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NOTES ON MORAL THEOLOGY

ETHICAL, THEOLOGICAL, AND LEGAL ISSUES IN GENETICS

INTRODUCTION

THE DEBATE OVER GENETICS in the U.S. has seen three historical phases.[1] The first phase during the 1900s was primarily academic and sociopolitical. During that time major scientific developments were made in the field of genetics and much of the theoretical foundations for current developments were established at major universities and research centers such as Cold Spring Harbor in New York. But these developments occurred in a sociopolitical context carried over from Britain. This was the legacy of eugenics which influenced discussions of IQ tests, understandings of poverty and mental illness, social worth, and immigration policy.[2] The excesses of this movement eventually died out, but one can still hear its echoes today in many contemporary debates over the use of various genetic screening technologies. The second phase was initiated by the discovery of recombinant DNA technologies in the mid-1970s by Cohen at Stanford University.[3] What this technology enabled scientists to do was snip apart a segment of DNA with chemical scissors and splice in a new segment of DNA. It soon became obvious that the new DNA could be from any species at all and a genuinely new organism could be manufac-

[1] For a convenient overview of issues, confer the various articles in the 107-page entry on genetics in *The Encyclopedia of Bioethics,* ed. Warren Reich, rev. ed. (New York: Macmillian, 1995) 2.907-1020. Each article has cross listings to related articles and bibliography.

[2] Hermann J. Muller, "Human Evolution by Voluntary Choice of Germ Plasm," *Science* 134 (8 September 1961) 643–49; and his *Out of the Night: A Biologist's View of the Future* (New York: Garland, 1984; original ed. 1935); Daniel J. Kevles, *In the Name of Eugenics: Genetics and the Uses of Human Heredity* (New York: Knopf, 1985); J. M. Friedman, "Eugenics and the 'New Genetics'," *Perspectives in Biology and Medicine* 35 (Autumn 1991) 145–54; Donald J. Dietrich, "Catholic Eugenics in Germany, 1920–1945: Hermann Muckermann, S.J., and Joseph Mayer," *Journal of Church and State* 34 (Summer 1992) 575–600; Stefan Kuehl, *The Nazi Connection: Eugenics, American Racism and German National Socialism* (New York: Oxford University, 1994).

[3] Stanley Cohen, "The Manipulation of Genes," *Scientific American* 233 (July 1975) 25–33; see also one of the first major public examination of these issues, President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Splicing Life: The Social and Ethical Issues of Genetic Engineering with Human Beings* (Washington: U.S. Government Printing Office, 1982).

tured. Additionally concern was raised about the safety of the process in that a newly created organism might escape the laboratory and cause harm. These recognitions led first to a pause in the research and second to the development of various regulations and committees to oversee and regulate the research.[4] The main federal committee, the Recombinant DNA Advisory Committee, is still in existence and has been instrumental in shaping the direction of gene therapy. The third phase began in the early 1990s with the initiation of the Human Genome Project, a 15-year and $3 billion project to map out the entire human genetic profile.[5] While on the one hand this is mainly a technical project, on the other hand knowing the location of various genes that cause disease opens the door for new developments both in the diagnosis of genetic diseases and in gene therapy. In this three-part Notes on Moral Theology we review these topics and other related material by focusing on the ethical, theological, and legal issues they raise.

[4] Paul Berg et al., "Asilomar Conference on Recombinant DNA Molecules," *Science* 188 (6 June 1975) 991–94; Nicholas Wade, "Recombinant DNA: NIH Sets Strict Rules to Launch New Technology," *Science* 190 (19 December 1975) 1175–79. For an overview of various responses to genetic engineering technologies, see Jonathan D. Moreno, "Private Genes and Public Ethics," *Hastings Center Report* 13 (October 1983) 5–6.

[5] James D. Watson, "The Human Genome Project: Past, Present, and Future," *Science* 248 (6 April 1990) 44–48; Daniel J. Kevles and LeRoy Hood, *The Code of Codes: Scientific and Social Issues in the Human Genome Project* (Cambridge, Mass.: Harvard University, 1992); Dorothy Nelkin and M. Susan Lindee, *The DNA Mystique: The Gene as Cultural Icon* (New York: W. H. Freeman, 1995). For a critique of the dominant ideology in the Human Genome Project, see R. C. Lewontin, *Biology as Ideology: The Doctrine of DNA* (New York: Harper, 1991), and his "The Dream of the Human Genome," a review/discussion of nine books on the Human Genome Project, in the *New York Review of Books,* 28 May 1992, 31–40.

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ETHICAL ISSUES IN GENETICS

THOMAS A. SHANNON

[The first section of the Notes on Moral Theology reviews ethical issues in genetics through the lenses of privacy-confidentiality; risk-benefit analysis in relation to prenatal diagnosis and gene therapy; and freedom-determinism/human dignity in the context of cloning. The author provides an overview of developments in genetics and highlights thematic issues common to these developments.]

PRIVACY

THREE TYPES of privacy have been identified: physical (freedom from physical contact), informational (which limits access to information about one's self), and decisional (the capacity to make decisions for one's self).[1] All are impacted by both genetic testing and various forms of prenatal diagnosis.[2] While the means of diagnosis are minimally invasive physically (a drop of blood or a single strand of hair is enough), obtaining such samples can constitute invasions of physical privacy. To learn whether there is a genetic component to a disease, elaborate family pedigrees must be constructed. Knowledge that one family member has a genetic predisposition for a disease has implications for other family members. If screening is a precondition for either insurance or employment, substantive privacy and social issues are raised. While insurance companies already screen potential customers through physical exams, some fear that genetic screening will also be required either through direct testing or the disclosing of previously taken tests.[3] Thus individuals with a genetic disposition for

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[1] William J. Winslade, "Privacy in Health Care," in *Encyclopedia of Bioethics,* ed. Warren T. Reich, rev. ed. (New York: Macmillan, 1995) 4. 2064–65.

[2] For a list and copies of proposed legislation on genetic privacy and confidentiality, see the website of The National Human Genome Research Institute, <http://nhgi.nih.gov>, and Philip R. Reilly, "Genetic Privacy Bills Proliferate," *The Gene Letter* 1 (May 1997), <http://www.geneletter.org>.

[3] Nancy Kass, "Insurance for the Insurers: The Use of Genetic Tests," *Hastings Center Report* 22 (November–December 1992) 6–11; Thomas H. Murray, "Genetics

breast cancer may be uninsurable because of the financial loss they represent to a company. Employers too have an interest in learning the genetic profiles of present or potential employees, but access to such information can violate both informational and decisional privacy.[4] While issues of discrimination and paternalism can arise in companies' employment policies, nonetheless some employees could be at risk because of certain jobs. While rectifying the environment is certainly one way to help resolve this, individuals still remain sensitive to certain pollutants. Public-policy issues for these agenda have not been resolved. Because genetic information is both private and social, we are only beginning to realize the impact that genetic screening will have on our traditional understanding of privacy and confidentiality.

Similar issues arise in prenatal diagnosis[5] that makes the health status of the fetus immediately accessible and visible, and thus available to insurance companies. This potentially compromises both the confidentiality of such information and the mother's decisional privacy by limiting her range of options, especially if the insurance company determines that the condition of the fetus is a preexisting one and will provide no reimbursement for medical care.

RISK-BENEFIT ANALYSIS

Risk-benefit analysis is a traditional way of deciding whether or not to undergo a particular procedure. While offering the promise of many benefits, new genetic interventions also present a new range of risks.[6] A new

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and the Moral Mission of Health Insurance," *Hastings Center Report* 22 (November–December 1992) 12–17.

[4] Thomas H. Murray, "Warning: Screening Workers for Genetic Risk," *Hastings Center Report* 13 (February 1983) 5–8.

[5] For overviews and more detailed discussions, see Barbara Katz Rothman, *The Tentative Pregnancy* (New York: Viking, 1986); "Genetic Grammar: 'Health,' 'Illness,' and the Human Genome Project," a special supplement in *Hastings Center Report* 22 (July–August 1992) S11–S20; Edward M. Berger, "Morally Relevant Features of Genetic Maladies and Genetic Testing," in Bernard Gert et al., *Morality and the New Genetics* (Sudbury, Mass.: Jones and Bartlett, 1996); R. Gregg, *Pregnancy in a High-Tech Age: Paradoxes of Choice* (New York: Paragon House, 1993); Larry Thompson, *Correcting the Code: Inventing the Genetic Cure for the Human Body* (New York: Simon and Schuster, 1994); Gwynne Basen, Margrit Eicher, and Abby Lippman, ed. *Misconceptions: The Social Construction of Choice and the New Reproductive and Genetic Technologies* (Quebec City: Voyageur, 1996).

[6] For an early framing of the issues, see President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Screening and Counseling for Genetic Conditions* (Washington: U.S. Government Printing Office, 1983).

issue is learning that one may be susceptible to a disease which will occur later in life, such as breast cancer or Huntington's disease; thus the term "presymptomatic disease."[7]

Because no therapies are yet available other than perhaps a drastic treatment such as prophylactic mastectomy and oophorectomy, some question the value of such information.[8] A particular problem is identifying the predisposition for a disease with the actual disease, which causes additional suffering for the individual as well as possibly disqualifying them for insurance. Another problematic category is the screening of young children and adolescents. The issue of informed consent is particularly difficult, especially when the minor is becoming mature but nothing can be done to treat the disease. Issues of self-esteem, stigmatization, and complex familial relations are of concern, to say nothing of the previously discussed insurance difficulties.[9]

Another dimension of the risk-benefit problems related to genetic test-

[7] For a highly critical view of genetic testing, see Ruth Hubbard and Richard C. Lewontin, "Pitfalls of Genetic Testing," *New England Journal of Medicine* 334 (2 May 1996) 1192–93. But see also Francis S. Collins, "BRCA1-Lots of Mutations, Lots of Dilemmas," *New England Journal of Medicine* 334 (18 Jan 1996) 186–88 which suggests positive strategies for utilizing genetic information on breast cancer; Jerome Groopman, "Decoding Destiny," *The New Yorker* 76 (9 February 1998) 42–48; Albert Rosenfeld, "At Risk for Huntington's Disease: Who Should Know What and When?" *Hastings Center Report* 14 (June 1984) 5–8; A. M. Cordi and J. Brandt, "Psychological Cost and Benefits of Predictive Testing for Huntington's Disease," *American Journal of Medical Genetics* 55 (1995) 618–25; Dorothy C. Wertz et al., "Genetic Testing for Children and Adolescents: Who Decides?" *Journal of the American Medical Association* 272 (1994) 875–81; Sandi Wiggins et al., "The Psychological Consequences of Predictive Testing for Huntington's Disease," *New England Journal of Medicine* 327 (12 November 1992) 1401–05. Abstracts and some articles in *New England Journal of Medicine* are available at their website, <http://www.nejm.org>. For an excellent British perspective, see *The Troubled Helix: Social and Psychological Implications of the New Human Genetics,* Theresa Marteau and Martin Richards, ed. (New York: Cambridge University, 1996).

[8] For example, a 30-year-old woman may gain 2.9 to 5.3 years of life expectancy from prophylactic mastectomy, and 0.3 to 1.7 years from prophylactic oophorectomy; see Deborah Schrag et al., "Decision Analysis—Effects of Prophylactic Mastectomy and Oophorectomy on Life Expectancy among Women with BRCA1 and BRCA2 Mutations," *New England Journal of Medicine* 336 (15 May 1997) 1465–71, and the accompanying editorial in the same issue by Bernardine Healy, "BRCA Genes—Bookmaking, Fortunetelling, and Medical Care" (ibid. 1464).

