THE EVOLUTION OF THE "PATIENT": SHIFTS IN ATTITUDES ABOUT CONSENT, GENETIC INFORMATION, AND COMMERCIALIZATION IN HEALTH CARE

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I. INTRODUCTION

A momentous ideological[1] change in the world of health care has accompanied the advent of managed care,[2] third party payers, soaring costs,[3] and sophisticated medical technology.[4] The ideological change

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I am grateful to Katherine R. Dieterich and Elizabeth Henries, both 2005 graduates of Hofstra Law School, for assistance with research and to Cindie Leigh, Reference Librarian, Hofstra Law School, for her insightful, intelligent, and generous help in identifying and locating research materials.

1. "Ideology" and "ideological," as used here, do not refer to a system of political beliefs. Rather, these terms refer to the essential assumptions (often unarticulated) through which a society makes sense of itself and its world. This use follows that of the French anthropologist Louis Dumont:

> Our definition of ideology thus rests on a distinction that is not a distinction of matter but one of point of view. We do not take as ideological what is left out when everything true, rational, or scientific has been preempted. We take everything that is socially thought, believed, acted upon, on the assumption that it is a living whole, the interrelatedness and interdependence of whose parts would be blocked out by the a priori introduction of our current dichotomies.

LOUIS DUMONT, FROM MANDEVILLE TO MARX 22 (1977).

2. *See* STEPHEN M. AYRES, HEALTH CARE IN THE UNITED STATES: THE FACTS AND THE CHOICES 187-88 (1996).

3. *See* JOHN ABRAMSON, OVERDO$ED AMERICA: THE BROKEN PROMISE OF AMERICAN MEDICINE 76 (2004) (reporting that in the last two decades of the twentieth century, "[p]er-person health care expenditures, adjusted for inflation, more than quadrupled"); REGINA E. HERZLINGER, MARKET-DRIVEN HEALTH CARE: WHO WINS, WHO LOSES IN THE TRANSFORMATION OF AMERICA'S LARGEST SERVICE INDUSTRY xxi-xxiii, 225-26 (1997) (noting hospital interest in expansion as method of attracting patients and physicians).

4. Managed care, third-party payers, and the increasing commercialization of health care have replaced the solo practitioner. General practitioners, making house calls and knowing patients from birth until death have been replaced by specialists and sub-specialists. *See* PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 355-59 (1982). Hospitals compete for patients in a commercial marketplace. HERZLINGER, *supra* note 3, at 225-26 (noting hospital interest in expansion as method of attracting patients and physicians). Sophisticated machinery and complicated medical tests have made the stethoscope practically obsolete. *See* LEWIS THOMAS, THE YOUNGEST SCIENCE: NOTES OF A MEDICINE-WATCHER 57-60 (1983) (describing place of computers and "complicated new technologies" in replacing clinical examinations that include

has facilitated a far-reaching transformation in the physician-patient relationship. A form of relationship grounded in hierarchy and trust[5] has been replaced by one grounded in the presumption that physician and patient should relate to each other as autonomous individuals.[6]

This Article suggests that alongside the salutary consequences of patient autonomy,[7] a set of troubling *excesses* has developed. The Article explores the parameters of those excesses. It argues that legal and social stress on the importance of patient autonomy has sometimes facilitated a set of worrisome consequences. Part II describes a set of structural and economic changes that transformed the world of health care in the United States, beginning in the last decades of the twentieth century. Part III then reviews the genesis of patient autonomy and its implications

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physicians touching patients and entering into dialogue with them).

5. The ideological change described in this Article is not unique to the world of health care. Over two centuries ago, the marketplace of the Industrial Revolution was shaped by the presumption of putatively equal, autonomous individuals, entering freely into bargains with other, similar individuals. The same set of presumptions has been essential to the development of contract law, and for about two centuries has served to distinguish the world of contract and commerce from that of familial, religious, and personal relationships, and to some, though a lesser, extent, from relationships between patients and physicians. *See generally* Janet L. Dolgin, *The Family in Transition: From* Griswold *to* Eisenstadt *and Beyond*, 82 GEO. L.J. 1519 (1994) (comparing presumptions underlying Lochner v. New York, 198 U.S. 45 (1905) from those underlying both Griswold v. Connecticut, 381 U.S. 479 (1965) and Eisenstadt v. Baird, 405 U.S. 438 (1972)).

