain constantly vigilant for abuses of genetics.[440]

As suggested by scholars such as Adrienne Asch and EEOC Commissioner Paul Miller well before the advent of bioinformatics and completion of a draft map of the human genome, a proliferation of genetic information will change attitudes towards life, death, and disability:[441]

> [I]n the future, how will we look upon those who have genetic defects? At present, we tend to sympathize with people who have genetic defects and offer compassionate care. . . . In the future, however, will we be as concerned about people with disabilities if we think their disability could have been avoided?[442]

Also, recall that one of the guiding rationales for the early eugenics movement was to lessen financial and medical demands on society, especially during the Great Depression.[443] The financial pressures introduced by the

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[440] James D. Watson, & Robert Mullan Cook-Deegan, *The Human Genome Project and International Health*, 263 JAMA 3322, 3324 (1990). "[T]he largest amount of money ever allocated for bioethical research (5 percent of the annual HGP budget), signals an admirably responsible public admission of the likely hornets' nest of problems that the HGP will unleash." CARRICK, *supra* note 165, at 210. *See generally* WATSON, *supra* note 20 (offering an historical overview of the discovery of DNA and the genetics revolution).

[441] For references to Adrienne Asch's work, see *supra* note 411. *See, e.g.*, Paul Steven Miller, *Genetic Discrimination in the Workplace*, 26 J.L. MED. & ETHICS 18, 189-90 (1998) (outlining growing concerns about discrimination based on genetic information); Paul Steven Miller, *Is There a Pink Slip in My Genes: Genetic Discrimination in the Workplace*, 3 J. HEALTH CARE L. & POL'Y 225 (2000). *See also* Paul Steven Miller, Analyzing Genetic Discrimination in the Workplace, Remarks at the EINSHAC Int'l Working Conversation on Enviro/Genetics Disputes and Issues (July 2001), *in* HUMAN GENOME NEWS, Feb. 2002, at 9, *available at* http://www.oml.gov/hgmis/publicat /hgn/v12n1/09workplace.html (last visited Sept. 24, 2003) (on file with the Connecticut Law Review); Paul Steven Miller, *Genetic Discrimination in the Workplace*, 3 GENETICS MED. 165 (2001), *reprinted in* AAPD NEWS, June 2001, at 8 (providing a description of the first genetic discrimination lawsuit settled by the EEOC); Paul Steven Miller, *Coming Up Short: Employment Discrimination Against Little People*, 22 HARV. C.R.-C.L. L. REV. 231 (1987) (suggesting legal strategies for overcoming employment discrimination against short people).

[442] PRIMER, *supra* note 2, at 152.

[443] *See supra* note 61 and accompanying text. As explained by Diane Paul,

> When asylums were first established in the mid-nineteenth century, the "feebleminded" were thought to be trainable, and their education was stressed. Later in the century they came to be viewed as objects of pity, in need of protection from an often cruel world. By the turn of the twentieth century, they were perceived as a social

genomics revolution over the next few decades may prove unprecedented, for our graying population[444] will continue to increase and demand the forthcoming generation of much more precise and expensive pharmaceuticals.[445] Genetic precision will fracture traditional disease classifications and markets, introduce genetic profiling and monitoring services and added demands on health care providers, and generally add complexity and raise costs[446]—at least until the advent of cures through gene therapies.[447] An increasing number of Americans with no insurance or who are underinsured and general exacerbation of health care finance tensions, may lesson collective social tolerance for those born with health conditions presumed preventable through PGD and raise expectations that prospective parents

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> menace and drain on the public purse. Over time, noble sentiments came increasingly to clash with economic demands. Charitable impulses gave way to utilitarian practices, and the economic value of the inmates' work came more and more to be stressed. But despite their superintendents' best efforts, the asylums never achieved self-sufficiency. During the world economic crisis of the 1930s, they everywhere came to be viewed as an unnecessary burden on society. And segregation gave way to compulsory sterilization.

PAUL, *supra* note 13, at 134 (citation omitted).

[444] *See Scientific American Frontiers: Never Say Die* (PBS television broadcast, 2000); *How to Build a Human: Predictor*, *supra* note 6; Tom Kirkwood, *As Society Gets Older and Healthier a Survey Shows That—Far From Dreading Their Retirement, Young People Relish the Prospect: Why Age is All the Rage*, EXPRESS, Apr. 4, 2001, at 30, LEXIS, News Library, Xpress File ("Even without recent breakthroughs in understanding the ageing process, our lifespan is continuing to climb and shows no sign of stopping.").

[445] *See supra* note 5 and accompanying text.

[446] *See* Noah, *supra* note 5, at 1, 4-11; *Market Implications*, *supra* note 5 at 32-34 (detailing the impacts of pharmacogenetics on research, testing, labeling and marketing of new drugs).

[447] The announcement in 2003 that French researchers reported curing four boys of severe combined immunodeficiency ("SCIDs" or "bubble boy disease") was tempered following an announcement months later that some of the genes delivered ended up in the wrong places and caused two of the boys to develop leukemia. Jeffrey L. Fox, *US Authorities Uphold Suspension of SCID Gene Therapy*, 21 NATURE BIOTECHNOLOGY 217 (Mar. 2003) [hereinafter *Suspension of SCID Gene Therapy*]; Paul Elias, *New Gene Therapy Technique Shows Promise, Journal* Says, at A06, DESERET MORNING NEWS (Salt Lake City, Utah), June 30, 2003, LEXIS, News Library, Desnws File; *see also* Andrew Pollack, *Cancer Risk Exceeds Outlook in Gene Therapy, Studies Find*, N.Y. TIMES, June 13, 2003, at A29 ("New studies suggest that gene therapy might have a greater chance of causing cancer than previously thought, adding to safety concerns that have troubled the fledgling field."). However,

> [c]urrently, gene therapy is being used in an effort to treat approximately fifteen diseases. Researchers have identified up to five thousand genes that may be linked to at least four hundred diseases, including breast cancer, cystic fibrosis, Huntington's disease, and sickle cell anemia. Also, genetic screening tests are available or under development for many of these diseases, even though, tragically, no cures now exist for the vast majority.