[9] Dorothy Wertz et al., "Genetic Testing for Children and Adolescents" 875–81. Other areas of application are testing children prior to adoption or deciding how to invest one's resources in one's children. Nancy Wexler, President of the Hereditary Disease Foundation and one of the team that discovered the gene for Huntington's disease, reports that a woman asked to have her two children tested for Huntington's because "she had only enough money to send one of them to Harvard" (Mary Murray, "Nancy Wexler," *New York Times Magazine,* 13 February 1994, 31).

ing (and screening) is the accuracy of the test itself as well as the number of false positives and false negatives it produces. While these are primarily technical questions related to the test itself, they also raise profound ethical questions: When should a test be made available? Is the test applied to all of the possible genes associated with a disease or only the more common sites tested (e.g., with cystic fibrosis, there are over 300 mutations which can cause cystic fibrosis, but typically about 60 to 70 sites are tested)? How expensive will the test be? Will the number of false positives or false negatives cause more harm than not making the test available?

Two important facts must be kept in mind in evaluating or using any genetic testing technologies. First, while literally thousands of genetic anomalies can be detected, we understand the health implications of only few of them. Second, we cannot cure any of the genetic anomalies that we detect. These two hard realities frame any ethical discussion, particularly discussions of late onset genetic diseases such as breast cancer. While some interventions can be made that alleviate some symptoms, or the information can be used to prepare families for what is to come, precious little can be done about the disease itself. Thus the choices are poor: either to avoid reproduction, to use donor sperm or egg, to abort, or to continue the pregnancy with the disease running its natural course. If the last option is chosen, little insurance and few social resources will be available to care for the child.

While prenatal diagnosis is offered typically to women in higher risk categories (women with a history of genetic disease or over 35 years of age[10]) and while only about two percent of such diagnoses lead to potential abortion, nonetheless prenatal diagnosis will become more common. First, as new genetic discoveries are announced, pressure will increase to detect these as early as possible. Second, given the current malpractice climate, prenatal diagnosis becomes a means of defensive medicine. Third, as childbearing is being delayed until later—with infertility increasing—and as people are having fewer children, pressure builds to have as healthy a child as possible.

Although one's child might have a so-called normal genome, that in itself does not mean that the child will be healthy, never contract a fatal disease, or have a pleasant personality. Genetic screening can raise expectations that cannot be met and unwittingly open the door to a new kind of eugenics, family eugenics. In this case the couple selects a genetic profile in the expectation of obtaining a certain type of child. Since currently one can already order somewhat custom-designed embryos, this application is not

[10] The reason for this age cut-off is that this is when the risks of having a child with Down syndrome balance the risks of miscarriage from amniocentesis.

far fetched.[11] Prenatal diagnosis may be setting up a situation in which children are desired for specific characteristics, not for who they are.

All of these issues surrounding prenatal diagnosis raise this critical question: What is the problem that prenatal diagnosis is meant to solve?

On the benefit side of the equation is the developing use of human gene transfer.[12] The first intervention is somatic cell therapy, which has three forms: (1) *ex vivo,* in which cells are removed from the body, corrected, and then returned so that the new function can be expressed and correct the disease; (2) *in situ,* in which the new gene is directly introduced into the locus of the disease; and (3) *in vivo,* in which the therapeutic gene is injected into the bloodstream and travels to the proper tissue.[13] The second intervention is germ line therapy, which corrects an anomaly by placing the corrected copy in the germ cells in the fertilized egg; this both corrects the condition for the individual and also allows the correct copy to be passed on to one's descendent.

In general, the ethical analysis of somatic cell gene therapy follows in broad outline an analysis similar to that of the introduction of any new medical therapy. Walters and Palmer identify seven key questions. (1) What disease is to be treated? (2) Are there alternative forms of therapy, and are they affordable? (3) What are the anticipated or potential harms of the therapy? For example, will the virus used to transport the new genetic material become reactivated and cause harm, will the new genetic material

[11] Confer the website Options, <http://www.fertility.options.com/>, for a sample of the genetic pedigrees that can be ordered from egg and sperm vendors.

[12] The single best book on gene therapy is LeRoy Walters and Julie Gage Palmer, *The Ethics of Human Gene Therapy* (New York: Oxford University, 1997). For the reflections and analysis of one of the main proponents and researchers in the field of gene therapy, see W. French Anderson: "Human Gene Therapy: Why Draw A Line?" *Journal of Medicine and Philosophy.* (December 1989) 681–93; "Genetics and Human Malleability," *Hastings Center Report* 20 (1990) 21–24; and "Genetic Engineering and Our Humanness," *Human Gene Therapy* 5 (1994) 755–59. For general overviews, see the following: Clifford Grobstein and Michael Flower, "Gene Therapy: Proceed with Caution," *Hastings Center Report* 14 (April 1984) 13–17; Burke K. Zimmerman, "Human Germ-Line Therapy: The Case for its Developments and Use," *Journal of Medicine and Philosophy* 16 (1991) 593–612; Maurice A. M. de Wachter, "Ethical Aspects of Human Germ-Line Therapy," *Bioethics* 7 (1993) 166–77; LeRoy Walters, "Human Gene Therapy: Ethics and Public Policy," *Human Gene Therapy* 2 (Summer 1991) 116–20; David A. Kessler et al., "Regulation of Somatic Cell Therapy and Gene Therapy by the Food and Drug Administration," *New England Journal of Medicine* 329 (14 October 1993) 1169–73; Nelson A. Wivel and LeRoy Walters, "Germ-Line Gene Modification and Disease Prevention: Some Medical and Ethical Perspectives," *Science* 262 (22 October 1993) 533–38; Jeff Lyon and Peter Gorner, *Altered Fates: Gene Therapy and the Retooling of Human Life* (New York: W. W. Norton, 1995).

[13] W. French Anderson and T. Friedmann, "Strategies for Gene Therapy," in *The Encyclopedia of Bioethics* 2.908.

reach the correct part of the cell, will there be any harmful long-term effects? (4) What are the expected or anticipated benefits? (5) Will patients be selected fairly? Children had traditionally been protected by not being included in research projects, but current thinking is that no group should be excluded from research, particularly if gene therapy can be potentially more beneficial when introduced earlier. (6) How will informed consent be ensured? While this question is critical for the adult population who may be desperate for a potentially life-saving therapy, it is also critical for children whose parents may frantically desire to save their children. (7) How will privacy and confidentially be preserved? Given the highly experimental nature of this research, its inherent newsworthiness, as well as the penchant for feeding frenzies on the part of the media, such concerns are not academic. Yet the identity of the two children who were the first subjects of gene therapy was kept confidential for over a year and eventually released only with the parents' permission.[14]

Three key ethical questions are: (1) How quickly should gene therapy move to clinical practice? Should a particular therapy prove successful, there will be tremendous pressure to move it from the laboratory to the bedside as soon as possible. But we need to remember that the critical ethical variable here is that the therapy must be proven to work and to have at least no negative short-term side-effects. (2) How efficacious or successful is the therapy? From 1990 to 1995, 100 clinical trials of gene therapy were initiated. Yet Leiden's assessment of these trials is that "[t]o date, there is little or no published evidence of the clinical efficacy of gene therapy."[15] Leiden does not see this as a condemnation of the field. Rather he draws three conclusions: that gene therapy is grounded in solid scientific principles, that the negative results so far are a function of the newness of the field, and that recent progress promises optimism for the future. (3) How will this resource be allocated?[16] While the consequences of genetic diseases are severe, the numbers of those affected by a particular genetic disease are relatively small—perhaps between 10,000 and 15,000. Can the cost of research and clinical trials for these diseases be justified? While it is true that much can be transferred to other technologies and strategies, it is even more true that victories will come at a high cost and the other health

[14] Walters and Palmer, *The Ethics of Human Gene Therapy* 36–44.

[15] Jeffrey M. Leiden, "Gene Therapy—Promise, Pitfalls, and Prognosis," *New England Journal of Medicine* 333 (28 September 1995) 871–73.

[16] I recall being at a meeting where one of the researchers for the first use of gene therapy was discussing the project. When asked the cost of the research, he replied that he had no idea because the National Institutes of Health (NIH) did not submit a bill. But obviously the NIH has a budget, one that has to be set in relation to other budgets in the health field, to say nothing of other national priorities.

needs of the nation are increasing. Thus the issues of allocation and priorities need substantive national debate.

Germ line gene therapy, by both preventing disease by inserting correct copies of genes into reproductive cells and enabling this correction to be passed on to succeeding generations, presents both technical and ethical problems. Wivel and Walters identify four technical problems that need to be resolved before any human trials could be initiated: the inserted gene will need to function normally; the insertion of the new gene must not cause impairment of normal gene function; there must be no residual effects from the original genetic defect; and there must be no genetic side-effects from the insertion of the new gene. Common to these problems is the challenge of physical placement of a new gene in the proper location. But it is also important that the new copy not cause a problem with the other genes near the site of insertion. The interaction of genes with their neighboring genes at locations along various strands is not well understood and is a major scientific obstacle to initiating human trials.

Because the genetic correction will be passed on to one's descendants, germ line therapy is surrounded by a major debate. The major arguments in favor are: that only this type of therapy, precisely because it is initiated on the fertilized egg, could prevent major damage at the embryonic stage; that such therapy prevents the children of those with a genetic disease from having to undergo somatic cell therapy or from having to make painful reproductive decisions of their own; that germ line therapy is more cost effective because, unlike somatic therapy which has to be repeated generation after generation, this is done once; that researchers are obligated to identify and develop better treatments to offer to their patients; and finally, that germ line therapy is a way to prevent serious health problems rather than attempting to repair the damage after it occurs.[17] The major negative arguments are: that if there are unforeseen negative side-effects, these will be passed down from generation to generation; that the therapy is not needed, since there are other means to prevent transmitting genetic diseases, such as preimplantation diagnosis or selective abortion following prenatal diagnosis; that germ line therapy will be expensive and available only to a small number of individuals; that perfecting the methods of germ line therapy will require much research on human embryos, which many would argue is inappropriate; and finally that, if the technique should prove to be of limited use in curing disease, the focus might shift to the enhance-

[17] Walters and Palmer, *The Ethics of Human Gene Therapy* 81–82. See also an earlier, but similar phrasing of the arguments in Eric Juengst, "Germ-Line Therapy: Back to the Basics," *Journal of Medicine and Philosophy* 16 (1991) 587–92. For selected European perspectives on the pros and cons of this debate, see Maurice A. M. de Wachter, "Ethical Aspects of Germ-Line Therapy," *Bioethics* 7 (1993) 166–77.

ment of one's genetic profile, which would further reduce the number of people who could utilize the technique.[18]

One other area of philosophical concern here is the status of the inherited human genome. As Maurice de Wachter puts it, "Germ-line gene therapy techniques would violate the rights of subsequent generations to inherit a genetic endowment that has not been intentionally modified."[19] Such a position raises several problems: Is there such a right and what is its basis? Since the human genome continues to be modified through evolution, on what basis is the present form privileged? And how is human dignity harmed if one can intervene to prevent a disease from harming an individual and his or her descendents?

