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Disease Management and Liability in the Human Genome Era

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Reuschlein Lecture

DISEASE MANAGEMENT AND LIABILITY IN THE HUMAN GENOME ERA

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I. INTRODUCTION

ON June 25, 2000, then President William Jefferson Clinton and Prime Minister Anthony Blair announced the identification of two-thirds of the approximately three billion "letters" that constitute the "genetic blueprint for human beings."[1] Although technically the announcement of this major scientific and technological milestone came from the international consortium on the Human Genome Project, these politicians were present because of the enormous promise of this international effort to understand the location and function of human genes.

President Clinton and Prime Minister Blair were also there to emphasize, to the dismay of some investors,[2] that after ten years of public and

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1. Press Release, The White House, Office of the Press Secretary, President Clinton Announces the Completion of the First Survey of the Entire Human Genome: Hails Public and Private Efforts Leading to this Historic Achievement (June 25, 2000), *available at* http://www.ornl.gov/hgmis/project/clinton1.html (last visited Nov. 5, 2000); *see also Cracking the Code*, WASH. POST, June 27, 2000, at C13 (sketching announcement briefly); Robert Cooke, *Genome Project: A Human Blueprint: Milestone for Humanity: 2 Research Teams Decode Human Genes, Unveiling New Possibilities for Medicine*, NEWSDAY, June 27, 2000, at D02 (summarizing some of initial findings and what they might mean to science).

2. *See Biotechnology Sector Ends Second Quarter on a High Note*, MARKETLETTER, July 17, 2000, *available at* 2000 WL 7542626, at *1 (commenting that the sector lost $100 billion in terms of market capitalization in a week after Clinton-Blair announcement); *Short Cuts: Genomics Firms Take Stock Hit on the News of Feat From Associated Press*, NEWSDAY, June 27, 2000, at A42 (noting that after Celera Genomics announced that it and government reached goal of assembling Human Genome, its stock plunged more than ten percent and that genomics stocks in general "took a beating yesterday"); Peter Gorner, *How Genes Interact Still a Puzzle*, CHI. TRIB., June 27, 2000, at 1-8 (noting that Venter, former NIH genome scientist who left his

private investment in "mapping" the Human Genome, the data would now be freely available via the Internet to scientists all over the world.[3] This political announcement ushered in the Human Genome Era, a period in which biomedical research will be dominated by the assumption that genetic knowledge will improve health care delivery and presumably overall health status—not only in this country, but throughout the world.[4]

The promises for human medicine are as wide as the imagination: increased longevity, new types of transplants, new drugs and new diagnostic tests and tools for the prevention of disease. Cystic fibrosis, certain forms of cancers and muscular dystrophy are already clearly on science's radar screen.[5] The rapidity of developments over the past few years suggests that we live in a time when the ethos of scientific progress—meaning growth in genetic data and knowledge—will dominate public discourse about the best ways to manage disease processes.[6]

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government position to found upstart biotech company Celera, was widely viewed as being forced into last-minute truce with government after his earlier announcement that he had completed sequence and would be providing it to subscribers).

3. *See* National Center for Biotechnology Information, *The Human Genome: A Guide to Online Information Resources* (providing draft, map and service to browse genome), *at* http://www.ncbi.nlm.nih.gov/genome/guide/human/ (last visited Nov. 5, 2001); *see also* Nature, Genome Gateway (providing comprehensive web resource devoted to genomics), *at* http://www.nature.com/genomics/ (last modified Nov. 5, 2001); *The Human Genome*, SCI., Feb. 16, 2001, at 1153 (explaining origin of sequencing project and how to access sequence data), *available at* http://www.sciencemag.org/content/vol291/issue5507/ (last visited Sept. 9, 2001); *Human Genome Project Information*, *at* http://www.ornl.gov/hgmis/ (last modified Oct. 31, 2001) (same); Andrew Denholm, *Battle Starts to Exploit the Commercial Potential*, SCOTSMAN, June 27, 2000, at 6 (noting that despite joint declaration by Bill Clinton and Tony Blair that human genome sequence must be freely available to all scientists, both US and UK administrations support gene patenting).

4. *See* Barbara Starfield, *Is US Health Really the Best in the World?*, JAMA, July 26, 2000, at 483 (noting difference between health status and health care delivery by reporting that of thirteen countries, United States ranked on average twelfth on sixteen available health indices despite having what one might call most technologically advanced healthcare delivery system in world).

5. *See, e.g.*, David G. Huntsman et al., *Early Gastric Cancer in Young, Asymptomatic Carriers of Germ-line E-Cadherin Mutations*, 344 NEW ENG. J. MED. 1904, 1904 (2001) (reporting new genetic approach to disease management); Jeffery N. Weitzel & Laurence E. McCahill, *The Power of Genetics to Target Surgical Prevention*, 344 NEW ENG. J. MED. 1942, 1942 (2001) (extolling Huntsman approach and, more generally, use of genetics to target cancer early). These operations were performed in both Canada and the United States, and although they were prophylactic in intent, their outcome was presumably curative. *See, e.g.*, Huntsman, *supra*, at 1904-06 (recommending genetic counseling and consideration of prophylactic gastrectomy in young, asymptomatic carriers of germ-line truncating e-cadherin (CDH1) mutations who belong to families with highly penetrant hereditary diffuse gastric cancer).

6. *See* LARRY I. PALMER, ENDINGS AND BEGINNINGS 3-18 (2000) (discussing ideology of linking practice of medicine with institutional science). The current political debate over whether to use federal funds to support research on the therapeutic potential of human stem cells is an example of the growing public interest. *See* NIH Director's Statement on Research Using Stem Cells, Department of Health and Human Services, National Institutes of Health (Dec. 1, 1999) (wel-

The Human Genome Era is a period in which we also will have to face up to the challenges of this technological achievement. Some of these challenges have already been documented: ensuring appropriate incentives for the development of useful products in health care and agriculture, protecting privacy, and preventing genetic discrimination.[7] Underneath these challenges lies a fear that an international scientific "gene rush" might lead to abuses of targeted ethnic or racial minorities—a fear captured by the term "Nazi Doctors."[8]

To assume that a set of legal doctrines, statutory formulations or regulatory regimes exist that would simultaneously meet these challenges and fulfill the promises of the Human Genome Project might be comforting. Despite the mountain of written commentary on many aspects of this scientific and technological achievement in both legal and popular literature, however, no coherent framework exists.[9] I suggest we begin building

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coming public comment on stem cell research guidelines), *at* www.nih.gov/news/stemcell/draftguidelines.htm (last visited Sept. 9, 2001).

7. *See, e.g.*, Janet L. Dolgin, *Personhood, Discrimination, and the New Genetics*, 66 BROOK. L. REV. 755, 763-98 (2000) (exploring ramifications for meanings of familial, ethnic and racial groups due to widespread availability of genetic information). *See generally* George J. Annas, *The Man on the Moon, Immortality, and Other Millennial Myths: The Prospects and Perils of Human Genetic Engineering*, 49 EMORY L.J. 753 (2000) (discussing possible place of genetic engineering in history as well as new issues that genetic engineering raises); June Mary Z. Makdisi, *Genetic Privacy: New Intrusion a New Tort?*, 34 CREIGHTON L. REV. 965 (2001) (discussing privacy issues created by possibility of new information made available by Human Genome); Mazwell J. Mehlman, *How Will We Regulate Genetic Enhancement?*, 34 WAKE FOREST L. REV. 671 (1999) (discussing effects that genetic enhancement could have on personal autonomy, social inequality and medical care).

8. Jeffery H. Barker, *Human Experimentation and the Double Facelessness of a Merciless Epoch*, 25 N.Y.U. REV. L. & SOC. CHANGE 603, 604-05 (1999) (recounting Nuremberg Trial of head Nazi doctor Karl Brandt before exploring medical ethics and philosophy behind human experimentation). *See generally* Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7 (1993) (accounting many atrocities related to human subjects research as result of conflicting commitments in doctors' caring for patients and searching for knowledge).

9. *See, e.g.*, Thomas Lizzi, *From Benevolent Administration to Government Employee Interventions, Human Genomes and Exclusive Licensing: Is Governmental Ownership of Patents Constitutional?*, 34 DUQ. L. REV. 299, 323-24 (1996) (concluding that governmental ownership of patents of its own issue is both unconstitutional and improper); Helena Gail Rubinstein, *If I Am Only for Myself, What Am I?: A Communitarian Look at the Privacy Stalemate*, 25 AM. J.L. & MED. 203, 206 (1999) (suggesting that Congress look to communitarian principles in order to resolve stalemate between privacy advocates and data users); Michael H. Shapiro, *The Technology of Perfection: Performance Enhancement and the Control of Attributes*, 65 CAL. L. REV. 11, 15-19 (1991) (defining trait alteration and other aspects of human enhancement and trait change); Michael S. Yesley, *Protecting Genetic Difference*, 13 BERKLEY TECH. L.J. 653, 659-63 (1998) (discussing impediments to creation of effective legislation to combat genetic discrimination). *See generally* Charles N. Aswad, *Views of Cloning from a Physician's Perspective*, 4 N.Y.U. J. LEGIS. & PUB. POL'Y 59 (2000) (briefly describing advantages and disadvantages of cloning); Kristie A. Deyerle, *Genetic Testing in the Workplace: Employer Dream, Employee Nightmare—Legislation Regulation in the United States and the Federal Republic of Germany*, 18 COMP. LAB. L.J. 547 (1997) (addressing then existing methods employers used to gain genetic

such a framework using an old fashioned methodology: a case which raises, but does not necessarily resolve, a number of the fundamental issues concerning how legal institutions should respond to modern medicine's methods of managing disease processes.

Greenberg v. Miami Children's Hospital Research Institute, Inc.[10] was filed in October 2000, less than six months after the announcement of the Human Genome's completion.[11] The plaintiffs, donors of human materials and tissue, allege that the defendants, a physician/scientist and a hospital, had a duty to disclose their intention to patent the gene and diagnostic test for Canavan disease, a progressive and fatal genetic central nervous system disorder.[12] I discuss in Part II of this Lecture whether the plaintiffs have stated a cause of action against the health care providers who patented products developed from their extracted genetic information.[13]

In Part III, I argue that determining the liability of the defendants in *Greenberg* requires an integration of two different perspectives on how health providers should manage human disease.[14] From the perspective of medicine, the first step in the management of genetic disease involves the screening of individuals to determine whether they carry the gene that causes the disorder. From the perspective of law, the first step in a court's analysis of disease management in the Human Genome Era is to deter-

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information about job applicants and employees and reasons that employers gave for using such information to screen individuals); Mark Christopher Farrell, *Designer DNA for Humans: Biotech Patent Law Made Interesting for the Average Lawyer*, 35 GONZ. L. REV. 515 (2000) (providing overview of basic terminology and property rights in relation to human genome); Peter H. Huang, *Herd Behavior in Designer Genes*, 34 WAKE FOREST L. REV. 639 (1999) (discussing economic perspectives related to ethical, legal and social issues at stake in using genetic technologies for trait enhancement selection); Eydith J. Kaufman, *Hitler on the Horizon: An Analysis of Germ-Line Genetic Therapy*, 3 U.S.F. J.L. & SOC. CHALLENGES 1 (1999) (describing gene therapy and constitutional issues involving germ line therapy); Sophia Kolehmainen, *Human Cloning: Brave New Mistake*, 27 HOFSTRA L. REV. 557 (1999) (discussing controversy created by possibility of cloning); Anne Lawton, *Regulating Genetic Destiny: A Comparative Study of Legal Constraints in Europe and the United States*, 11 EMORY INT'L L. REV. 365 (1997) (comparing United States and European treatment of issues related to human genome); Susan P. Pauker, *Clinical Commentary: The Challenges of Genetic Medicine to the Patient-Physician Relationship*, 26 J.L. MED. & ETHICS 221 (1998) (discussing unique aspects of genetic information and related physician liability); Gail Rogers, *Yin and Yang: The Eugenics Policies of the United States and China: Is the Analysis that Black and White?*, 22 HOUS. J. INT'L L. 129 (1999) (discussing sterilization practices in United States and China and noting permissive policies in United States which may implicitly endorse eugenic practices).

10. Complaint (N.D. Ill. Oct. 30, 2000) (No. 00-CV-6779).

11. *See* Complaint ¶ 1, *Greenberg* (No. 00-CV-6779) (alleging "breach of informed consent, breach of fiduciary duty, unjust enrichment, fraudulent concealment, conversion, and misappropriation of trade secrets").

12. *See id.* ¶¶ 33-39 (stating allegations of lack of informed consent).

13. For a discussion of whether the Canavan Disease Case plaintiffs have stated a valid cause of action, see *infra* notes 28-56 and accompanying text.

14. For a discussion of the integration of perspectives on how health care providers should manage human disease, see *infra* notes 57-98 and accompanying text.

mine the effect of denying a couple's right to choose *not* to procreate or a woman's right to choose "eugenic abortion."[15] To integrate the two perspectives, the court in *Greenberg* should rely upon an earlier line of cases involving the failure of health care providers to offer genetic tests to prospective parents and pregnant women.[16] This analysis of court developed doctrine illustrates first that liability claims against health care providers are a special branch of tort law captured by the term "medical malpractice."[17] This analysis also illustrates that claims involving genetic information are relatively novel aspects of medical liability doctrine.