CARRICK, *supra* note 165, at 208-09 (citation omitted). In February 2003, the National Institutes of Health Recombinant DNA Advisory Committee ("NIHRAC") and the Biological Response Modifiers Advisory Committee ("BRMAC"), an advisory panel of the FDA, recommended continuing suspension of X-lined SCID trials, but resuming others. *Suspension of SCID Gene Therapy*, *supra*, at 217; Jeffrey L. Fox, *FDA Panel Recommends Easing Gene Therapy Trial Limits*, 21 NATURE BIOTECHNOLOGY 344-45 (Apr. 2003). Also, an announcement in June 2003 that a team of Japanese and Belgian scientists had temporarily treated hemophiliac mice using just tiny fragments (nanoparticles) of the hepatitis B virus has renewed some enthusiasm. *See* Elias, *supra*.

will utilize this technology.[448] Perhaps government policy will encourage "healthy choices" in procreation. In zero-sum health care finance decision-making, collective intolerance for procreation without genetic screening as preventive care is likely to shape health finance policy,[449] meaning that there may be added costs to pay for choosing a PGD-free pregnancy.

Although experience with eugenics during the first half of the twentieth century may be cited as authority for the proposition that reproduction should remain a private affair free from government intrusion, that experience also is authority for the proposition that science may be used against people deemed less desirable—to the point of actually threatening their

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[448] Priorities in health policy appear to have shifted:

> Whereas ethical questions in the past were directed toward medical procedures (for example, informed consent, transplantation of organs, and allowing patients to die), today and in the immediate future the more prominent ethical issues in health care will be social issues: why and how to provide health care for the poor, how to preserve quality of care in the face of government controls and fiscal constraints, how to preserve the values of medicine in the face of efforts to commercialize health care, and how to choose which health care services should be covered from the many valuable services that are available.

PRIMER, *supra* note 2, at xii. Some have asserted that a deluge of additional costs associated with medical innovation will force "economic triage" in health policy:

> As the limited supply, growing demand, and rising costs associated with many types of high-tech, life-sustaining therapies such as kidney dialysis, neonatal intensive care, and open-heart surgery become increasingly parasitic on our nation's economy, this conflict of duty may well lead to a new form of economic triage, according to which those who could not personally pay for certain costlier maladies would simply be economically doomed to die of them. In the United States, most citizens are painfully aware of the rising costs of medical care, and they continue to harbor doubts about reversing this trend.

CARRICK, *supra* note 165, at 217. However, others point out that the victims of genetic disease are the strongest proponents for the genomics revolution:

> One of the most powerful sources of pressure for further research and treatment in medical genetics has come from the victims of genetic diseases and their families. . . . They not only support research but also lobby for their constituencies. Not surprisingly, they tend to take a skeptical view of the distress voiced in recent years over interference with the human genome, and they welcome the powerful new tools for prenatal diagnosis emerging from the accelerating advance of biomedical knowledge and techniques, especially the methods of recombinant DNA.

KEVLES, *supra* note 28, at 293 (footnote and citations omitted); *see also id.* at 291 (citations omitted) ("In 1983, at a conference on gene therapy, Ola Huntley, the mother of three sickle-cell anemic children and a counselor of sickle-cell patients, declared, 'I am angry that anyone presumes to deny my children the essential genetic treatment of a genetic disease. I see such persons as simplistic moralists.'").

[449] For example, as observed by Francis Fukuyama:

> If large numbers of people make the choice to, for example, extend their lives for another ten years at the cost of, say, a 30 percent decrease in functionality, then society as a whole will have to pick up the tab for keeping them alive . . . . While any individual will want to postpone death as long as possible, people in the aggregate may not enjoy living in a society whose median age is 80 or 90, where sex and reproduction become activities engaged in by a small minority of the population, or where the natural cycle of birth, growth, maturity, and death has been interrupted. In one extreme scenario, the indefinite postponement of death will force societies to put severe constraints on the number of births allowed.

FUKUYAMA, *supra* note 6, at 96-97; *cf.* John V. Jacobi, *Genetic Discrimination in a Time of False Hopes*, 30 FLA. ST. U. L. REV. 363, 363-64 (2003) (arguing that genetic equity should be regarded as an aim consistent with the broader movement toward equitable access to health care).

very existence.[450] Available technology has been limited in relative terms, but our experience to date validates these concerns. Now routine prenatal diagnostics such as sonograms and amniocentesis, technology introduced to increase the knowledge and choice of prospective parents, already have introduced pressures against bearing potentially health-impaired children and inspired practices such as aborting female fetuses in many parts of the world.[451] We must draw from this experience when trying to discern the contours of the rapidly approaching horizon:

> The temptation to use medical knowledge and skills to manipulate or coerce entire classes of people or whole societies in the name of improved health, social well-being, or cost control is likely to become increasingly potent, and enormously seductive, in the years ahead. With the terrible example of the eugenics movement of the late nineteenth and early twentieth centuries in mind, it is a development to be watched carefully and generally resisted. Coerced abortions, mandated genetic screening and prenatal diagnosis, and excessive pressure to change health-related habits are not theoretical hazards. The coercion of people by medical means represents a potential threat that is already in many places clear and present: a threat to the institution of medicine and to human liberty and dignity.[452]

To reap the health care potential of advances in genetic medicine and ART, the interests of individuals wishing to control genetics during their procreation must be tempered against the broader, cumulative interests of society:

> Indeed, if we insist on absolute reproductive autonomy we must accept the use of genetic technologies to prevent the birth of those who are unwanted for any reason: that they will be the "wrong" gender, or sexual orientation, or of short stature, or prone to obesity, or . . . Used this way, medical genetics will surely reinforce a host of social prejudices. A history of eugenics that is sensitive to its complexities alerts us to the fact that genetic technologies present more than one kind of danger—and that if we are not very careful, we may avoid one only to court another.[453]

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[450] *See supra* notes 411-13 and accompanying text.