This question also focuses on a particular problem in the debate: What is human nature? An important contribution has been made by W. French Anderson, one of the major scientists involved in human gene transfer, who is also well read in the ethical and philosophical literature. Originally concerned that germ line intervention could irreversibly change human nature, Anderson has recently argued that the Platonic resolution of human nature into body and soul is correct. Therefore, since the essence of our nature resides in our soul, no bodily alteration can harm human nature. Thus Anderson winds up with a Platonic/Cartesian dualism that sees the body as a *res extensa* with no relation to our human nature or our person. This position is substantively critiqued by James Keenan, S.J., who in a seminal article argues for the subjectivity of the body and who reasons that a separation such as Anderson proposes misunderstands personhood. Keenan also demonstrates the necessity of keeping the body-person at the center of ethical analysis because "recent genetic research substantiates the position that the human body is in its genetic roots profoundly relational and that this position provides substantial guidelines for the genetic manipulation of our progeny."[20] To change the body, therefore, is to change the person. And that is the locus of the next issue, the genetic enhancement of humans.

Will we move beyond therapy to enhance particular human characteristics? A major problem is that no particular single gene has been definitely associated with a particular behavioral characteristic, e.g. intelligence. The enhancement debate is also characterized by an unacknowledged genetic determinism, namely that we can do only as our gene tells us. This assumption—that all behaviors, no matter how complex, are caused by a single

[18] Walters and Palmer, *The Ethics of Human Gene Therapy* 82–83.

[19] de Wachter, "Ethics of Human Germ-Line Therapy" 175.

[20] James Keenan, S. J., "Genetic Research and the Elusive Body," in Lisa S. Cahill and Margaret A. Farley, ed., *Embodiment, Morality, and Medicine* (Dordrecht, The Netherlands: Kluwer Academic, 1995) 59–73, at 59.

gene—neglects the role of the environment, both physical and social, in developing our characteristics.[21]

Nonetheless, such theoretical arguments will not slow the quest for enhancement, the primary evidence of which is the growing market in sperm, eggs, and embryos from vendors who list their own appearance, their educational and social background, as well as that of their parents and grandparents. Prenatal diagnosis offers another way to select preferred genomes, and as long as parents want both better children and strategies to achieve them, enhancement will be with us. Now the primary method of enhancement is social, through various child-rearing and educational strategies; in the future it may be attempted by selecting desired genotypes. But no matter the means, desire for enhancement brings dangers. In a most interesting discussion of enhancement, Glen Magee has identified five sins of enhancement to avoid: calculativeness, overbearingness, shortsightedness, hasty judgment, and pessimism.[22]

Consideration of some dimensions of human gene transfer brings us back to many of the same issues previously encountered in discussions of genetic testing: human dignity, the extent of human control over nature, understanding of human nature, and our relation to our descendants.

FREEDOM–DETERMINISM AND HUMAN DIGNITY

The categories of freedom–determinism and human dignity show up sharply in the cloning debate. Does our genetic profile determine who we are? Will our acts be determined by our genome? Is our genome our fate?

Four types of cloning must be distinguished lest the debate become even more confused. Gene cloning and cellular cloning are two methods of increasing supplies of DNA or various cells to facilitate experiments; they have nothing to do with whole organism cloning. A third form of cloning is called blastomere separation or embryo division; it involves artificially twinning an embryo to produce multiple copies. While this form is utilized in the livestock industry routinely, it has been attempted in humans only in the experiment reported by Hall and Stillman.[23] The fourth type is the one

[21] At a meeting attended primarily by scientists to discuss germ line therapy and possible guidelines for its implementation, James Watson suggested that a serious candidate for a disease to be cured by germ line therapy was stupidity (Gina Kolata, "Scientists Brace for Changes in Path of Human Evolution," *New York Times,* 21 March 1998, A1 and A7).

[22] Glen McGee, *The Perfect Baby: A Pragmatic Approach to Genetics* (Lanham, Md.: Rowman and Littlefield, 1995) 123–33.

[23] Jerome L. Hall et al., "Experimental Cloning of Human Polyploid Embryos Using an Artificial Zona Pellucida," a paper presented at the 1993 annual meeting of the American Fertility Society. For an overview of this experiment and its

that has occupied center stage since the report of the cloning of Dolly in February 1997.[24] This is somatic cell nuclear transfer, or whole organism cloning, in which an egg has its nucleus removed and replaced with the nucleus of another cell which produces an identical genetic copy of the donor. What is of utmost importance in the Dolly experiment is demonstrating that the genetic material in fully differentiated adult cells can be reactivated to generate a whole new being. Such reactivation was previously thought to be impossible (though some now question this because of the impossibility of proving that the cell used for Dolly was in fact an adult cell, though such claims may be ended with the announcement of the cloning of 50 mice, some of which were clones of clones[25]). Second, such a method of reproduction is asexual and occurs without fertilization, hardly the standard way of mammalian reproduction.

When the Dolly story was first made public (the announcement was delayed until three months after her actual birth in order to allow time for the appropriate patents on the technique to be filed), most focused on the application to humans. What had been the stuff of science fiction now appeared to be one more scientific conquest. Yet even in this case most of the debate was misplaced, unless one were a genetic reductionist or determinist. The most common scenario imagined the replication of an almost infinite series of desired genotypes on the assumption that they would

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subsequent discussion, see the *Kennedy Institute of Ethics Journal* 4 (September 1994) which devoted the entire issue to this topic. Also Andrea L. Bonnicksen, "Ethical and Policy Issues in Human Embryo Twinning," *Cambridge Quarterly of Healthcare Ethics* 4 (1995) 268–84.

[24] For early discussions see, James D. Watson, "Moving Toward Clonal Man: Is This What We Want?" *The Atlantic,* May 1971, 50–53; Martin Ebon, ed. *The Cloning of Man: A Brave New Hope—or Horror?* (New York: New American Library, 1978); Margaret Brumby and Pascal Kasimba, "When Is Cloning Lawful?" *Journal of In Vitro Fertilization and Embryo Transfer* 4 (August 1987) 198–204; Ira H. Carmen, *Cloning and the Constitution: An Inquiry into Governmental Policymaking and Genetic Experimentation* (Madison: University of Wisconsin, 1985). The most comprehensive discussion of cloning can be found in the National Bioethics Advisory Commission, *Cloning Human Beings: Report and Recommendation of the National Bioethics Advisory Commission* (Rockville, Md.: NBAC, 1997); see also the commentary on this report "Cloning Human Beings: Responding to the National Bioethics Advisory Commission's Report," in *Hastings Center Report* 27 (September–October 1997) 6–22; Gina Kolata, *Clone: The Road to Dolly and the Path Ahead* (New York: William Morrow, 1998); Gregory E. Pence, *Who's Afraid of Human Cloning?* (Lanham, Md.: Rowman and Littlefield, 1998). The entire issue of *Cambridge Quarterly of Healthcare Ethics* 7 (1998) is devoted to cloning.

[25] Vittorio Sgaramella and Norton D. Zinder, "Letter to the Editor," *Science* 279 (30 January 1998) 636–66, together with Wilmut's response; see also Gina Kolata, "In Big Advance in Cloning, Biologists Create 50 Mice," *New York Times,* 22 July 1998, A1 and A20.

essentially be the same person—all Michael Jordan clones would be superior basketball players and all James Watson clones would be superior scientists. There are two major errors in these scenarios. First, the fact that two individuals share the same genetic identity does not mean they are the same person (any more than traditionally conceived identical twins are the same person). Nor does the fact that they share a genetic identity diminish or violate the dignity of either. Second, these scenarios rest on any number of varieties of genetic reductionism that identifies the self with the genome or argues that one's genome alone sets one's life course and all one's choices. Such positions deny any transcendent dimension to the person, any freedom, and simply ignore the role of environment on personal development, either behaviorally or physically. While arguments will continue over the degree of interaction of all these elements, it is clear that the major error of the human cloning debate was genetic reductionism.

Other arguments focused on the violation to human dignity from the process of cloning: not being conceived in the normal fashion, not having two biological parents, not having one's unique genotype.[26] These arguments are not new; they are identical or similar to those raised earlier in discussions of *in vitro* fertilization. And they involve inherently the same problems.[27] Precisely how is human dignity compromised by a conception that is artificially achieved? What is the basis of the asserted right to be conceived "naturally," to be conceived biologically through heterosexual intercourse, or to have two heterosexual parents? Even the position that human life begins at fertilization is impossible to hold, because in cloning there is no fertilization and no sperm. And what is one to think of current research in which "nucleic DNA from several species—rats, sheep, pigs, and rhesus monkeys—[is inserted] into cows' eggs whose own nuclei have been removed, and the eggs activated the nucleic DNA to produce a clone of the donor of the DNA."[28] If this research is successful, it will solve the problem of the shortage of human eggs for use in assisted reproduction. Thus cloning continues to force the debate over the moral status of the human embryo, and it will heighten the already complex debate over

[26] See Congregation for the Doctrine of Faith *"Donum vitae,* Instruction on Respect for Human Life in Its Origin and on the Dignity of Procreation" (22 February, 1987); this document along with a commentary can be found in Thomas A. Shannon and Lisa S. Cahill, *Religion and Reproduction* (New York: Crossroad, 1988). Such positions are not unique to Roman Catholicism; Paul Ramsey, e.g., argues that any reproductive technology that separates reproduction from heterosexual intercourse is immoral (*Fabricated Man: The Ethics of Genetic Control* [New Haven: Yale University, 1970]).

[27] See Edward Vacek, S.J., "Vatican Instruction on Reproductive Technology," *Theological Studies* 49 (1988) 110–31.

[28] Lori B. Andrews, "Human Cloning: Assessing the Ethical and Legal Questions," *Chronicle of Higher Education,* 13 February 1998, B4–B5.

whether or not early human embryos can be created for the exclusive purpose of research or whether or not already created embryos can be used for that purpose. For if the cloning of humans is to go forward, it must be proceeded by some research on human embryos to evaluate both safety and efficacy.

One can distinguish, however, between the means of assisted reproduction and the context of reproduction. If cloning becomes another form of assisted reproduction, it will become another means in a very competitive and lucrative reproductive market. And here the context of reproduction becomes important for moral analysis. First, assisted reproduction is a multimillion dollar per year market, which means that there is keen competition for clients among clinics. Thus there is a strong incentive immediately to implement any new technology that might give one clinic an edge. Andrews reports the statement of a fertility clinician: "We go from mindside to bedside in two weeks. We make things up and try things on patients. We never get their informed consent, because they just want us to make them pregnant."[29] One can hardly expect responsible research on cloning in such a success-driven context. Second, the assumption is that autonomy reigns in this area as in all others in American culture. This of course begs the question whether individual choice is in fact the only morally relevant value in such discussions. Third, and somewhat related, is the assumption that all reproductive choices are private and, therefore, immune from social evaluation. There are social costs to pregnancy that society must bear: higher insurance premiums for plans that subsidize assisted reproduction, increased use of newborn intensive care units resulting from the increase in multiple pregnancies following *in vitro* fertilization, increase and exacerbation of class division between those who can and those who cannot afford the technologies. Fourth, the residual effects and influence of genetic determinism in attempts to custom design children. As the possibilities of selection increase, so too will pressure to select the "best" eggs and sperm from the "best" genetic heritage. Such efforts will create a complex childhood as well as a narrowing of the range of experiences to which a child may be exposed. Growing up has always had its difficulties; growing up with specific expectations grounded in a carefully selected genetic profile may be even more difficult. Finally, it is clear beyond all doubt that we are gaining incredible control over reproduction; the means of reproduction are being instrumentalized. Consequently, we need to keep clearly in mind the larger ends to which these means are being used and the context in which they are being implemented. While I would argue that there is nothing inherently immoral with any form of assisted reproduction, there is a danger that we may lose the sense of a child as a

[29] Ibid. B4.

gift and come to look upon children as means to an end, an end that is as carefully designed and programmed as possible. Such social determinism closes a child's future and violates a child's dignity. How we use our powers of reproduction will reveal much about us and our priorities.