For the plaintiffs in *Greenberg* to succeed, an explication of the different duties to disclose information in therapeutic and research settings is needed—a theory of liability based on the need for information flow in the Human Genome Era.[18] Genetic approaches to disease management should, as I demonstrate in Part IV,[19] transform one important aspect of the medical liability system: duties of disclosure will be imposed by liability rules rather than contract terms.[20]

Moore v. Regents of the University of California,[21] a case in which the California Supreme Court established a physician's duty to disclose his research and financial interest in a patient's DNA, is certainly relevant to whether the defendants in *Greenberg* had a legal duty to disclose their intentions to patent the gene for Canavan disease. Nevertheless, although

15. *See* Gleitman v. Cosgrove, 227 A.2d 689, 694 (N.J. 1967) (Francis, J., concurring) (originating term "eugenic abortion"). "Eugenic abortion" refers to abortion intended solely to eliminate a potentially defective fetus, and is used to differentiate that form of abortion from "therapeutic abortion," which is an abortion performed to protect a woman's health. *See* Hummel v. Reiss, 608 A.2d 1341, 1343 (N.J. 1992) (citing lower court opinion defining "eugenic" versus "therapuetic" abortion).

16. For a further discussion of cases bringing actions for "wrongful life" or "wrongful birth," see Lori B. Andrews, *Torts and the Double Helix: Malpractice Liability for Failure to Warn of Genetic Risks*, 29 HOUS. L. REV. 149, 150-61 (1992) (analyzing history and future of "wrongful birth" and "wrongful life" cases where liability hinged on failure to test for or warn about genetic risk). *See generally* Carolyn Lee Brown, *Genetic Malpractice: Avoiding Liability*, 54 U. CIN. L. REV. 857 (1986) (discussing perils of genetic counseling); Janet L. Tucker, *Wrongful Life: A New Generation*, 27 J. FAM. L. 673 (1989) (covering "wrongful life" cases, which she defines as "an action brought by or on behalf of an infant born with genetic defects").

17. *See* CLARK C. HAVIGHURST ET AL., HEALTH CARE LAW AND POLICY 923 (2d ed. 1998) (noting that medical practice is governed by "well-established principles of the common-law tort system").

18. *See* Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157, 165-68 (1998) (arguing that failing to recognize that subjects who volunteer for sake of advancement of science are differently situated from patients who stand to benefit from treatment results in analysis that misconceives purpose of disclosure).

19. For a discussion of basing disclosure duties on liability rules as opposed to contract terms, see *infra* notes 99-116 and accompanying text.

20. *But see generally* Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899 (1994) (discussing different manifestations of informed consent doctrine and advocating contractual view of medical liability).

21. 793 P.2d 479 (Cal. 1990).

Moore is often discussed in the legal literature,[22] it is seldom cited favorably by other courts.[23]

Because judges rely upon precedent in deciding cases, the paucity of case law directly supporting the plaintiffs claim means they have an uphill battle in getting past the motion to dismiss.[24] Accordingly, Part V presents

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22. *See, e.g.*, Mary Taylor Danforth, *Cells, Sales, and Royalties: The Patient's Right to a Portion of the Profits*, 6 YALE L. & POL'Y REV. 179, 198-201 (1988) (using facts of *Moore* to show that bioengineering research subjects should be insured with licensing agreements); Thomas P. Dillon, *Source Compensation and Cells Used in Biotechnical Research: Why a Source Shouldn't Share in the Profits*, 64 NOTRE DAME L. REV. 628, 629-36 (1989) (asserting that appeals court decision in *Moore* improperly recognized body part property right); Roy Hardiman, *Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue*, 34 UCLA L. REV. 207, 213 (1986) (discussing *Moore* as then pending case and predicting that *Moore* would set a "valuable precedent" for patient-property rights cases); Erik B. Seeney, Moore *10 Years Later—Still Trying to Fill the Gap: Creating a Personal Property Right in Genetic Material*, 32 NEW ENG. L. REV. 1131, 1133 (1998) (arguing that despite holding in *Moore*, one should have sufficient property rights in one's body); Michael M. J. Lin, Note, *Conferring a Federal Property Right in Genetic Material: Stepping into the Future with the Genetic Privacy Act*, 22 AM. J.L. & MED. 109, 110-18, 130 (1996) (discussing *Moore* and its impact, and noting that because of "concentration of the biotechnology industry on the west coast," few opinions will likely contradict this California Supreme Court decision).

23. Only one line of cases seems to view *Moore* positively, citing it to argue that courts should look to statutory law rather than to other forms of law such as conversion and contract when dealing with human biological materials. *See* Perry v. St. Francis Hosp. & Med. Ctr., Inc., 886 F. Supp. 1551, 1563 n.7 (D. Kan. 1995) (finding contract approach inapplicable when deceased patient's family members claimed that hospital removed decedent's eyes and major bones when family only consented to removal of corneas and bone marrow); Wilson v. Adkins, 941 S.W.2d 440, 442 (Ark. Ct. App. 1997) (finding that no cause of action existed for breach of agreement to donate bone marrow in exchange for $101,500); Cornelio v. Stamford Hosp., 1997 WL 430619, at *5-7 (Conn. Super. 1997) (explicitly following *Moore* in refusing to find that plaintiff had proprietary interest in her pap smear slides). Other lines of cases citing *Moore* refused to extend, differentiate, or reject its holding, and included cases involving research and cell lines. *See* United States v. Arora, 860 F. Supp. 1091, 1098-99 (D. Md. 1994) (differentiating *Moore* from case in which researcher at government facility who tampered with and caused death of samples of new research cell line); Miles, Inc. v. Scripps Clinic & Research Found., 810 F. Supp. 1091, 1095-99 (S.D. Cal. 1993) (noting that unlike *Moore*, instant case involved pharmaceutical company's right to commercialize line rather than right to cell line itself but that *Moore* decision still prevented cause of action because it was essentially breach of contract or patent law claim against co-developer of line, neither of which covered alleged violation).

24. *See* Richard A. Posner, *The Problematics of Moral and Legal Theory*, 111 HARV. L. REV. 1637, 1639 (1998) (emphasizing that moral theory cannot be primary basis for decision). Although Posner's argument is not anti-moral theory, it suggests that judges should use a greater degree of empirical analysis in their decision-making processes. *See id.* at 1649, 1693-1709 (discussing examples of cases that create moral dilemmas). The choice of social goals or values is insufficient to be definitive concerning law and public policy either descriptively or prescriptively. Instead, institutional choice must be considered in order to understand law and public policy. *See generally* Larry I. Palmer, *Life, Death and Public Policy*, 81 CORNELL L. REV. 161 (1995) (reviewing and applying theories described in NEIL K. KOMESAR, IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC

three fundamental questions, which should determine *Greenberg*'s ultimate outcome in the appellate courts:

1. Are the liability rules regarding disclosure different in therapeutic and research settings?
2. Does the so-called "Nuremberg Code" provide a basis for expanding the duty of researchers to disclose their intentions regarding patenting?
3. Should courts use liability rules to impose a duty to disclose information that might not be required by federal regulations?[25]

Without discussing a theory of damages or other remedies, I will argue that the plaintiffs ought to survive the motion to dismiss.[26] My thesis is that liability law can operate as a limited constraint on our patent law system, which is now desperately trying to support and regulate a frenetic search for gene-based cures and therapies.[27] The constraint imposed by the liability system that I am proposing will not inhibit the granting or pursuing of gene-based patents. Rather, it will simply provide an incentive for those researchers who move beyond the electronic "map" of the Human Genome to disclose their commercial intentions to the human beings that they "use" in their pursuit of knowledge.

POLICY (1994), who argues that what passes for social analysis of problem, particularly when issue is something like protecting value of autonomy, is based on premise that some institutional processes are faulty).

25. For a discussion of how the three questions underlying the liability of the defendants in *Greenberg* should be answered by the court, see *infra* notes 117-62 and accompanying text.

26. *See, e.g.*, Bradshaw v. Daniel, 854 S.W.2d 865, 869-73 (Tenn. 1993) (holding that physician-patient relationship is not necessary for maintenance of negligence action for breach of duty to warn of risk). Plaintiff, the son of the wife of the defendant physician's patient, who had Rocky Mountain Spotted Fever, brought a negligence action arising from his mother's death. *See id.* at 867 (stating facts). Most important, although Rocky Mountain Spotted Fever was not contagious, the court imputed the defendant physician with scientific knowledge of the disease. *See id.* at 872-73 (holding that physician has duty to warn in exercise of reasonable care). The court used duty analysis to impose the burden of informing the family member, a third party to whom the physician did not owe a fiduciary duty, of the risks of her exposure to the disease. *See id.* at 872-73 (concluding that existence of physician-patient relationship is sufficient to impose affirmative duty to warn identifiable third persons in patient's immediate family).

27. *See* Rebecca S. Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783, 794-800 (2000) (discussing lack of clarity regarding how patent law applies to genetic discoveries and stating that patent law is better suited for world of "bricks and mortar"). *See generally* John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101 (2001) (illustrating problems that patent law system faces concerning genes and similar biotechnological innovations).

II. THE CANAVAN DISEASE CASE:[28] *GREENBERG V. MIAMI CHILDREN'S HOSPITAL RESEARCH INSTITUTE, INC.*

Canavan disease is a rare neurological disorder that leads to brain degeneration and results in mental retardation, loss of motor skills and other difficulties.[29] The symptoms of Canavan disease become noticeable in early infancy, and death usually occurs before a child reaches ten years of age.[30] The lack of a certain enzyme, aspartoacylase, is now known to cause the disease.[31] If both parents carry the recessive gene—the result of a mutation some time in the past—their children have a one in four chance of being born with the disease.[32] Canavan disease is one of a group of genetic—in common parlance, inherited—disorders that affect the growth of nerve fibers in the brain and has some relation to the better known Tay-Sachs disease. Canavan disease affects persons of Eastern European Jewish ancestry more frequently than members of other ethnic groups.[33]

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28. Although my discussion focuses on the resolution of the motion to dismiss in *Greenberg*, the case is about a great deal more than the narrow legal issue discussed here. As a "case" it is also about the nature of scientific discovery, how "volunteers" are recruited in the Human Genome Era and much more. As this case develops both inside and outside of the courts, it could become a seminal tool for teaching about the interface of law and genomics. For a discussion about how an early case of human experimentation performed a similar pedagogical function, see JAY KATZ ET AL., EXPERIMENTATION WITH HUMAN BEINGS: THE AUTHORITY OF THE INVESTIGATOR, SUBJECT, PROFESSIONS, AND STATE IN THE HUMAN EXPERIMENTATION PROCESS 9-65 (1972) (performing early human experimentation pedagogical function by discussing Jewish Chronic Disease Hospital case) (reviewed by Larry I. Palmer, *The High Priests Questioned or at Least Cross-Examined*, 5 RUTGERS-CAM. L.J. 237 (1974)).

29. For a detailed discussion of Canavan disease, see generally Reuben Matalon et al., *Canavan Disease: From Spongy Degeneration to Molecular Analysis*, 127 J. PEDIATRICS 511 (1995) (discussing in detail causes, diagnoses, studies and individual cases of Canavan disease).

30. *See id.* (tracing clinical manifestations of Canavan disease).

31. *See* Rajinder Kaul et al., *Canavan Disease: Mutations Among Jewish and Non-Jewish Patients*, 55 AM. J. HUM. GENETICS 34, 34 (1994) (detailing mutations that were identified in aspartoacylase gene).

32. *See* National Tay-Sachs & Allied Disease Association, Inc., *What Every Family Should Know: Canavan Disease* (defining and explaining Canavan disease), *at* http://www.ntsad.org/ntsad/canavan.htm (last modified June 22, 1998). In scientific terms, Canavan disease is an autosomal recessive disorder. *See id.* Sickle Cell Anemia is another example of an autosomal recessive disorder, which means that with both disorders, if both parents carry the gene responsible for the disorder, their children will be: (1) homozygous unaffected, or without the disease and without carrier status; (2) homozygous affected, or with the disease; or (3) carriers, or inherit one affected gene. *See* Kangpu Xu et al., *First Unaffected Pregnancy Using Preimplantations Genetic Diagnosis for Sickle Cell Anemia*, JAMA, May 12, 1999, at 1703-04 (explaining autosomal recessive disorders and risk of inheriting Sickle Cell Anemia).

33. *See* National Institute of Neurological Disorders and Stroke, *NINDS Canavan Disease Information Page* (noting tendency of Eastern European Jewish people to be affected), *at* http://www.ninds.nih.gov/health_and_medical/disorders/canavn_doc.htm (last visited July 1, 2001). *But see* Rachel Myerowitz & Norman D.

With no "cure" for Canavan disease at present, the short-term goal of disease management is to treat the affected child's symptoms and to be supportive of the child and his or her parents.[34] The long-term goal, as with other genetic disorders, is one of "prevention." With genetic disorders, the first tool of prevention is to identify the gene that causes the disease. This requires access to human beings who might possess the genetic trait associated with Canavan disease.[35]

Hogikyan, *Different Mutations in Ashkenazi Jewish and Non-Jewish French Canadians with Tay-Sachs Disease*, SCI., June 27, 1986, at 1646 (noting that incidence rate of Tay-Sachs disease in French Canadians located in eastern Quebec is at least equal to incidence rate in Ashkenazi Jews).