[451] GOALS, *supra* note 224, at 33.

[452] *Id.* at 33-34.

[453] PAUL, *supra* note 13, at 135. *See generally* Asch, *Contradictory or Compatible?*, *supra* note 410 (examining the impact of selective abortion to prevent disability on equality for disabled people); Dolgin, *supra* note 12 (exploring the ideological implications of maintaining a pro-choice position on

The Ethics Committee of the ASRM already has observed this tension between individual and societal choices in procreation and issued a responsive guidance: "[I]n applying the personal criterion, one must take into account that the human person is both individual and social. Hence, what is [beneficial] or detrimental to the person cannot be assessed solely in terms of individual impact but must take into account overall social impact as well."[454]

While meaning is being added to the map of the human genome, we must determine what role, if any, government and law are to play in the field of ART beyond protecting the safety of human subjects and the practice of good medicine. Especially given that HGP was a U.S. government-launched and sponsored initiative and that the U.S government, federal and state, has and continues to fuel the biotechnology economy directly and through responsive policy,[455] the ethical, legal, and social implications of folding this technology into the field of ART deserve immediate and serious consideration.[456] Given our eugenics past and the possibilities of a eugenics future, the coupling of technology and assisted reproduction should not be allowed to remain adrift in the free market:

> Free markets work well much of the time, but there are also market failures that require government intervention to correct. Negative externalities do not simply take care of themselves. We do not know at this point whether these externalities will be large or small, but we should not assume them away out of a rigid commitment to markets and individual choice.[457]

Though our meaningful knowledge about human genetics is nascent and humble, a map of the human genome and solid, empirically measur-

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abortion generally while discouraging selective abortion); Holland, *supra* note 420 (recommending regulation of ART due to the social and historic implications of genetic testing); Mahowald, *supra* note 420 (examing a range of eugenic practices and what makes them "good" or "bad").

[454] THE ETHICS COMMITTEE OF THE AMERICAN FERTILITY SOCIETY, ETHICAL CONSIDERATIONS OF ASSISTED REPRODUCTIVE TECHNOLOGIES 15 (Nov. 1994).

[455] *See* Michael J. Malinowski, *Biotechnology in the USA: Responsive Regulation in the Life Science Industry*, 2 INT. J. BIOTECHNOLOGY 16, 18-20 (2000) (describing how responsive policy has allowed biotechnology to flourish in the U.S.); Michael J. Malinowski & Nick Littlefield, *Transformation of a Research Platform into Commercial Products: The Impact of United States Federal Policy on Biotechnology*, *in* THE COMMERCIALIZATION OF GENETIC RESEARCH: ETHICAL, LEGAL, AND POLICY ISSUES 29, 32-45 (Timothy A. Caulfield & Bryn Williams-Jones eds., 1999) (detailing U.S. policy measures that have facilitated development of biotechnology).

[456] The very existence of the ESLI program supports this proposition. *See supra* note 440 and accompanying text (comments of James Watson, founder of HGP); CARRICK, *supra* note 165, at 210 (discussing need based on past political misuse of eugenics for science and medical communities to remain vigilant for abuses).

[457] FUKUYAMA, *supra* note 6, at 100. *But see* Wasserman, *supra* note 396, at 313 (arguing for an unrestricted regime of prenatal testing over one restricted by the criterion of severity).

able natural science now replace the murky concoction of social science and speculation that drove our eugenics past so forcefully.[458] The mere possibility that externalities driving the flow of the free market will turn out to be an unprecedented level of social intolerance of genetic differences is a potential cost too great to be ignored.[459] Therefore, we must overcome the contemporary tendency to reduce the role of government in procreation-related health services where "[t]he integrity of medicine itself is at stake. An excessive and unbalanced commercialization and privatization of medicine is a dire threat to the very goals of medicine."[460] Government must assume a meaningful role; the combination of ART and the genetics revolution cannot be trusted to medicine and market forces:

> It is not within the capacity of medicine to determine what is the overall good of society. For it to play a general role in the promotion of social well being beyond that of enhancing the health of citizens, medicine would need the capacity to make such judgments, to determine when its skills could be put to the service of, or subordinated to, social goals. It has no such capacity and, indeed, would run the severest dangers to its own integrity and goals were it to allow itself to be so

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[458] *See supra* notes 14, 37-38, 47, 156 and accompanying text.

[459] As explained by Francis Fukuyama:

> A utilitarian framework has particular difficulty encompassing moral imperatives, which tend to be regarded as just another type of preference. . . .There are, in other words, things that people believe to be morally wrong regardless of the utilitarian benefits that might flow from them. So it is with biotechnology. . . . What is ultimately at stake with biotechnology is not just some utilitarian cost-benefit calculus concerning future medical technologies, but the very grounding of the human moral sense, which has been a constant ever since there were human beings.

FUKUYAMA, *supra* note 6, at 100-02. *See generally* Asch, *supra* note 411 (examining the impact of selective abortion to prevent disability on equality for disabled people); Dolgin, *supra* note 12 (exploring the ideological implications of maintaining a pro-choice position on abortion generally while discouraging selective abortion); Holland, *supra* note 419 (recommending regulation of ART due to the social and historic implications of genetic testing); Mahowald, *supra* note 419 (examing a range of eugenic practices and what makes them "good" or "bad").

