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Genetics and Artificial Procreation in the U.S.A.

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Carl E. Schneider[1] *and Lynn D. Wardle*[2]

I General information on the legal situation

We national reporters have been asked to provide in a few pages such a range of information about the law and practice of medicine generally, genetic and artificial reproductive techniques specifically, and related family law and human rights issues that probably no country's reporter could pretend to have succeeded. We reporters for the United States, particularly, must stress the limitations of our report at the outset. It is difficult to summarize the American law and practice because they are so extraordinarily various and dynamic. There are several reasons for this, most of which will in uncanny ways confirm many of the foreign observer's preconceptions about American law.

First, American law and practice are various because American government remains in important ways genuinely federal. Family law has traditionally been confided to the fifty state governments, each of which is largely free to regulate reproductive technologies as it wishes. Second, law and practice are various because American government remains in important ways committed to the principle of separation of powers. This means that the power to regulate those technologies is divided among the various branches and agencies of the federal and the state governments.

Third, law and practice are various because of a series of inhibitions on governmental regulation of social life. It is well known, for example, that Americans have historically had – and in telling ways retain – a generally laissez-faire, anti-*dirigiste* view of government's role. That orientation is reinforced by our common law tradition. That tradition prefers a gradual rather than a pre-emptive legal response to novel social problems in which courts deal with aspects of the problem only as each aspect presents itself, waiting until the extent of the problem has become apparent before attempting a broad solution to it. Yet further inhibiting governmental regulation of reproductive technology is the power of rights thinking and – more specifically – the specter of *Roe v. Wade*,[3] the controversial 1973 case

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3 410 U.S. 113 (1973).

M.-T. Meulders-Klein et al. (eds.), Biomedicine, the Family and Human Rights, 55–86.

in which the United States Supreme Court held that the states' power to regulate abortions is severely constrained by women's constitutional right to make decisions about reproduction. That decision provoked such intense and sustained criticism of 'judicial legislation' that the Court has generally avoided taking the policy-making initiative in other cases involving controversial biomedical issues.[4] Nevertheless, the potential for *Roe-* like preemptive judicial action remains a significant influence.

A. *General Principles of Medical Law*

Medical law in the United States of America rests on three fundamental principles: patient autonomy, public welfare, and professional competence. The first two principles particularly influence the direct legal regulation of family-related genetic engineering and artificial procreation in the United States. The last principle works indirectly, through economic constraints associated with civil liability.

1. *Consent and privacy*

Patient autonomy historically has been protected by the firmly established rule that a physician must have his or her patient's consent before a treatment can be administered.[5] Two separate doctrines of patient consent have developed: first, traditional consent rooted in battery, and second, and most recently, informed consent grounded in negligence.[6] The earliest and best-known statement of traditional consent is from the 1914 New York case of *Shloendorff v. New York Hospital:*[7] 'Every human being of adult years and sound mind has a right to determine what shall be done with his own body: and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages. . . . '[8] A doctor who fails to obtain consent or who exceeds the scope of consent commits the tort of battery, defined in the American common law as 'an intentional touching of, or use of force upon, another person without the person's consent.'[9] If a patient has given consent, he or she may not later assert a claim of battery. Informed consent theory provides a remedy when a medical service provider fails to disclose the material risks or consequences of a treatment.

4 See, e.g., *Vacco v. Quill*, 521 U.S. 743 (1997); *Washington v. Glucksberg*, 521 U.S. 702 (1997).
5 See generally Carl E. Schneider, *The Practice of Autonomy: Patients, Doctors, and Medical Decisions* (1998).
6 Frank T. Flannery, *et al*, Consent to Treatment in *Legal Medicine*, at 197 (American College of Legal Medicine, Harold L Hirsch, ed., 1988,) (hereinafter 'Legal Medicine').
7 211 N.Y. 215, 105 N.E. 92 (1914). See also *id.* at 198; Stephen Wear, *Informed Consent* 21 (1993).
8 *Id.*
9 *Id.*

That failure deprives the patient of his or her right to give (or withhold) genuine consent and constitutes negligence because it is deemed to fall below a reasonable standard of expected professional conduct. As a court put it in the famous case of *Canterbury v. Spence*:

> The scope of the physician's communication to the patient must be measured by the patient's need, and that need is the information material to the decision. Thus, the test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risks potentially affecting the decision must be unmasked.[10]

Under both doctrines, consent may be either express or implied. Treatment provided in a *bona fide* medical emergency (when consent generally is presumed) is protected.

The doctrine of informed consent today requires a competent patient 'to be adequately informed of the nature and consequences of a particular medical procedure, process, or treatment prior to giving consent for that treatment.'[11] Thus, the doctrine generally requires doctors to adequately advise their competent patients regarding (1) the problem or diagnosis, (2) the recommended intervention together with its risks and benefits, (3) the expected result without intervention, and (4) any alternative interventions together with their risks and benefits.[12]

Informed consent is not required in three general situations - when (a) the patient is threatened with serious harm or death if not treated immediately (the emergency exception), or (b) the patient voluntarily gives up the right to be informed and consents, in advance, to whatever action the physician considers appropriate, or (c) the physician has strong reason to believe that disclosure itself would result in serious physical or psychological harm to the patient (the therapeutic-privilege exception).[13] Also, a doctor has no duty to advise patients as to matters of common or actual knowledge.[14] As a general rule, a patient's 'competence should be presumed unless sufficient reasons to the contrary are identified, e.g., gross mental deficits or incapacity.'[15] If a court has determined that a patient is incompetent, the patient's court-appointed guardian is authorized to give consent; otherwise, the patient's closest known relative is generally allowed to give consent.[16] As a

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10 464 F.2d 772 (D.C. Cir. 1972).

11 *Legal Medicine*, *supra*, at 198. See also Charles L. Spring & Bruce J. Winick, Informed Consent, in *Legal Aspects of Medicine* 62-65 (James Vevaina, Roger C. Bone, Edwin Kassoff, eds, 1989).

12 See generally *Informed Consent* at 6; *Legal Medicine* at 200.

13 Informed Consent at 6; *Legal Medicine* at 202.

14 Informed Consent at 8. A lack of informed consent is negligence and is actionable only if emotional or physical injuries result.

15 Informed Consent at 6; *Legal Medicine* at 200.

16 *Legal Medicine* at 200-01.

matter of law, minors are legally presumed to be incompetent; thus '[t]he general legal principle, although with numerous exceptions, is that a minor is incapable of giving effective consent for the administration of medical treatment. The minor is generally defined as someone below the age of eighteen or twenty-one. Therefore, in most circumstances, a physician must obtain the consent of a parent or guardian prior to embarking on the examination or treatment of a minor.'[17] However, by statute many states have created exceptions to the parental-consent rule in order to encourage minors to obtain prompt medical treatment in situations (such as treatment for drug addiction, pregnancy, sexually transmitted diseases, etc.) when parental disclosure might dissuade many teens from seeking medical care. Also, minors may be deemed capable of giving consent during emergencies, if adjudicated to be mature or medically emancipated and when it is physically impracticable to obtain consent.[18]

The ideals of autonomy and independence run deep in American culture. Indeed, some bioethicists, doctors, and patients are even beginning to suggest that patients not only have a right to make their own medical decision, but have a duty to do so. They argue that patients who make their own decisions benefit medically from becoming involved in their own care and that patients have a moral duty to make for themselves the decisions that shape their lives. Some doctors add that they are glad to be relieved of making momentous decisions for other people.

Nevertheless, empirical studies also reveal that a substantial number of patients would rather not make their own medical decision. What is more, the sicker the patient, the less likely he or she is to want to seize the reins of control. In addition, it has become plain that, however hard doctors try to inform patients about their illness, patients all too often take away from the encounter far less information than they need to make informed decisions and retain too much misinformation to make decisions really well.[19]

In recent years, recognition of patients' legal right to refuse treatment has underscored the principle of patient autonomy. While the United States Supreme Court has rejected the claim that the Constitution requires states to permit assisted suicide,[20] in a famous case involving withdrawal of life-support systems the Court stated that '[t]he principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions.'[21] Patient autonomy as a fundamental substantive value has been

17 *Id.*

18 *Id.* at 251, 254.

19 See generally Carl E. Schneider, *supra* note 5.

20 See, e.g., *Vacco v. Quill*, 521 U.S. 793 (1997); *Washington v. Glucksberg*, 521 U.S. 702 (1997).

21 *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990). In this case, the Court ruled that a state did not have to permit withdrawal of food and hydration tubes to an incompetent patient when there was not clear and convincing evidence that the incompetent patient desired to have the life support terminated. Nor did the state have to defer to the 'substituted judgment'

further highlighted by court decisions respecting the 'right to choose' even morally controversial medical treatments such as abortion and sex-change operations. The right to choose seems to be one of the driving principles in American medical law at this time.