The new biology and the new genetics are revealing that medical information (particularly the most intimate details about one's genome) is no longer private. This information has profound consequences for one's employment opportunities, insurance possibilities, and social standing. How this new consciousness will be integrated into traditional American concerns on privacy has yet to be thought through. Similarly, we have yet to evaluate the social risks that information such as this and the development of gene therapies offer. Though one can develop analogies and appeal to a variety of models, one will still not know the impact of information or therapy until they are actually tried. And then, of course, the impact cannot be withdrawn. The dynamic in American culture has been to do first and question later, if at all. And this tendency may present one of our biggest problems.

A second major issue is the exponentially rapid rate of scientific and technological development. Since the announcement of Dolly, we have also seen the cloning of 50 mice (some of which were clones of clones), the cloning of eight calves, the production of human stem cells from different types of human embryonic tissue, and the claim of using a human-cow embryonic hybrid as another method of developing human stem cells.[30] One can barely keep up with the reports, much less think through the issues. And this pace will continue. A central concern is that many of these developments are produced in private biotech companies that receive no federal funding. This means that there is no necessity of review by an ethics committee or an institutional review board. While some companies have ethical review committees, they are essentially discretionary. Given that research will continue to be controversial as well as complex, we need a way to engage in before-the-fact, responsible discourse over the directions of such research and applications. The Asilomar Conference called by scientists in the wake of the developing recombitant DNA technology in the late 1970s provides a useful model. Perhaps the time for another such conference has come.

[30] Thomas A. Shannon, "Remaking Ourselves? The Ethics of Stem-Cell Research," *Commonweal* 125 (December 4, 1998) 9–10.

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THEOLOGICAL ISSUES IN GENETICS

JAMES J. WALTER

[Theological reflection can contribute a distinctive perspective from which to analyze and evaluate moral debates about issues in modern genetics and reproductive medicine. The author appeals to two hermeneutical themes, human beings as "images of God" and the tendency of humans to "play God," in order to discuss various church statements and theological literature on human gene transfer, somatic cell nuclear transplant cloning of human beings, and patenting of human genes.]

CONTEMPORARY molecular genetics and reproductive medicine are posing far-reaching questions for theological reflection. In this second section of the Notes on Moral Theology my focus is on three topics that highlight some of these questions. I will consider these topics in the light of two hermeneutical themes that are currently shaping and informing moral debates. Both have biblical foundations and are frequently used to describe the human person—created good in the divine image but, since the fall, prone to hubris and the irresponsible exercise of freedom. My analysis focuses on statements from Christian committees and task forces, as well as various pronouncements on these topics from ecclesial communities and theological writings.

IMAGO DEI

The distinctiveness of human beings in the plan of creation is often described in reference to the fact that they are created in the image of the divine. However, given the variety of meanings of *imago Dei* within Christian theology, I will discuss only two aspects of that theme: stewardship and created cocreatorship.[1] The decision about which of the many aspects to

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[1] Two other models have been recently proposed as well. James Gustafson has proposed a "participant" model in his *Ethics from a Theocentric Perspective* 2: *Ethics and Theology* (Chicago: University of Chicago, 1984) 13 and 294; and Arthur Peacocke has proposed a "co-explorer" model in his *Creation and the World of Science* (Oxford: Clarendon, 1979) 304–6.

select depends not only on how one reads Scripture (especially Genesis, Psalm 8, and the accounts of Jesus' healing of the sick) but also partially on where one stands vis-à-vis two important theological themes: the nature and extent of human responsibility to pursue genetic progress, and the theological doctrine that grounds both human intervention into genetic material and our knowledge of God's purposes.

Human Gene Transfer

There are four types of human gene transfer that are likely to be developed as a result of the Human Genome Project: somatic cell therapy, germ line therapy, somatic cell enhancement, and germ line enhancement. Nearly all the task forces, ecclesial communities, and individual theologians who have addressed the first of these types, somatic cell therapy, have approved of its use once the scientific and technical difficulties have been solved.[2] On the other hand, many of the same have rejected the use of both types of enhancement gene transfer (somatic and germ line).[3] The one

[2] For example, see John Paul II, "Biological Research and Human Dignity," *Origins* 12 (October 22, 1982) 342–43; and his "The Ethics of Genetic Manipulation," *Origins* 13 (November 17, 1983) 385, 387–89; Science and Human Values Committee of the National Conference of Catholic Biships, "Critical Decision: Genetic Testing and Its Implications," *Origins* 25 (May 2, 1996) 769, 771–72; The [British] Catholic Bishops' Joint Committee on Bioethical Issues, *Genetic Intervention on Human Subjects: The Report of a Working Party of the Catholic Bishops' Joint Committee on Bioethical Issues* (London: Linacre Centre, 1996) 28 and 42; World Council of Churches, *Manipulating Life: Ethical Issues in Genetic Engineering* (Geneva: WCC, Church and Society, 1982) 6; National Council of the Churches of Christ in the U.S.A., *Human Life and the New Genetics: A Report of a Task Force Commissioned by the NCC* (New York: Office of Family Ministries and Human Sexuality, 1980) 43; 70th General Convention of the Episcopal Church (July 1991); United Church of Christ, "The Church and Genetic Engineering" (Seventeenth General Synod of the UCC, Fort Worth, Texas, June 29–July 4, 1989) 1–5, at 3; and The United Methodist Church Genetic Science Task Force Report to the 1992 General Conference, "New Developments in Genetic Science Challenge Church and Society," *Church and Society* (1992) 112–23, at 121. Also, see Pius XII's earlier address on genetics, "Moral Aspects of Genetics" (1953), in Kevin D. O'Rourke, O.P., and Philip Boyle, ed., *Medical Ethics: Sources of Catholic Teachings* (Washington: Georgetown University, 1993) 130–31.

[3] See Paul Abrecht, ed., *Faith and Science in an Unjust World: Report of the World Council of Churches' Conference on Faith, Science and the Future* 2: *Reports and Recommendations* (Philadelphia: Fortress, 1980) 66; United Methodist Church, "New Developments in Genetic Science" 122; Allen Verhey, "'Playing God' and Invoking a Perspective," *Journal of Medicine and Philosophy* 20 (1995) 347–64, at 361; and the summary in Ted Peters, "Intellectual Property and Human Dignity," in Mark S. Frankel and Albert Teich, ed., *The Genetic Frontier: Ethics, Law, and Policy* (Washington: American Association for the Advancement of Science, 1994) 215–24, at 221. Interestingly, neither John Paul II nor the Catholic Health Asso-

remaining form of human gene transfer, germ line therapy, remains theologically and morally the most contentious.[4]

Examination of the positions on human gene transfer clearly reveals different theological models of the *imago Dei* that shape and inform the authors' moral visions and judgments. Stewardship over creation is historically one of the aspects of the *imago* most frequently appealed to as a model, for it accentuates the fact that humans are entrusted with responsibility for conserving and preserving creation. It tends to place limits on human freedom to alter what the divine has created, and at times it claims some knowledge of God's purposes by reference to a doctrine of creation. The U.S. National Council of Churches adopts many aspects of this theological model as the presupposition of its moral acceptance of somatic cell therapy. The human role in the creative process of creation involves responsibility for what God has made and for living in harmony with all creation.[5] Joseph Cassidy and Edmund Pellegrino also argue morally for somatic cell therapy and against all forms of enhancement technologies based on their view of the human as the steward (not cocreator) over human germ plasm for future generations. In addition to the scriptural sources and the teachings of the magisterium, they contend that we acquire insight into God's will by using the knowledge God has built into creation.[6]

Another aspect of the *imago* has recently emerged as a model in both Protestant and Catholic circles; it is most often characterized as "created cocreator."[7] This model recognizes that we are indeed created beings, and

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ciation in the U.S. have in principle taken negative positions on either form of these genetic enhancements; see John Paul II, "The Ethics of Genetic Manipulation," 385, 387–89, at 388, and The Catholic Health Association of the United States, *Human Genetics: Ethical Issues in Genetic Testing, Counseling, and Therapy* (St. Louis: *CHA,* 1990) 22. Also, Ted Peters has argued that we should not close the door to enhancement technology; see his "'Playing God' and Germline Intervention," *Journal of Medicine and Philosophy* 20 (August 1995) 365–86, at 365.

[4] For a summary of the moral and theological arguments for and against this form of therapy, see James J. Walter, "'Playing God' or Properly Exercising Human Responsibility? Some Theological Reflections on Human Germ-Line Therapy," *New Theology Review* 10 (November 1997) 39–59.

[5] National Council of Churches of Christ, *Human Life and the New Genetics* 42; see also the Panel on Bioethical Concerns of the NCC/USA, *Genetic Engineering: Social and Ethical Consequences* (New York: Pilgrim, 1984) 24.

[6] Joseph D. Cassidy, O.P., and Edmund D. Pellegrino, "A Catholic Perspective on Human Gene Therapy," *International Journal of Bioethics* 4 (1993) 11–18, at 12. Another way to ground our moral agency and responsibilities is in the doctrine of the Incarnation; see John S. Feinberg and Paul D. Feinberg, *Ethics for a Brave New World* (Wheaton, Ill.: Crossway, 1993) 280.

[7] The Protestant theologian Philip Hefner is generally credited with the naming of this model, but the Jesuit theologian Karl Rahner had already anticipated the substance of the model in the late 60s. See Philip Hefner, "The Evolution of the

thus we ultimately rely on the divine for our existence. Though only God creates *ex nihilo,* we mirror the divine in our capacity to create, even if that ability is restricted to fashioning materials already in the created order. Since creation itself is not complete (*creatio continua*), we have responsibilities to help bring it to completion. Furthermore, because we cocreate with the divine, we have greater freedom than in the previous model to intervene into our genetic material. Ronald Cole-Turner has adopted this model in his moral acceptance of somatic cell therapy. He argues that, though the divine works through the processes of nature, God's creative intentions transcend nature. As cocreators, we must discover these divine purposes so that we may intervene into the moral disorder within nature, i.e., the disorder that is both pervasive and an inevitable byproduct of the evolutionary process, in order to correct it. Cole-Turner does not turn to the doctrine of creation for knowledge of God's will but to the doctrine of redemption, which provides the necessary noetic clue to God's purposes for curing genetic diseases.[8]

Ted Peters takes this model one step further by morally justifying not only human gene transfer for therapeutic purposes but also for the ends of enhancement (somatic and germ line). He grounds human responsibility and knowledge of God's purposes neither in the doctrine of creation nor in redemption but in the doctrine of eschatology. He argues that the created cocreator model is superior to all others because it begins with a vision of openness to God's future and responsibility for the human future. Such a vision is founded on our vision of the promised kingdom of God, and this framework of future possibilities orients and directs our moral activity in genetics.[9] Prolepsis is the structure of ethical reasoning, and it is a concrete actualization within the present of what we see to be the case in the future-transformed reality. According to Peters, we must begin our ethical think-

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Created Co-Creator," in Ted Peters, ed., *Cosmos as Creation: Theology and Science in Consonance* (Nashville: Abingdon, 1989) 211–33. For Rahner's two widely read and influential essays, see "The Experiment with Man: Theological Observations on Man's Self-Manipulation," in *Theological Investigations* 9, trans. Graham Harrison (New York: Herder and Herder, 1972) 205–24; and "The Problem of Genetic Manipulation," ibid. 225–52. For an interesting comparison between Rahner's two articles, see David F. Kelly, "Karl Rahner and Genetic Engineering: The Use of Theological Principles in Moral Analysis," *Philosophy and Theology* 9 (Autumn-Winter, 1995) 177–200.