[460] GOALS, *supra* note 224, at 43. "More broadly, the hazards of the market include the introduction of an alien set of economic values into the institution of medicine, whose inherent ends have historically been philanthropic and altruistic, not commercial; despite market ideology, an actual decrease in patient choice." *Id.*; *see also* PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH 342 (2003) ("We must recognize the roles business managers are required to play, and simply set in counterposition to them a group with a fundamentally different role. Against businesses, whose first job is profit, we must set groups whose first job is safety."). *But see* FDA, IMPROVING INNOVATION IN MEDICAL TECHNOLOGY: BEYOND 2002 (2003) [hereinafter IMPROVING INNOVATION] *available at* www.fda.gov/bbs/topics/news/2003/beyond2002/report.html. (last visited Sept. 24, 2003) (on file with the Connecticut Law Review) (the FDA's agency-wide initiative to accelerate product review); *Business and Regulatory News: FDA Releases Bold Plan*, 21 NATURE BIOTECHNOLOGY 219 (Mar. 2003) [hereinafter *Bold Plan*] (reporting that Commissioner Mark McClellan announced bold plans to accelerate FDA product reviews); Alan Dove, *Walking the Drug Regulatory Tightrope*, 21 NATURE BIOTECHNOLOGY 495, 495 (May 2003) ("Regulatory agencies are being pulled in several directions at once, and drug developers must learn to adapt swiftly to a rapidly changing landscape.").

> used. A society that used medicine to weed out the unfit, to serve partisan political goals, to become the handmaiden of political authority, or even a servant of the will of the people would soon cease to have its own center and its own integrity.[461]

At the very least, government regulation of ART must be extensive enough to ensure public awareness of emerging practices. Given the pace of advancement of PGD enabling technologies and the fact that some of this technology already has matured into application, we no longer can rely on less direct approaches such as HGP's ESLI program.[462] We also cannot rely so heavily on national commissions staffed with professional bioethicists and subject so heavily to political, professional, and personal influences.[463] "We need institutions with real enforcement powers."[464] Meaningful legislation is a prerequisite to creating such institutions.[465] "A number of countries have in fact moved beyond the stage of national commissions and study groups to actual legislation[,]" and in the field of ART we must follow their lead.[466] Many opinions wholly opposed to the imposition of law into areas of life science and medical technology have been shifted

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[461] GOALS, *supra* note 224, at 34-35; *see also* FUKUYAMA, *supra* note 6, at 215-16 (referring to the mistakes made by the agriculture sector in trying to wholly self-regulate, and addressing how the government regulation came after the product was in commerce, and on the thrust of public demand); HILTS, *supra* note 460, at 342 ("We must recognize the roles business managers are required to play, and simply set in counterposition to them a group with a fundamentally different role. Against businesses, whose first job is profit, we must set groups whose first job is safety."). *But see* Botkin, *supra* note 280, at 265-66 (proposing heavy reliance on professional medical standards for regulation of assisted reproduction).

[462] *See* FUKUYAMA, *supra* note 6, at 204.

[463] For example, bioethicists often "face an uphill struggle winning the respect of the scientists they must deal with, and are hardly likely to do so if they tell them they are morally wrong or if they depart significantly from the materialist worldview that the scientists hold dear." *Id.*

[464] *Id.*

[465] For example, as pointed out by one commentator, the FDA's present legislative authority is not broad enough to enable the agency to grapple with pressing issues such as human cloning and genetic enhancement:

> The FDA is not set up to make politically sensitive decisions concerning the point at which selection for characteristics like intelligence and height ceases to be therapeutic and becomes enhancing, or whether these characteristics can be considered therapeutic at all. The FDA can disapprove a procedure only on the grounds of effectiveness and safety, but there will be many safe and effective procedures that will nonetheless require regulatory scrutiny. The limits of the FDA's mandate are already evident: it has asserted a right to regulate human cloning on the legally questionable grounds that a cloned child constitutes a medical "product" over which it has authority.

Id. at 213.

[466] *Id.* at 205. Often cited examples include the Human Fertilization and Embryology Authority ("HFEA") in England and the Reproductive Technology Accreditation Committee ("RTAC") in Australia. Adamson, *supra* note 21, at 932.

by recent positive experiences including modernization of the Food and Drug Administration.[467] The United States should follow this example in the area of ART. Rather than attempt to enact extensive technical legislation (consider legislative chaos over cloning and stem cells),[468] the United States should enact legislation that creates sufficient regulatory jurisdiction over this technology implemented by those with scientific expertise, who should become directly engaged in ART through the dynamism of ongoing regulation reflective of the changing nature of the underlying science and public opinion.[469] With such authority in the hands of those with technical scientific expertise, it may even be possible to draw often strained distinctions between therapy and enhancement and impose greater restraints on the latter.[470] As stated by one commentator in support of this position:

> The original purpose of medicine is, after all, to heal the sick, not to turn healthy people into gods. We don't want star athletes to be hobbled by bad knees or torn ligaments, but we

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[467] *See generally* IMPROVING INNOVATION, *supra* note 460 (discussing the FDA's plan to improve and expedite the approval process); *Bold Plan*, *supra* note 460 (discussing announcement of the FDA's new plan). *See also* Michael J. Malinowski, *Overview of FDA Regulation of Human Medicinal Products Developed with Biotechnology*, *in* BIOTECHNOLOGY LAW 2002: BIOTECHNOLOGY PATENTS & BUSINESS STRATEGIES 979, 997-1000 (2002) (addressing the current state of FDAMA and acknowledging pressing concerns).

[468] Examples include legislative attempts to ban abuses of genetic testing and genetic information while not impeding research and responsible medical use of this technology, with the ultimate goal of utilizing the technology to maximize human health benefits. *See generally Snake Oil*, *supra* note 5 (describing how regulation of predictive genetic testing threatened development and use of the technology). Another angle was added to the stem cell controversy in May 2003 when scientists working with mice announced that they had successfully derived egg cells from embryonic stem cells through a process called parthenogenesis. William Hathaway, *Creating Life from Scratch in the Laboratory*, HARTFORD COURANT, June 8, 2003, at 13. In the U.S., federal funding may be used to engage in research with human cell lines in existence as of 9 p.m. on August 9, 2001. *See* Raja Mishra, *Stem Cell Research Runs into Roadblocks*, BOSTON GLOBE, May 12, 2002, at A1, LEXIS, News Library, Bglobe File (identifying holders of stem cell lines eligible for government funded research, but noting that "nearly three-quarters of the 78 stem cell batches that met Bush's conditions for support remain unavailable to US researchers . . . ."). Therefore, theoretically, these cells lines and federal money could be used to create human embryos.