Patient autonomy is further enhanced by the strong principle of confidentiality protecting the privacy of patients. In the United States, 'every patient has the right to expect that his or her privacy of person will be respected and that confidential communications will not be divulged unless he or she has given permission for, or the law requires, disclosure.'[22] However, state laws generally require disclosure in the public interest in cases of child abuse or certain communicable diseases, such as HIV/AIDS (though most HIV/AIDS reporting preserves patient anonymity). Traditional evidentiary privileges protect patient privacy by precluding a doctor from testifying in court, but there are exceptions. Some states have held that a physician's wrongful breach of confidence gives rise to a civil action for damages.

2 *Medical treatment and human experimentation in general*

As potent as the principle of patient autonomy is in American law and culture, it must sometimes yield to the interests of public welfare. Thus concern for stopping epidemics of contagious diseases in public schools may override a person's desire not to be vaccinated.[23] Likewise, even though some advocates of abortion argue that abortions may be done as safely by laymen as by doctors during the early stages of pregnancy, the Supreme Court has repeatedly upheld laws requiring that abortion be performed only by licensed physicians.[24] Public mores reflected in the law also may prohibit some technically feasible procedures, such as physician-assisted suicide. The clash between public health interests and other public policy values often produces challenging public policy dilemmas. For instance, public anti-discrimination policies designed to protect the handicapped have led to the enactment of the Americans with Disabilities Act of 1990 (ADA)[25] and state disability laws. Despite significant differences between communicable diseases and physical disabilities (such as impairments of sight, hearing, walking, etc.) the ADA applies to both. The Supreme Court has ruled that even people with contagious diseases such as tuberculosis cannot be dismissed from teaching school without implicating ADA claims.[26] In a number of cases, mandatory testing for HIV/AIDS of certain professionals (nurses, firefighters) and potential transmitters (eg., non-

of the incompetent patient's parents who sought to have her life support discontinued on the grounds that that was what the daughter would have wanted.

22 Legal Medicine, *supra*, at 208-12. See also id. at 381.

23 See generally *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

24 *Connecticut v. Menillo*, 423 U.S. 9 (1975); *Mazurek v. Armstrong*, 521 U.S. 968 (1997).

25 42 U.S.C. §§ 12101-12213 (1988 & Supp. V 1993).

26 *School Board v. Arline*, 480 U.S. 273 (1987).

consensual partners and sexual offenders) has been challenged, though most such requirements have been upheld.[27]

Nontherapeutic research and experimentation are permissible when statutorily mandated consent has been secured. Since 1975, the U.S. Department of Health has established regulations that detail the way human research must be conducted in order to protect human subjects by requiring and defining the scope of patient informed consent.[28] These regulations were initially adopted shortly after the Tuskegee Syphilis Study was exposed. That government study involved the forty-year monitoring by government doctors of hundreds of African-Americans who were infected with syphilis. Even after effective penicillin treatment became available, treatment was not offered to the subjects, and those who asked were sometimes discouraged from seeking treatment.[29] The federal regulations apply to all government agencies and government-funded or -aided research (effectively most significant medical research) and set standards for mandatory written consent from human research subjects. These regulations also mandate the establishment of institutional review boards (IRBs) consisting of at least five people of diverse but knowledgeable backgrounds whose role it is to see that risks to human research subjects are minimal and reasonable in light of anticipated benefits, to guarantee that informed consent is obtained, and to approve, require modification of, or disapprove all human research involving human subjects.[30]

Related to IRBs are ethics committees, which began to appear in American hospitals in the 1980s. Ethics committees consist of people experienced in addressing issues arising from the conflict of law and morality. Unlike IRBs, however, these committees do not police clinicians or interfere in the patient-physician relationship. Rather, their knowledge and skills in ethics and the law may be consulted by doctors, nurses, patients, and families who face ethical dilemmas regarding medical treatment.[31]

Medical innovation and research are generally favored. A famous case from the early days of the heart pump illustrates that policy. When Dr. Denton Cooley had exhausted other ways of keeping his patient, Haskell Carp, alive, he implanted the first completely mechanical heart into Mr. Carp. Mr. Carp died 32 hours later, and a wrongful death suit was brought. A federal court however, directed a verdict

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27 See, e.g., *Leckelt v. Board of Comm'rs of Hosp. Dist. No. 1*, 909 F.2d 820 (5th Cir. 1990) (mandatory HIV testing for licensed practical nurse); *Anonymous Fireman v. City of Willoughby*, 779 F.Supp. 402 (N.D.Ohio 1991) (mandatory HIV testing for firefighters and paramedics upheld); In *re Juveniles A, B, C, D, E*, 121 Wash.2d 80, 847 P.2d 455 (1993) (mandatory testing of convicted sexual offenders, including juvenile offenders upheld).

28 *Basic HHS Policy for Protection of Human Research Subjects*, 45 C.F.R., Part 46. See generally Legal Medicine at 204; Harold M. Ginzburg, Protection of Research Subjects in Clinical Research, *Legal Aspects of Medicine* 51-59 (James R. Vevaina, et al, eds., 1989).

29 See generally James H. Jones, *Bad Blood: The Tuskegee Syphilis Experiment* (1981).

30 45 C.F.R. §§ 46.101-46.124.

31 George A. Kanoti, Ethics, Medicine, and the Law, in *Legal Aspects of Medicine*, 77, 79-80.

for Dr. Cooley.[32] Thus, medical researchers in the United States walk a tightrope stretched between the pole of cultural values favoring innovation and independence in research and the pole of principles disfavoring the exploitation or manipulation of the vulnerable and uninformed by the powerful and expert.

Experimentation on fetuses, embryos, and pre-embryos takes the issue of protection of human subjects (discussed *infra* in Part III.B.5) to a very fine, and not unimportant, point. Some people argue that since the fetus is not a 'person,' experimentation that holds some promise of benefit to humanity is morally justified. Others strongly believe that using human fetuses or embryos for research is morally reprehensible.[33] The issue remains highly volatile and highly political. For example, when President Clinton lifted a ban on research involving tissue or cells from embryos or fetuses killed by elective abortion (imposed by President Bush to avoid a potential incentive for elective abortions), Congress responded by enacting a federal statute to regulate federal support of research in this area.[34]

3 Professional Competence and Malpractice Liability

Professional competence traditionally has been encouraged by professional self-regulation and civil liability for malpractice. Self-regulation historically has been minimal, and the members of the medical guilds have generally supported each other against external (especially legal) constraints. Civil liability for malpractice, however, has been a major influence on medical attitudes and probably has encouraged improvements in medical procedures. Because contingency-fee agreements between attorneys and clients are permitted in medical malpractice cases, even the poorest injured patients can obtain competent legal assistance to aggressively seek compensation, and their lawyers have a direct pecuniary motive to maximize the recovery.

A dramatic increase in loss-payments by medical malpractice insurance companies (averaging more than 14% annually for more than a decade) generated a 'medical malpractice crisis' in the 1980s, as doctors experienced great increases in their insurance premium payments and physicians in some high-risk specialities became nearly uninsurable.[35] Consequently, many states have enacted medical malpractice reforms that limit the ability to recover excessive judgments by establishing pretrial screening requirements, mandating alternative dispute resolution procedures before

32 *Karp v. Cooley*, 493 F.2d 408 (5th Cir. 1974).

33 Fletcher, infra at note 112 at S:4, citing Alto Charo.

34 Fletcher, *infra*, at S:5-6 (Addendum). Restrictions on research on fetuses in utero is contained in 42 USC § 289g(b) and 45 C.F.R. § 46.208(a)(2). *See* Biolaw S:60 (January 1999).

35 David J. Nye, et al, The Causes of the Medical Malpractice Crisis: An Analysis of Claims Data and Insurance Company Finances, 76 Geo. L. J. 1495 (1988).

allowing civil litigation, limiting the amount or types of recovery (such as capping pain and suffering damage awards), and adopting no-fault schemes for certain kinds of injuries (replacing tort remedies with administratively administered compensation recovery programs).[36] Medical malpractice liability, nonetheless, continues to be an economic restraint against overly aggressive consumer marketing of artificial procreation products and services, although such marketing seems hardly necessary in the current environment of aging baby-boom generation adults belatedly anxious to discover the joys of childrearing.

B. International Law

The United States has generally been more reluctant than most other industrialized countries to enter into the kind of treaties that affect family law, biomedicine, and human rights. The reasons for this are too copious, complex, and controversial to summarize fully. However, any account should start with the federalist principle. As we suggested earlier, much of family law and health law is constitutionally confided to the state, not the federal governments. It is true that the federal government has broadly interpreted powers to regulate interstate commerce and that the billions of dollars the federal government distributes to state governments can be used as a lever to influence state law. Nevertheless, the federalist principle retains authority in many quarters for at least two reasons. First, from colonial times many Americans have been suspicious of the power of the central government. Second, in a country as large and various as the United States federalism has been one way of keeping government close to the people. The federalist principle, then, raises a presumption (however rebuttable) that family and health law questions are not properly questions of federal law. Indeed, there may even be an argument that the federal government's authority to enter into treaties regarding such questions is constitutionally dubious.