34. *See generally Parents' Plea Illustrates Gene Therapy Dilemma*, GENE THERAPY WEEKLY, Mar. 23, 2000, *available at* 2000 WL 11696003, at *1 (noting that researchers searching for new treatments at Thomas Jefferson University in Philadelphia are applying for permission to start new trial using virus to carry new copies of apartoacyclase gene into Canavan disease patients' brains); *see also* Charles W. Henderson, *Disease Brain Gene Therapy Begins for Illinois Girl*, WORLD DISEASE WKLY. PLUS, April 6, 1998, at 1 (describing Canavan disease symptoms as including "mental retardation, loss of acquired motor skills, abnormal muscle tone, an abnormally large head, paralysis, blindness and deafness," and then death by age five to seven). Gene therapy has already been attempted for Canavan Disease. *See Parents' Plea Illustrates Gene Therapy Dilemma*, *supra*, at *1 (explaining that initial therapy used liposome to carry the new gene into an affected brain). Parents of a child who received treatment remarked that the treatment was initially very effective, although it gradually wore off. *See id.* (noting that each treatment showed marked changes in brain).

35. *See* Dolgin, *supra* note 7, at 786-98 (introducing some social and ethical dilemmas that genetic research presents for ethnic groups). Professor Dolgin reports that:

> Jews have participated enthusiastically in a wide variety of genetic screening and research programs. Encouraged to do so by researchers seeking subjects from communities presumed to be more homogenous genetically than the population as a whole, and perhaps also—as several commentators have suggested—by their own traditional interest in science and research. More recently, however, leaders of Jewish organizations, as well as Jewish scientists and researchers, have begun to question whether the disadvantages of communal participation in such research and screening projects may be greater than the advantages. Jewish participation in genetic screening and research efforts has resulted in more genetic information about Jews than about any other groups. And that information may entail a series of interconnected dangers for Jewish communities.

Id. at 789-90. Other articles also discuss genetic research and the Jewish population. *See, e.g.*, P. Tonin et al., *Frequency of Recurrent BRCA1 and BRCA2 Mutations in Ashkenazi Jewish Breast Cancer Families*, 2 NAT. MED. 1179, 1179-83 (1996) (studying correlation between presence of particular gene mutations and breast-ovarian cancer syndrome in Jewish families); Judy Garber, *A 40-Year-Old Woman with a Strong Family History of Breast Cancer*, JAMA, Nov. 24, 1999, at 1958 (noting that test for breast cancer costs $475 for Jewish woman as compared to $2,400 for non-Jewish woman and that price difference is due to greater knowledge of cancer in relation to Jewish population). A listing and description of genetic disorders that have been identified in the Jewish community is maintained by the Jewish Genetic Disorders Program at Children's Memorial Hospital, which was established with the support of the Michael Reese Health Trust. *See Center for Jewish Genetics Disorders*

The primary plaintiffs in this case are a group of parents whose children either have Canavan disease or have died from it.[36] These plaintiffs claim that in 1987 Daniel Greenberg, the father of two children with Canavan disease, approached the defendant physician, Dr. Reuben Matalon, introduced him to the rare disease and asked him to begin searching for the gene.[37] Plaintiffs claim that Dr. Matalon had no special knowledge concerning the disease and that their initiative was the sole cause of his research endeavor.[38] The plaintiffs allege that over the next seven years they provided the defendant and his research team with tissue samples from their dead children's autopsied bodies, blood from themselves and other family data.[39] Furthermore, along with the non-profit organizational plaintiffs—the Canavan Foundation, National Tay-Sachs and Allied Disease Association, and Dor Yeshorim, a group providing screening and counseling services to members of the Jewish community—these parents claim that they helped the defendant and his research team collect data and body tissue, blood and other samples from families afflicted with Canavan disease from around the world.[40]

As a result of their assistance, the defendants were able to develop tests to determine if a fetus has a genetic structure that indicates the eventual presence of the disease and if prospective parents carry the recessive gene for Canavan disease.[41] In 1994, the defendant physician filed for a patent on the gene and diagnostic test for Canavan disease.[42] Although

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(providing links to information about various diseases common among Jewish community), *at* http://www.jewishgenetics.org/ (last visited Sept. 9, 2001).

36. *See* Complaint ¶¶ 4-7, Greenberg v. Miami Children's Hosp. Research Inst., Inc. (N.D. Ill. Oct. 30, 2000) (No. 00-CV-6779) (naming plaintiffs as four parents of Canavan disease afflicted children, five of whom have died and none of whom is still living).

37. *See id.* ¶ 15 (alleging that purpose of approaching Dr. Matalon was so that "doctors everywhere could offer carrier and prenatal testing for the disease").

38. *See* Peter Gorner, *Parents Suing over Patenting of Genetic Test: They Say the Researchers They Assisted Are Trying to Profit from a Test for a Rare Disease,* CHI. TRIB., Nov. 19, 2000, at C1 (noting that there were number of researchers who had capability to go ahead and do research). The Matalon group had no special skills or knowledge—in fact, they applied for funding from the National Institutes of Health (NIH), but did not receive it because they had no track record in gene research. *See id.* (noting three-step process used in determining who receives federal funding for research).

39. *See* Complaint ¶¶ 17-21, *Greenberg* (No. 00-CV-6779) (alleging that samples and confidential information provided based on understanding that the research would "benefit the population at large").

40. *See id.* ¶¶ 18-19 (alleging that worldwide collection effort included creation of "international Canavan Registry").

41. *See id.* ¶¶ 25-28 (alleging that Dr. Matalon and his research team "isolated the Canavan disease gene in 1993").

42. *See* U.S. Patent No. 5,679,635 (issued Oct. 21, 1997), *available at* http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1='5,679,635'.WKU.&OS=PN/5,679,635&RS=PN/5,679,635 (patenting Canavan disease diagnostic test) (last visited Nov. 5, 2001). The patent is certainly broader than the test and the claims for

we might have expected researchers and disease-specific advocacy groups to be jubilant at the prospect of an effective screening device and the hope of more effective treatments for children born with this disease, we are now clearly in a period where the control of any fragment of genetic data is a potential source of economic return.[43]

Shortly after the patent was granted in 1997, the defendants started notifying testing centers, including those of the organizational plaintiffs, of their intentions to vigorously defend their "intellectual property rights."[44] The hospital's purpose in limiting access to the test was to make the licensing rights more attractive to potential commercial partners.[45] This move prompted an organizational plaintiffs' member to call *Greenberg* "the ultimate nightmare of how a gene patent can be used against the very families who made possible the discovery of the gene."[46]

The lawsuit against the physician/scientist and the assignee of the patent, a university-owned hospital, is based on what I will call a breach of

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genetic therapy, etc., because patent law, unlike copyright law, does not allow others to use patented material. *See* Mathew G. Wells, Note, *Internet Business Method Patent Policy*, 87 VA. L. REV. 729, 735 (2001) (explaining that exclusive use of patented invention for seventeen years is price federal government is willing to pay for economic benefit of disclosure of invention to public). Commentators argue over the varying degrees to which the patent law system inhibits the development of more effective or new cures and treatments that could have been developed from a cell line but for the patent. *See, e.g.*, Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1182-87, 1198-1211 (2000) (discussing inability of current patent law to deal with science and technology investment in research and "naturally fluid" discovery of information); *see also* National Institutes of Health, *Bioethics Resources on the Web: Gene Patenting*, *at* http://www.nih.gov/sigs/bioethics/genepatenting.html (reporting several discussions on genetic patenting) (last modified Jan. 1, 2001).

43. *See generally* Sheldon Krimsky, *The Profit of Scientific Discovery and Its Normative Implications*, 75 CHI.-KENT L. REV. 15 (1999) (providing narrative of biotechnology patents' development into profitable industry).

44. *See generally* Letter filed with Complaint, Greenberg v. Miami Children's Hosp. Research Inst., Inc. (N.D. Ill. Oct. 30, 2000) (No. 00-CV-6779) (announcing plaintiffs' intentions to protect their rights).

45. *See* Gorner, *supra* note 38, at C1 (explaining that intent of restriction was to "recoup the millions . . . spent to discover the gene"). The defendant hospital in the Canavan Disease Case claimed that it hoped to attract one large company to do all the testing by granting it an exclusive license. *See id.* (explaining that widespread testing would eventually result as word got out). Therefore, the hospital began informing institutions that were performing the Canavan disease test that it would cost $25 per test in addition to a licensing fee. *See id.* (noting that fee was part of hospital's campaign to enforce its patent). It later lowered the cost per test to $12.50. *See id.* (noting slight easing of fee); *see also* Margaret Graham Tebo, *The Big Gene Profit Machine*, 87 A.B.A. J. 46 (2001) (discussing profitability of gene patents and other issues surrounding scientists and corporations that profit from gene research).

46. Gorner, *supra* note 38, at C1 (quoting Judith Tsipis, professor of biology at Brandeis University and vice-president of National Tay-Sachs and Allied Disease Association).

covenant, not a breach of promise.[47] The individual and organizational plaintiffs allege that they not only supplied tissue, blood, urine, autopsy information and money for research to the physician/scientist, but that they did so with the *implicit* understanding that the physician/scientist shared their goal of developing an affordable and accessible diagnostic test "modeled after the Tay-Sachs Testing" program, which apparently means active cooperation with researchers and eventually "free" screening and testing.[48]

A critical part of the plaintiffs' complaint turns on the timing and manner of taking informed consent. Prior to 1994, the plaintiffs allege that the defendants did not request a written informed consent when obtaining samples.[49] This lack of written consent adds support to their claim that they and the members of the affected community formed a "partnership" with researchers to search for effective tools of genetic screening. When a written consent form was presented, it stated that the purpose of the research was to "identify mutations in the Canavan gene which may lead to carrier detection in my family."[50] The plaintiffs argue that this statement comports with their reasonable assumption that the test derived from their genetic materials would not be commercially exploited.[51]

Plaintiffs also argue that the statement supports their assumption that the "Tay Sachs model" was operative.[52] That the United States government holds the Tay-Sachs patent because a researcher at the National Institutes of Health discovered the gene and its associated diagnostic test is worth noting.[53] The federal government's ownership of the patent helps

47. Breach of a promise implies that their agreement was contractual in nature, which creates problematic connotations. *See* LARRY I. PALMER, LAW, MEDICINE AND SOCIAL JUSTICE 34-38 (1989) (arguing that contractual law takes autonomy of patient too far because it creates physician-patient relationship that is both minimalist and maximalist and encourages individuals to concentrate solely on their self-interests in matters of health). The term breach of covenant is appropriate because the relationship between the parties was not contractual. *See generally* Ralph Cranshaw et al., *Patient-Physician Covenant*, JAMA, May 17, 1995, at 1553 (asserting that physicians are intellectually and morally obliged to advocate for sick). *But see* Schuck, *supra* note 20, at 956-59 (advocating more contractual view of informed consent).

48. *See* Complaint ¶¶ 22-23, *Greenberg* (No. 00-CV-6779) (alleging that plaintiff Greenberg first approached Dr. Matalon at Tay-Sachs community screening event).

49. *See id.* ¶ 37 (alleging that in addition to no consent forms before 1994, consent forms provided after 1994 were deficient).

50. *Id.*

51. *See id.* ¶¶ 38-39 (alleging that if research team's true intentions were known, plaintiffs would not have participated).

52. *See id.* (requesting permanent injunction against defendants requiring them to refrain from enforcing their patent).

53. *See* U.S. Patent No. 5,679,635 (issued Oct. 21, 1997), *available at* http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1='5,679,635'.WKU.&OS=PN/5,679,635&RS=PN/5,679,635 (awarding patent for Tay-Sachs disease gene screening test).

guarantee that the Tay-Sachs disease test is both inexpensive and widely available.[54]

The defendants' pending motion to dismiss essentially alleges that the duty of disclosure is limited to the doctor-patient relationship and does not govern the researcher-subject relationship.[55] As a consequence, the defendants have asked the court to rule on whether physician/scientists who engage in genetic research have a duty to disclose their intentions to patent their discovery to those who volunteer to be human subjects.[56] The plaintiffs must get past this motion to dismiss in order to explain to the court what they mean by the "Tay-Sachs model."

III. LEGAL THEORY UNDERLYING THE CANAVAN DISEASE CASE

The legal theory underlying the *Greenberg* plaintiffs' complaint is that the physician/scientist was obliged to disclose his intention to seek a patent and commercialize the discovery of the gene for Canavan disease, both before and after he had filed for the patent. Without determining whether the defendants' or the plaintiffs' characterization of the issue is correct, we should realize that the Canavan Disease Case is not the first time liability law has encountered issues related to genetic disease. A judge ruling on a motion to dismiss needs to consider what lessons can be derived from examining the earlier cases dealing with Tay-Sachs and other genetic disorders and conditions.[57]

A. *The Standard of Care for Genetic Disease*

Over twenty-five years ago, parents of children born with Tay-Sachs and Down Syndrome sued physicians for failing to warn them of the risk of bearing children with the disorders.[58] These "duty to disclose genetic in-

54. *See* Gorner, *supra* note 38, at C1 (noting that test for cystic fibrosis was explicitly limited by its inventor to two dollars per test and that test for breast cancer can run up to $2,850 per test). Gorner states that one in four laboratories have stopped performing certain genetic tests because of patent restrictions or excessive costs. *See id.* (noting that University of Pennsylvania, among other laboratories, was unhappy with situation); *see also* Krimsky, *supra* note 43, at 37 (contrasting Tay-Sachs disease patent, which is held by Department of Health and Human Services and costs only about $100 per test, with screening test for two breast cancer genes which is held by Myriad Genetics and costs $2,400 per test).