[469] *Cf. Snake Oil*, *supra* note 5 (discussing the benefits of regulation over legislation in the field of predictive genetic testing).

[470] "Regulators are called on all the time to make complex judgments that cannot be held up to precise theoretical scrutiny." FUKUYAMA, *supra* note 6, at 211. Consider, for example, that standards are set for water and air quality:

> [A] properly functioning democratic political system allows people with a stake in the regulator's decision to push and shove against one another until a compromise is reached. Once we agree in principle that we will need a capability to draw red lines, it will not be a fruitful exercise to spend a lot of time arguing precisely where they should be placed. As in other areas of regulation, many of these decisions will have to be made on a trial-and-error basis by administrative agencies, based on knowledge and experience not available to us at present.

Id. *But see* Palmer, *supra* note 289, at 242, 263 (proposing reliance on the judiciary and theories of liability rather than regulation).

> also don't want them to compete on the basis of who has taken the most steroids. This general principle would allow us to use biotechnologies to, for example, cure genetic diseases like Huntington's chorea or cystic fibrosis, but not to make our children more intelligent or taller.[471]

Although some commentators support the creation of entirely new government institutions to regulate the combination of ART and the genetics revolution,[472] much could be accomplished by expanding our existing regulatory infrastructures to encompass ART. Proposals set forth below include recognizing that experimental ART procedures constitute experimentation on human subjects and regulating them as such, and otherwise expanding the roles of CDC and FDA to ensure the practice of good medicine in the field of ART.

A. *Recognition and Regulation of Experimentation on Human Subjects*

Experimentation on human beings in the context of assisted reproduction should be deemed and regulated as such, meaning that this experimentation should only take place with the oversight of a qualifying IRB that reports to OHRP.[473] In recent years, with the increased privatization of biomedical R&D,[474] there has been measurable support for removing the federal funding prerequisite on the Common Rule applicability and extend-

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[471] FUKUYAMA, *supra* note 6, at 208-09. This commentator challenges the notion that, pragmatically, the distinction between therapy and enhancement is unworkable, observing:

> While it is the case that certain conditions do not lend themselves to neat distinctions between pathological and normal, it is also true that there is such a thing as health. . . . It has often seemed to me that the only people who can argue that there is no difference in principle between disease and health are those who have never been sick: if you have a virus or fracture your leg, you know perfectly well that something is wrong. And even in the cases where the borderline between sickness and health, therapy and enhancement; is murkier, regulatory agencies are routinely able to make these distinctions in practice.

Id. at 209-10.

[472] *See supra* note 466 and accompanying text. Francis Fukuyama suggests such an approach:

> [A]ny new regulatory agency not only would have to have a mandate to regulate biotechnology on grounds broader than efficacy and safety but also would have to have statutory authority over all research and development, and not just research that is federally funded. Such an agency, the Human Fertilisation and Embyology Authority, has already been created in Britain for this purpose. Unification of regulatory powers into a single new agency will end the practice of complying with federal funding restrictions by finding private sponsors and, it is hoped, will shed a more uniform light on the whole biotech sector.

FUKUYAMA, *supra* note 6, at 215.

[473] *See* discussion *supra* Part IV.

[474] Academia and industry have integrated in the midst of a proliferation of biotechnology companies, most of them private, directly engaged in biomedical research. *See* CONVERGENCE, *supra* note 251; BOSTON CONSULTING GROUP, THE PHARMACEUTICAL INDUSTRY INTO ITS SECOND CENTURY: FROM SERENDIPITY TO STRATEGY 38-39 (1999); *Genomics Players: From Discovery to Integration—Business and Technology Assessment*, M2 PRESSWIRE, Feb. 19, 2003, LEXIS, News Library, M2pw file.

ing the scope of the Rule to all instances allowable under the Commerce Clause of the United States Constitution.[475] As an incremental beginning for this kind of broader reform, the scope of the Common Rule should be extended to cover experimentation in ART. Alternatively, or perhaps additionally, the scope of FDA's definition of "human subject" should be expanded to fully encompass ART, which would necessitate expansion or increased enforcement of FDA's jurisdiction over biologics.[476] The ART commercial sector is extremely intrastate and, in fact, international.[477] The sector engages in aggressive DTC marketing and does so regionally, nationally and even internationally. Regardless of absence of federal funding and the involvement of academic institutions, those who engage in experimentation on human beings should report to independent IRBs which, in turn, should report directly to OHRP.

B. *Further Regulation to Ensure the Practice of Good Medicine, and Ongoing Accountability and Public Oversight*

The non-experimental practice of ART also must be regulated to ensure oversight and accountability and compliance with good laboratory and good medicine practices. There are several options to accomplish comprehensive regulation of ART. The first option is federal regulation through expansion of the roles of CDC, FDA, or both. Given that the most meaningful direct federal government regulation of ART presently in place is CLIA which is implemented under CDC,[478] expanding CLIA or introduc-

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[475] NATIONAL BIOETHICS ADVISORY COMMISSION ("NBAC"), REPORT INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE, VOL. I, REPORT AND RECOMMENDATION OF THE NATIONAL BIOETHICS ADVISORY COMMISSION, 59-60 (1999), *available at* http://www.georgetown.edu/research/nrcbl/nbac/hbm.pdf; Helena Gail Rubinstein, *If I Am Only for Myself, What Am I? A Communitarian Look at the Privacy Stalemate*, 25 AM. J.L. & MED. 203, 221 (1999).