The American interpretation of the democratic principle probably also works to make the country more hesitant to enter treaties in these areas. To be sure, treaties are agreed to by democratically elected governments. But their terms are not worked out through the usual kinds of democratic negotiation. And once a treaty becomes law, it is interpreted by unelected courts. Americans have an exceptionally strong principle of judicial review, and both the right and the left have come to believe (at different points in history) that that power is most troublesome when courts interpret documents (like the Constitution and treaties) which cannot be readily amended by the legislature. In recent years, the Supreme Court's innovations in precisely the area of family law and biomedicine – principally in *Roe v. Wade* –

36 Barry R. Furrow, Thomas L. Greaney, Sandra H. Johnson, Timothy Jost, & Robert L. Schwartz, *Health Law*, Chapter 9, at 332-363 (1995).

have seemed problematic to many conservatives and moderates. This has probably made treaty-making in this area even more unpalatable.

None of this should suggest, however, that the question whether the United States should sign treaties of this kind often rises to the level of political controversy. It does not. This is partly because it is the rare American who thinks he can best accomplish what he wants domestically through such treaties or who believes that treaties in these areas will much affect genuinely deplorable conduct abroad. If anything, these treaties tend to be regarded quite skeptically as grand but vague statements of principles complacently signed even by countries with no intention of adhering to them. When to all this is added the American history of isolationism (much abetted by the considerable size of the country and its oceanic separation from all but two other countries), it may even seem unsurprising that Americans have not rushed to sign these treaties.

Despite all these factors, the United States has signed the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights in 1966.[37] The United States also has signed the Universal Declaration of Human Rights.[38] Obviously, the United States of America is not a party to European regional agreements. Among the relevant regional documents relating to biomedical, family, and human rights law that do not apply in the United States are the European Convention on Human Rights, the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (commonly referred to as the 'Convention on Human Rights and Biomedicine'), the Treaty of Rome, the Council of Europe Protocol banning human cloning, the Draft Additional Protocol on Transplantation of Organs and Tissues of Human Origin for Application to the Convention on Human Rights and Biomedicine (2-3 Feb. 1999);[39] and the Additional Protocol on the Prohibition of Cloning Human Beings.[40] The United States also has not ratified the UN Convention on the Rights of the Child, due largely to questions about the ability of the federal government to enter such a treaty and concerns about some ambiguous and controversial substantial provisions. Nor has the United States subscribed to the United Nations Educational, Scientific and Cultural Organization (UNESCO) Universal Declaration on the Human Genome

37 *A Guide to the U.S. Treaties in Force* at 27 (Igor I. Kavass, ed., 1996). The Covenants entered into force on March 3, 1976, and September 8, 1992, respectively.

38 1948-49 U.N.Y.B. 53, U.N. Sales No. 1950 1.11.

39 Steering Committee on Bioethics (CDBI), Abridged Report of the 15th Meeting of the CDBI (Strasbourg, 7-10, December 1998) (<http://www.coe.fr/cm/reports/1998/98cm212add1.htm> (excluding reproductive cells like sperm, eggs, embryos and fetal/embryo tissue) (visited June 22, 1999).

40 Additional Protocol to the Convention for the Protection of Human Rights and Dignity of Human Beings with Regard to the Application of Biology and Medicine on the Prohibiting of Cloning Human Beings, ETS No. 168, signed by 19 nations on January 12, 1998.

and Human Rights (November, 1997).[41] Applications have not been made to international courts by the United States concerning biomedical issues. There is, of course, judicial review of the constitutionality of biomedical regulations in the courts of the United States.[42]

II Genetics: Statutes, Case Law, Research

A. *Introduction*

American public policy toward genetic engineering is influenced by five general tendencies of American public policy. First, public policy is ordinarily more centrally concerned for the individual than the group. Second, individual liberty frequently takes priority over social welfare. Third, innovation and progress are commonly valued more than conformity. Fourth, research is often driven by the market, and regulations are often influenced by companies and people with financial and personal interests in them. Fifth, public policy tends to develop case by case rather than through the early establishment of general pre-emptive regulations.[43]

Contemporary biomedical issues typically involve fierce, unresolved tensions including morality versus efficiency, pro-life values versus pro-choice values, principles versus convenience, and immediate-versus-long-term perspectives. Yet all these values and tensions interact in an environment pervaded by the American spirit of pragmatism and in a constitutional system where the structural morality encourages policy-making by accommodation, compromise, and consensus. Getting along and getting the job done usually seem to matter most in America, and that spirit seems to moderate some of the extremes in values, viewpoints, and personality that thrive in the open and individualistic American milieu.

In the United States, there are few regulations regarding genetic engineering or cloning and even fewer regarding artificial-reproduction technology. U.S. laws relating to cloning are in a state of fumbling transition. Traditionally, most genetic and fertility research has been conducted in the private sector, where financial considerations often seem to outweigh social and ethical considerations. (See *infra* Part III.B.5.)

41 Report by the Director-General on the Implementation of the Universal Declaration oon the Human Genome and Human Rights <http://unesdoc.unesco.org/images/0011/001115/111566e.pdf> (visited June 22, 1999).

42 For a good discussion see Roger B. Dworkin Limits, 15-18 (1996,).

43 See Generally Lisa Sowle Cahill, Generics, Ethics and Social Policy: The State of the Question in *The Ethics of Genetic Engineering* at xi (Maureen Junker-Kenny & Lisa Sowle Cahill eds., Concilium, SCM Press LTC., 1998).

1 Genetic Discrimination and Genetic Privacy

As information about the human genetic code burgeons, advocates of privacy and sunshine clash. The former fear that the disclosure of someone's genetic abnormalities will lead insurers to discriminate against him unfairly; the latter fear that concealing genetic information will cause fraud, manipulation, and undue expense. On one hand, ordinary citizens increasingly fear for the privacy of their genetic information. On the other hand, as Professor Richard Epstein writes, '[t]he plea for privacy is often a plea for the right to misrepresent one's self to the rest of the world.'[44]

Some genetic information clearly is relevant to risk assessment.[45] Thus, insurers, who want to identify risks more accurately and allocate costs to risks more efficiently, now request, in addition to information about smoking and occupation, information about infection with the Human Immunodeficiency Virus (HIV).[46] Some insurance companies have charged applicants increased premiums or have denied them coverage or benefits because they are particularly likely to develop a disease. This has sparked a vehement reaction in some quarters against 'genetic discrimination.' For example, Vice-President Gore has said, '[G]enetic progress should not become a new excuse for discrimination.'[47]

Public concern about misuse of genetic information has caused some state legislatures to enact laws to prevent discrimination based on genetic information. These laws, in turn, have also generated controversy. For example, the president of the California Health Care Institute spoke for many insurers when he argued that public 'fears . . . are producing a spate of ill-advised laws that will have serious unintended consequences in the private insurance industry.'[48] Other insurance industry representatives have decried the lack of uniformity in 'patchwork' state

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44 Richard A. Epstein, The Legal Regulation of Genetic Discrimination: Old Responses to New Technology, 74 B.U. L. Rev. 1, 12 (1994), cited in Meredith A. Jagutis, Comment, Insurer's Access to Genetic Information: The Call for Comprehensive Federal Legislation, 82 Marquette L. Rev. 429, 444 (1999) (hereinafter 'Jagutis').

45 For example, females with a mutation to the gene BRCA1 may have an eighty-five percent chance of developing breast cancer, and a fifty percent chance of developing ovarian cancer, and a person with the genetic marker for Huntington's chorea is nearly certain to develop the disease, and of course, someone with the HIV virus is almost certain likely to contract AIDS. *See generally* John V. Jacobi, The Ends of Health Insurance, 30 U.C. Davis L. Rev. 311, 330 (1997) (hereinafter 'Jacobi').

46 Jacobi, at 330-331.

47 *See* Reuters, Genes and Discrimination: Gore Urges Laws Banning Bias in Hiring and Insurance, Newsday, Jan. 21, 1998, at A20, cited in Jagutis at 429.

48 David Gollaher, All Can Use Gene Tests ... Except Poor Screening Helps Insurers and (Surprise) Patients with Risks and Money, Seattle Post-Intelligencer, Jan. 11, 1998, at E1, cited in Jagutis at 429.

legislation drafted by local lawmakers who do not always understand the science,[49] and there have been calls for federal legislation.[50]

Laws regarding use by insurers of genetic testing appear to have gone through three phases in the United States. First, laws prohibited insurance underwriting based on specifically identified genetic traits. Next, states barred the use of genetic testing altogether in underwriting. Finally, laws barring insurance industry use of genetic information broadened beyond information collected in laboratory tests. Legislation in this area is a growth industry. For example, in 1997, 153 bills concerning genetic discrimination or genetic privacy were introduced in state legislatures in America. The apparent goal of some of these bills was to encourage the use of genetic tests by individuals by protecting the privacy of the results.[51] Concern about the spread of AIDS has spawned a number of bills (including bills mandating testing and disclosing results for sex offenders and prostitutes and reporting epidemiological information) which have engendered controversy between victims, rights advocates and public health officials, on one hand, and, on the other, AIDS activists who fear that to AIDS patients may be stigmatized by the inadvertent disclosure of AIDS/HIV-positive status or who fear that the reporting requirements will discourage voluntary testing.