6. Ruth Faden and Tom Beauchamp describe "[r]espect for autonomy" in their history of the informed consent doctrine. *See* RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 7 (1986). They write:

> Respect for autonomy . . . is conceived as a principle rooted in the liberal Western tradition of the importance of individual freedom and choice, both for political life and for personal development. "Autonomy" and "respect for autonomy" are terms loosely associated with several ideas, such as privacy, voluntariness, self-mastery, choosing freely, the freedom to choose, choosing one's own moral position, and accepting responsibility for one's choices.

Id. In what they describe as a more "sustained analysis" of the term, Faden and Beauchamp explain that autonomy depends on "intentionality," *Id*. at 7, 241; on understanding by the actor of an action, *Id*. at 248; and on the actor's being "free of—that is, independent of, not governed by—controls on the person, especially controls presented by others, that rob the person of self-directedness." *Id*. at 256.

The significance of safeguarding autonomy and individual rights within the world of health care has become a central motif in bioethical discourse in the last three decades. ONORA O'NEILL, AUTONOMY AND TRUST IN BIOETHICS 2 (2002) (noting that "no themes have become more central in large parts of bioethics, and especially in medical ethics, than the importance of respecting individual rights and individual autonomy").

Thus, the transformation of medical practice from cottage industry to big business has, not surprisingly, been accompanied by momentous shifts in understandings of the various actors who populate the world of health care. *See* AYRES, *supra* note 2, at 132.

7. *See, e.g.*, JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 14 (2d ed. 2001) (describing focus on "autonomy and concern for individual well-being" and the informed consent doctrine, undergirded by those values, as "cornerstone doctrine of contemporary medical ethics and health law in the United States").

for understandings of the doctor-patient relationship. Part IV describes three settings within which stress on patient autonomy, though generally beneficial, has proved of questionable value or has proved openly harmful to health care. The first setting, that of the development of the informed consent doctrine, has resulted in what this Article refers to as the *elaboration of individualism*. The second setting, that of rules about the disclosure of genetic information, has resulted in what the Article refers to as the *perversion of individualism*. The third setting, a consumer marketplace in infertility treatment, differs somewhat from the other two. It is not centrally concerned with information. Moreover, it has largely developed in the absence, rather than through the promulgation, of legal rules and regulations. The development of a consumer market in infertility care has led to what this Article refers to as the *generalization of individualism.*[8]

II. AUTONOMOUS INDIVIDUALITY WITHIN THE WORLD OF HEALTH CARE

This Part summarizes a set of structural and economic changes in the world of health care, beginning in the late twentieth century. It then describes the ideological shifts on which the re-shaping of the doctor-patient relationship in the same years was premised.

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8. A disclaimer is in order. Although this Article, of necessity, refers to and describes aspects of the broad transformation that has changed the nature of medical care in the United States in the last several decades, it does not expressly delineate the implications of that general history except insofar as it has affected the development of the ideological perspective this Article considers in detail.

Beyond and beside the ideological shifts described in this Article is a myriad of political, social and economic factors, both internal and external to the world of health care. These factors have played a central role in transforming health care. *See, e.g.*, STARR, *supra* note 3, at 8-9 (noting that the transformation of American medicine has occurred within a much larger social and political structure). These other factors are only addressed in this Article insofar as their development is essential for understanding the ideological changes on which the Article focuses.

Among useful, scholarly works delineating the broader history of American medicine are AYRES, *supra* note 2; HERZLINGER, *supra* note 4; SICKNESS AND HEALTH IN AMERICA: READINGS IN THE HISTORY OF MEDICINE AND PUBLIC HEALTH (Judith Walzer Leavitt & Ronald L. Numbers eds., 3d ed. 1997); STARR, *supra* note 4.