[8] Ronald Cole-Turner, "Is Genetic Engineering Co-Creation?," *Theology Today* 44 (October 1987) 338–49, at 345–47; and his *The New Genesis: Theology and the Genetic Revolution* (Louisville: Westminster/Knox, 1993) 98–103.

[9] Ted Peters, *Playing God? Genetic Determinism and Human Freedom* (New York: Routledge, 1997) 144–56.

ing about human gene transfer by projecting a vision of the new creation and then work back to the present to discover our moral responsibilities.[10]

Somatic Cell Nuclear Transplant Cloning

Applying the same framework to human cloning indicates again that moral judgments are shaped by theological models of the *imago Dei*. Because this type of cloning will be employed in the future as a form of assisted reproductive technology, the theological theme of responsibility for intervening into and improving upon human reproduction becomes relevant.

A large portion of the literature does not support morally this type of human cloning, and most utilize theological resources to inform their positions.[11] Nevertheless, there is a sizable minority that either has cautiously endorsed human cloning or at least can find no convincing theological reason to oppose it categorically.[12] Those who use the stewardship model of the *imago* to frame this issue tend not to support it morally, and those who use the created cocreator model tend to permit it, or at least not to oppose it, on theological grounds.

Two examples illustrate this point. The United Methodist Genetic Science Task Force's statement on cloning begins with a theological affirmation of how humanity is created in the image of God as stewards, and then it develops its policy statement calling for a ban on human cloning.[13] On the other hand, Ted Peters, who has been an ardent proponent of the co-

[10] Ted Peters, *For the Love of Children: Genetic Technology and the Future of the Family* (Lousiville: Westminster/Knox, 1996) 155.

[11] For example, the Congregation for the Doctrine of the Faith, "Instruction on Respect for Human Life in Its Origin and on the Dignity of Procreation," *Origins* 16 (March 19, 1987) I, no. 6; Cardinal Keeler, "The Problem with Human Cloning," *Origins* 27 (February 26, 1998) 597 and 599–601; General Assembly of the Church of Scotland, "Motions on Cloning," in Ronald Cole-Turner, ed., *Human Cloning: Religious Responses* (Louisville: Westminster/Knox, 1997) 138; and The Christian Life Commission of the Southern Baptist Convention, "Against Human Cloning: March 6, 1997," in National Bioethics Advisory Commission, *Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission* (Rockville, Md.: U.S. Government Printing Office, 1997) 56.

[12] For example, see Joseph Fletcher, "Ethical Aspects of Genetic Controls," *New England Journal of Medicine* 285 (April 1971) 776–83; Ted Peters, "Cloning Shock: A Theological Reaction," in Cole-Turner, *Human Cloning* 12–24; and Philip Hefner, "Cloning as Quintessential Human Act," *Insights* (August 1997) 18–21.

[13] Genetic Science Task Force, "Statement from the United Methodist Genetic Science Task Force: May 9, 1997," in Cole-Turner, *Human Cloning* 143–45, at 143; see also R. Albert Mohler, Jr., "The Brave New World of Cloning: A Christian Worldview Perspective," ibid. 91–105.

creator model, has strongly contended that "[r]eproductive and genetic technologies, along with technologies to create a child through cloning, can express responsible created co-creatorship."[14]

Patenting Human Genes

The scientific laboratories that are mapping and sequencing the human genome are also applying for patents on the genes they are discovering. There are numerous moral and legal problems with this topic, but there are many theological issues as well. One such issue involves a theological discussion of whether or not the *imago Dei* is present in human DNA and thus whether genes deserve to be treated differently from other created material.

Richard Land and C. Ben Mitchell argue morally against the patenting of human genes, and part of their argument is based on a theological construal of the *imago Dei*. They assert that only human beings are created in the image of the divine, and this image "pervades human life in all of its parts."[15] Others have argued that DNA provides the biological blueprint for humans as the image of God, and thus all patenting of human genetic material is inappropriate.[16] On the other hand, Peters does not accord human DNA any special status and argues that it is precisely because we are created in the image of God (created cocreators) that we are called to use our creativity to make this world a better place. If the patenting of DNA can further this cause by eliminating debilitating genetic diseases, then on the basis of this image of God we should morally permit the patenting of life.[17]

PLAYING GOD

A second theological framework that has shaped the discussion of these contemporary topics in genetics concerns the question of whether or not humans, by intervening in the very material that constitutes life, are exceeding their limits, and thus playing God. Of course, where one stands on

[14] NBAC, *Cloning Human Beings* 47. Cole-Turner himself adopts a created co-creator model when he claims he does not believe "that a compelling theological argument can be made against cloning for reproductive or for experimental purposes" ("At the Beginning," in Cole-Turner, *Human Cloning* 119–30, at 120).

[15] Richard D. Land and C. Ben Mitchell, "Patenting Life: No," *First Things* 63 (May 1996) 20–22, at 21.

[16] See the discussion of this view by Mark J. Hanson, "Religious Voices in Biotechnology: The Case of Gene Patenting," *Hastings Center Report* 27 (November-December 1997) 1–21, at 4.

[17] Ted Peters, "Patenting Life: Yes," *First Things* 63 (May 1996) 18–20, at 19; see also his *Playing God?* 139.

this question is partially determined by which theological model of the *imago Dei* one adopts. Because the stewardship model tends to limit human activity through its emphases on conserving and preserving creation, the charge of improperly playing God will frequently be raised by those who subscribe to this model. The reverse tends to be the case for those who argue for a created cocreator model. Beyond that, however, this framework implies two theological themes: (1) the status of human DNA, and (2) one's position on the sovereignty of God and the divine ownership of creation.

Though there has been a spate of books that include this phrase somewhere in their titles,[18] what is clear is that there is no common understanding of what "playing God" means.[19] Some find the phrase not very helpful and believe that bioethical discussions could be enhanced without its use,[20] while others argue it can serve as an important and distinctively theological perspective from which to assess scientific and technological innovations. When used as a theological perspective it can function either negatively as a concern or warning, with specific prohibitions attached to it, or positively as an invitation to "play God" by imitating God's purposes of care and grace. Consequently, there may be both proper and improper ways of playing God.[21]

Human Gene Transfer

When the U.S. President's Commission on genetic engineering submitted its report in 1982, it noted that there was an objection from religious groups that scientists were playing God in their recombinant DNA (rDNA) research. Applied to this research, the precursor to techniques in human gene transfer, the expression "playing God" reflected concern about the consequences of exercising great human powers over nature.[22] The U.S. National Council of Churches echoed a similar concern when it

[18] See, e.g., Ted Howard and Jeremy Rifkin, *Who Should Play God? The Artificial Creation of Life and What It Means for the Future of the Human Race* (New York: Delacorte, 1977); and R. C. Sproul, Jr., *Playing God: Dissecting Biomedical Ethics and Manipulating the Body* (Grand Rapids: Baker, 1997).

[19] Some recent attempts have been made to clarify the meaning of the phrase; see, e.g., Verhey, "'Playing God' and Invoking a Perspective" 347–64, and Lisa Sowle Cahill, "'Playing God': Religious Symbols in Public Places," *Journal of Medicine and Philosophy* 20 (1995) 341–46.

[20] See Howard Brody, *Ethical Decision in Medicine* (Boston: Little, Brown, 1976) 82.

[21] Verhey, "'Playing God' and Invoking a Perspective" 358.

[22] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Splicing Life* (Washington: U.S. Government Printing Office, 1982) 54.

used this phrase to describe the fact that human beings now possess the ability to do "God-like" things, i.e. to direct and redirect the life processes of nature itself.[23] The Church of the Brethern took this concern one step further and questioned whether humans are now playing God by changing the genetic structures of life and thus overstepping the boundaries God has set for humankind.[24] Each of these groups expresses concern about human intervention into DNA whether at the somatic or germ line level. Part of this concern has to do with the status of DNA or the human genome. Is it sacred and thus beyond the boundaries of human manipulation and control, or is it more or less similar in status to other bodily matter and thus open to human intervention and control?[25] If the former, then scientists are improperly playing God when they intervene into the human genome, because they overstep the boundaries given to them by God; if the latter, then scientists are properly playing God, i.e., serving God's own purposes, when they intervene at some level (somatic or germ line) to cure and prevent disease or, for some, to enhance the human. In the literature surveyed, it appears that most authors have argued that, though human DNA is a cause of great wonder, it does not possess a sacred status, but is like other parts of the body and thus in principle may be altered within certain therapeutic limits.[26] It goes without saying that those few who have supported morally somatic and/or germ line enhancements have denied the special or sacred status of DNA.[27]

Somatic Cell Nuclear Transplant Cloning

Lee Silver, a biologist, contends that all ethical arguments used to prohibit human cloning are really hidden religious arguments about the wrongfulness of playing God.[28] As intriguing as this claim might be, in the end it misunderstands much of the contemporary theological debate[29] and

[23] NCC, *Genetic Engineering* 27.

[24] Church of the Brethren, "1987 Annual Conference Statement on Genetic Engineering" (1987 Annual Conference Minutes) 451–56, at 453.

[25] For a discussion of some of these issues, see Bernard Baertschi, "Devons-nous respecter le génome humain?" *Revue de théologie et de philosophie* 123 (1991) 411–34.

[26] See Cassidy and Pellegrino, "A Catholic Perspective on Human Gene Therapy" 12; and Report of the Working Party of the [British] Catholic Bishops, *Genetic Intervention on Human Subjects* 32. Jeremy Rifkin, who has protested against this view, is a notable exception; see his *Algeny* (New York: Penguin, 1983).

[27] Ted Peters, *Playing God* 117.

[28] Lee M. Silver, "Cloning, Ethics, and Religion," *Cambridge Quarterly of Healthcare Ethics* 7 (1998) 168–72, at 169.

[29] See, e.g., the argument against human cloning based on biological diversity in Richard A. McCormick, S.J., "Should We Clone Humans?" *Christian Century* 110 (November 17–24, 1993) 1148–49.

the important disputes that took place between Joseph Fletcher and Paul Ramsey in the 1960s and 1970s on the topics of human cloning and assisted reproductive technologies. Two of the most often quoted phrases about playing God were constructed during these decades and on this topic. Fletcher's bold claim "let's play God" laid down the gauntlet for those who would morally oppose the development of these new technologies.[30] In a retort that has become famous, Ramsey cautioned those who would arrogate to themselves control over human reproduction: "Men ought not to play God before they learn to be men, and after they have learned to be men they will not play God."[31] Fletcher's perspective on "playing God" had little to do with God; in fact, he used this phrase as a way of signaling the death of the "God of the gaps" and the need for humans to take up their responsibilities.[32] These responsibilities, however, were fashioned out of a Baconian desire to dominate and control the processes of human reproduction, to put an end to "reproductive roulette." Ramsey's perspective on playing God vis-à-vis cloning was quite different; he sounded a warning that, whenever God is absent or superfluous, humanity becomes the creator and engineer of the future and nature, and human nature will be controlled with messianic ambition.[33] The results of this situation for Ramsey were that morality would be reduced to consequentialism and human nature would be left with no dignity of its own.[34]

Patenting Human Genes

When the framework of playing God is used to inform moral deliberation and judgments about the patenting of human genes, we encounter once again the theological themes of the status of human DNA and the sovereignty of God over creation. In general, those who have invoked the perspective of playing God seek to show how this form of patenting involves tampering with the blueprint for life forms and constitutes arrogant disregard for God's ownership over life.[35] Thus, patenting human genes is considered an improper form of playing God.

Some have argued theologically that human DNA and the genome itself are sacred because they possess characteristics integral to human identity

[30] Joseph Fletcher, *The Ethics of Genetic Control: Ending Reproductive Roulette* (Garden City, N.Y.: Anchor, 1974) 126.