The genetic privacy and nondiscrimination laws that the states have enacted vary significantly, since they define terms differently and contain different exceptions. By 1996, at least twenty-four states had legislation that either provided protection against genetic discrimination or prohibited genetic testing in insurance or employment, and similar legislation was introduced in 1997 in at least eighteen other states.[52] Many states also prohibit insurers from requiring or requesting genetic tests; six states even bar insurers from considering whether the insured or applicant has applied for or refused a genetic test.[53] For example, a California law declares:

'No [health care service] plan shall refuse to enroll any person or accept any person as a subscriber after appropriate application on the basis of a person's genetic characteristics that may, under some circumstances, be associated with disability in that person or that person's offspring' nor 'require a higher rate or charge, or offer or provide different terms, conditions, or benefits, on the basis of a person's genetic characteristics . . . .'[54]

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49 Robert Pear, States Pass Laws to Regulate Use of Genetic Testing, N.Y. Times, Oct. 18, 1997, at A1, cited in Jagutis at 430.

50 Jagutis at 430.

51 Jagutis at 435.

52 The Council for Responsible Genetics, Laws Regarding Genetic Discrimination <http://www.gene-watch.org/legislate.html>(updated August 27, 1997).

53 Jagutis at 439-441.

54 Calif. Health & Safety Code: Insurance § 1374.7 (Deering 1990).

At the federal level, little significant legislation has yet been enacted,[55] but at least nine bills to prohibit genetic discrimination or protect genetic privacy have been introduced.[56] These federal bills typically propose to prohibit a group health plan from denying, limiting, or canceling a plan based on genetic information or on the request or receipt of genetic information. These bills generally are supported by organizations such as the American Cancer Society, the National Breast Cancer Coalition, the Council for Responsible Genetics, the National Action Plan on Breast Cancer, and the National Advisory Council for Human Genome Research.[57] While insurance is primarily regulated by the states, some important federal laws regulate insurance companies, and the problem is national, not local. The most significant federal legal initiative probably is the Equal Employment Opportunities Commission's interpretation of the Americans With Disabilities Act (ADA), an interpretation which indicates that the enforcing agency believes that the Act prohibits 'discrimination on the basis of genetic information relating to illness, disease or other disorders.'[58]

The antidiscrimination approach reflects the strong egalitarian strain in American politics and society. However, there obviously are limits to this approach. All genes are not equal. Thus, while American generally oppose 'genetic discrimination' in insurance coverage, when it comes to allocation of funds to fight disease they willingly discriminate by giving much more money to study some genetic conditions than others. In any event, with or without new laws, the explosion in knowledge about genetics will surely transform the worlds of insurance, employment, privacy, and public health.[59]

2 *Genetic Screening of Newborns*

Screening of newborn infants is widely advocated and widely practised. But it is not unproblematic. Despite the educational benefits and low costs of obtaining parental consent to neonatal screening, mandatory neonatal genetic testing *without* meaningful parental informed consent is widespread.[60] 'Today, every state and the District of Columbia tests for PKU and for congenital hypothyroidism, while

55 For instance, the federal Health Insurance Portability and Accountability Act of 1996, Pub. L. NO. 104-191, 110 Stat. 1936, 1961 (1996), prohibits the use of 'genetic information' to deny coverage of employment-based group health insurance when an employee changes jobs. See generally Reilley, *supra* at 17.

56 The Council for Responsible Genetics, Laws Regarding Genetic Discrimination <http://www.gene-watch.org/legislate.html>(updated August 27, 1997).

57 Jagutis at 443.

58 E.E.O.C. Compliance Manual §902.8 (Definition of the Term 'Disability') (March 1995), quoted in Furrow *et al, supra.*

59 Jagutis at 433.

60 Diane Paul, "Contenting Consent: The Challenge to Compulsory Neonatal Screening for PKU", 42 *Perspectives in Biology* 207, 207-08 (1999) (hereinafter 'Paul').

48 [states] test for galactosemia, 44 for sickle-cell anemia, 24 for maple syrup urine disease, 16 each for homocystinuria and congenital adrenal hyperplasis, 19 for biotinidase deficiency, 4 for CF [cystic fibrosis], 2 each for toxoplasmosis and tyrosinemia, and 1 for congenital hearing deficit.'[61]

B Regulation of Specific Techniques

1 General regulation

The following techniques are legally permitted in the United States: preimplantation genetic diagnosis,[62] prenatal genetic diagnosis,[63] and genetic diagnosis of newborns, children, adolescents, engaged couples, and couples considering having a child.[64] Research on human embryos is permitted in some instances and illegal in others.[65] This kind of research is legally permitted and requires no particular consent beyond the general consent outlined earlier; often genetic counseling is offered, but such counseling is not mandatory.[66] Private research costs are met by private money whereas public research funding is obtained through the Department of Health and Human Services. Public research generally is subject to much greater governmental constraint than is private research.

2 Genetic Diagnosis

Genetic diagnosis is legal in the United States. It is most often used to screen for birth and health defects.[67] Testing for gender selection is opposed by many but occurs often in clinics around the country because there are no laws prohibiting genetic selection.

3 Paternity and Maternity Tests

Paternity tests are legal in the United States under certain conditions. Thirty-nine station allow for the admission in court of blood tests, sixteen states expressly allow

61 Paul, supra at 212.
62 *Ethics of Genetic Engineering* at 10; Genetic Ethics: *Do the ends justify the genes*, John Kilner, 1997 at 142.
63 *Ethics of Genetic Engineering* at 10; *Genetic Ethics* at 142; *Limits* at 85-86.
64 *Genetic Engineering* at 129, 158.
65 See IB1 supra; *Ethics of Genetic Engineering* at 59; *Limits* at 82-84.
66 *Genetic Ethics* at 146-155.
67 *Id.* at 136-145.

admission of DNA testing (and *de facto* all states now use and prefer DNA testing), and forty-eight states expressly allow HLA testing.[68]

Debate is growing over the extent to which scientific tests that can accurately identify biological parentage should be used to establish legal parentage. Historically, legal parentage has been predicated upon biological parentage. However, as biotechnology increases the ability to procreate without human sexual relations, the old biological presumption is eroding. At the same time, biotechnology is increasing the ability to challenge and disprove historic presumptions of biological parentage (particularly the husband's paternity of a child born to an adulterous wife). This has given rise to some hotly debated decisions regarding the constitutionality or rationality of state laws which support or deviate from the old biological presumptions of legal paternity. If an adulterous paramour can prove with new biotechnology (usually DNA testing) that he is the biological father of the child born to a married woman, is he instead of (or in addition to) her husband entitled to paternity rights, including custody, or visitation, or inheritance? (A famous Supreme Court decision ruled that the Constitution did not require states to grant the paramour such an entitlement.)[69] If a husband can prove in a divorce proceeding that he is not the biological father of a child born to his adulterous wife during their marriage, is he nonetheless obligated to support the child, despite his wife's infidelity and deception? (Several state courts have ruled that he is.)[70] Some cases suggest a strict liability theory of paternity – absent legislation providing an exception, a male is strictly held to the financial responsibilities of paternity, if his sperm conceived the child – even if the mother promised (falsely) to use birth control or to abort, even if she expressly agreed (falsely) not to pursue paternity or child support, even if she obtained his sperm while he was unconscious, without his consent.[71] The controversy is not likely to abate soon.

4 *Medical Confidentiality and Responsibility*

Protecting the confidentiality of a patient's medical history has long been a tradition in medicine.[72] The Hippocratic Oath states, 'And whatever I shall see or hear in the course of my profession, . . . it if be what should not be published abroad, I will never divulge, holding such things to be holy secrets.'[73] However, while

68 "Scientific Evidence of Paternity: A survey of state statutes", Allan Z. Litovsky, 39 *Jurimetrics J.* 79, 84-88, Fall, 1998.

69 *Michael H. v. Gerald D.*, 491 U.S. 110 (1989).

70 See generally Laura W. Morgan, It's Ten O'Clock: Do You Know Where Your Sperm Are? Toward a Strict Liability Theory of Parentage, 11 *Divorce Litig.* 1 (Jan. 1999).

71 *Id.*

72 *Genetic Ethics* at 127. See also *Limits* at 95-104.

73 *Id.*

confidentiality is important, it is not absolute. Some obligations are valued more than confidentiality.[74] One such obligation is the duty to protect and preserve life.