Even more, the Article focuses on only certain aspects of one ideological change that has reshaped understandings of physician and patient. Because the Article is concerned with describing and analyzing practical and ideological excesses, it does not describe in detail the beneficial consequences of a model for relationship that prizes autonomous individuality. Useful analyses that present the salutary dimensions of having appropriated a model for action that values autonomous individuality within the world of health care include: FADEN & BEAUCHAMP, *supra* note 6; ALBERT R. JONSEN, THE BIRTH OF BIOETHICS (1998).

A. Background: Structural and Economic Changes

Until the second half of the twentieth century, the practice of medicine in the U.S. was a cottage industry.[9] Physicians typically worked as sole practitioners or as members of small partnerships.[10] Most patients paid physicians directly for medical care.[11] Although the image of the physician-of-yesteryear as compassionate, caring healer is in some part mythic,[12] doctors typically made house calls, touched their patients in the course of clinical examinations,[13] and entered into life-long conversations with them.[14] On the other side, the trust that defined the physician-patient relationship was not always "reasonable trust."[15] That notwithstanding, the relationship between patients and physicians was largely unmediated before the end of the twentieth century.[16] Paul Starr explained:

> Prior to the rise of third parties, doctors stood in direct relation to their patients as healers and benefactors. According to traditional ideals, which are not entirely fictitious, doctors gave care according to the needs of the sick and regulated fees according to the patients' ability to pay, which was, in effect, the doctors' ability to charge.[17]

By the 1980s, only vestiges of that world survived. In his comprehensive history of the "transformation" of American medicine Starr asserted in 1982 that health care in the U.S. was "in the early stages

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9. *See* AYRES, *supra* note 2, at 132 (noting change during the second half of the twentieth century from health care as "fee-for-service, solo-practice environment to one with increasing penetration of large group practices that use a variety of managed care techniques to contain costs").

10. *See id.*

11. *See* Kate Borten, *Privacy in the Healthcare Industry, in* INFORMATION SECURITY MANAGEMENT HANDBOOK 45, 45 (Harold F. Tipton & Micki Krause eds., 5th ed. 2003).

12. *See* HERMAN MILES SOMERS & ANNE RAMSAY SOMERS, DOCTORS, PATIENTS, AND HEALTH INSURANCE: THE ORGANIZATION AND FINANCING OF MEDICAL CARE 457 (1961) (describing "popular conception of the doctor-patient relationship" as "a mixture of fact and fancy").

13. *See* THOMAS, *supra* note 4, at 56-57 (noting the need of sick people to be touched and that contemporary physicians can treat patients from "another building without ever seeing the patient" due to computers and modern diagnostic testing).

14. *See id.* at 59 (describing "talking with the patient" as the "biggest part of medicine" in the early years of twentieth century).

15. O'NEILL, *supra* note 6, at 18 (critics of traditional doctor-patient relationship claimed "patients who placed trust in their doctors were like children who initially must trust their parents blindly").

16. The issue of health insurance first appeared in the United States at about the time of World War I. *See* STARR, *supra* note 4, at 236. The appearance of the "Blues" (Blue Cross and Blue Shield) in the 1920s was an important step in the growth of third-party payers. *Id*. at 295-98 (placing "Birth of the Blues" between 1929 and 1945). After World War II, health insurance usually covered hospitalization. *Id.* at 313.