[31] Paul Ramsey, *Fabricated Man: The Ethics of Genetic Control* (New Haven, Conn.: Yale University, 1970) 138.

[32] Fletcher, *The Ethics of Genetic Control* 200.

[33] Ramsey, *Fabricated Man* 91–96.

[34] See Verhey, "'Playing God' and Invoking a Perspective" 356.

[35] See Rebecca S. Eisenberg, "Patenting Organisms," in *Encyclopedia of Bioethics,* Warren T. Reich, ed. (New York: Macmillan, 1995) 4.1911–14, at 1911.

and personhood. Furthermore, DNA provides the biological blueprint for humans created in the image of God, and it is even possible to accord this genetic material the social and cultural functions of the soul.[36] In addition, Land and Mitchell argue that the very image of God in humans pervades human life in all its parts, and this certainly includes DNA.[37] Several argue that to patent human genes is to play God improperly because such actions take away God's sovereign ownership over these genetic materials. For example, the Southern Baptist Convention and the United Methodist Church Community both have argued against such patenting on the theological ground that only God can and does own life.[38]

On the other hand, those who are open to some patenting of human genes have neither used the framework of playing God, nor argued for the sacred status of human DNA. For example, Cole-Turner contends that theists believe only God is sacred, and thus everything else is God's creation. He argues there is no metaphysical difference between DNA and other complex chemicals, and so there is no distinctly religious ground for objecting to patenting of DNA.[39] Finally, Mark Hanson has argued that there are two significant problems with the divine ownership claim: first, patents do not confer ownership, so the theological claim against human ownership does not hold; and second, such arguments based on divine sovereignty are consistent with a narrow conception of some doctrines of God.[40] He contends that other views of God's ownership need to be constructed, e.g., one that might approach divine ownership as God's reserving the right to define the purpose and value of created realities.[41]

A brief summary of the key theological issues on the selected bioethical topics will serve as a conclusion to this section of the Notes. It is important to observe that theological reflection can contribute a distinct perspective from which to evaluate morally these complex topics. Theological frameworks or hermeneutical themes can be constructed from the Christian faith that in turn possess the power to shape and inform moral assessment. For the moral judgments on the topics we have considered rely, at least par-

[36] For a summary of this position, see Hanson, "Religious Voices in Biotechnology" 4.

[37] Land and Mitchell, "Patenting Life: No" 21.

[38] Report of Committee on Resolutions, "On the Patenting of Animal and Human Genes," *SBC Bulletin* (1995) 7–8, at 7; and United Methodist Church Task Force, "New Developments in Genetic Science" 117.

[39] Ronald Cole-Turner, "Religion and Gene Patenting," *Science* 270 (October 6, 1995) 52.

[40] Hanson, "Religious Voices in Biotechnology" 9–10.

[41] I wish to acknowledge the generous assistance I received in preparing this manuscript from my graduate assistant Timothy Sever and from John H. Evans of Princeton University.

tially, on prior judgments about (1) the nature and extent of human responsibility to pursue genetic progress; (2) the limits, if any, to the human capacity to alter the very material that constitutes life; and (3) the moral status of human DNA. Theological construals of God's purposes in creation, of the sovereignty of God over creation, and of divine ownership of human life are key to arriving at judgments on these questions.

Review of various ecclesial statements and of theological opinions has indicated that there is no universal agreement on the morality of these topics. One suggestion that might be offered for future discussion concerns the importance of focusing reflection more squarely on theological presuppositions. Development of a consensus on the central theological issues at stake might prove a helpful first step toward articulating an acceptable range of moral judgments.

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JURISPRUDENCE AND GENETICS

M. CATHLEEN KAVENY

[This section of the Notes in Moral Theology attempts to grapple with the proper relation of law and morality on three emerging issues connected with genetics: cloning, discrimination on the basis of genetic information, and patenting of genetic material.]

WHAT CHALLENGES WILL political communities face in crafting a legal response to recent developments in genetics? Is formulating a wise jurisprudential stance a matter of extending existing legal concepts in bio-law and family law, or will it require fundamentally rethinking them? Focusing on cloning, genetic privacy, and gene patenting, I suggest that the second course of action will be necessary in all three cases.

CLONING

Broadly speaking, it is fair to say that the dominant model for addressing reproduction in American law and policy is individualistic, voluntaristic, and dualistic. Because the desire to have (or not to have) a child is determinative of an individual's identity, it should be a matter of personal choice unfettered by legal constraints. An individual decides to have a child; she then uses the reproductive material necessary to carry out her choice. Those who cannot (or do not want to) use their own material to produce a child may use the sperm, oocytes, or embryos donated or sold by others.

The appearance of Dolly in early 1997 called into question the dominant understanding of reproduction, because it prompted widespread outcry about the nature and the motivation of the choice to produce a child through cloning. Eighteen months after Dolly's appearance, however, that outcry has been largely muted.[1] The U.S. has quietly folded cloning into the laissez-faire legal stance that it has long taken toward emerging issues

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[1] Gina Kolata, "On Cloning Humans: 'Never' Turns Swiftly into 'Why Not,' " *New York Times,* 2 December 1997, A1.

in reproductive technology.[2] A key factor in this outcome was the report, "Cloning Human Beings," issued by the National Bioethics Advisory Commission (NBAC) in June 1997.[3]

The NBAC report made the following policy recommendations: (1) to continue the moratorium initiated by President Clinton on the use of federal funding to "support any attempt to create a child by somatic cell nuclear transfer"; (2) to issue an immediate request to scientists and clinicians who do not receive federal funds, asking them to refrain from such attempts;[4] and (3) to enact federal legislation (with a sunset clause) prohibiting anyone from attempting to create a child through somatic cell nuclear transfer.[5] Two features of the report are crucial: the scope of its recommended prohibition, and the basis for it.

[2] The European response has been more decisively negative. On January 12, 1998, nineteen of the forty member states of the Council of Europe signed an Additional Protocol to the Convention on Human Rights and Biomedicine, which prohibits human cloning. It is available at ⟨http://www.coe.fr/eng/legaltxt/168e.htr⟩. See also the survey of European countries in Andrea L. Bonnicksen, "Procreation by Cloning: Crafting Anticipatory Guidelines," *Journal of Law, Medicine, and Ethics* 25 (1997) 273–82. See also UNESCO's "Universal Declaration on the Human Genome and Human Rights," available online at ⟨http://www.umn.edu/humanrts/instree/Udhrhg.htm⟩.

[3] National Bioethics Advisory Commission, *Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission* (Rockville, Md.: NBAC, June 1997). A symposium on the report can be found in *Jurimetrics* 38, no. 1 (Fall 1997); see also Susan M. Wolf, "Ban Cloning? Why NBAC is Wrong," *Hastings Center Report* 27, no. 5 (1997), and the debate between John Robertson and George Annas in "Sounding Board," *New England Journal of Medicine* 339 (1998) 119–25.

[4] Organizations that have supported the voluntary moratorium include the American Society for Reproductive Medicine, the Biotechnology Industry Organization, the American Medical Association, the Federation of American Society of Experimental Biology, RESOLVE (the National Infertility Association), and the Society for Developmental Biology.

[5] Congress did not enact the recommended prohibition. Although several anti-cloning bills were introduced, none passed. However, some of the objectives behind the prohibition were achieved indirectly, when the Food and Drug Administration asserted its jurisdiction over any effort to produce a live-born human being through the process of cloning. By statutory mandate, the FDA will concern itself solely with the safety and efficacy of the process. Consequently, its focus is consonant with the NBAC report's emphasis on the risk of tangible harm to the cloned child as a basis for its proposed prohibition (Rich Weiss, "Human Clone Research Will Be Regulated; FDA Asserts It Has Statutory Authority to Regulate Attempts at Human Cloning," *Washington Post*, 20 January 1998, A1). On the basis for FDA regulatory authority in this area, see also David Kessler et al., "Regulation of Somatic Cell Therapy and Gene Therapy by the Food and Drug Administration," *New England Journal of Medicine* 329 (1993) 1169–73.

Scope of Prohibition

In condemning only "the attempt to create a child through somatic cell nuclear transfer," the NBAC report studiously avoids condemning experiments in cloning that fall short of the birth of a child.[6] Why? In part, because of the benefits promised by embryo research that uses somatic cell nuclear transfer. For example, by combining that technique with human stem cell therapy, scientists hope to customize stem cell lines to replace non-regenerating damaged tissue for heart attack or burn victims.[7] Two questions arise about such research. First, is it morally justified, or does it involve the wrongful manipulation of the early human embryo? Second, even if such research is morally permissible in itself, should it be restricted because it will enable the perfection of techniques that will make inevitable the creation of a cloned child?[8]

However, if the NBAC had explicitly grappled with these questions, it would have reinvigorated an old controversy. In response to a hotly debated 1994 National Institutes of Health report on the ethics of human embryo research, the U.S. Congress reached for a political solution, rather than a reasoned moral viewpoint to guide American policy. As a consequence, no form of nontherapeutic research on human embryos is prohibited by federal law; at the same time, no such research is supported with federal funds.[9] Three years later, Congress decided to fold cloning research on unimplanted embryos into this politically based schema. By and large, state law does not fill the regulatory gap. Only a minority of states have enacted laws restricting experimentation on the unborn; in some of these,

[6] The report's prohibition would not encompass the cloning of embryos by blastomere separation, nor the use of somatic cell nuclear transfer to create embryos that will not be transferred to a surrogate mother for gestation. Furthermore, the phrase does not even clearly exclude the creation of a cloned *fetus* by somatic cell nuclear transfer, provided that it is aborted before being brought to term.

[7] The biotechnology industry criticized some of the anti-cloning bills introduced into Congress for restricting too greatly primordial stem cell research ("Prepared Testimony of Michael D. West Regarding Cloning of Human Beings," and "Prepared Testimony of Jill Van Wart Hood Regarding Human Cloning Policy Development" *Federal News Service* [12 February 1998], available on-line through Lexis or Westlaw).

[8] See Mary Warnock, "The Regulation of Technology," *Cambridge Quarterly of Healthcare Ethics* 7 (1998) 173–75. This issue contains a symposium on "Cloning, Technology, Policy, and Ethics."

[9] *Departments of Labor, Health and Human Services, and Education Appropriations Act,* Public Law 105–78 §513(a) (1998). More generally, federal law and regulations governing research involving human subjects apply only to federally funded research.

the relevant restrictions are designed to protect fetuses destined for abortion and do not apply to embryos, especially before implantation.

Basis of Prohibition

Although the NBAC took testimony from a range of religious and secular moralists, in the end it was hesitant to anchor restrictive public policy in their deep but diffuse concerns about the familial and social implications of cloning, including implications for the dignity of the cloned child. Instead, the NBAC seems to have relied on the liberal harm principle, a narrow version of which holds that legal (especially criminal) restrictions on human freedom are justified only in order to prevent a high likelihood of tangible harm to identifiable individuals.[10] Because the still imperfect techniques of cloning could result in damage to a cloned child, the NBAC report's proposed ban on producing a child through somatic cell nuclear transfer is currently justified under the harm principle.

However, once science advances to the point that cloning is not likely to produce a damaged child, the basis for the NBAC's recommended prohibition in (a narrow version of) the harm principle may be eroded.[11] The question whether cloning should be protected as a form of reproductive freedom, or instead understood as an innovative form of "replication" that does not merit heightened legal protection, will then be fully joined.