> Two groups, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research in 1983 and the Committee on Genetic Risks of the Institute of Medicine of 1994, have identified conditions under which confidentiality could ethically be breached and relatives informed about genetic risks. In their view, relatives could be informed if: 1) all attempts to illicit voluntary disclosure from the patient have failed; 2) there is a high probability of irreversible or fatal harm to the relative without disclosure; 3) the disclosure of the information will prevent the harm; 4) the disclosure is limited to the information necessary for the diagnosis and/or treatment of the relative.[75]

Doctors who make these disclosure decisions carelessly run the risk of being sued by their patients.[76]

Concerns about 'genetic privacy' create a dilemma for lawmakers. The fundamental goals of the health care system – good care, universal coverage, equitable treatment, and consumer choice at a reasonable cost – cannot be achieved without thorough, complete, accurate health data.[77] However, collecting personal health data invades privacy. As Lawrence O. Gostin puts it: 'Health information is perhaps the most intimate, personal, and sensitive of any information maintained about an individual. As the nation's health care system grows in size, scope, and integration, the susceptibility of that information to disclosure will also increase.'[78] Americans who cherish their privacy generally believe that it is not adequately protected. In a 1993 poll, eighty percent of the Americans surveyed thought consumers had lost all control over how medical information about them is circulated and used; eighty-five percent said protecting the confidentiality of medical records is an absolutely essential or very important part of national health care reform.[79]

Several private groups of scientists, doctors, and health-law experts have proposed model laws to protect genetic privacy or prevent genetic discrimination.[80] An influential California law, for example, requires that in state-sponsored

74 *Id.* at 131.
75 *Id.*
76 *Limits* at 86-93.
77 Gostin, "Health Information Privacy", 80 Cornell L.J. 451, 452 (1995) (hereinafter 'Gostin').
78 *Id.* at 455.
79 *Id.* at 454.
80 See, e.g., George J. Annas, Leonard H. Glantz, & Patricia A. Roche, "Drafting the Genetic Privacy Act: Science, Policy and Practical Considerations", 23 *J. Law, Medicine & Ethics* 360 (1995); The Council for Responsible Genetics, A Proposed Model Law To Prevent Genetic Discrimination (November 1996) <http://www.gene-watch.org/modelbill.html> (searched June 2, 1999).

hereditary disorder programs, '[a]ll testing results and personal information from hereditary disorders programs obtained from any individual . . . [shall] be held confidential and be considered a confidential medical record [except as parents or guardians or the individual consent to release].'[81] However, it has been said that American law neither adequately protects privacy nor ensures fair information practices, and some experts are skeptical that the public 'can have it both ways: that adequate legal protection of informational privacy will eliminate the need to significantly limit the collection of health data.'[82]

Another privacy concern is associated with the ubiquitous use of computers by health care providers, health services, and the health insurers. Computerization of health records has increased the possibility of inadvertent disclosure to third persons or access to confidential records by third persons.[83]

Genetic research and engineering clearly have opened numerous new legal issues pertaining to genetic identity, discrimination, personhood, screening, diagnosis, parentage, and confidentiality. While some fear-driven legislative and regulatory responses have emerged, the prevailing tendency in America has been to wait and see, to address the legal questions only when they arise, and to combine faith in the future with respect for human dignity and for individual genetic integrity.

III Artificial Reproductive Technology and the Law: Statutes, Case Law, and Practice

A Introduction

The American tradition described in the General Introduction is not the only factor that inhibits any unified governmental response to the rise of reproductive technologies. Several more specific factors deter such a response. The first, of course, is the speed with which those technologies arise, proliferate, and mutate. The second is the entrepreneurial spirit of American medicine, which encourages individual doctors and medical centers to respond aggressively and imaginatively to the demand for medical services and even to try to stimulate demand for them. The third is the absence of a national system of paying for health care and the presence of a system which permits a variety of responses to each new development in medical ingenuity.

81 Calif. Health & Safety Code: Genetic Prevention Service Hereditary Disorders Act § 124980 (j) (Deering 1997).

82 Gostin at 456.

83 See generally Gostin, *supra,* at 451.

B The Several Technologies: Their Law and Practice

Having explained why any attempt to summarize the practice and law of reproductive technologies in the United States must fail, we will proceed, nonetheless, to examine several of the major techniques many civil law jurisdictions. Official registration of birth and civil status is highly and formally regulated and has significant legal ramifications. But in the United States, establishing parentage historically has been and largely still is quite informal. For most parents and children, parentage is established by three presumptions – the presumption of the maternity of the woman who gave birth to a child, the presumption of the paternity of her husband, if she is married, and the presumption of paternity by open acknowledgment or cohabitation if she is not.[84] Because artificial procreation can create situations which defy the assumptions upon which these presumptions are based, many parentage controversies have arisen about it.

1 Surrogacy

The trends we described in the introduction are perhaps best illustrated by the story of arrangements in which a woman agrees to bear another woman's child – a practice Americans have come to refer to as surrogate motherhood. When surrogacy became technically possible, entrepreneurs quickly began to offer their services as brokers in bringing together surrogates and people who wished to hire them. Because this arrangement was novel, states did not have statutes regulating it. Typically, the policy issue first achieved prominence as a legal issue in a case – *Matter of Baby M*.[85] There a married woman entered into a contract in which she agreed to be impregnated by artificial insemination with sperm coming from the husband of another married couple. When the child was born, the woman refused to give the child to the couple. The New Jersey Supreme Court held that the contract was unenforceable because it conflicted with New Jersey statutes concerning adoption and the termination of parental rights and with public policy concerning families and the formation of contracts. For example, the court said, 'This is the sale of a child, or, at the very least, the sale of a mother's right to her child,'[86] which New Jersey law prohibited. The court then treated the case as a child-custody dispute and awarded custody to the biological father.

Another variation on surrogacy appeared in a later, somewhat less prominent, case – *Johnson v. Calvert*.[87] In that case, a married couple signed a contract with

84 See generally *1 Contemporary Family Law* § 9:02 (Lynn D. Wardle, Christopher L. Blakesley & Jacqueline Y. Parker, eds. 1988).
85 537 A.2d 1227 (NJ 1988).
86 *Id.* at 1248.
87 851 P2d 776 (CA 1993).

a woman in which she agreed to have implanted in her womb an embryo created by the sperm and egg of a married couple. Here too the woman refused to give the child to the couple when it was born. The California Supreme Court gave custody to the married couple, since 'she who intended to procreate the child – that is, she who intended to bring about the birth of a child that she intended to raise as her own – is the natural mother under California law.'[88]

As these opinions suggest, courts asked to decide disputes arising out of surrogacy contracts have based their decisions on common law principles (e.g., principles about which contracts are void because they violate public policy) and on statutes not written with these contracts in mind (e.g., statutes regulating adoption and specifying the treatment of children born out of wedlock). All of the parties to these disputes have been able to find sustenance for their arguments in the Constitution. Courts, however, have been reluctant to make those very difficult arguments the bases for their conclusions, not least because each party can make some colorable constitutional claim.

In response to judicial decisions of this kind (and indeed to calls for help from the courts), state legislatures began to pass statutes specifically regulating surrogacy contracts. Several states have proscribed the arrangement where money is exchanged, and others have strictly regulated the procedure (although the effectiveness of such regulation remains unclear).[89] For example, New Hampshire requires the parties to a surrogacy contract to jointly petition the court for a judicial preauthorization of the surrogacy agreement based on, among other things, genetic and psychological evaluations of the parties.[90]

2 *In Vitro Fertilization*

In vitro fertilization is much more common than surrogacy arrangements, but it is even less regulated. It is available to consenting adults in approximately 350 clinics throughout the United States. In general, however, only the wealthy can afford such treatments, since the cost of each 'cycle' can exceed $8,000, and the procedure is not covered by most health insurance plans. A survey from the Centers for Disease Control of 300 of these clinics suggested that more than 64,000 such attempts were made in 1996 and that somewhat more than 20,000 children were born of these efforts, a disproportionate number of them in multiple births.[91]

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88 *Id.* at 782.

89 See, e.g., Ian McCallister, "Modern Reproductive Technology and the Law: Surrogacy Contracts in the United States and England", 20 Suffolk Transnat'l L. Rev 303, 380-10, Winter 1996. And Abby Brandel, "Legislating Surrogacy: A Partial Answer to Feminist Criticism", 54 *Md. L. Rev.* 488, 1995, (giving detailed information on the eighteen states at the time which had addressed surrogacy).

90 N.H.R.SA. 168-13:21 (1994).

91 UP, Science News, *CDC: In Vitro Methods A Baby Boom*, February 2, 1999.

Egg donation is one of the fastest growing areas of IVF. The CDC reported more than 5,000 such donations in some 227 clinics in 1996. The procedure in which eggs are removed from the donor is not undemanding. Furthermore, the pool of donors is not unlimited, since the preferred donor is a woman under the age of 35 with an unremarkable medical history. Thus donors typically can command between $2,500-$3,500 and even up to $5,000 in large urban areas like New York.