55. *See* Miami Children's Hospital's Motion to Dismiss at 8-9, *Greenberg* (No. 00-CV-6779) (arguing that informed consent covers only research itself and not results of research).

56. *See id.* at 11 (arguing that imposing duty to disclose intentions to research subjects would bring medical research to halt).

57. *See* Michael J. Malinowski, *Coming into Being: Law, Ethics, and the Practice of Prenatal Genetic Screening*, 45 HASTINGS L.J. 1435, 1469-79 (1994) (presenting stories of person working for genetics lab, family that chose to abort their genetically defective fetus and family living with genetically defective child).

58. *See* Berman v. Allan, 404 A.2d 8, 14 (N.J. 1979) (sustaining cause of action for wrongful birth of child with Down's Syndrome). Conditions prompting suits for wrongful birth and wrongful life include Down Syndrome, congenital rubella

formation" cases first reached the courts in the context of causes of action for "wrongful birth" and "wrongful life."[59] The only difference between these causes of action is that the defective child's parents bring wrongful birth claims, while the child or the child's representative brings a claim for wrongful life.

Currently, a majority of states recognize claims for wrongful birth,[60] while only a few states recognize claims for wrongful life.[61] These causes of action are not premised on the assumption that the physician caused the infant's defect. Rather, most courts recognize that they are based on the parents' right to make an informed decision concerning their procreative rights.[62]

Two cases illustrate the theory of liability used by various courts to protect the central role of the parents' rights in deciding whether to bear a child with a genetic disease. Consider first a 1981 case, *Schroeder v.*

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syndrome, spina bifida, Tay–Sachs disease, cystic fibrosis, sickle cell anemia, Larsen syndrome, retinoblastoma and Hemophilia B. *See* Jeffery R. Botkin, *Reproduction, Law, Wrongful Birth, and Wrongful Life Actions*, in 2 ENCYCLOPEDIA OF ETHICAL, LEGAL, AND POLICY ISSUES IN BIOTECHNOLOGY 996, 997 (Thomas H. Murray & Maxwell J. Mehlman eds., 2000) (discussing rise of wrongful birth and wrongful life cases following *Roe* and noting that failure to provide prompt information according to proper standard of care may subject physicians to liability).

59. These wrongful birth cases differ from malpractice cases brought against physicians because of failed sterilization operations, which although are more accurately called actions for "wrongful pregnancy" are sometimes called "wrongful birth" actions. *Compare* Patricia Baugher, *Fundamental Protection of a Fundamental Right: Full Recovery of Child-Rearing Damages for Wrongful Pregnancy*, 75 WASH. L. REV. 1205, 1208, 1218 (2000) (using term "wrongful pregnancy"), *with* Flowers v. District of Columbia, 478 A.2d 1073, 1076 (D.C. 1984) (using term "wrongful birth"); McKinney v. State, 950 P.2d 461 (Wash. 1998) (same).

60. *See* Andrews, *supra* note 16, at 676 n.17 (discussing first eight cases recognizing wrongful life suits in several states, including Illinois, New York, New Jersey, Pennsylvania, California and Washington).

61. California, New Jersey and Washington recognize causes of action for wrongful birth. *See* Turpin v. Sortini, 643 P.2d 954, 957 (Cal. 1982) (noting that lower California courts recognized wrongful birth actions); Procanik v. Cillo, 478 A.2d 755, 758 (N.J. 1984) (noting that in *Berman* New Jersey recognized that parents may recover for emotional distress for wrongful birth of child born with birth defects); Harbeson v. Parke-Davis, Inc., 656 P.2d 483, 492 (Wash. 1983) (taking "major step" recognizing wrongful birth action). A lower court in Connecticut also recognized this cause of action. *See* Quinn v. Blau, 1997 WL 781874, at *2 (Conn. Super. Ct. 1997) (stating that "Connecticut courts have recognized a cause of action for wrongful birth brought by parents"). *But see* Becker v. Schwartz, 386 N.E. 807, 812-13 (N.Y. 1978) (dismissing wrongful life claim for failure to state legally cognizable action).

62. Most courts acknowledge that the right to procreative choice stems from a woman's right to an abortion established in *Roe*. *See, e.g.*, Hummel v. Reiss, 608 A.2d 1341, 1343 (N.J. 1992) (discussing recognition by courts after *Roe* of causes of action for parents of infants harmed by doctors' negligence to inform). Recently New Jersey, a state that recognizes causes of action for both wrongful life and wrongful birth, explicitly refused to recognize a cause of action that accrued before the United States Supreme Court's decision in *Roe*. *See id.* at 1346 (explaining that right to abortion on which claim was based had not yet been established when alleged wrongs occurred).

Perkel,[63] where parents of a child born with cystic fibrosis alleged that two pediatricians' negligent failure to diagnose cystic fibrosis in their first child four years earlier deprived them of their right to choose not to have a second child.[64] The New Jersey Supreme Court observed that the scope of duty in negligence, except as limited by policy considerations, is coextensive with the negligent act's reasonably foreseeable consequences.[65] Therefore, the court reasoned, a physician's duty may extend beyond the interests of a patient to members of the patient's immediate family who might be adversely affected by the physician's breach of duty.[66] The court rejected the pediatricians' argument that they did not owe a duty to the parents because there was no physician-patient relationship between them when the parents decided to have a second child.[67] The decision in *Schroeder* thus opened the door to creating an affirmative duty on the part of physicians to disclose or inform third parties about their patients' genetic conditions.

Later, in a 1995 case, *Pate v. Thelkel*,[68] the Florida Supreme Court became one of the first courts to hold that a physician has a duty to warn a parent of the genetically inheritable nature of his or her disease.[69] In 1987, the plaintiff's mother was diagnosed with a form of carcinoma that was alleged to be genetically transferable.[70] In 1990, the patient's adult

63. 432 A.2d 834 (N.J. 1981).

64. *See Schroeder*, 432 A.2d at 836 (noting that doctor's failure to recognize cystic fibrosis in first child and failure to inform parents that they were carriers of disease deprived them of informed choice to assume risk of second child).

65. *See id.* at 838-39 (discussing foreseeability of injury to family of one who is actually injured due to legal relationships among family members and bond between parents and child).

66. *See id.* at 839 (noting that "family life . . . create[s] a web of interconnected legal interests").

67. *See id.* at 838-40 (stating that physician owed parents independent duty "to disclose daughter's medical condition").

68. 661 So. 2d. 278 (Fla. 1995).

69. *See* Jeffery W. Burnett, *A Physician's Duty to Warn a Patient's Relatives of a Patient's Genetically Inheritable Disease*, 36 HOUS. L. REV. 559, 569-73 (1999) (discussing *Pate* and related case, *Safer v. Estate of Pack*, and noting rarity of cases similar to *Pate*); Michelle R. King, *Physician Duty to Warn a Patient's Offspring of Hereditary Genetic Defects: Balancing the Patient's Right to Confidentiality Against the Family Member's Right to Know—Can or Should* Tarasoff *Apply*, 4 QUNNIPIAC HEALTH L.J. 1, 22-25 (2000) (discussing *Pate* as common law approach to creating physician's duty to warn non-patient of hereditary genetic defect); Graeme T. Laurie, *Challenging Medical-Legal Norms: The Role of Autonomy, Confidentiality, and Privacy in Protecting Individual and Familial Group Rights in Genetic Information*, 22 J. LEGAL MED. 1, 42-46 (2001) (citing *Pate* among cases at beginning of trend to extend duty of care to relatives of persons diagnosed with genetic disease); *see also* Genetic Privacy Act, N.J. STAT. ANN. § 17B:30-12 (West 1998) (limiting reach of *Safer*); Reisner v. Regents of the Univ. of Cal., 37 Cal. Rptr. 2d 518, 521 (Cal. 1995) (creating duty similar to one in *Pate*, but in HIV context); Safer v. Estate of Pack, 677 A.2d 1188, 1191-93 (N.J. 1996) (declining to follow *Pate*, holding that "in all circumstances, the [physician's] duty to warn will be satisfied by informing the patient").

70. *See Pate*, 661 So. 2d. at 279 (discussing plaintiff's mother's medical condition).

daughter learned that she had the same form of carcinoma.[71] The court allowed the liability suit by the adult daughter against her mother's physician on the theory that the physician had a duty to warn the mother that her disease was possibly inheritable.[72] The court's theory required the daughter to allege and prove that her mother would have informed her of her own risk of developing the disease, leading to earlier detection and treatment.[73] By ruling that the physician's duty to disclose was owed to the mother and not the daughter, the court did more than simply avoid a possible conflict with the statutory obligation of confidentiality. The court implicitly advanced the notion that knowledge of genetic disease creates new kinds of duties beyond those established by the traditional physician-patient relationship.[74]

At one level, these two cases might not appear relevant to the Canavan Disease Case because the defendants in *Greenberg* were not treating physicians, but rather researchers.[75] The rationale of these cases is not best understood, however, as a part of the special form of consent liability in medical care where a physician-patient relationship is necessary. Rather, they are best understood as an expansion of the general theory of negligence to deal with the recent rise in knowledge about the genetic nature of disease. In other words, the "standard of care" for physicians, or at least those specialists in gynecology and obstetrics, includes their having some knowledge about inheritable conditions and to share that knowledge with their patients.[76]

The lesson to be learned from these two cases and their progeny is that they are in fact about "standard of care," rather than about the expansion of "lack of informed consent," which I discuss in Section IV.[77] The *Pate* and *Schroeder* cases imply that for alleged failures in disease management, the scope of liability depends upon the underlying conditions. That is, while the duty of care in disease management is framed in general by

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71. *See id.* (noting that plaintiff discovered her medical condition three years after her mother learned of her condition).

72. *See id.* at 280-81 (concluding, by applying Florida statute, that health care providers had duty to inform mother that children should be tested for cancer).

73. *See id.* at 282 (holding that patient's children were within foreseeable zone of risk and patient can ordinarily be expected to pass on warning).

74. *See* L.J. Deftos, *Genomic Torts: The Law of the Future—The Duty of Physicians to Disclose the Presence of a Genetic Disease to the Relatives of Their Patients with the Disease*, 32 U.S.F. L. REV. 105 (1997) (describing case and statutory law regarding genetic information as developing into area of law dubbed "genomic torts" and proposing that genomic concepts of privity and privilege will dissolve third-party shield that often protects defendants from remote plaintiffs).

75. *See* Complaint ¶¶ 12-13, Greenberg v. Miami Children's Hosp. Research Inst., Inc. (N.D. Ill. Oct. 30, 2000) (No. 00-CV-6779) (alleging that Dr. Matalon led research team).

76. *See* PALMER, *supra* note 47, at 27-34.

77. For a discussion of "lack of informed consent", see *infra* note 113 and accompanying text.

professional standards,[78] to realize that this duty varies depending upon whether the care involves invasive treatment such as surgery, the treatment of a chronic condition, or a genetic disease or condition is important. In effect, the existence of a genetic condition places the legal duty analysis in context.[79] With the Tay-Sachs model as a backdrop, the plaintiffs might be able to invoke an older line of cases involving the failure to disclose the risks of Tay-Sachs to couples of Eastern European descent.[80]

The judge deciding the motion to dismiss in *Greenberg* should start with an analysis of the defendants' duties to the plaintiffs instead of with

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78. *See* James A. Henderson, Jr. & John A. Siliciano, *Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 CORNELL L. REV. 1382, 1383-1400 (1994) (discussing how tort law seeks to police delivery of health care); Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 654-62 (2001) (discussing evolution and development of standard of care physicians are held to in medical malpractice cases); Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 201-05 (2000) (discussing history of standard of care for physicians in medical malpractice and arguing that courts are moving towards integration of malpractice cases into broader fabric of general negligence law); Edward A. Marshall, Note, *Medical Malpractice in the New Eugenics: Relying on Innovative Tort Doctrine to Provide Relief When Gene Therapy Fails*, 35 GA. L. REV. 1277, 1294-1301 (2001) (discussing traditional standard of care for doctors and its place in context of gene therapy).

79. *See, e.g.*, Canesi v. Wilson, 730 A.2d 805, 818 (N.J. 1999) (discussing different causes of action in relation to child born with limb reduction abnormalities after doctor prescribed his mother drug Provera). Courts have found different duties concerning causes of action for wrongful life or wrongful birth cases as opposed to causes of action for malpractice. *See id.* (stating that malpractice requires only that defect was foreseeable risk, whereas wrongful life and birth cases require proof that woman would have had an abortion if apprised of risk of fetal defect). In wrongful life or birth cases, liability is based on the plaintiffs' being deprived of their legal right to choose, and these plaintiffs must only prove that the child's defect was a foreseeable risk posed by the doctor's malpractice and that inadequate disclosure deprived them of their right to make birth-related decisions. *See id.* (stating that proximate cause question is "not whether the doctor's negligence caused the fetal defect"). For causes of action based on malpractice, the court continues to require plaintiffs to prove medical causation. *See id.* at 812 (stating standard rule for recovery for medical malpractice).