17. *Id.* at 235-36.

of a major transformation in its institutional structure" that could create "an industry dominated by huge health care conglomerates."[18] Many factors were responsible for that transformation. These included the skyrocketing costs of health care,[19] the diminishing promise of ever more impressive medical care,[20] and the unmet health care needs of a large segment of the population.[21] Partly in response to these factors, the government began to exercise far more interest in regulatory control over health care in the United States.[22]

> American medicine, the consensus held, was overly specialized, overbuilt and overbedded, and insufficiently attentive to the needs of the poor in inner-city and rural areas. The system needed fewer hospitals, more "primary" care, incentives to get doctors into underserved communities, and better management and organization. And most of all, Americans required national health insurance . . . .[23]

In responding to the perceived crisis, the public and private sectors voiced increasing support for health maintenance organizations (HMOs).[24] However, the HMOs that developed at this time differed from the model constructed by Kaiser Permanente in the 1940s. That model, as the phrase "health maintenance organization" suggests, focused on safeguarding health.[25] The HMOs of the 1970s, focused not on safeguarding health so much as on minimizing costs.[26] By the 1980s, enrollment in health maintenance organizations had become the norm in at least some states,[27] and by the 1990s, the American Medical Association ceded its opposition to group practices and offered its support for the concept of HMOs.[28]

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18. *Id.* at 428.
19. *See id.* at 379, 381-83.
20. *See id.* at 379.
21. *See id.* at 382.
22. *See id.* 379-80.
23. *Id.* at 382.
24. In early 1971, then-President Richard Nixon asked Congress to support the development of health maintenance organizations (HMOs). *See id.* at 396. Starr asserts that the health care industry attracted commercial investors after the creation of Medicare and Medicaid. These programs, Starr suggests, made health care "lucrative." *Id*. at 428.

The HMO model was also taken up by the state governors in New York (Nelson Rockefeller) and California (Ronald Reagan). *See id.* at 396 (noting that in the 1970s, the "conservative, cost minded critics of medical care" took up the HMO model that had previously been seen as a product of "the cooperative movement" and as vaguely "subversive").
25. *See* HERZLINGER, *supra* note 3, at 109.
26. *See id.*
27. *See* AYRES, *supra* note 2, at 129. (noting that by the 1980s HMOs covered over 50% of the population in places such as Minneapolis and Northern California).
28. *See id.*

With the move to HMOs,[29] insurance companies and other third-party payers began increasingly to direct the practice of medicine, including patients' choice of doctors.[30] In all likelihood, HMOs were not directly responsible for the weakening of the physician-patient relationship. Yet, their development was facilitated by an earlier transformation of that relationship[31] that resulted from a combination of physician specialization (reducing the importance of contact between patients and their doctors) and malpractice litigation.[32] In any event, by the 1970s, the development of health maintenance organizations significantly eroded trust and loyalty between physicians and patients.

B. Support from Constitutional Jurisprudence

Other changes, within and outside the world of health care, facilitated the transformation of the relationship between patients and physicians in the same years. Among these, a new focus in constitutional jurisprudence in the last half of the twentieth century prepared the ground on which the physician-patient relationship was redefined by courts and legislatures.

Brown v. Board of Education[33] symbolizes, perhaps more than any other case, the flowering of a jurisprudence committed to the protection of individual rights. *Brown* was grounded in the text of the Fourteenth Amendment,[34] but it foreshadowed later cases that relied on a less

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29. As the HMO model proliferated, it began to replace indemnity insurance. *See* HERZLINGER, *supra* note 3, at 129.

30. As people change jobs and as employers switch from one HMO to another, patients are often compelled to change doctors (or to pay their own doctor bills). There have been many other essential changes that have developed as a result of managed care. *See, e.g.*, HERZLINGER, *supra* note 3, at 110-27 (discussing effects of managed care). This Article focuses on the effects on patients' abilities to choose their doctors because that matter is of importance to the character of the relationship between doctors and patients.

31. *See* STARR, *supra* note 4, at 445. John C. Burnham similarly describes the transformation away from the image of doctor-as-hero in the decades preceding the widespread appearance of HMOs. *See* John C. Burnham, *American Medicine's Golden Age: What Happened to It?, in* SICKNESS & HEALTH IN AMERICA, *supra* note 8, at 284. Burnham notes that, among other factors reshaping the physician/patient relationship in the United States after World War II was the "widespread anti-institutional sentiment along with a general disillusionment with many aspects of American life." *Id*. at 287.