Intracytoplasmic sperm injection (ICSI) was developed approximately seven years ago and is now widespread in the United States. The procedure, which costs roughly $10,000 per attempt, fertilizes an egg by injecting a single sperm cell past both the outer and inner membrane of the egg cell. The treatment remedies most deficiencies in male sperm production – inability to ejaculate, immature sperm, weak sperm, or low sperm counts. Prior to ICSI, only 5% of cases of male infertility were treatable. With it, nearly 99% of 'infertile' males can produce biological children. Recently, however, ICSI has provoked some concerns. At least one study has suggested that the procedure may cause cellular damage to the egg.[92]

Although the first American IVF birth occurred more than fifteen years ago, the field has been largely unregulated by the federal government. The federal government's first significant step into the area was more informational than regulatory: In 1992, Congress passed the Fertility Clinic Success Rate and Certification Act of 1992 (the Wyden Bill), which required an accounting of IVF births.[93] Even this modest gesture, however, had only a postponed effect, since the Department of Health and Human Services declined to fund the project until 1995.

State regulation is similarly sparse. Approximately sixteen states have laws that even mention human cell transfers. Some of these statutes require certification by state boards, some screening of donors, and some annual reporting. However, most states have been content to let the industry regulate itself.[94]

3 The Fate of the Embryo: Who Decides?

The rise of *in vitro* fertilization has led to questions about who should decide the fate of the fertilized eggs (which can endure in cryogenic limbo for years). Ordinarily, of course, the couple who contributed the genetic material have that power. And the practice – often given legal force through contracts between clinics and clients – has generally been that where the parties fail to act, the IVF clinic takes on the authority. Nevertheless, the predictable disputes have arisen, which have initiated law's response to the problem by bringing in the courts.

92 Nature - (March 1999).
93 42 U.S.C.A. §§201, 263 a-1–263a-7 (Supp. 1996).
94 Keith Alan Byers, "Infertility and In Vitro Fertilization", 18 *J. Legal Med* 29 (1997).

Courts have faced the question of embryo ownership in two spectacular state cases this decade, cases which reached results which were not necessarily consistent. In *Davis v. Davis*,[95] the attempts of a married couple, Mary Sue and Junior Davis, to have a child through IVF had yielded a number of frozen embryos (zygotes). The Davises then decided to divorce. Mary Sue wanted to donate the zygotes to another woman, but Junior did not want to become a father. The Tennessee Supreme Court held for Junior. It said that a woman's right to privacy does not encompass a general right to procreate and that Junior's right not to become an unwilling parent outweighed Mary Sue's right to donate the zygotes. The court was probably grateful not to have to determine who would have won had Mary Sue wished to utilize the zygotes herself instead of donating them to a third party.

Kass v. Kass,[96] on the other hand, involved a couple who, before beginning IVF, had signed forms that required the consent of both parties before the clinic could release the zygotes to either party and that gave the clinic permission to donate the zygotes for research if the parties did not reach an agreement. After a divorce, Maureen Kass, who was forty years old and regarded the frozen zygotes as her best hope of having children, sought the zygotes without her former husband's permission. A New York trial court awarded them to her over her ex-husband's objection, holding that the consent forms were so badly drafted that they were unenforceable and noting that the constitutional right of privacy, which includes both a right to procreate and a right not to become a parent against one's will, supported Maureen's claim. The court said that a husband has no right to procreate or avoid procreation because he has no role in the decision to have an abortion. On appeal, however, the judgment was reversed. The New York Court of Appeals unanimously held that the parties' clearly expressed intent that the IVF clinic be able to donate the zygotes for research controlled, that the woman's constitutional right to procreative privacy and bodily integrity was not implicated, and that the zygotes were not 'persons' in the constitutional sense.

Cases of this kind have evoked some legal responses. While statutes specifically regulating the status of frozen embryos have generally not been enacted,[97] the typical forerunners of legislation have begun to emerge. For example, the American Bar Association's Section on Genetics and Reproduction is drafting

95 842 SW2d 588 (Tenn. 1992).

96 696 NE 2d 174 (1998). See e.g.,Blaine Harden, "Court to Decide Fate of Divorced Couples Embryos", The Record, p. A4, April. 6, 1998, and Radhika Rao, "Reconceiving Privacy: Relationships and Reproductive Technology", 45 UCLA L Rev 1077, 1086-89 (1998). See 1995 WL 11 0368 (N.Y. Sup. Jan. 18, 1995) (No. 19858193); 235 A.D. 2d 150, 663 N.Y.S. 2d 581 (N.Y.A.D. 2d Dept, Sep. 8, 1997).

97 696 N.E.2d at 178.

a code it hopes will guide legislatures.[98] In addition, federal law prohibits donating most embryos for federally funded research.[99]

4 Posthumous Reproduction

The legal problems presented by the new reproductive technology are about to become yet more complex, for it has become possible to take sperm from a dead man. The first fetus known to be produced by the posthumous removal of gametes was due in March 1999. The sperm donor, the woman's husband, died in 1994. However, within 30 hours of his death his wife asked that his sperm be removed in order to permit her to undergo IVF at some later date. Four years later she conceived using his sperm. Post-mortem removal of gametes has recently become prominent enough that the American Society of Reproductive Medicine has developed a protocol – 'Posthumous Reproduction' – to govern it. Although reliable estimates of the number of postmortem removals are difficult to come by, a 1997 study conducted by the University of Pennsylvania's Center for Bioethics found that at least fourteen clinics in eleven states had performed the procedure.[100]

In January of this year, a New York state legislator introduced legislation that would ban posthumous sperm collection in the absence of prior written consent. In the meantime, because legislation in this area is only nascent, doctors are left to their consciences whether to perform these operations. It might be argued that a spouse can 'donate' a dead partner's gametes to herself or himself under the Uniform Anatomical Gift Act, which is law in all fifty states.[101] Whether such a donation would qualify as 'transplantation' under the act is unclear, however. The attempt to make this novel situation fit a statute written without that situation in mind is, however, typical of efforts to adapt old law to new reproductive techniques.

Although posthumous sperm donation is too novel to have produced case law, much less legislation, posthumous reproduction has reached the courts in a different guise. In a recent case in California,[102] *Hecht v. Superior Court*, a man by contract and will expressly donated and bequeathed vials of his frozen sperm to his girlfriend before he committed suicide. However, his adult children by a former marriage sought to enjoin the girlfriend from receiving the vials. The California Court of Appeals awarded the ownership of the frozen sperm to the girlfriend on the grounds that the sperm were not subject to the property division with the former wife and that the dead man had clearly expressed his intent to give the sperm to his girlfriend.

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98 *Id.*
99 *Id.*
100 Lori B. Andrews, "The Sperminator", NY Times, §6, p. 62 (March 28, 1999).
101 Health and Sab. C. 7150 et seq.
102 *Hecht v. Superior Court*, 16 Cal.App.4th 836, 840- 845, 20 Cal.Rptr.2d 275 (1993),

Cases like *Davis* and *Hecht* raise questions about the legal status of reproductive material that courts have struggled to answer. Does such material – and particularly do fertilized eggs – have any of the quality of 'human life'? The *Davis* court, for instance, said that 'preembryos are not, strictly speaking, either 'persons' or 'property,' but occupy an interim category that entitles them to special respect because of their potential for human interest.' Even if questions of this sort can be resolved, others will remain. Can genetic material be owned? Can it be the subject of binding contracts? Should its control be determined according to the usual rules of child custody? These remain unanswered questions with which the courts and legislatures of the federal government and of the fifty states are wrestling.

5 *Cloning*

Dr. Ian Wilmut's announcement in February 1997 that a lamb named Dolly had been produced by cloning an adult sheep evoked an unusually rapid – if still quite partial – legal response in the United States. (As one comment put it, 'Dolly, the famous cloned sheep, has sparked much more than 'three bags full' of controversy.')[103] President Clinton quickly called for a moratorium on human cloning research and directed the National Bioethics Advisory Commission to study the implications of human cloning. In June 1997 the panel recommended a moratorium on any clonal research for three to five years and suggested that federal legislation in this area was needed.[104] The committee also said that the Food and Drug Administration (which had ardently opposed human cloning) should have oversight over any effort, public or private, to clone a human. Accordingly, President Clinton sent Congress his proposed Cloning Prohibition Act of 1997, and the President also issued an executive order banning the use of federal funds for research into cloning human beings.[105] In Congress, at least nine bills were introduced in 1997 to prohibit the use of federal funds for research on the cloning of humans.[106] However, none of the bills passed. At present, there are no federal statutes regulating human cloning research except the general laws regulating human research.

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103 See *Human Cloning* at Illinois Right to Life homepage, http://www.illinoisrighttolife.org/-newpage3.htm (checked May 27, 1999).

104 National Bioethics Advisory Commission, *Cloning Human Beings: Report and Recommendation of the National Bioethics Advisory Commission* 3(1997) (hereinafter NBAC Report).

105 President's Remarks Announcing the Prohibition on Federal Funding for Cloning of Human Beings and an Exchange with Reporters, 33 WEEKLY COMP. PRES. DOC. 278-79 (Mar. 10, 1997).