80. *See* Goldberg v. Ruskin, 471 N.E.2d 530, 537-38 (Ill. App. Ct. 1984) (discussing wrongful life and birth claims against doctors who failed to inform parents of Tay-Sachs risk, where court held that doctors had affirmative duty to disclose information necessary for parents to make informed decision to keep or abort their child); Howard v. Lecher, 366 N.E.2d 64, 66 (N.Y. 1977) (holding that although doctor was negligent in failing to take proper measures to determine whether fetus suffered from Tay-Sachs disease, mental distress and emotional disturbance damages were not recoverable because doctor's negligence was not direct cause of child's death); Naccash v. Burger, 290 S.E.2d 825, 830-32 (Va. 1982) (permitting emotional damages for parents with children afflicted with Tay-Sachs disease); *see also* Munro v. Regents of the Univ. of Cal., 263 Cal. Rptr. 878, 884-85 (Cal. Ct. App. 1989) (holding that health care providers are not liable for failure to recommend testing for Tay-Sachs disease when neither parent disclosed information that made their carrier status reasonably probable).

the necessity of privity between the defendant and the plaintiff.[81] The entire concept of genetic disease or genetic health is based on the premise that some other person(s)—the parent(s) passing on the gene(s) creating the disease—are involved. This analysis stands in stark contrast to the paradigm of acute health care where we envision the question of law to be whether the professional followed the correct procedures or even disclosed the risks of those procedures.[82]

The rules of disclosure were developed under a rubric of lack of informed consent. They were based on theories of negligence, rather than battery, and generally involved cases of invasive procedures aimed at treating acute illness.[83] With chronic illnesses, the issues of disease management involve the degree to which the patient is involved in his or her own care.[84] As chronic illnesses have become more visible to judges, even California courts have limited the scope of the physician's duty. For example, the California Supreme Court ruled that a jury should not have been told that a cancer specialist owed a duty to disclose the statistical survival rate for pancreatic cancer.[85] Furthermore, a contextualist approach to liability in disease management explains why the Maryland Supreme Court refused to find any liability on the part of a physician who resuscitated an AIDS patient with a "living will."[86]

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81. This initial duty analysis comports with the theory that this case should be handled through tort liability rules rather than through contract. For a discussion of problems concerning application of contract law to medical injury claims, see *supra* note 47 and accompanying text.

82. *See, e.g.*, Canterbury v. Spence, 464 F.2d 772, 786-87 (D.C. Cir. 1972) (holding that test for determining whether potential peril must be divulged is its materiality to patient's decision); Cobbs v. Grant, 502 P.2d 1, 7-12 (Cal. 1972) (analyzing physician's duty to patient and determining that there is duty of reasonable disclosure concerning available choices with respect to proposed therapy and dangers inherently and potentially involved).

83. *See Canterbury*, 464 F.2d at 785 (holding standard for measuring physician performance is reasonable conduct under circumstances); *Cobbs*, 502 P.2d at 10 (applying reasonable disclosure analysis).

84. *See generally* Larry I. Palmer, *Ethical and Legal Implications of Diabetes Self-Management*, 8 PRAC. DIABETOLOGY 1 (1989) (discussing potential physician liability and related issues in programs of self-management).

85. *See* Arato v. Avedon, 858 P.2d 598, 607-08 (Cal. 1993) (noting that statistical morbidity rates derived from experience of population groups are "inherently unreliable and offer little assurance regarding the fate of an individual patient," yet affirming *Cobbs* patent-based standard of disclosure).

86. Wright v. Johns Hopkins Health Care Sys. Corp., 728 A.2d 166, 176 (Md. 1999) (holding that estate could not recover damages from health care professionals for administering cardiopulmonary resuscitation contrary to written advance directive of AIDS patient). How this ethical objection is enforced within the legal system creates considerable conceptual difficulties. Some of the confusion is a function of trying to understand the nature of the "right" to refuse treatment. The plaintiffs in *Wright* tried to argue that the patient had either a common law, statutory or constitutional right that the physician had ignored. *See id.* at 167-68 (referencing Maryland's Life-Sustaining Procedures Act, which governs directives of health care). The court held in effect that this right was a function of statutory enactment, and the lack of certification by two physicians that his condition was

The right to choose parenthood, which underlies the wrongful life and wrongful birth cases, is not derived from liability law. In fact, it derives from the change in constitutional law resulting from the decision in *Roe v. Wade*.[87] *Roe* led courts to impose liability for a physician's failure to respect the procreative rights of parents discussed above.[88] The plaintiffs' claim in *Greenberg*, however, involves the patent system, raising the question as to whether the court should use developments in patent law to defeat the plaintiffs' claim.

B. *Patent Law and Liability Paradigms*

Patent law and liability doctrines provide the competing paradigms for resolving what the researcher's duties are in the Canavan Disease Case.[89] If the court chooses the patent law paradigm, the defendants should prevail. In choosing the patent law paradigm, the court would frame the issue in a way that would minimize any interference with the patent law system.[90] A court can achieve this by ruling that the disclosure of the physical risks—for instance, of drawing blood—is a function of liability law.[91] The court could maximize the patent law system's goals by

"terminal," as required by the statute, was fatal to any claim of negligence. *See id.* at 175 (holding that under Life-Sustaining Procedures Act, plaintiff did not meet requirement that physician certify his condition as terminal and death imminent, therefore never activating plaintiff's Living Will).

87. 410 U.S. 113 (1973).

88. *See, e.g.*, Berman v. Allan, 404 A.2d 8, 20-21 (N.J. 1979) (holding physician liable for not respecting procreative rights of parents, for first time in New Jersey) (cited in Hummel v. Reiss, 608 A.2d 1341, 1342 (N.J. 1992)).

89. *See* Janet L. Dolgin, *Choice, Tradition, and the New Genetics: The Fragmentation of the Ideology of the Family*, 32 CONN. L. REV. 523, 551 (2000) (noting that doctrine of informed consent is "attractive . . . in part because it placates concerns about variations of privacy while interfering less with the goals of industry and science than rules defining genetic information as property").

90. *See* Golden, *supra* note 27, at 122-31 (discussing problems that patent law faces due to biotechnological innovations); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 93-152 (1999) (discussing how goals of intellectual property would be maximized not through stronger intellectual property rights, but through norms that "militate against the securing of such rights").

91. Legislatures also place limits on physician liability. *See* Hecht v. Kaplan, 645 N.Y.S.2d 51, 52-53 (N.Y. App. Div. 1996) (holding that under New York statutes on informed consent, plaintiff must prove that there was some "uncommented affirmative violation" of her physical integrity in order to sustain cause of action). In *Hecht*, the physician drew an extra vial of blood and performed a blood test for Human T-cell Leukemia Virus (HTLV), a contagious disease, while his patient only consented to have her blood tested for cytomegalovirus (CMV). *See id.* at 52 (discussing plaintiff's claim that testing of blood for HTLV amounted to "human research without her consent"). Although the HTLV test result was positive, the physician failed to inform the patient of the results of the test for several months. *See id.* (stating that failure to inform endangered plaintiff's husband's health); *see also* N.Y. PUB. HEALTH LAW § 2805-d(2) (McKinney 2001) (stating that right of action to recover for medical malpractice based on lack of informed consent is limited to those cases involving either (a) non-emergency treatment, proce-

refusing to find researchers liable for failing to inform subjects of their intent to patent the results of their research.

A court framing the issue in this way would rely upon the 1980 ruling in *Diamond v. Chakrabarty*,[92] in which the United States Supreme Court ruled by a 5-4 majority that a biological organism was patentable.[93] This ruling was the Court's attempt to "modernize" the patent law system to accommodate emerging biotechnologies.[94] This ruling also paved the way for the "gene rush" and the growth of the biotechnology industry.[95]

On the other hand, choosing the liability paradigm only creates the possibility that plaintiffs will survive the motion to dismiss. This possibility exists because of *Moore v. Regents of the University of California*,[96] in which the California Supreme Court ruled in 1990 that a physician has a duty to inform a patient of his or her research and financial interests in the patient's blood, cells or other parts of the body from which the patient's DNA might be extracted or mined.[97] *Moore* uniquely explored the relationship between lack of informed consent liability or the duties to disclose, biomedical research and patent law.[98]

The court's ruling in the Canavan Disease Case will force courts to revisit the relationship of patent law as explicated in *Chakrabarty* and the principles of liability announced in *Moore*. The federal district court and ultimately the Seventh Circuit, however, will decide *Greenberg* in a very different context than that presented to the judges and justices in both *Moore* and *Chakrabarty*.

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dure or surgery, or (b) diagnostic procedure requiring invasion or disruption of integrity of body).

92. 447 U.S. 303 (1980). *See generally* Daniel J. Kevles, *Ananda Chakrabarty Wins a Patent: Biotechnology, Law, and Society, 1972-1980*, 25 HISTORICAL STUDIES IN THE PHYSICAL AND BIOLOGICAL SCIENCES 111-35 (1994) (discussing *Chakrabarty* and long standing tenet of common patent law that it defeated).

93. *See Chakrabarty*, 447 U.S. at 2211-12 (construing Congress' statutory intent regarding genetically engineered organisms included under patent protection).

94. *See id.* at 2211 (noting breadth of genetic research undertaken by scientists). For a discussion of the problems patent law faces in dealing with emerging biotechnologies, see Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 737-44 (1990) (arguing that denying patent protection to DNA will not solve problems that some hope it will).

95. *See* Julie A. Davies & Lawrence C. Levine, *Biotechnology's Challenge to the Law of Torts*, 32 MCGEORGE L. REV. 221, 235 (2000) (describing biotechnology as "new frontier" in tort law and advocating application of tort principles in biotechnology context).

96. 793 P.2d 479 (Cal. 1990).

97. *See Moore*, 793 P.2d at 489 (explaining that "a physician must disclose possible conflicts," because certain personal interests may affect professional judgment).

98. *See generally id.* (discussing cause of action against physician, university researcher and licensees of rights to patented cell line, where plaintiff claimed conversion and breach of physician's duty to disclose).

IV. *MOORE* AND DISEASE MANAGEMENT

Moore exemplifies how judges viewed the problem of disease management at the beginning of the Human Genome Project.[99] John Moore was Dr. Golde's patient at the UCLA Medical Center in 1976.[100] Dr. Golde recommended the removal of Moore's spleen as part of the successful treatment of his hairy cell leukemia.[101] Upon examination of Moore's excised spleen, Dr. Golde discovered that his DNA was unique because it overproduced proteins that regulate the immune system.[102] Over the next seven years, Moore returned to the UCLA Medical Center from his home in Seattle for tests and provided Dr. Golde with blood, skin tissue, bone marrow and sperm.[103]

Dr. Golde and his laboratory assistant developed a cell-line—the "Mo cell line"—from tissue, blood and other body fluids that Moore provided.[104] Dr. Golde filed a patent on the cell-line, granted a license to a biotechnology company and received stock options and a consulting arrangement with the biotechnology company.[105] Once Moore discovered

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99. *Moore* literally occurred at the beginning of the Human Genome Project. The United States government officially began the Human Genome Project in 1990. *See History of the Human Genome Project* (describing timeline of major events in Human Genome Project), *available at* http://www.ornl.gov/hgmis/project/hgp.html (last visited Sept. 8, 2001). Celera began its work to decipher the Human Genome in 1998. *See Human Genome Is Not for Sale, Say British Experts*, AGENCE FRANCE-PRESSE, Feb. 12, 2001, *available at* 2001 WL 2340365, at *1 (noting criticism of private company's concurrent deciphering effort for profit); *see also* A.J. Hostetler, *Genome Genius: Faithfully Exploring the Book of Life*, RICHMOND-TIMES DISPATCH, Apr. 23, 2001, at A1 (discussing one Human Genome Project scientist's views on how religion and science converge in relation to how deciphered DNA code should be used).

100. *See Moore*, 793 P.2d at 481 (discussing Moore's treatment for hairy-cell leukemia).

101. *See id.* (noting that physician "recommended that Moore's spleen be removed because Moore should fear for his life and the proposed operation was necessary to slow down the progress of his disease").

102. *See id.* at 482 n.2 (discussing Moore's compliance with physician's requests without his knowledge of what was being done with blood and serum he supplied to physician).

103. *See id.* at 481-82 (discussing Moore's travels and compliance with defendant physician's demands); *see also* Helen R. Bergman, *Case Comment:* Moore v. Regents of the University of California, 18 AM. J.L. & MED. 127, 130 (1992) (noting that when Moore mentioned that he could not afford to continue to travel to Los Angeles, Dr. Golde allegedly told Moore that he could obtain grants for his trips and thereafter offered to pay Moore's expenses at "luxurious hotel in Beverly Hills").

104. *See Moore*, 793 P.2d at 481 (describing occasions on which Dr. Golde drew samples of Moore's tissue, blood and other fluids).

105. *See id.* at 481-82 (summarizing Dr. Golde's actions). Dr. Golde was made a paid consultant and received 75,000 shares of common stock. The Genetics Institute also promised to pay Golde and the University $330,000 over three years. *See id.* at 482 (specifying compensation). That amount included a pro rata share of Golde's salary and was later increased by $110,000 when Sandoz was added to the agreement. *See id.* (detailing compensation agreement).

that the "Mo cell line"[106] had been used to develop powerful drugs for the treatment of several forms of cancer, he sued Dr. Golde, the University of California, the assignee of the patent, and the various biotechnology firms involved in the development and distribution of the drugs.[107]

Moore argued thirteen theories of liability, one of them being that the defendants had misappropriated his "property" by using his DNA to develop the cell-line and drugs.[108] The California Supreme Court rejected Moore's claim of conversion, which was based on the theory that the various defendants had interfered with Moore's possessory interest in his spleen, tissue, blood and other bodily fluids.[109] The court then rejected Moore's claim based on his alleged property interest in his unique DNA and, accordingly, dismissed the claims against the assignee of the patents—the biotechnology companies.[110]

The court did hold, however, that a physician/scientist has a duty to disclose his research and financial interests in the patient's cells, tissue and DNA.[111] Presumably, this means that Dr. Golde should have told John Moore of his interest in developing the cell-line and pursuing the patent and of his financial arrangements with the companies developing the drugs.[112] Although the case was settled after this ruling, the court's result uses the judicially-developed "doctrine of lack of informed consent" to balance the interests of patients and physician/scientists.[113] The result in *Moore* protects scientific innovation because the duty to disclose established by the court exempts companies that might bring successful prod-

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106. U.S. Patent No. 4,438,032 (issued Mar. 20, 1984), *available at* http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1='4,438,032'.WKU.&OS=PN/4,438,032&RS=PN/4,438,032 (awarding patent for cell line).