32. STARR, *supra* note 4, at 445.

33. *See* 347 U.S. 483 (1954).

34. The first section of the Fourteenth Amendment declares:

> All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

specific set of constitutional referents to extend constitutional protection to individuals within other, especially familial, settings.[35] Many of the legal cases that recognized the right of family members to autonomous choice concerned reproductive liberties.[36] These cases therefore implicated matters of health care as well as the place of individuals within families. The cases suggested, albeit implicitly, that individual patients were entitled to constitutional protection just as individual family members were so entitled.[37] The message of these decisions harmonized with the notion being developed at about the same time by lawmakers and bioethicists,[38] that patient autonomy deserves respect in clinical and experimental settings.[39]

C. The Ground for New Guidelines: Changing Ideological Presumptions

Other currents merged with the structural and economic shifts in the world of health care,[40] and with the development of a constitutional jurisprudence protecting *individual* rights,[41] to reinforce the significance of patient autonomy. Central among these currents was the appearance of bioethics[42] as a field of practical and academic inquiry, beginning in

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U.S. CONST. amend. XIV, § 1.

35. *See, e.g.*, Griswold v. Connecticut, 381 U.S. 479 (1965) (invalidating state birth control law through reference to constitutional penumbras that defined a right to privacy). In *Griswold*, the Court explained that "[v]arious guarantees create zones of privacy." *Id*. at 484. The Court then located these "zones of privacy":

> The right of association contained in the penumbra of the First Amendment is one, as we have seen. The Third Amendment in its prohibition against the quartering of soldiers "in any house" in time of peace without the consent of the owner is another facet of that privacy. The Fourth Amendment explicitly affirms the "right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures." The Fifth Amendment in its Self-Incrimination Clause enables the citizen to create a zone of privacy which government may not force him to surrender to his detriment. The Ninth Amendment provides: "The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people."

Id. at 484.

36. *See id.*

37. *See, e.g.*, Cruzan v. Dir., Mo. Dep't Health, 497 U.S. 261, 278 (1990) (describing constitutional protection for dying individuals and upholding a Missouri statute that required clear and convincing evidence of patient wishes in the case of a woman in a persistent vegetative state, and noting "liberty interest in refusing medical treatment").

38. *See infra* notes 42-47 and accompanying text (noting development of bioethics as a field of study).

39. *See, e.g.*, *Cruzan*, 497 U.S. 261.

40. *See supra* notes 9, 18-19 and accompanying text.

41. *See supra* note 8 and accompanying text.

42. Bioethics is defined as "the systematic study of the moral dimensions—including moral vision, decisions, conduct and policies—of the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting." JONSEN, *supra* note 8, at vii (citing WARREN

the 1960s.[43] Scholars, lawyers, physicians, and others, defining themselves as bioethicists, have played a key role in framing the autonomy of patients and research subjects as crucial to the morality of health care and biomedical research.[44] In these contexts, autonomy is generally understood to include some aspect of liberty, dignity, individuality, independence, privacy, voluntariness, and free choice.[45]

III. INDIVIDUALISM AND COMMERCIALISM IN THE WORLD OF HEALTH CARE

Bioethical theory began to coalesce in the years after World War II in response to the horrific abuses committed by Nazi doctors.[46] Later, other revelations about the abuse of human subjects in the U.S., motivated bioethicists and lawmakers to fashion guidelines for the protection of research subjects.[47] Central to these responses was broad support for safeguarding individual autonomy in clinical and

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T. REICH, *Introduction* to THE ENCYCLOPEDIA OF BIOETHICS xxi (rev. ed. 1995)).

There is some debate about when the term "bioethics" was first used, but at least by the early 1970s, it had appeared. The Kennedy Institute, founded in 1971, was named The Joseph and Rose Kennedy Institute for the Study of Human Reproduction and Bioethics. *See* O'NEIL, *supra* note 6, at 1. (citing W.T. Reich, The Word 'Bioethics': Its Birth and the Legacies of Those Who Shaped It, 4 KENNEDY INSTIT. ETHICS J. 319 (1994)).