106 Heidi Forster & Emily Ramsey, "Legal Responses to the Potential Cloning of Human Beings", 32 Val. U. L. Rev. 433 (1998). *See also* The Council for Responsible Genetics, Laws Regarding Genetic Discrimination <http://www.gene-watch.org/legislate.html>(updated August 27, 1997). See generally http://thomas.loc.gov/cgi-bin/query/z?c105:H.922.

State legislators also were quick to respond to the possibility of human cloning research. Legislation was introduced in at least twenty-eight states to prohibit or regulate human cloning.[107] However, the first and only state to pass such legislation was California, which did so on January 1, 1998. The legislation (1) creates a panel of experts to study cloning and requires the panel to report to the governor and legislature, (2) is only in effect for five years, (3) prohibits any person from cloning a human being, (4) bars purchasing or selling an ovum, zygote, embryo, or fetus for the purpose of human cloning, and (5) gives the state health director authority to punish violators (whether corporations or individuals) with fines up to one million dollars.[108]

The ban on federally funded human cloning research has not prevented privately funded research. A controversial Chicago physicist, Richard Seed, announced in 1997 that he will set up a laboratory for cloning studies in Japan, where he will create clones of rare species, pets, and human beings, and he said that he would clone himself to prove that his cloning procedure works.[109] However, most reputable American scientific organizations oppose human cloning research at the present time. For example, the American Society of Reproductive Medicine, the Biotechology Industry Organization, and the Federation of American Societies of Experimental Biology have all stated that their members will not participate in any efforts to clone a human being.[110]

Despite the number of bills introduced in federal and state legislatures to prohibit cloning, it appears that more and more forms of cloning are becoming politically acceptable. In November 1998, President Clinton supported the ban of funding for cloning research because the benefits were hypothetical. Five months later, in March 1999, President Clinton said that it was 'time to take another look.' Much of Clinton's change of heart occurred when the Department of Health and Human Services (DHHS) informed the National Institutes of Health (NIH) that research using pluripotent stem cells derived from human embryos can be funded by the federal government and could be valuable both to research and health.[111] In 1994, the (NIH) Human Embryo Research Panel determined that federal funding would cover research with two kinds of human embryos–excess embryos from IVF artificial procreation and IVF embryos created for research.[112] This was

107 *Legal Responses* at 441-53.

108 *Id.* at 442 describing . Cal. Health & Safety Code § 24185-89 (Deering 1997).

109 *More On A Human Clone Clinic in Japan, Human Cloning Eyed for Japan,* Mainichi Shimbun, http://thefuturist.net/WebBioTech4GeneTherapy-News6.html(From:http://www.mainichi.co.jp/-mdn/dom2.html) (checked 27 May 1999).

110 See generally ASRM. (Jan. 21, 1998), Agence-Fy-Presse, 1998 WL 2204901 (June 1, 1999).

111 See Bioworld Today, Thursday, March 4, 1999, 1999 WL 7738034; M2 Presswire, Friday April 23, 1999, 1999 WL 15761343.

112 John C. Fletcher, "Current Debate on Embryo Research", 11 *Biolaw* S:1 (1999) (hereinafter 'Fletcher').

criticized on moral grounds by people with 'pro-life' values and on the pragmatic ground that there was inadequate evidence of real benefit from research on living human embryos.[113] President Clinton ordered the NIH not to support research involving the second kind of embryos–those specifically created for research. Congress went one step further and banned all federal funding of life-threatening (rather than life-enhancing) research involving human embryos. The Federal law prohibits spending federal tax dollars for 'the creation of a human embryo' for research purposes (e.g., paying someone to conceive and abort embryos or to donate IVF embryos), and also bars federal funding of 'research in which a human embryo [is] destroyed, discarded or knowingly subjected to risk of injury or death.' An embryo is defined as any organism 'that is derived by fertilization, parthenogenesis, cloning or any other means from one or more human gametes or diploid cells.'[114] The application of this law to research on pluripotent stem cells (PSC) derived from human blastocysts has been controversial. The controversy came to a head most recently when Dr. James Thomson reported in November 1998 that his team at the University of Wisconsin, using only private funding, had isolated stem cells from human embryos and 'coaxed' them to grow, without differentiating, into five 'immortal' cell lines. Several other similar research projects were also underway at the time at other universities in America and other countries. Some scientists believe that with further research they may 'be able to tailor stem cells genetically so that they would avoid attack by a patient's immune system, then direct them to specialize into a particular kind of tissue and transplant them into diseased organs,' such as into a damaged heart, to regenerate healthy tissue.[115]
After the Thomson research report of PSC research success in 1997, and following the disclosure (the same month) by the head of a biotechnology company that his company had fused an enucleated cow's egg with a human cell, President Clinton asked the National Bioethics Advisory Commission to study the PSC situation.[116] The response emphasized that fusing a human cell and nonhuman egg to clone human beings should not be funded.

On January 19, 1999, following a favorable legal opinion from the Office of General Counsel of the Department of Health and Human Services, the Director of the NIH announced to the National Bioethics Advisory Commission that NIH intends to support research using pluripotential stem cells and will develop regulations covering such research.[117] The DHHS's legal opinion concluded that

113 Fletcher *supra* at S:2.
114 "A Versatile Cell Line Raises Scientific Hopes, Legal Questions", 282, 283 *Science* 1014 (Nov. 6, 1998) (hereinafter '*Science*'). *See* Prohibitions on Federal Funding for Human Embryo Research are in Omnibus Consolidated and Emergency Supplemental Appropriations Act, Fiscal year 1999, Public Law 105-277, § 511.
115 *Science*, *supra* at 1015.
116 Fletcher, *supra* at S:3.
117 Fletcher, *supra*, at S:5 (Addendum).

pluripotential stem cells and cell lines developed from them are not 'human embryos' as defined in the statute because they are not 'organisms' and cannot develop into a human being even if transferred to a uterus.[118] However, since PSCs are manipulated from human embryos, the integrity of that legal opinion is controversial. Seventy members of the House of Representatives and seven Senators have responded to it by writing to the Secretary of Health and Human Services repudiating that interpretation of the federal funding ban.[119]

6 *Alternative Reproduction and the Health of the Child*

No federal legislation requires that clinics or doctors collect genetic information about gamete donors, and only a handful of states require the collection of such information. Among the most comprehensive of the statutes is New Hampshire's, which requires the screening of all gamete donors and says in pertinent part:

> No gamete shall be used in an in vitro fertilization or preembryo transfer procedure, unless the gamete donor has been medically evaluated and the results, documented in accordance with rules adopted by the department of health and human services, demonstrate the medical acceptability of the person as a gamete donor.[120]

However, few states can claim a system as comprehensive as New Hampshire's. Indeed, many facilities need not be licensed, although some may come under the ambit of general statutes regulating 'tissue banks.' Consequently, the responsibility for screening gametes for genetic defects lies initially with clinics and ultimately with the supervising physician.

Of greater practical import is the medical standard of care imposed by the Ethics Committee of the American Fertility Society, which requires doctors to take genetic histories from donors, egg donors, embryo donors, and surrogates in order to eliminate carriers of the Tay-Sachs gene.[121] However, even such informal measures are not beyond legal question. For example, in 1998 a husband and wife sued the University of Pennsylvania Medical Center on the grounds that its policy of requiring blood tests, psychological evaluations, and genetic screening as a condition of participation in its *in vitro* fertilization program violated their rights under Title III of the Americans With Disabilities Act.[122] While the suit was dismissed, similar challenges would not be astonishing.

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118 Fletcher, *supra*, at S:5 (Addendum).
119 *See* 11 Biomed at S:64-66 (1999).
120 N.H.R.S.A. 168-B:14 (1999).
121 *See* generally Philip G. Peters, "Harming Future Persons: Obligations to the Children of Reproductive Technology", 8 S. *Cal. Interdisciplinary L.J.* 375 (1999).
122 *Sheils v. U. Penn Med Ctr*, 1998 NDLR (LRP) LXIS 229 (E.D. Pa, March 27, 1998).

C Uniform Laws

At least four separate 'uniform laws' dealing with parentage have been proposed in the United States that could apply to artificial procreation. These acts are not binding when drafted but are promulgated as model laws by the National Conference of Commissioners of Uniform State Laws, a group of state-appointed legal experts. Generally the American Bar Association also recommends them to the various state legislatures for adoption. However, until a legislature of a particular state enacts them, they are of no legal effect.

The Uniform Act on Paternity (UAP) was proposed in 1960 but was only adopted by six states.[123] The UAP primarily addressed the paternity and support obligations of fathers of children born out of wedlock and added little to the existing common law and statutes of most states. It relied entirely on the presumption of natural procreation. The Uniform Parentage Act (UPA) was promulgated in 1973 and was adopted by 17 states.[124] Again, the bulk of the UPA dealt with the paternity of children conceived naturally but born out of wedlock; for example, it accorded parental status to the 'natural mother' of a child, – i.e. the woman who had 'given birth to the child.' It also attempted some regulation of parentage of children born by artificial insemination by providing that the man who consented in writing to the artificial insemination of his wife was deemed the natural father of the child and that the semen donor who delivered semen to a licensed physician for anonymous artificial insemination had no parental rights or duties.[125] But that simple provision was the extent of the UPA's regulation of artificial procreation.