107. *See Moore*, 793 P.2d at 480 (naming defendants).

108. *See id.* at 483 n.4 (listing thirteen causes of action asserted by Moore).

109. *See id.* at 488-97 (holding that tort of conversion should not be extended to give Moore cause of action). Rejection of the conversion claim is an often-criticized aspect of *Moore*. *See* Lin, *supra* note 22, at 108 (criticizing rejection of conversion claim in *Moore*); Hardiman, *supra* note 22, at 248-52 (same); Seeney, *supra* note 22, at 1164-67 (same). *But see* Dillon, *supra* note 22, at 632-33 (criticizing recognition of property rights in one's tissues and cells).

110. *See* Michael Baram et al., *Patent Rights and Licensing*, 6 B.U. J. SCI. & TECH. L. 3, 38 (noting that patent rights for Mo cell line had yielded fifteen million dollars for Sandoz Pharmaceutical Corporation, and estimated three billion dollars worth of drugs that followed from it).

111. *See Moore*, 793 P.2d at 483-85 (holding that physician seeking consent for medical procedure must disclose personal interests, whether research or economic, that may affect his medical judgment).

112. *See id.* at 485-86 (concluding that Dr. Golde had duty to disclose his research and economic interests).

113. *See id.* at 483 (citing *Cobbs v. Grant*, 502 P.2d 1, 11 (Cal. 1972), to support proposition that scope of physician's duty to communicate to patient must be "measured by the patient's need, and that need is whatever information is material to the decision").

ucts to market, while protecting the patient's interest in autonomy by granting a theoretical right not to participate in the research.

One way of interpreting *Moore* is to argue it is a case of pure human experimentation, as Moore's lawyer attempted to do. Another way of interpreting *Moore* is to view it as a case of a patient seeking necessary treatment and monitoring of his disease. The majority of the judges apparently accepted this view when they found the physician had a fiduciary duty to disclose.[114] If the latter approach is taken, *Moore*'s applicability to *Greenberg* is limited because none of the Canavan plaintiffs are patients.[115] In fact, some of the plaintiffs are non-profit patient advocacy groups.[116] On the other hand, if *Moore* is viewed more broadly as a measure of liability in the course of disease management in the Human Genome Era, a host of new issues arise, particularly in the context of the Canavan Disease Case.

V. DISCLOSURE DUTIES IN THE HUMAN GENOME ERA

The plaintiffs in the Canavan Disease Case, who are represented on a pro bono basis by the Chicago-Kent Law School Clinic, are obviously out to make "new law."[117] The suit has been filed in federal court in Illinois and is facing numerous procedural objections to keeping the suit in Illinois.[118] I will leave the procedural issues to the civil procedure experts. Whatever the outcome of the motions to dismiss, the plaintiffs—because of their institutional representation—have the capacity to take the case to the Seventh Circuit. That court, with judges such as Chief Judge Posner who have a penchant for writing provocative opinions on matters involving health care, economics and jurisprudence, is likely to have something to

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114. *See id.* at 485-87 (stating that Dr. Golde could be liable for breach of duty, yet Regents, Quan, Genetics Institute and Sandoz could only be secondarily liable because they had neither fiduciary duty to Moore, nor duty to obtain his informed consent).

115. *See* Complaint ¶ 21, Greenberg v. Miami Children's Hosp. Research Inst., Inc. (N.D. Ill. Oct. 30, 2000) (No. 00-CV-6779) (alleging research relationship with Dr. Matalon).

116. *See id.* ¶¶ 8-10 (describing organizational plaintiffs).

117. Lori B. Andrews, a professor of law at Chicago-Kent Law School who filed an amicus curiae brief in *Moore*, has published several prominent articles concerning reproductive technology and medical liability issues. *See generally* Lori B. Andrews & Nanette Elster, *Regulating Reproductive Technologies*, 21 J. LEGAL MED. 35 (2000); Lori B. Andrews, *Reproductive Technology Comes of Age*, 21 WHITTIER L. REV. 375 (1999); Lori B. Andrews, *Is There a Right to Clone?: Constitutional Challenges to Bans on Human Cloning*, 11 HARV. J.L. & TECH. 643 (1998); Lori B. Andrews, *Prenatal Screening and the Culture of Motherhood*, 47 HASTINGS L.J. 967 (1996); Andrews, *supra* note 16.

118. *See generally* Miami Children's Hospital's Motion to Dismiss, *Greenberg* (No. 00-CV-6779) (objecting to suit on grounds that Illinois Federal United States District Court for the Northern District of Illinois lacks personal jurisdiction over hospital because plaintiffs' court's exercise of jurisdiction would violate due process).

say about this case.[119] Because very few precedents exist that are relevant to the precise issues in the case, the court will have to explore several different lines of cases. This exploration of court-developed doctrines will boil down to three fundamental issues concerning the law's response to disease management in our present era.

A. *Are the Rules of Disclosure Different in Therapeutic and Research Settings?*

While the doctrine of informed consent has been debated in the literature in terms of respecting autonomy,[120] the Human Genome Era presents an opportunity to determine if "information flow" should be the focus of the analysis. This requires case analysis in addition to systemic analysis.[121] For the plaintiffs to survive the motion to dismiss, they must argue that informed consent has a different function in research settings than in therapeutic settings.[122] This argument is necessary because the information flow in the two settings must accomplish different goals. In the research setting, the purpose of information flow is to allow subjects to determine if they should participate in the research. In contrast, the purpose of information flow in the therapeutic setting is to allow patients to determine if the risks of a medical procedure, drug, test or other treatment, as well as its possible health benefits, are worth undertaking.

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119. *See, e.g.*, Herdrich v. Pegram, 170 F.3d 683, 687 (7th Cir. 1999) (petition for rehearing en banc) (Chief Judge Posner, and Judges Easterbrook, Flaum and Wood dissenting from majority opinion to deny rehearing) (accusing majority of putting all managed healthcare systems at risk and committing court to "long course" of distinguishing "good" managed-care systems from "bad" ones), *rev'd*, 530 U.S. 211 (2000).

120. *See* Dolgin, *supra* note 89, at 551 ("In fact, if not in theory, informed consent rules often function largely as a 'moral trump.'"). *See generally* Katz, *supra* note 8 (discussing informed consent).

121. *See* Larry I. Palmer, *Patient Safety, Risk Reduction, and the Law*, 36 HOUS. L. REV. 1609, 1642 (1999) (noting interaction of law with healthcare system).

122. *See* Morin, *supra* note 18, at 165-68 (distinguishing doctrine of informed consent in context of experimentation from doctrine in context of treatment). For further discussion of the importance and manifestation of the informed consent doctrine, see Ezekiel J. Emanuel et al., *What Makes Clinical Research Ethical?*, JAMA, May 24, 2000, at 2701, 2701 (proposing seven universal requirements to ensure ethical research). The authors argue that informed consent is necessary; however, they also believe that it is not always sufficient for clinical research. *See id.* at 2706-07 ("[A]ll requirements need to be satisfied, but they may have to be adjusted and balanced given the circumstances of different types of research."). Nevertheless, they do not explicitly recognize the need for a researcher to disclose his commercial interests in the research to his or her patient. *See id.* at 2708 (declaring seven discussed requirements as only essential ones). *But see* Francis H. Miller, *Trusting Doctors: Tricky Business When It Comes to Clinical Research*, 81 B.U. L. REV. 423, 436-37 (2001) (criticizing Emanuel essay because it never alludes to fact that clinical researcher's conflicts of interest, financial or otherwise, also pose serious impediments to conduct of ethical research on human subjects). Miller argues that although disclosure is a "critically important issue[ ], minimizing investigator conflicts of interest is equally crucial to long-term public support for experimental research and intensely important to the human subjects of those studies." *Id.* at 436.

Addressing this question requires an examination of both an old and a new line of cases. In the new line of cases, plaintiffs have argued—in the therapeutic context—that health care providers have a duty to provide comparative data about the experience of the provider in addition to the effectiveness of various treatment alternatives. In the only case to date in which plaintiffs have succeeded in surviving a motion to dismiss, the Wisconsin Supreme Court held that a neurosurgeon had a duty to disclose his level of experience with a procedure and the "morbidity and mortality" differences between himself and more experienced neurosurgeons.[123]

The Wisconsin court's ruling has been labeled the "second revolution" of the informed consent doctrine.[124] Even in the strictly therapeutic context, scholars have argued that courts should expand the informed consent doctrine to include a duty to disclose "provider-risk information" because of the growth of such information in today's health care system.[125] With the growth of managed care, much more data is available about the relative effectiveness of providers in performing certain procedures.[126] The bottom line of this argument is that forcing disclosure of readily available data increases consumer/patient choice. In our increasingly competitive health care system, with advertisement by all kinds of providers and multiple health care plans from which to choose, information flow to consumers (advertisement) and patients (informed consent liability) is crucial to the law's respect for autonomy.

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123. *See* Johnson v. Kokemoor, 545 N.W.2d 495, 507 (Wis. 1996) (concluding that when physicians have substantially different success rates with same procedure and reasonable person would consider that material, court may admit as evidence). *But see* Duttry v. Patterson, 771 A.2d 1255, 1259 n.2 (Pa. 2001) (explicitly rejecting notion of informed consent used by *Kokemoor* and *Moore* courts). The court held that a surgeon's level of experience is irrelevant to the doctrine of informed consent. *See id.* at 1259 (holding that physician's personal characteristics and experience are irrelevant to informed consent claim). The Pennsylvania Supreme Court views the informed consent doctrine as based on the theory of battery, rather than negligence. *See id.* at 1258 (reiterating court view on grounds of informed consent claim).

124. *See generally* Aaron D. Twerski & Neil B. Cohen, *The Second Revolution in Informed Consent: Comparing Physicians to Each Other*, 94 NW. U. L. REV. 1 (1999) (discussing changes that might occur due to Supreme Court of Wisconsin's decision in *Johnson v. Kokemoor*); Suzanne K. Ketler, Note, *The Rebirth of Informed Consent: A Cultural Analysis of the Informed Consent Doctrine After* Schreiber v. Physicians Insurance Co. of Wis., 95 NW. U. L. REV. 1029 (2001) (discussing *Kokemoor* and new case which further expands informed consent in Wisconsin in therapeutic setting). For a more moderate perspective on the expected effect of *Kokemoor*, see Lynn M. LoPucki, *Twerski and Cohen's Second Revolution: A Systems/Strategic Perspective*, 94 NW. U. L. REV. 55, 75 (1999) (arguing that effect of change will be moderate rather than revolutionary and that Twerski and Cohen focus on legal issues that *Kokemoor* court left undecided).

125. *See* Twerski & Cohen, *supra* note 124, at 31-38 (proposing that courts recognize cause of action for physician's failure to give patients provider-risk information).

126. *See id.* at 31 (noting that managed health care industry will become greatest repository of comparative provider information).

The argument for applying this information analysis in the Human Genome Era of medicine is strong. With the "completion" of the Human Genome Project, we are moving into a new phase of how genetic research will be conducted, captured by the new term, "genomics." The best way to describe genomics is to think of biology and biological research from the perspective of the Internet. First, the "map" of the Human Genome and the genome of many forms of animal and plant life is available in electronic form and thus basically located on servers somewhere in the world.[127] Second, the model of research changes: Gene research used to involve a reductionist approach by a scientist and his or her assistants doing what used to be called recombinant DNA work in search of a clue as to where a gene is. Today, groups of scientists and engineers do what is now called high–input sequencing by running electronic scans against these human genome data banks in order to formulate hypotheses and form research proposals. The term genomics signals a shift to the use of highly sophisticated tools for large-scale data acquisition and analysis. Thus, the new work involves large-scale DNA sequences, computational biology and microchip technology.

For example, if one were trying to determine whether a particular gene "causes" cancer, a research team might start with the mouse genome and genetically modified mice to determine which gene or combination of genes cause that form of cancer in mice.[128] Once the gene is located on the mouse genome, the researcher then would have some idea of where to look on the Human Genome for a mutation of the similar gene of persons with cancer. This search might involve computerized searches of the Human Genome sequences and the use of microchips to find and isolate the gene or genes. The process of discovery in the genomics era essentially is a process of information management and analysis. The organization, a private industrial laboratory, government laboratory or university, with the ability to access the information and rapidly place it into the appropriate conceptual framework, will bring forth new products, methods of diagnosis and cures.