Although bioethics may well be more a "meeting ground" for dialogue than a full-fledged academic discipline as the British philosopher Onora O'Neill has claimed, "bioethicists" have gained increasing clout and prestige in the last several decades. *Id.*

43. *See* JONSEN, *supra* note 8, at vii.

44. At one of the first "Bioethics" conferences, held at Reed College in Oregon in 1966 (and called "The Sanctity of Life"), Professor Abraham Kaplan, a philosopher from UCLA summarized the conference proceedings:

> The moral judgment must accord with the principle of moral autonomy, as it has been known in philosophy since Immanuel Kant. The moral will must be a lawgiver unto itself; . . . in that case, we are committed to respecting the *moral autonomy* of other moral agents as well.

Id. at 18 (emphasis added) (describing Kaplan's summary to have "presaged a dominant principle of future bioethics").

45. The list was compiled by O'Neill. She relied in part on Gerald Dworkin, who noted that autonomy has been equated with:

> Liberty (positive or negative) . . . dignity, integrity, individuality, independence, responsibility and self-knowledge. . . . self-assertion. . . . critical reflection . . . freedom from obligation . . . absence of external causation . . . and knowledge of one's own interests.

O'NEILL, *supra* note 6, at 21 (citing GERALD DWORKIN, THE THEORY AND PRACTICE OF AUTONOMY 6 (1988); Gerald Dworkin, *The Concept of Autonomy*, *in* THE INNER CITADEL 54 (John Christman, ed. 1989)) (alteration in original). She also relied on Ruth Faden and Thomas Beauchamp who noted that autonomy has been linked with: "privacy, voluntariness, self-mastery, choosing freely, choosing one's own moral position and accepting responsibility for one's choices." O'NEILL, *supra* note 6, at 22 (citing FADEN & BEAUCHAMP, *supra* note 6).

46. *See infra* note 52 and accompanying text.

47. *See infra* notes 58-59 and accompanying text.

experimental settings.

This Part reviews this history. It also considers the somewhat different, though not unrelated, appearance of patient autonomy in the marketplace of late twentieth century health care, a phenomenon also facilitated by the growing significance of patient autonomy. The creation of a consumer market in infertility care provides a powerful illustration. A review of both sets of developments, the construction of guidelines ensuring patient autonomy and the development of the patient-as-consumer, is a necessary prerequisite to the discussion in the next Part of the Article of three kinds of ideological excesses that have accompanied the increasing stress on individual autonomy in the world of health care.

A. The Development and Elaboration of Individualism: The Informed Consent Example

This Section reviews the development of the informed consent doctrine in the United States. It provides background for the discussion in the next Part of the elaboration and perversion of the doctrine.

The informed consent doctrine developed from two strands of ethical concern, one for protection of human subjects of experimental research, the other for protection of patients in clinical settings.[48] These two strands in the development of the notion of informed consent are considered, respectively.

1. Development of the Informed Consent Doctrine in the Context of Research Involving Human Subjects

In both research and clinical settings, development of the informed consent doctrine rested on a broad cultural shift that provided for recognition of the *autonomous* research subject and for the *autonomous* patient. The informed consent requirement appeared in research settings a few years before it was applied in clinical settings.[49] In research settings, the doctrine was constructed in express response to the revelation of abuses of human subjects by researchers. The deliberations that followed led to construction of the informed consent doctrine and to the institutionalization of "bioethics" as an area of study and practice. One theorist referred to the discourse about experimentation that surrounded the revelation of such abuses of human subjects of research as the "defining moment for bioethics."[50]

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48. *See* FADEN & BEAUCHAMP, *supra* note 6, at 151.

49. *See, e.g.*, *id.* at 151-99 (summarizing the history of informed consent rules in the context of human subject research).