[476] *See* discussion *infra* Part VII.B. FDA's definition of "human subject" is tied to the license applications it receives for access to the market to engage in research and also to the products it reviews. *See* Malinowski & Rose, *supra* note 174, at 9-3 to 9-4, 9-8, 9-18. FDA implements that latter by requiring an assurance of compliance with human subject protection regulations as a prerequisite for accepting data for new product applications. This proposal for an expanded role for FDA is addressed below. *See* discussion *infra* Part VII.B.

[477] *See* FINAL REPORT, *supra* note 11, at 1. For ongoing information about the sector, visit the sites of the ASRM at http://www.asrm.org (last visited Sept. 24, 2003) (on file with the Connecticut Law Review), and SART, at http://www.sart.org/home_text.html (last visited Sept. 24, 2003) (on file with the Connecticut Law Review). Also visit the site of the National Infertility Association, referred to as Resolve, at http://www.resolve.org/main/national/index.jsp?name=home (last visited Sept. 24, 2003) (on file with the Connecticut Law Review). Resolve is a national consumer organization with the mission of helping people who are considering ART.

[478] Pub. L. No. 100-578, 102 Stat. 2903, § 1, (1988) (codified at 42 U.S.C. § 201 (1994)); CENTER FOR MEDICARE AND MEDICAID SERVICES, CLINICAL LABORATORY IMPROVEMENT AMENDMENTS, *available at* http://cms.hhs.gov/clia (last visited Sept. 24, 2003) (on file with the Connecticut Law Review). The scope of CLIA regulation is limited to clinical proficiency via imposition of standards for laboratory performance, personnel, and so forth.

ing parallel legislation to encompass some consideration of good medicine practice standards for ART is an obvious consideration. Some of the more troubling aspects of ART center on use of rapidly expanding predictive genetic testing capabilities, and proposals have been made to introduce regulation of "home-brew"[479] predictive genetic testing services through the introduction of a clinical utility standard for such tests via CLIA.[480] However, arguments also have been made to the contrary (by this author and others) based upon the observations that there are an overwhelming number of laboratories regulated under CLIA, and the reliability of CLIA is marred by reporting deficiencies and inconsistent enforcement.[481] Also, one must pay serious attention to the very nature of CLIA and question whether CLIA is "the appropriate mechanism to resolve complicated patient care issues such as informed consent, confidentiality, counseling, and the clinical soundness of medical decisions to use [this technology]."[482]

Alternatively, or perhaps additionally, the scope of FDA's definition of tissue products regulated as biologics should be expanded to include ART—for example, the example should include the manipulation of sex cells in any manner, extending to manipulation through hormone therapy, or the creation of embryos as tissue products, or both.[483] A defined FDA

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[479] These are tests performed in-house by their manufacturers and generally sold to the public through health care providers. Such tests escape the FDA's "device" category under present agency enforcement practices, meaning federal regulation of them is limited to CLIA. As stated by Professor Robertson and his co-authors:

> The Food and Drug Administration (FDA) has primary responsibility for regulating PGx tests to ensure their validity and utility. PGx tests sold as kits are medical diagnostics, which require FDA premarket review. Tests kits also may be used as investigational devices. To date, however, most genetic tests have been sold as "clinical services" by the academic centers and laboratories that have developed "home brews"—chemicals and reagents that a lab develops on its own—to test DNA samples sent to them. The FDA has been less diligent with policing "home brews" than test kits, although it now requires the reagents used in "home brews" be registered.

Robertson, *supra* note 245, at 159; *see also* Anny Huang, *FDA Regulation of Genetic Testing: Institutional Reluctance and Public Guardianship*, 53 FOOD & DRUG L.J. 555, 557 n.15 (1998). *See generally* Genetic Testing Under the Clinical Laboratory Improvement Amendments, 65 Fed. Reg. 25,928 (May 4, 2000); SACGT RECOMMENDATIONS, *supra* note 299; SACGT, PRELIMINARY RECOMMENDATIONS ON THE ADEQUACY OF OVERSIGHT OF GENETIC TESTS (2000); NATIONAL HUMAN GENOME RESEARCH INSTITUTE, FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING: PROMOTING SAFE AND EFFECTIVE GENETIC TESTING IN THE U.S. (Sept. 1997), *available at* http://www.genome.gov/10001733 (last visited Sept. 24, 2003) (on file with the Connecticut Law Review).

[480] *See Snake Oil*, *supra* note 5, at 41-42.

[481] *Id.* at 42.

[482] *Id.* (emphasis omitted).

[483] Given that FDA's definition of "human subject" is tied to the license applications it receives for access to the market it controls, this modification would also extend the applicability of FDA's regulations to protect human subjects who participate in clinical research under INDs and IDEs and in the context of data churned in anticipation of filing New Biologics Applications ("NBLAs") and New Device Applications ("NDAs"). *See* 21 C.F.R. §§ 50.1-.56 (laying out the FDA's version of the Common Rule).

track for tissue products has been forthcoming for years now, and those efforts have included collaboration among FDA and sister agencies that has generated tangible proposals.[484] And now the FDA is under increased pressure. In May 2003, FDA was sharply criticized for failing to meaningfully regulate human tissue products following the death of Brian Lykins, a young man who received contaminated knee cartilage harvested from a cadaver.[485] This tragedy prompted testimony before a Senate Investigative Committee and a legislative proposal.[486] Moreover, the decision by the Bush Administration to consolidate review of *all* drugs, biologics and traditional drugs, in the Centers for Drug Evaluation and Research ("CDER") could emancipate CBER resources in a manner conducive to better enabling the FDA to rise to enact and implement meaningful tissue track regulations.[487] However, it must be noted that this reform has been made in the context of imposition of extraordinary responsibility on FDA and CDC for homeland security initiatives and epidemiological challenges like West Nile Virus, SARS, and monkeypox.[488] Given that FDA has not voluntarily assumed regulatory responsibility over predictive genetic testing services beyond those put before the FDA for approval as medical devices,[489] the agency is not likely to do so here. Nevertheless, the Bush-appointed Commissioner of FDA, Mark B. McClellan, has a background in sophisticated research and certainly is capable of recognizing this need and taking