On the commercial side, there are companies that solicit blood samples through the Internet, where one is given the opportunity to contribute to scientific research on the origins of disease by filling out a health profile that the company uses to determine if one's blood might be helpful in their research.[129] For example, at www.dna.com, there are a host of

127. For a list of Internet websites providing access to the human genome, see *supra* note 3.

128. *See generally* David Malakoff, *The Rise of the Mouse: Biomedicine's Model Mammal*, SCI., Apr. 14, 2000, at 248 (noting unprecedented demand for inbred rodents to model human disease); Eliot Marshall, *Public-Private Project to Deliver Mouse Genome in 6 Months*, SCI., Oct. 13, 2000, at 242 (discussing consortium funding DNA sequencing of particular strain of laboratory mouse).

129. *See, e.g.*, DNA Sciences, *The Genetics Discovery Company* (soliciting volunteers to help study links between genetics and disease), *at* www.dna.com (last visited Sept. 3, 2001).

diseases listed—everything from asthma and Alzheimer's to breast cancer and eating disorders—as possible research interests of the organizers.[130]

There are a few cases from the pre-Human Genome Era that have a bearing on the research setting informed consent theory put forth in the Canavan Disease Case. These cases involve clinical experiments where there is a risk of physical harm to a subject who was not a patient.[131] Throughout this line of cases, courts suggested that a lack of informed consent is similar to a form of strict liability based in fraud and battery—an unconsented to touching of the human body.[132] A battery-based theory of informed consent in the research context suggests that its purpose is to allow potential human subjects the opportunity to refuse to participate or to withdraw from the project at any time. The Canavan Disease Case plaintiffs would prefer for the court to view their claim in light of this older line of cases because the corresponding emphasis on strict liability would increase their likelihood of winning. To push their case towards the strict liability notion of informed consent, however, the plaintiffs must provide the court with a coherent theory for thinking about the more numerous cases on informed consent in therapeutic settings.

My proposal stems from the fact that the liability system has traditionally responded to the health care system in two ways. The main response has been to establish a particular standard of care for medicine that is dependent upon what professionals do.[133] To prove a violation of the duty of care in health care liability cases, the plaintiffs must show a deviation from the standard of care in the particular profession, such as medicine or nursing, or a specialty within the profession.[134] A secondary response has been to find liability based on the doctrine of informed con-

130. *See, e.g.*, DNA Sciences, *The Genetics Discovery Company: Disease Center* (providing extensive information about numerous diseases and conditions), *at* http://www.dna.com/sectionHome/sectionHome.jsp?site=dna&link=diseasesconditions.htm (last visited Sept. 3, 2001).

131. *See* Halushka v. Univ. of Saskatchewan, 53 D.L.R.2d 436, 444 (Can. 1965) (holding researchers liable for trespass because plaintiff/subject had not given his informed consent to experiment). The court stated that "[t]he subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent." *Id.* at 444. The court held that the subject necessarily had to rely upon the special skill, knowledge and experience of the researchers, whose duty to disclose arose irrespective of whether or not they failed to disclose innocently or with fraudulent intent. *See id.* (stating that researchers were placed in fiduciary position). For a discussion of this case in relation to the doctrine of informed consent, see Morin, *supra* note 18, at 202 (summarizing court's holding).

132. *See* Ketler, *supra* note 124, at 1034-39 (providing explanation of this older line of battery-based cases concerning informed consent as well as shift to using negligence-based liability).

133. For a discussion of the history of standard of care, see *supra* note 78 and accompanying text.

134. *See* Daniel W. Shuman, *The Standard of Care in Medical Malpractice Claims, Clinical Practice Guidelines, and Managed Care: Towards a Therapeutic Harmony?*, 34 CAL. W. L. REV. 99, 100 (1997) (noting that common set of instructions provides that "the duty of a professional [is] to use such skill, prudence and diligence as

sent.[135] The informed consent doctrine in therapeutic settings is actually an outgrowth of the standard of care doctrine for medical professionals and is considered a form of negligence.[136] When we as lawyers use the term "medical malpractice" we are lumping together the rules associated with standard of care adjudication and the rules of liability associated with the informed consent doctrine in therapeutic settings.

The plaintiffs must convince the court that "no" is the answer to my first question of whether the rules of disclosure are the same in research and therapeutic settings. The plaintiffs should argue that the duty to disclose in the research context means that researchers must not only disclose any physical risks of harm, but in the Human Genome Era, must also disclose, without the plaintiffs' asking, their intentions regarding the patenting of genetic knowledge and other data they obtain.

B. *Does the Nuremberg Code Provide a Basis for Liability?*

For many commentators, the duty to disclose in the research context has its origins in the judgments against Nazi physicians who conducted experiments on concentration camp inmates without their consent.[137] Because several German physicians were executed and others received long prison terms for "war crimes" and "crimes against humanity,"[138] some form of civil liability for violation of the requirements of "consent" during the course of research appears to be a reasonable extension of the legal principles established in the international criminal law context.

Some of the most ethically troublesome human experiments in the United States, such as the Tuskegee Study of Untreated Syphilis in the Negro Male and the Human Radiation Experiments,[139] seem to scream

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other members of his profession commonly possess and exercise") (quoting Bily v. Arthur Young & Co., 834 P.2d 745, 772 (Cal. 1992)).

135. For a list of cases exemplifying the informed consent doctrine for medical treatment, see *supra* note 82.

136. *See* Dorothy Derrickson, *Informed Consent to Human Subject Research: Improving the Process of Obtaining Consent from Mentally Ill Persons*, 25 FORDHAM URB. L.J. 143, 148 (1997) (noting that doctrine of informed consent arose from action of battery and developed into action based on negligence).

137. *See generally* Katz, *supra* note 8 (accounting many atrocities related to research on human subjects); Barker, *supra* note 8 (same).

138. *See* Jonathan A. Bush, *Lex Americana: Constitutional Due Process and the Nuremberg Defendants*, 45 ST. LOUIS U. L.J. 515, 531 (2001) (noting that in second round of Nuremberg Trials, only half of twenty-six defendants sentenced to death were actually executed, while remaining portion of 142 convicted were given long prison terms—although most were released soon afterwards).

139. *See* Larry I. Palmer, *The Problem of Human Experimentation*, 56 MD. L. REV. 604, 604-18 (1997) (analyzing legacy of Tuskegee Study). *See generally* PUBLIC HEALTH SERVICE, FINAL REPORT OF THE TUSKEGEE SYPHILIS STUDY AD HOC PANEL TO THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE (1973) (examining human experimentation by government doctors on African American men); FINAL REPORT OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS (1995) [hereinafter RADIATION REPORT] (examining experiments on patients involving injection of radiation into their bodies to monitor effects).

out for an application of the "Nuremberg Code." The Human Radiation Experiments came to light in the mid-1990s, when it was revealed that the United States government had sponsored various experiments employing patients and institutionalized children to study the effects of radiation on the human body during the Cold War, where no consent was either sought or obtained.[140] The Tuskegee Syphilis Study was a forty-year effort to understand the effects of untreated syphilis in African Americans that continued long after penicillin was discovered as a cure for the disease.[141] The subjects were in fact "patients" of the United States Public Health Service who believed they were receiving treatment for their "bad blood" over several years, when in fact no treatment was ever provided.[142] Yet, the few United States judges who have ever cited the Nuremberg Code in a human experimentation case, such as the lawsuit filed over one of the human radiation experiments,[143] never deal explicitly with the main issue: whether the Nuremberg Code's requirement of informed consent is in fact a part of the domestic law of the United States.[144]

The Tuskegee Syphilis and Radiation studies' discussions of consent in the research context are examples of ethically horrific cases that invoke rhetorical charges of violating the Nuremberg Code. They are not, however, legal precedents that clearly establish the need for a different standard of informed consent in the research and therapeutic contexts.[145] Lawsuits resulting from these studies ended in settlements without full adjudications and were filed against governmental agencies, not private individuals.

Despite these doubts about whether, on a purely technical basis, the Nuremberg Code applies, some institutional lessons from those judgments remain and might be helpful in resolving the Canavan Disease Case as well as other cases of genetic disease management. Most of the attention to

140. *See generally* RADIATION REPORT, *supra* note 139.

141. *See* JAMES H. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT 1 (1993) (noting that 399 men who had disease were subjects in study).

142. For a detailed account of the Tuskegee Syphilis Study, see generally *id.* (exploring how study could have lasted for forty years).

143. *See* United States v. Stanley, 483 U.S. 669, 686 (1997) (O'Connor, J., concurring in part and dissenting in part) (arguing that no judicially crafted rule should insulate involuntary and unknowing human experimentation); *In re* Cincinnati Radiation, 874 F. Supp. 796, 803 (S.D. Ohio 1995) (discussing exploitation of poor, mostly African American cancer patients who were subject to high levels of radiation that were performed in Department of Defense study to determine biological effects of radiation); *see also* Barker, *supra* note 8, at 623 n.24 (noting documents indicating federal government had sponsored almost 4000 human radiation experiments from 1944 to 1974); Palmer, *supra* note 139, at 618-23 (discussing Cincinnati Radiation litigation).

144. *See generally* Roger S. Clark, *Crimes Against Humanity*, *in* THE NUREMBERG TRIAL AND INTERNATIONAL LAW 177 (G. Ginsburg & V.N. Kudriavtsev eds., 1990) (discussing origin of "crimes against humanity" offense).

145. *See, e.g.*, RADIATION REPORT, *supra* note 139, at 220 (suggesting that experiments obviously wrong by today's standards must be judged in proper historical perspective).

the Nuremberg Judgment fails to note the legal distinction, even in the context of international law, between experiments that were "war crimes" and those that were "crimes against humanity." The Nazi malaria experiments, which were like their American counterparts, involved prisoners and were aimed at resolving problems of infection arising on the battlefield.[146] The criminal convictions for these experiments are more properly thought of as "war crimes." In effect, the Nazi researchers violated the rules of war by contributing to the excessive deaths and needless infliction of suffering resulting from their attempts to develop more effective treatments for malaria. The war crimes convictions of the Nazi physicians and scientists do not turn on the lack of consent.[147]

The Nazi sterilization experiments, including the tests of the effectiveness of powerful drugs and X-rays as sterilization devices on concentration camp inmates, are more properly thought of as "crimes against humanity" because their goal was the elimination of civilian populations—Russians, Poles, Jews and other groups—by the "most scientific and least conspicuous means" available.[148] One purpose of maintaining the distinction between war crimes and crimes against humanity is that the latter doctrine might be developed in the civil context to deal with experiments that are performed on populations selected on the basis of their race or ethnic status.

I am not suggesting that the goal of the nationwide screening of Eastern European Jews, and their subsequent genetic counseling, fetal testing and decisions about terminating pregnancy, is a plot to eliminate that population. The irony of this particular ethnic group being subjected to so much scrutiny in our quest for genetic health does suggest, however, the need for a more cautious approach to claims for participation by laypersons in the decision-making process which is the essence of the plaintiffs' claim in the Canavan Disease Case.

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146. *See* Dawn Joyce Miller, Comment, *Research and Accountability: The Need for Uniform Regulation of International Pharmaceutical Drug Testing*, 13 PACE INT'L L. REV. 197, 198 (2001) (noting that Nazi concentration camp prisoners were exposed to malaria, jaundice and typhus to monitor progression of those diseases).

147. *See* Jon M. Harkness, *Nuremberg and the Issue of Wartime Experiments on U.S. Prisoners*, JAMA, Nov. 27, 1996, at 1672, 1673-74 (claiming that Dr. Andrew Ivy, American Medical Association's expert consultant to prosecutors, misrepresented process of obtaining consent for America's own war-time experiment with prisoners regarding malaria); *see also* Jon M. Harkness, Correspondence, *The Significance of the Nuremberg Code*, NEW ENG. J. MED., Apr. 2, 1998, at 995, 995-96 (correcting Dr. Evelyne Schuster's account of Dr. Andrew Ivy, who was called to rebut criticism of research on prisoners in Illinois that was invoked by Nazi defendants at Nuremberg trial, for her failure to acknowledge that many postwar medical researchers did not think that lessons of Nuremberg applied to them).

148. *See, e.g.*, Christopher Scott Maravilla, *Rape as a War Crime: The Implications of the International Criminal Tribunal for the Former Yugoslavia's Decision in* Prosecutor v. Kunarac, Kovac, & Vukovic *on International Humanitarian Law*, 13 FLA. J. INT'L L. 321, 325 (2001) (characterizing "systematic and well-organized policy of raping Muslim women as method of 'ethnic cleansing'" as "crimes against humanity").

The crime against humanity doctrine in the Nuremberg Judgment provides analytical support for the notion that liability law should maintain a distinction between research and therapy in the Human Genome Era.[149] In the context of the Canavan Disease Case, the Nuremberg Code does not give the plaintiffs a trump card in the pending motion to dismiss. Rather the important lesson from the Nazi physicians' trials is that a total professionalization of the decision-making process about scientific advancement can set in motion dangerous social forces in our quest for genetic health.[150]

C. *Should Courts Use Liability Rules to Impose a Duty to Disclose Information That Might Not Be Required by Federal Regulations?*

An institutional explanation exists for why there are so few cases actually supporting the plaintiffs' claim: the emergence of the regulatory regime in human research. Since the revelations surrounding the Tuskegee Study in the mid-1970s, research with human subjects has been covered by a number of federal regulations.[151] Generally this has meant that once the regulatory standards for obtaining and administering consent have been followed, the researcher's legal obligations are assumed to have been discharged. Furthermore, when a problem with consent has emerged, the research community and bioethicists have usually focused on modifying the regulations or suspending the research until the problem could be resolved.[152]

If federal funds were used in the Canavan Disease Case, some type of "institutional review committee" is assumed to have reviewed and approved the particular informed consent form signed by the individual plaintiffs after 1994.[153] The primary purpose of this review would have been to protect the subjects from any unacceptable levels of risk of harm,

149. *See generally* Morin, *supra* note 18 (presenting inclusive view of human experimentation including Nuremberg, Tuskegee, DES, and others, as well as recommending different duty to disclose information depending on whether subject is patient or volunteer research subject).