It is highly unlikely that the current Supreme Court will announce a new constitutionally protected positive liberty interest in having a child, particularly through the cloning process. The cases it has decided thus far have protected only negative reproductive liberties (e.g. freedom to prevent childbearing by contraception and abortion).[12] Nonetheless, many legal scholars and at least one federal district court[13] have suggested that reproductive liberty should also encompass a positive right to have a child,

[10] One can, of course, hold a broader version of the harm principle that would consider the risk of intangible harm done to the child and to the society to be a legitimate basis on which to prohibit cloning. These intangible harms are reflected in the comments of the theologians testifying before the NBAC (e.g. Lisa Sowle Cahill and Gilbert Meilaender), as well as the Catechism's admonition that "a child may not be considered a piece of property" (*Catechism of the Catholic Church* [New York: Doubleday, 1995] no. 2378).

[11] Only two states (Michigan and California) had passed such laws as of July 1998.

[12] See *Griswold v. Connecticut,* 381 U.S. 479 (1965); *Eisenstadt v. Baird,* 405 U.S. 438 (1972); *Carey v. Population Services International,* 431 U.S. 678 (1977); *Roe v. Wade,* 410 U.S. 113 (1973); *Planned Parenthood v. Casey,* 505 U.S. 833 (1992). However, dicta in other opinions can be used to support a positive right to reproductive liberty; see, e.g., *Skinner v. Oklahoma,* 400 U.S. 995 (1971), and *Meyer v. Nebraska,* 262 U.S. 390 (1923).

[13] *Lifchez v. Hartigan,* 735 F.Supp. 1361, 1376–77 (N.D.Ill. 1990).

through reproductive technologies if necessary. Furthermore, the laissez-faire legal approach adopted by Congress and by most states is favorable to an expansive understanding of reproductive liberty. By and large, states have been slow to prohibit or even regulate the use of such technologies as surrogate motherhood and in vitro fertilization with donor gametes.[14] Few states regulate the practices of fertility clinics; very few have systemically sorted through the complex familial relationships that can arise in such situations, by adopting some version of the Uniform Status of Children of Assisted Conception Act.[15] It is not difficult to imagine this laissez-faire approach being expanded to include cloning. If it is, what will be the consequences?

Fissure of Parental Relationships

When most of us think of cloning, we think of a unique concentration of parenthood in one individual, the person who serves as the "template" for the clone. Without denying the significance of this novel "parental" role, it is also important to see that cloning is likely to exacerbate the fissure of parental roles already begun by existing reproductive technologies. At least eight such roles can be identified in the creation of a clone: (1) the initiator of the cloning process; (2) the template who contributes the nuclear DNA; (3 and 4) the genetic parents of the template, who will also be genetic parents of the clone; (5) the donor of the enucleated egg fused with the template's nucleus who contributes mitochondrial DNA; (6) the gestational mother; and (7 and 8) the rearing parents.

Advocates of a reproductive liberty expansive enough to include cloning will need to sort through the respective claims of these parties. Will any of them have a positive right to contribute to the cloning of a human being? Conversely, will any have a negative right to prevent the creation of a clone to whom she will stand in one of the foregoing relationships? In a recent article[16] John Robertson resolves these questions in a way that not only makes cloning a positive reproductive right, but gives it a macabre pride of place.[17] For example, he suggests that parents should be able to clone a

[14] See Karen M. Ginsberg, "FDA Approved? A Critique of the Artificial Insemination Industry in the United States," *University of Michigan Journal of Law Reform* 30 (1997) 823–51.

[15] Uniform Status of Children of Assisted Conception Act, 9B U.L.A. 184 (Supp. 1998); only North Dakota and Virginia have adopted the Uniform Status of Children of Assisted Conception Act.

[16] John A. Robertson, "Liberty, Identity, and Human Cloning," *Texas Law Review* 76 (May 1998) 1371–1456.

[17] Robertson, "Human Cloning" 1371, 1372, 1391–92, and 1403. Compare this with his earlier writings in which he asserts cloning falls outside the scope of procreative liberty: John A. Robertson, *Children of Choice* (Princeton, N.J., Prince-

minor child despite her lack of legal capacity to consent. Moreover, he also suggests that the parents of an adult child cannot prevent her from cloning herself, although they will stand in essentially the same genetic relationship to the clone as they do to their own child.[18]

Ironically, in order to expand the borders of reproductive freedom to include cloning, Robertson must abandon two elements that he (and many other liberal theorists) have previously placed at its center: (1) the identification of reproductive liberty's core concern with the creation of a child to whom one has a genetic tie, and (2) the paramount importance of an individual's negative right not to reproduce (i.e., not to bring into being a child with whom one has a genetic connection).[19] Now identifying reproduction's core with the right to rear a child, Robertson unequivocally supports only one absolute limit: he withholds the right to initiate the cloning process from a person who is not committed to rearing the cloned child.[20]

Robertson's article shows, I believe, that the question of cloning cannot be adequately addressed if we do not move beyond the dominant view of reproductive liberty. The procreation and education of the next generation is not merely a matter of an indiviudal's disembodied desire to "have" a child, but is a question of the common good that requires us to attend to the embodied and social aspects of human nature. Furthermore, the fact that a version of the harm principle narrowly focused on tangible harms may not capture these concerns points not to the illegitimacy of the latter, but to the inadequacy of the former in dealing with a revolutionary practice whose implications are not fully understood.

GENETIC PRIVACY

As of summer 1998, scientists had identified and developed tests for genes associated with approximately 600 diseases, including breast cancer, Alzheimer's disease, and Huntington's disease.[21] Because our techniques for identifying human genes are so much more advanced than our abilities to alter them, the immediate challenges that the Human Genome Project

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ton University, 1994) 34, 41, and 167–70; and his "Liberalism and the Limits of Procreative Liberty: A Response to My Critics," *Washington and Lee Law Review* 52 (1995) 233, 242.

[18] Robertson, "Human Cloning" 1446, 1448–49.

[19] Robertson, *Children of Choice* 22–23, 26–29; "Response to My Critics" 240–43.

[20] Robertson, "Human Cloning" 1442–43. Overall, Robertson is inconsistent about whether genetic ties, gestation, or rearing constitutes the essence of reproduction; see his "Human Cloning" 1387–88, 1393, 1395, 1398–1403, 1442–43.

[21] This information was provided by HELIX: Genetic Testing Resource, whose internet address is ⟨http://healthlinks.washington.edu/helix⟩.

presents for policymakers pertain to the control of genetic information.[22] Recent discussion of this issue has focused on the Genetic Privacy Act, proposed as model federal legislation by George Annas, Leonard Glantz, and Patricia Roche.[23] As described below, the act attempts to make the current conception of medical privacy safe for genetic data about individuals, rather than grappling with the ways in which the nature of such data calls that conception into question.

The Genetic Privacy Act defines protected genetic information narrowly, to include only information that is obtained by analysis of the DNA of that person or her relatives. A large portion of the act is devoted to protecting the DNA sample itself. Two questions arise. First, is there a justifiable basis for defining protectable genetic information so narrowly? It seems illogical to limit protection to information that is indirectly obtained by taking the medical history of family members, or by performing tests for the proteins expressed by particular genes. However, as the act's authors note, once the definition is broadened to include any information about a person's genome, no matter what the source, it becomes very difficult to segregate it from other information contained in a patient's record.[24]

A second, equally fundamental question is why genetic information per se, particularly as narrowly defined in the act, should be considered more "private" than other sensitive medical data.[25] In the commentary to the act, the authors analogize it to a "future diary" chronicling intimate aspects of a person's life in the years to come. Yet as compelling as this metaphor seems initially, disanalogies quickly present themselves. A diary chronicles personal reactions to the day's events; genetic information presents raw statistical probabilities that have yet to be filtered through a diary writer's framework of meaning.[26]

[22] The best volume on this question is Mark A. Rothstein, ed., *Genetic Secrets* (New Haven: Yale University, 1997).

[23] George J. Annas, Leonard H. Glantz, and Patricia A. Roche, "The Genetic Privacy Act and Commentary," available online at ⟨http://www.bumc.bu.edu/www/sphlw/gpa⟩. The authors of the act describe its purpose in "The Genetic Privacy Act: A Proposal for National Legislation," *Jurimetrics* 37 (1996) 1–11. See also Edwin S. Flores Troy, "The Genetic Privacy Act: An Analysis of Privacy and Research Concerns, *Journal of Law, Medicine, and Ethics* 25 (1997) 256–72, and several articles in *Genetic Secrets*.

[24] George J. Annas, Leonard H. Glantz, and Patricia A. Roche, "Drafting the Genetic Privacy Act: Science, Policy, and Practical Considerations," *Journal of Law, Medicine, and Ethics* 23 (1995) 360–66.

[25] On the meaning of privacy, see Anita L. Allen, "Genetic Privacy: Emerging Concepts and Values," in *Genetic Secrets* 31–59.

[26] Thomas H. Murray so argues in "Genetic Exceptionalism and 'Future Diaries': Is Genetic Information Different from Other Medical Information?" in *Genetic Secrets* 60–73.

From a pragmatic perspective, the significance of genetic privacy is closely intertwined with two questions: Who should have access to genetic information? And for what purposes can it be used? With some exceptions, the law assumes that the information contained in a patient's medical record concerns only that particular patient. Consequently, it holds (again with exceptions) that only the patient can authorize release of her record. In relying almost exclusively on the prevailing consent model for release of information, the act affords it protection that is at once too broad and too narrow.

The Genetic Privacy Act attempts to bring genetic information under the prevailing model by defining it in terms of its source from the DNA of a particular person, who must consent to its release. But why should genetic information be defined in terms of its source, rather than its referent? Such information tells us not only about the patient herself, but also about her parents, siblings, and even children not yet born. Do not they have a claim to know about it, at least under some circumstances? In order to account for the familial nature of genetic information,[27] we may need to rethink our notion of the physician-patient relationship in a clan-based way, creating a new ethos of the "family physician."

Family members are not the only ones who might seek information about an individual's genetic makeup. Employers[28] and health insurers[29] also are interested in obtaining that information. By avoiding employees and enrollees who are more likely to become ill, both groups can control costs and increase profits. Persons with abnormal genotypes find only

[27] Genetic privacy issues and the family are addressed in Mary Anne Bobinski, "Genetics and Reproductive Decision-Making," in Thomas H. Murray, Mark A. Rothstein, and Robert F. Murray, Jr., ed., *The Human Genome Project and the Future of Heatlh Care* (Bloomington and Indianapolis: Indiana University, 1996) 79–112; Rosamond Rhodes, "Genetic Links, Family Ties, and Social Bonds: Rights and Responsibilities in the Face of Genetic Knowledge," *Journal of Medicine and Philosophy* 23 (1998) 10–30; and Lainie Friedman Ross, "Disclosing Misattributed Paternity," *Bioethics* 10 (1996) 114–30.

[28] Paul M. Schwartz, "Privacy and the Economics of Personal Health Care Information," *Texas Law Review* 76 (1997) 1–92; Adrienne Asch, "Genetics and Employment: More Disability Discrimination," in Murray et al., ed., *Human Genome Project* 158–72; Joseph S. Alper, "Does the ADA Provide Protection Against Discrimination on the Basis of Genotype?" *Journal of Law, Medicine, and Ethics* 23 (1995) 167–72.

[29] See Karen H. Rothenberg, "Genetic Information and Health Insurance: State Legislative Approaches," *Journal of Law, Medicine, and Ethics* 23 (1995) 312–19; Mark A. Hall, "Insurers' Use of Genetic Information," *Jurimetrics* 37 (1996) 13–22; Deborah A. Stone, "The Implications of the Human Genome Project for Access to Health Insurance," and Herbert Nickens, "The Genome Project and Health Services for Minority Populations," both in Murray et al., *The Human Genome Project* 133–57 and 58–78, respectively.

spotty protection against "genetic discrimination" in existing state and federal law.[30] Unfortunately, in requiring an elaborate process of informed consent before the disclosure of such information, the act does little to remedy the problem; employers and insurers can still require persons to consent to disclosure of genetic information as a condition of doing business with them; very few individuals will be able to resist disclosure.