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[484] *See* WORLD TECHNOLOGY EVALUATION CENTER ("WTEC"), FINAL REPORT: TISSUE ENGINEERING RESEARCH (Jan. 2002) (noting the collaboration of the DARPA, FDA, National Aeronautics and Space Agency ("NASA"), National Institutes of Health ("NIH"), National Institute of Science and Technology ("NIST"), National Science Foundation ("NSF")), *available at* http://www.wtec.org/loyola/te/final/te_final.pdf; *see also* Center for Biologics Evaluation and Research *at* http://www.fda.gov/cber/index.html (website for the Center for Biologics Evaluation and Research, a branch of the FDA) (last visited Sept. 24, 2003) (on file with the Connecticut Law Review). For discussion of FDA regulation of human tissues and reproductive cloning in a case-study manner, see generally Richard A. Merrill, *Human Tissues and Reproductive Cloning: New Technologies Challenge FDA*, 3 HOUS. J. HEALTH L. & POL'Y 1 (2002).

[485] The FDA was criticized "for failing to issue regulations governing hundreds of tissue banks despite at least one death linked to infected tissue and investigations that have found widespread problems." Laura Meckler, *FDA Criticized as Lax on Soft-Tissue Rules*, BOSTON GLOBE, May 15, 2003, at A9, LEXIS, News Library, Bglobe file; *see also* Jerome Groopman, *Do You Know Where That Cartilage Came from?*, N.Y. TIMES, May 17, 2003, at 1 (commenting on how the FDA had failed to regulate human tissue transplants despite an increase in the number of procedures performed).

[486] Brian Lykins Tissue Transplant Safety Act of 2003, S. 1063, 108th Cong. (2003).

[487] See *FDA Completes Final Phase of Planning for Consolidation of Certain Products from CBER to CDER*, M2 PRESSWIRE, Mar. 18, 2003, LEXIS, News Library, M2pw file.

[488] Malinowski, *supra* note 467, at 14, 35-36; *see also* Daniel Yee, *15 U.S. States Tracing Monkeypox*, TORONTO STAR, June 12, 2003, at A08, LEXIS, News Library, Tstar file (reporting that the CDC rose to the challenge of meeting the public health challenges of SARS and monkeypox).

[489] *See supra* note 479 and accompanying text.

action.[490]

To make such added governmental responsibilities workable, at least as an interim measure, the government could draw from its experience implementing CLIA—meaning implementation through considerable self-regulation by delegating certification and compliance inspection responsibilities to qualifying professional entities that adhere to government specifications. CDC already has moved in this direction by contracting with SART to collect data on ART practices in the United States, and the federal government relies heavily on those compilations.[491] However, this would require significantly changing the essence of SART-ASRM from a voluntary professional society that strongly encourages data reporting by members to an entity that enforces technical government requirements or standards and imposes sanctions for noncompliance, or placing the responsibility elsewhere. SART-ASRM and other professional organizations in the field of ART would be well advised to strengthen their efforts at meaningful self-regulation through increased technical requirements and rigorous enforcement, even at the cost of members, before they lose that option.[492] This could be readily accomplished by drawing from and expanding upon the standard-setting and enforcement experiences of organizations such as the College of American Pathologists ("CAP") and the National Committee on Clinical Laboratory Standards.[493] Nevertheless, ultimately, reliance on self-regulation is questionable, especially in light of the CLIA experience.[494] The fact that ART has burgeoned into a major commercial and medical presence largely without the restraint of controlling regulatory checks suggests those vested and benefiting are not likely to give up independence willingly, especially in the absence of dependence on third-party payers.

Another option, an option also embodied in CLIA but seldom exercised,[495] is to delegate implementation responsibility to the states and enforce that responsibility through funding of state Medicare and Medicaid programs. The federal government could transform the CDC's model certification program developed in accordance with the Fertility Clinic Suc-

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[490] Comments of James T. O'Reilly, Visiting Professor of Law, University of Cincinnati, College of Law, at the ABA event, New Frontiers, *supra* note 280, in the context of a question and answer session with the panel, including the author.

[491] FINAL REPORT, *supra* note 11, at 1; Adamson, *supra* note 21, at 933.

[492] SART-ASRM efforts to date are identified *supra* in Figure 4, and these and additional professional society ethical guidelines pertaining to ART are summarized *supra* in Figure 3. In addition to SART-ASRM, relevant professional organizations include the American College of Obstetrics and Gynecology ("ACOG"), the Society of Reproductive Endocrinologists ("SRE"), the Reproductive Biologists Professional Group ("RBPG"), and the Reproductive Laboratories Technology Professional Group ("RLTPG"). *See* Adamson, *supra* note 21, at 940-41.

[493] *Snake Oil*, *supra* note 5, at 45 & n.98.

[494] *Id.* at 42.

[495] *See* Malinowski & Rose, *supra* note 303, at 10-25 to 10-26.

cess and Certification Act of 1992[496] into a mandatory program and enhance relevant requirements. However, the resources, capabilities, and reliability of state departments of public health vary immensely throughout the country, especially in the midst of regional epidemiological problems such as West Nile Virus and challenges associated with realizing homeland security.[497] A consistent blanket of federal regulation is desirable to offer the public balanced access to quality ART services regardless of where they live. Too much reliance on state regulation in such a controversial area could result in a "race to the bottom" where states that offer higher standards push ART providers into other jurisdictions.