The Uniform Putative and Unknown Fathers Act (UPUFA), proposed in 1988, was drafted to confer greater parental rights upon fathers of children born out of wedlock, but it explicitly excluded from protection as a father 'a donor of semen used in artificial insemination or *in vitro* fertilization whose identity is not known to the mother of the resulting child or whose semen was donated under circumstances indicating that the donor did not anticipate having any interest in the resulting child.'[126] However, the UPUFA was not adopted by any state. Finally, the Uniform Status of Children of Assisted Conception Act (USCACA) was promulgated in 1988. It provides that the husband of a woman who gave birth through assisted conception with his consent is the father of the child, that donors for assisted conception (except married persons donating to conceive a child of the marriage) are not parents, and that a dead person is not a parent of a child of assisted conception. It also provides for court-approved surrogacy agreements by which

123 9B Uniform Laws Annot. 347 (1987).

124 9B Uniform Laws Annot. 287 (1987); see Unif. Parentage Act Refs. & Annos in Uniform Laws Annotated (Westlaw, search 27 May 1998).

125 *Id.* at §§ 4-5.

126 9B Uniform Laws Annot. 51 at §1(3) (1994 Cum. Supp.).

the intended (not biological) parents are the legal parents.[127] However, the USCACA has been adopted by only two states.

The most obvious point that emerges from this brief review of 'uniform acts' in the United States is that there is no uniformity in American statutes regulating artificial procreation. Even the drafters of 'uniform laws' have produced divergent rather than uniform recommendations, and the state legislatures have largely ignored the efforts to create uniformity by model legislation. The independence of the American character and the pragmatic American approach to issues thus has led American legislatures to deal incrementally with issues rather than to create a system of anticipatory rules that may be unnecessary – or even counterproductive – in dealing with the unexpected realities that emerge from scientific developments. As one legal commentator put it,

> attention to the costs of mistakes counsels caution in resorting to law at all and suggests a preference for relatively low-level responses (common law, some administrative responses, some noncriminal state legislation) unless and until one is persuaded that a real and pressing need, which can only be met by extreme measures, exists, and that the costs or resorting to the extreme measures will not outweigh the gains.[128]

D Conclusion

In sum, this brief survey suggests that the American response to the new genetic and reproductive technologies has been a cautious one. Courts have generally been the legal institution asked to take the first step by deciding specific cases. The legislation which has followed such steps has generally sought to deal with particularly problematic aspects of some new development and has generally not attempted to write comprehensive rules for an uncertain future.

1 Reflections About Genetic Technology Developments in American Law

Many difficult personal ethical and public policy dilemmas arise with the development of new genetic technologies that directly affect families.[129] For instance, does a subject who learns through genetic testing that he or she has a

127 Uniform Laws Annot., Unif.Status of Children of Assisted Conception Act §§ 1-9 (Westlaw, searched 27 May 1999). The USCACA actually provides two alternatives regarding surrogacy: Alternative A provides that surrogacy agreements are void and the birth mother is always the legal mother of the child; alternative B permits strictly supervised paid surrogacy agreements if the surrogate's spouse agrees and the court approves.

128 See generally Roger B. Dworkin, *Limits*, at 18 (1996).

129 See generally Philip R. Reilly, Mark F. Boshar, & Steven H. Holtzman, "Ethical issues in genetic research: disclosure and informed consent", 15 *Nature Genetics* 16 (Jan. 15, 1997) (hereinafter 'Reilly').

serious genetic risk factor have a duty to share that information with close relatives (like siblings or children) who are also at risk or with spouses whose lives may be gravely affected? Do the health care professionals who perform such tests have a duty (or even a right or privilege) to warn a patient's relatives of genetic risks they discover? If a test reveals that someone may develop a serious disease because of a genetic condition, is there more than a 'minimal risk' so that weightier duties of disclosure and consent apply? To what extent should parents be allowed to consent to genetic testing for their minor children? To what extent should tests be encouraged when many of them are of limited use or accuracy, or may disclose conditions for which no remedies exist?[130]

Clearly, some strategic thinking is necessary if we are to anticipate and avoid serious moral quagmires and legal inconsistencies regarding genetic technologies and individual and family rights. Yet it seems premature and unwise to enact overly broad legal restrictions before the full ramifications and potential benefits and detriments of the evolving technologies are realistically understood and rationally considered. The clash between potential medical benefits to individuals and potential moral and ethical harms to society is significant, and both sides promote values that are important to the quality of life in any society in which caring and responsible human beings would care to live. There are no 'easy answers' to these difficult issues, and we should beware of the Kelsean illusion that law-making is a panacea for these profound scientific and moral dilemmas.

2 *Reflections About Artificial Reproduction Developments in American Law*

In many respects, the new reproductive techniques seem to pose no particular difficulties for American family law. These techniques are generally used by married couples to produce children who are biologically related to both parents. On the other hand, these same techniques obviously have considerable potential to make it easier for the unmarried to reproduce and can create situations in which the identity of the parents is disputable.

By themselves, the use of these new reproductive techniques may not be greatly consequential. What may make them so, however, is the way they fit with other developments in family law. American family law is currently going through what might be called a process of rationalization. That is, family law is increasingly parsing, probing, and eroding the social institutions and assumptions which give rise to the deep-seated sense of obligation which is necessary to restrain people's destructive impulses in social living. The wind driving this erosion is the tendency

130 Reilly, *supra* at 16; Paul, *infra* at 214 (false positives in tests for PKU outnumbered true positives 32:1 in some circumstances).

of family law to subject those institutions and assumptions to a very rationalistic kind of scrutiny.

The conventional response of American legal scholars and many American courts to the new reproductive techniques may be seen as part of this process of rationalization. These novel bio-medical developments lead us to re-examine intimate social relations and to make new distinctions among them, distinctions which eat away at the kind of automatic and ingrained sense of duty which leads people to behave well in family life. They create a class of 'mothers' who must not care for the children they have borne and of 'fathers' who need not support and may not raise the offspring they have sired. They ask us, in some of their incarnations, to separate procreation from parental obligation. It is this aspect of the new techniques which may ultimately pose the greatest challenge to American family law.

Summary of

Genetics and Artificial Procreation in the U.S.A.

by

Professor Carl E. Schneider and Professor Lynn D. Wardle

American law and practice regarding genetic, artificial reproduction and family law are extraordinarily various and dynamic for many reasons. American government remains in important ways genuinely federal and family law has traditionally been confided to the fifty state governments, each of which is largely free to regulate reproductive technologies as it wishes. American government also remains committed to the principle of separation of powers, which means that the power to regulate those technologies is divided among the various branches and agencies of the federal and the state governments. Americans have a strong streak of independence and a traditional dislike for centralized government regulation. The common law approach that prefers a gradual rather than a pre-emptive legal response to novel social problems is well-established in the American legal culture. A powerful 'individual rights' ideology also restrains government law making in the area of genetics and artificial reproduction.

Medical law in the United States of America generally rests upon three fundamental principles. Patient autonomy is protected by individual consent and privacy rules. Public welfare is of special concern regarding human experimentation and public health epidemics. Professional competence is regulated in large part by rules of liability for medical malpractice.

The United States has generally been more reluctant than many other industrialized countries to enter into the kind of treaties that affect family law, biomedicine, and human rights. The reasons for this are numerous, complex, and controversial, but the constitutional structure of government and traditional insularity are among the key influences.

American public policy toward genetic engineering is influenced by five general tendencies of American public policy. First, public policy is ordinarily more centrally concerned for the individual than the group. Second, liberty frequently takes priority over social welfare. Third, innovation and progress are commonly valued more intensely than conformity. Fourth, research is often driven by the market, and regulations are often influenced by companies and people with financial and personal interests in them. Fifth, public policy is likely to develop case by case rather than through the early and centralized establishment of general regulations. Genetic discrimination and genetic privacy are two policy concerns that color many genetic policy disputes. Genetic screening, medical confidentiality, and moral concerns about erosion of respect for human life and diminution of personal responsibility are current issues.

The speed with which new technologies are developing, the entrepreneurial sprit of American medicine, and the absence of a national health system are among the major influences upon artificial procreation policies. For most persons, parentage is established by three presumptions – the presumption of the maternity of the woman who gave birth to a child, the presumption of the paternity of her husband, if she is married, and the presumption of paternity by open acknowledgment or cohabitation if she is not. Because they may create situations which defy the procreative assumptions upon which these legal presumptions are based, many parentage controversies have arisen recently involving artificial procreation. Surrogacy, *in vitro* fertilization, embryo status, posthumous reproduction, and human cloning are current issues.