Some initiatives have responded to these scenarios with clumsy attempts to make genetic information virtually invisible, by prohibiting its use in making employment or underwriting decisions. For example, the Health Insurance Portability and Accountability Act of 1996 prohibits group health plans from denying individuals coverage on the basis of genetic information, or using such information to charge them higher rates (but it does not prohibit charging higher rates to employers).[31] The Americans with Disabilities Act has been interpreted to prohibit employers from taking into account genetic information about asymptomatic applicants when making job offers (but not to prohibit them from obtaining such information after making an offer).[32]

But there are two difficulties with the "invisibility" strategy. First, is it fair to confer such protection on persons who suffer from genetic disorders, while denying it to those whose disorders are manifest by other types of tests? Second, the strategy of recreating a world untainted by genetic information is ultimately futile, because that information is not invisible to the persons who are its source. For example, insurance companies legitimately fear that genetically compromised persons will purchase added insurance.

One might argue that the Genetic Privacy Act and other recent legal initiatives offer the best hope of integrating the explosion of genetic information into the existing biolegal framework. In my view, however, the flaws in these initiatives point to the need to rethink key elements of that framework. The prevailing understanding of medical information sees patients as atomistic individuals whose interests—and records—can neatly be separated from those of their families. The prevailing (American) system of health insurance presupposes a view of fairness in which each individual should pay according to her risk. By highlighting the relational nature of all

[30] See Lisa N. Geller et al., "Individual, Family and Societal Dimensions of Genetic Discrimination: A Case Study Analysis," *Science and Engineering Ethics* 2 (1996) 71–88; also Susan Wolf, "Beyond 'Genetic Discrimination': Toward the Broader Harm of Geneticism," *Journal of Law, Medicine, and Ethics* 23 (1995) 345–53.

[31] Health Insurance Portability and Accountability Act of 1996, *U.S. Code* vol. 42, secs. 201 *et seq.*

[32] Americans with Disabilities Act of 1990, *U.S. Code* vol. 42, secs. 12101 *et seq.*

human beings, the Human Genome Project challenges such individualism at its core.

PATENTING

In order to be eligible for a patent, a product or a process must first of all be an invention, not merely a discovery of even a very complicated fact of nature. It is therefore impossible to patent genes, cells, or chemical processes, as they naturally occur, including in the human body. However, one can obtain a patent for purified or isolated biological materials, as well as the processes, tests, or procedures used to identify them.

The realm of patentable material now includes living matter, not because we relaxed the standards for patentability, but because human ingenuity has expanded to meet them. In 1980, the U.S. Supreme Court held that a patent could be issued for a bacteria strain that was genetically altered to break down oil.[33] In 1987, the U.S. Patent and Trademark Office (PTO) declared that genetically altered animals could be patented, clearing the way for the patenting of the Harvard "oncomouse" that was genetically altered to increase its susceptibility to cancer. Patents have also been issued for living matter stemming from human beings, such as genetically altered or isolated cell lines, and genes isolated through technical processes.[34] Europe is now moving in the same direction. In May 1998, it appeared that a 1995 moratorium imposed by the European Patent Office on patenting plant and animal life would be lifted, to follow a new European Union directive on biotechnological inventions that will also allow patents on isolated genes whose functions are known (but not on clones or manipulated human embryos).[35]

Many of the most pressing moral questions arising from patents on living material (particularly human genetic material or cell lines) involve important but nonetheless straightforward policy analysis.[36] Will allowing pat-

[33] *Diamond v. Chakrabarty,* 447 U.S. 303 (1980).

[34] The PTO has indicated that the Thirteenth Amendment to the Constitution would prohibit patenting transgenic human persons (but this prohibition would likely not apply to embryos); see Stephen F. Sherry, "The Incentive of Patents," in John F. Kilner, Rebecca D. Pentz, and Frank E. Young, ed., *Genetic Ethics* (Grand Rapids: Eerdmans, 1997) 113–23.

[35] Alison Abbott, "Europe's Life Patent Moratorium May Go," *Nature* 393 (21 May 1998) 200; "MEPS Give Formal Approval for Patenting Inventions," *European Report* (16 May 1998), available online through ⟨WESTLAW⟨ 1998 WL 8801930⟩. See also Darrell G. Dotson, "The European Controversy Over Genetic-Engineering Patents," *Houston Journal of International Law* 19 (Spring 1997) 919–1207.

[36] See David B. Resnik, "The Morality of Human Gene Patents," *Kennedy Institute of Ethics Journal* 7 (1997) 43–61.

ents on human genetic material advance or impede scientific progress?[37] Will patenting of human genetic material allow scientists in economically developed countries to exploit commercially the genetic material of populations in developing countries?[38] Will the gap between rich and poor be widened in every country, as biotechnology companies charge prohibitive prices for newly developed treatments?

However, the prospect of expansive patenting of living material and human genetic material also raises two more fundamental and elusive issues. First, should decisions to grant or deny a patent take into account the morality of the invention itself? American patent law has firmly separated morality from patentability, emphasizing that a patent confers upon its holder only a negative right to exclude others from using the invention for a period of time (now 20 years), not a positive right to use it oneself. Under this framework, it would be possible to patent an invention whose most likely uses would violate the law. In contrast, under European law patents can be denied to inventions that are against public morals.[39]

Is it wise to segregate one area of the law from broader moral considerations? Advocates of segregation point out that the legislature, not the PTO, is best equipped to decide whether to prohibit or regulate the use of inventions. However, although this fact may call for a certain amount of caution, it does not require the PTO to abjure moral evaluations entirely. Moreover, a segregationist approach ignores the fact that law works holistically to shape the moral imagination of a people; it is not restricted by the subject matter boundaries laid out by legal academics. The moral credibility of a government is eroded when it issues patents for inventions whose uses will clearly be inimical to the common good (e.g., if a government granted a patent for an instrument of torture while proclaiming human rights).

In the spring of 1998, the American PTO moved closer to the European model, when it refused to consider an application to patent a human-animal chimera because the invention violated public morals.[40] This move

[37] Rebecca Eisenberg, "Patents: Help or Hindrance to Technology Transfer," in Frederick B. Rudolph and Larry V. McIntyre, ed., *Biotechnology* (Joseph Henry, 1996) 161–74; Michele Svatos, "Biotechnology and the Utilitarian Argument for Patents," *Social Philosophy and Policy* 13:2 (1996) 113–44.

[38] Kara H. Ching, "Indigenous Self-Determination in an Age of Genetic Patenting: Recognizing an Emerging Human Rights Norm," *Fordham Law Review* 66 (1997) 687–730.

[39] European Patent Convention, Article 53(a), "Exceptions to Patentability," 13 *International Legal Materials* 268, 286 (1974).

[40] U.S. Patent and Trade Office Media Advisory, No. 98-6 (1 April 1998). The application was filed by Stuart A. Newman and Jeremy Rifkin to promote public debate; see Thomas D. Mays, "Biotech Incites Outcry," *National Law Journal* 20 (22 June 1998) C1.

is likely to be challenged as an erroneous application of the current statute, whose requirement of "usefulness" as a condition of patentability has not been interpreted as encompassing moral considerations. Consequently, Congress may well be forced to reconsider the wisdom of maintaining American patent law's longstanding distinction between the usefulness of an invention and its moral status, as well as the feasibility of a more holistic approach.

A second question pertains to what James Boyd White has called the "constitutive" function of the law, its ability to channel not only how we answer questions about matters pertaining to our common life, but how we ask questions in the first place. Patent law is designed to further the commercialization of human ingenuity. It contemplates that profit-seeking inventors will license their inventions to others, who in turn will use them to make a profit for themselves. Mark Hanson has shown that a key issue behind religious objections to patenting of life forms and genetic materials is how "commodification" will alter our understanding of them.[41] Will we begin to value human genes, and the traits they code for, in terms of their ability to meet the desires of the marketplace? Will not the market not only satisfy purchaser's desires with respect to improvements in human geneotypes, but also create and shape those desires?

Needless to say, the market affects how we understand and seek out other basic aspects of human existence, such as food, clothing, and shelter. However, a key difference is that we worked out a basic sense of the meaning and purpose of those goods prior to the explosion of commodification, which can be used as a check against the lures of the market.[42] In contrast, our understanding of the symbolic meaning of genetic material, and our practical responsibilities in light of our newfound knowledge of that material, will be forged in a frenzy of commercial distribution. In my view, that is the specter lurking in the inmost recesses of the controversy over the patenting of living materials.

In summary, the genetic revolution is a jurisprudential revolution as well as a scientific one. In order to deal adequately with topics such as cloning, genetic privacy, and patenting of the human genome, it will not be sufficient to extend the existing legal framework to encompass new possibilities in human genetics. Instead, it will be necessary to rethink the fundamental normative assumptions undergirding the way the law deals with the broader issues of human reproduction, medical confidentiality, and the relationship of medicine and the market. Essentially, it will be necessary to

[41] Mark J. Hanson, "Religious Voices in Biotechnology: The Case of Gene Patenting," *Hastings Center Report* 27 (1997) SS 1–21.

[42] M. Cathleen Kaveny, "Genetics and the Future of American Law and Policy," *Concilium* 225 (1998) 69–70.

counteract the multifaceted individualism that permeates the legal system in these areas, particularly in the U.S.

First, in order wisely to address the problem of cloning, the American legal system needs to abandon its tendency to see the decision to procreate as an individual's private act of self-realization, with no significant ramifications for the child, the immediate family structure, or the broader society, provided that the procedure used is physically safe and effective. Those who decide to procreate using somatic cell nuclear transfer do not redefine parenthood solely for themselves; they contribute to a radical shift in our common understanding of the nature and purpose of parent-child relationships. Second, in order to discern how we should protect highly sensitive genetic information, American law needs to recognize that embodied human persons are not isolated individuals, but members of clans with whom they share overlapping medical destinies. In developing a proper understanding of medical privacy, we can no longer draw on an outdated notion of medical information as relevant only to the person whose body was the source of that information. Third, in dealing with emerging issues of genetic patenting, we need to recognize the power of the market to shape the way we all view the persons and goods under its sway. The patent system is not simply a neutral tool for rewarding individual inventors and investors, which facilitates the distribution of goods without altering their essential meaning. By commodifying human genes, we may begin wrongly to reduce the worth of the persons who have those genes to their instrumental value in the marketplace. On all three of these issues, American law could learn much by studying the approaches of other countries, which seem to take more account of the common good in formulating public policy.

The challenge that genetics poses to the law is essentially moral in nature. It is an issue that is profitably addressed not only by those with technical expertise in the workings of the legal system, but also by theologians and philosophers equipped to think more broadly about the way human beings should order their lives together. In my view, it is an issue on which the Catholic tradition has much to contribute, largely because of its uncompromising recognition of both the equal dignity and the essentially social nature of human persons. For example, one way for Catholic thinkers to alter the debate would be to insist on framing the fundamental jurisprudential question in this way: What legal stance on cloning, genetic privacy, and gene patenting will give the virtue of solidarity the best chance of taking root and flourishing in the hearts of our neighbors and in our own hearts? If we are to be good stewards of some of the most powerful knowledge ever to have come into human possession, we must work out a sensitive and thoughtful answer to this question.