VIII. CONCLUSION

ART is a distinguishable area of clinical service: rapidly emerging technology and medicine are inherently mixed, the patient group is extraordinarily vulnerable, commercial influences are intense, and standard accountability and good medicine checks on clinical practice through third-party payer scrutiny do not pertain.[498]

Assisted reproduction has become a burgeoning, multi-billion-dollar industry that often commingles clinical care and experimentation.[499] The range of consequences includes expansion of procreative liberty, successful deliveries, dangerous multiple pregnancies, and the birth of premature and otherwise health-compromised children.[500]

This article has set forth regulatory proposals to ensure that ART is practiced with enforcement of good research and medicine standards.[501] Emphasized objectives are to protect the health of mothers and resulting children, to check influences on and the practices of ART providers, and to replace the present voluntary reporting by ART clinics with public accountability.[502] The latter is essential to regulate present practices and to contemplate our eugenics future before it arrives.[503] Our eugenics legacy speaks loudly to the seduction of capabilities to combine genetic intervention and procreation with the potential of improving the human condition, the need to question our present insufficient regulation of ART in the midst of the genomics revolution, and the moral imperative to contemplate the

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[496] Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. § 263a-1 to –7 (2000).

[497] This statement is based upon the author's observations working in regions as varied as Arizona, Delaware, Louisiana, Massachusetts, and New York. The work of the New York State Task Force on Life and The Law has been cited as evidence that states can and in some instances have assumed a meaningful role in ART. *See, e.g.*, Adamson, *supra* note 21, at 937.

[498] *See generally* discussion *supra* Part VI.

[499] *See generally* discussion *supra* Part VI.B.

[500] *See generally* discussion *supra* Part VI.B.

[501] *See generally* discussion *supra* Part VII.

[502] *See generally* discussion *supra* Part VII.

[503] *See generally* discussion *supra* Part VII.

implications of present actions for the future we are shaping today.[504] Conscious of this legacy, recent Nobel Laureate Sir Paul Nurse, in the context of honoring the 50th anniversary of the discovery of the double helix shape of DNA by James Watson and Jim Crick, warned, given the complexity of interpreting the influence of genes in combination with environmental factors, "[W]e need to be extremely careful how this technology is used to shape our society. This is why it is so important to have a proper public debate—we need to discuss what genetics can and can't deliver and what sort of society we want as a result."[505]

The 1997 motion picture GATTACA depicts a United States society in the not-too-distant future obsessed with genetic perfection in which ART and PGD are the standard of care for conceiving a child.[506] Everyone's genetic diary is an open book.[507] The main character, Vincent, portrayed by Ethan Hawke, has the misfortune of being an "In-Valid"—meaning one conceived in the back seat of an automobile the "old-fashioned way" rather than via the use of pipettes and computers. At the outset of the movie, Vincent reflects, "I'll never understand what possessed my mother to put her faith in God's hands rather than those of the local geneticist. Ten fingers, ten toes—that's all that used to matter. Not now. Now, only seconds old, the exact time and cause of my death was already known."[508] As we listen to Vincent's voice-over, a nurse in the delivery room collects a droplet of blood from his heel, feeds that into a computer, and shares the analysis: "Neurological condition—60 percent probability. Manic Depression—42 percent probability. Attention deficit disorder—89 percent probability. Heart disorder (pause)—99 percent probability. . . early fatal potential. Life expectancy. . .30.2 years."[509] Vincent's parents are careful to engage their local geneticist for the conception of their second child, and Vincent and his brother are raised commensurate with their genetic expectations. But, alas, Vincent beats his genetic odds: he does not succumb to a heart condition. Rather he assumes the identity of a member of the genetic elite and travels into space with the Gattaca Aerospace Corporation.

When GATTACA was released, spokespeople for the biotechnology industry were quick to characterize the film as a work of "science fiction,

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[504] *See* discussion *supra* Parts II and III; *supra* notes 423-72 and accompanying text.

[505] Tim Radford, *Fear of Genetic Apartheid: Debate Urged on Consequences of Health Predictions*, GUARDIAN, Mar. 4, 2003, at 2, LEXIS, News Library, Guardn file. Sir Paul shared the 2001 Nobel prize for genetic research and chairs the U.K. Royal Society's Science in Society Programme. *Id.*

[506] GATTACA (Columbia Pictures 1998).

[507] *Id.*

[508] *Id.*

[509] *Id.*

not fact."[510] With a map of the human genome in hand, a SNPs consortium, the DNA of nearly entire populations such as those of Iceland and Estonia available for a price, and bioinformatics capabilities almost unfathomable five years ago, scenes from GATTACA are being shown at law and policy conferences and interpretations have changed to "science fiction?"[511] Renowned bioethicists such as George Annas and Lee Silver, respected broadcast journalists, and others are referring to GATTACA as a prophetic depiction of the society we could become.[512] Their message has been echoed throughout this article: Now is the time for us to reflect upon our eugenics past, ponder our present practices in ART in the context of ongoing biomedical R&D, and ask ourselves what kind of society we want to become.

[510] The author was managing government affairs for the Massachusetts Biotechnology Council, Inc., a biotechnology trade organization, at this time and speaks from that personal experience.

[511] *E.g.*, *Cracking the Code*, *supra* note 238; *Making Babies*, *supra* note 6; Michael J. Malinowski, Presentation: Genes and Disability Through a Historic Lens, Symposium: Florida State University School of Law, (Mar. 4, 2003) (on file with the Connecticut Law Review).

[512] *E.g.*, *60 Minutes*, *Secrets of the Code* (CBS television broadcast, Apr. 17, 2002); *Making Babies*, *supra* note 6; *Cracking the Code*, *supra* note 238. *See generally* KASS, THE CHALLENGE, *supra* note 355 (discussing society's tendency towards a lack of bioethical control and its effect on the future); MCKIBBEN, *supra* note 14 (discussing advances in biotechnology and their necessary societal limiations).