150. *See generally* Dolgin, *supra* note 89 (discussing sociological and legal reaction to impact of bio-genetics on "traditional family").

151. *See* Morin, *supra* note 18, at 168-95 (discussing evolution of governmental regulation of experimentation with human subjects).

152. *See* Daniel S. Greenberg, *Stricter Regulation Proposed for U.S. Gene-Therapy Trials*, LANCET, June 3, 2000, at 1977, 1977 (describing initial heightened regulatory response to death of eighteen-year-old Jesse Gelsinger during gene therapy research trial at University of Pennsylvania); Barker, *supra* note 8, at 623 n.56 (listing research centers that halted research involving human subjects); *see also* Wilder J. Leavitt, Comment, *Regulating Human Gene Therapy: Legislative Overreaction to Human Subject Protection Failures*, 53 ADMIN. L. REV. 315, 326 (2001) (describing some requirements of NIH's extensive guidelines); Philip J. Hilts, *New Voluntary Standards are Proposed for Experiments on People*, N.Y. TIMES, Sept. 29, 2000, at A16 (discussing proposal for increased requirements for human experimentation).

153. *See* 45 C.F.R. § 46.109 (2001) (requiring that IRB review and approve all research activities covered by Federal Policy for the Protection of Human Subjects).

be it physical, social or psychological.[154] A well functioning Institutional Review Board (IRB)[155] would be concerned with protecting the privacy of individuals whose names were in the Canavan disease registry allegedly given to the defendant physician.[156] Once the regulations were complied with, the question becomes whether any reason or basis exists for a liability suit.

Surprisingly, the answer to this question is found in the regulations' requirements for consent, which state:

> No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents for liability for negligence.[157]

Whatever the intended purposes of the federal regulations governing human subjects research, this language clearly states that meeting the requirements of informed consent does not absolve the researchers or physicians from liability.

The question that must be resolved is whether the duty to disclose one's intentions regarding patenting is based in negligence or a particular theory of strict liability. The duty the *Greenberg* plaintiffs are urging the court to adopt should be viewed as based in general duties of negligence. The essence of the complaint is that the physician/researcher should have known that volunteers who were brought to the researcher's attention by patient advocacy groups would have expected wide access to any diagnostic tests in exchange for their cooperation in the research.[158] The strict liability aspect of their suit will become relevant only if they are able to survive the motion to dismiss and have a chance to argue the degree to which causation plays a role in their ultimate ability to obtain some relief.

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154. *See* 45 C.F.R. § 46.111 (2001) (listing minimization of risk to subjects as one of several approval requirements).

155. *See* National Institutes of Health, *Bioethics Resources on the Web: Human Subjects Research and IRBs* (describing function and operation of Institutional Review Board), *at* http://www.nih.gov/sigs/bioethics/IRB.html (last visited Sept. 13, 2001).

156. *See* Complaint ¶ 19, Greenberg v. Miami Children's Hosp. Research Inst. Inc. (N.D. Ill. Oct. 30, 2000) (No. 00-CC-6779) (alleging that registry provided defendant physician with "critical contact information and pedigree and familial data").

157. 45 C.F.R. § 46.116 (2001); *see also* National Science Foundation: Protection of Human Subjects, 45 C.F.R. § 690.116 (2001) (adopting regulations equivalent to 45 C.F.R. § 46.116); Exec. Order No. 12,975, 64 Fed. Reg. 50,733 (1995-1999), *reprinted in* 42 U.S.C. § 6601 (creating National Bioethics Advisory Commission).

158. *See generally* Complaint, *Greenberg* (No. 00-CC-6779) (alleging lack of informed consent to use of research for patenting of resulting diagnostic and screening tests).

For the purposes of the motion to dismiss, the plaintiffs need to emphasize their status as human subjects in order to make the patient-based doctrines of disclosure, causation and other barriers to their recovery inapplicable.

On the other hand, the federal regulations are structured for prevention, not for resolving after-the-fact adjudication of duties in novel situations. The federal regulations diffuse responsibility for obtaining informed consent among the investigator, the IRB and the institution.[159] Within this regulatory context, researchers' values and interests are likely to dominate the decision-making process. The normal rules for reviewing the ethical appropriateness of research are now considered by some to require modification as we move into novel areas such as human stem cell research.[160] A general concern is also growing about the overall effectiveness of the IRB process in monitoring the obtaining and administration of consent from volunteers.[161] The regulations themselves do not provide immunity from civil suits,[162] nor do they limit attempts by individuals to exercise social control over professionals and their organizations as they manage disease processes in the Human Genome Era.

VI. CONCLUSION

For the plaintiffs in the Canavan Disease Case to survive the motion to dismiss, the court must view their liability claim as a problem in comparative institutional analysis.[163] Once the plaintiffs demonstrate that they are

159. *See* 45 C.F.R. § 46.116 (describing general requirements for informed consent).

160. *See* National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants*, May 18, 2001 (recommending changes to system which protects human research subjects), *available at* http://bioethics.gov/press/finalrecomm5-18.pdf (last visited Sept. 1, 2001); *see also National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells*, 65 Fed. Reg. 51,976 (2000) (providing guidance on how to conduct NIH-funded stem cell research both ethically and legally), *available at* http://www.nih.gov/news/stemcell/stemcellguidelines.htm (last visited Sept. 1, 2001).

161. *See* D. Christian Addicott, *Regulating Research on the Terminally Ill: A Proposal for Heightened Safeguards*, J. CONTEMP. HEALTH L. & POL'Y 479, 481-96 (1999) (critiquing IRBs while discussing federal regulation of research involving human subjects with focus on vulnerable populations); Kerry Burke, Note, *Loose-Fitting Genes: The Inadequacies in Federal Regulation of Institutional Review Boards*, 3 B.U. J. SCI. & TECH. L. 10, 12-47 (1997) (discussing problems with IRBs in context of breast cancer).

162. *See, e.g.*, Medtronic v. Lohr, 518 U.S. 470, 501-02 (1996) (holding that none of plaintiff's claims based on allegedly defective manufacturing or labeling are pre-empted by Medical Device Amendments to Federal Food, Drug, and Cosmetic Act).

163. For an explanation and application of comparative institutional analysis, see Neil K. Komesar, *The Perils of Pandora: Further Reflections on Institutional Choice*, 22 LAW & SOC. INQUIRY 999, 1000 (1997) (discussing difficulties in realities of institutional choice analysis); Neil K. Komesar, *Injuries and Institutions: Tort Reform, Tort Theory, and Beyond*, 65 N.Y.U. L. REV. 23, 25-26 (1990) (introducing comparative institutional analysis); Lynn M. LoPucki, *The Systems Approach to Law*, 82 CORNELL

human subjects, they must argue that their giving "informed consent" to the taking of DNA from their blood and tissue under federal regulation does not preclude the possibility of liability on the part of the researchers. In addition, the Nuremberg Code on informed consent provides analytical support for the expansion of liability for lack of disclosure in the Human Genome Era. Finally, the liability rules regarding the obligations to disclose information have different theoretical justifications in research and therapeutic settings. In the latter, liability rules for failing to disclose information allow courts in hindsight to weigh the benefits and risks of medical intervention, and are perhaps skewed in favor of defendant providers. In the former, the obligation to discuss all relevant information is grounded in notions of strict liability because the underlying purpose is to protect the subject's right to non-participation.

Access to human populations is a crucial aspect of disease management in the Human Genome Era.[164] A duty to disclose one's intentions regarding patenting would not significantly impede the functioning of the patent system as long as liability is placed on the researchers. The underlying theory of disclosure proposed here for the Canavan Disease Case is one of protecting information flow, not just individual autonomy. Without the cooperation of groups of individuals identified by social and ethnic status, the promises of the Human Genome Era will not be realized.

Law professors, particularly those who teach about medicine and related matters, might like to speculate about how to avoid past abuses as we talk about the promises of the future. Nevertheless, we are in the "disaster business"—searching in all human disasters for pedagogical fruits or "teachable moments." The Human Genome Project has already produced some such "disaster-fruits" in the form of gene therapy gone awry at the University of Pennsylvania Hospital, where a young man died during the course of experimental gene transfer treatment.[165] Unsurprisingly, the young man's family filed a lawsuit against the University of Pennsylvania,

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L. REV. 479, 481 (1997) (defining "systems analysis"); see also Palmer, *supra* note 24, at 167-78 (providing evaluation and example of application of institutional analysis).

164. The importance of researchers' access to different population groups transcends national borders, and the problem of international "bioprospecting" of genetic material and the patenting of products from those materials has already been addressed at international levels. *See* Annie Wu, Note, *Surpassing the Material: The Human Rights Implications of Informed Consent in Bioprospecting Cells Derived from Indigenous People Groups*, 78 WASH. U. L.Q. 979, 981 (2000) (arguing that "international intellectual property protection afforded by Biodiversity Convention and TRIPS Agreement are not sufficient to protect indigenous people groups from bioprospectors who fail to obtain informed consent"); *see also* Cindy Hamilton, Comment, *The Human Genome Diversity Project and the New Biological Imperialism*, 41 SANTA CLARA L. REV. 619, 621 (2001) (discussing how United States intellectual property law affects populations sampled).

165. *See generally* Greenberg, *supra* note 152, at 1977 (discussing intentions to tighten restriction on informed consent, conflicts of interest and regulatory requirements for clinical trials, intentions to impose fines up to million dollars for their violation, and University's reaction to Jesse Gelsinger's death).

the physicians involved in the experiment, the biotech company that produced the product used in the experimental treatment and the director of Penn's Center for Bioethics.[166] That lawsuit was recently settled.[167]

Thus, the Canavan Disease Case may be one of the first cases in which we will at last have a full adjudication of the nature of legal duties under liability law of those seeking to manage genetic disease. Its significance lies not only in the novelty of its legal issues, but also in the plaintiffs' attempts to have a voice in how the gene rush should be conducted. If they succeed in establishing the duty, it remains to be seen if individuals will cooperate with research efforts knowing the specter of commercial benefit for the researchers.[168] One means of preventing an outcome similar to that experienced by the plaintiffs in *Greenberg*, is for the volunteers to file as co-inventors on the patent application for the genetic test derived from their human materials.[169] If the duty to disclose proposed for the Canavan Disease Case inhibits the patenting of the gene for other diseases, we must entertain the possibility that allowing the patenting of genes—as opposed to imposing liability rules—might have slowed the pace of research for cures.[170] Liability law provides merely an incentive for researches and clinicians to manage genetic disease in accordance with the evolving social norms of the Human Genome Era.[171]

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166. *See* Mary R. Anderlik & Nanette Elster, Symposium, *Currents in Contemporary Ethics*, 29 J.L. MED. & ETHICS 220, 220 (2001) (describing named defendants in Gelsinger's lawsuit).

167. *See* Anderlik & Elster, *supra* note 166, at 221 (noting November 3, 2000 settlement on undisclosed terms). For a discussion of the legislative reaction to the Gelsinger incident, see generally Greenberg, *supra* note 165.

168. *See* Miller, *supra* note 122, at 443 (arguing that "[d]isclosure of such information will not deter most potential subjects from participating in clinical trials, because medical profession still enjoys a high degree of trust from most people"). Miller argues that despite the high trust placed in physicians by most people, disclosure pays the respect owed to the autonomy of human subjects. *See id.* (supporting disclosure of information vital to subject's informed consent).

169. *See* Tebo, *supra* note 45, at 46 (noting that patient advocacy group filed joint patent application with researchers); Eliot Marshall, *Families Sue Hospital, Scientist for Control of Canavan Gene*, SCI., Nov. 10, 2000, at 1062 (noting that Canavan Disease Case prompted other patient groups to head off clashes by working out legal agreements in advance and citing University of Hawaii joint patent application as example).

170. The Patent Office is becoming concerned with the tendency to patent every bit of genetic data as opposed to new drugs based on genetic knowledge. *See* Tebo, *supra* note 45, at 48 (stating that since 1980 about 1000 patent applications involving animal or human DNA have been filed). ,Or put another way, it is not clear that the researcher who discovers the gene is in the best position to determine the most effective means of managing disease processes in the Human Genome Era. *See id.* (noting unprecedented power patent holder can wield). Some patent scholars give the impression that without patent law there would be no "invention" from the Human Genome Project. *See generally* Eisenberg, *supra* note 27 (illustrating nature of scientific enterprise surrounding genomics).

171. For a discussion of other proposals on how law can deal with patents in the context of biotechnology, see O'Rourke, *supra* note 42, at 1180 (arguing that traditional assumption that patentees will efficiently license their inventions is

breaking down as market failures are becoming endemic). O'Rourke argues that "to ensure that patent law achieves its constitutional goals, it should, like copyright law, use a fair use defense to address problems of market failure." *Id.* at 1177; *see also* Alexander K. Haas, *The Wellcome Trust's Disclosure of Gene Sequence Data into the Public Domain & the Potential for Proprietary Rights in the Human Genome*, 16 BERKLEY TECH. L.J. 145, 157-59 (2001) (arguing that disclosure of genome's raw sequence destroys its patentability by destroying novelty of disclosed sequences).