50. *Al Jonsen Produces Sourcebook and History of Bioethics*, U. WK., July 23, 1998,

More specifically, the informed consent requirement emerged as the most important concretization of the realization that it is essential as a matter of morality to safeguard the autonomy of human research subjects. As lawyers, doctors, church representatives, and philosophers, faced with horrors such as those committed by Nazi doctors, balanced the "social good" of human experimentation against increasing respect for individual autonomy, the later principle emerged the victor.[51]

One of the most consequential statements about the ethical principles that should govern research involving human subjects emerged from the deliberations of the judges that tried Nazi doctors and researchers[52] at Nuremberg after World War II.[53] The trial, referred to as the Nazi Doctors Trial,[54] resulted in the conviction of fifteen Nazi doctors. The opinion of the Nuremberg court included a broad assessment of basic moral obligations owed by researchers to human subjects of research. This assessment, referred to as the Nuremberg Code,[55] delineated basic moral principles to guide those engaged in research and experimental work with human subjects. Among other things, these principles require subject consent to participation in research and require researchers to focus on avoiding harm to research subjects.[56] The first principle delineated by the court at Nuremberg

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available at http://depts.washington.edu/~uweek/archives/1998.07.JUL_23/article14.html.

51. JONSEN, *supra* note 8, at 334-35. Dr. Jay Katz, noting the need to respect the autonomy of human subjects of biomedical research, explained that society has been "all too willing, in our longing to conquer disease and death, 'to possess the end and yet not be responsible for the means, to grasp the fruit while disavowing the tree, to escape being told the cost, until someone else has paid it irrevocably.'" Jay Katz, *Human Experimentation and Human Rights*, 38 ST. LOUIS U. L.J. 7, 39 (1994) (quoting Edmond Cahn, *Drug Experiments and the Public Conscience*, *in* DRUGS IN OUR SOCIETY 255, 260 (Paul Taladay ed., Johns Hopkins Press 1988) (1964)).

52. The experiments done by the Nazi doctors who were tried at Nuremberg (charged with "murder, tortures and other atrocities committed in the name of medical science") included forced sterilization that involved exposing the gonads of concentration camp inmates to radiation, long-term exposure of inmates to freezing temperatures and low air pressure in order to study the process of their deaths, and exposure of inmates to deadly pathogens so that the course of the resulting disease and death could be detailed by the researchers. BERG, *supra* note 7, at 250. Some other experiments done by Nazi doctors involved burning prisoners to study treatments for scarring, experiments involving grafting of bone and muscle, experiments with gases and burning fluids, sexual surgery and electroshock. *See* Document F321, For the International War Council at Nuremberg ("Das Licht"), http://www.technologyartist.com/concentrationcamp/index.html (last visited Oct. 15, 2005).

53. *See* KENNETH GETZ & DEBORAH BORFITZ, INFORMED CONSENT: THE CONSUMER'S GUIDE TO THE RISKS AND BENEFITS OF VOLUNTEERING FOR CLINICAL TRIALS 98-101 (2002). *See generally* THE NAZI DOCTORS AND THE NUREMBERG CODE (George Annas & Michael Grodin eds., 1992).

54. *See* GETZ & BORFITZ, *supra* note 53, at 99.

55. THE NUREMBERG CODE (1949), http://www.ushmm.org/research/doctors/Nuremberg_Code.htm (last visited Oct. 15, 2005) [hereinafter NUREMBERG CODE].

56. The Code begins by declaring that "[t]he voluntary consent of the human subject is

predicates ethical research on the researcher's having received "[t]he voluntary consent of the human subject."[57] The judges explained the principle to require:

> that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.[58]

The Nuremberg Code provided a useful model for U.S. lawmakers in the 1960s and 1970s, when they fashioned a response to revelations about abuses of human subjects in research settings in the U.S. The most well-known of these abuses,[59] known as the Tuskegee study, involved a long-term study of syphilis conducted by the U.S. Public Health Service on poor African-American men.[60] The subjects were deprived of

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absolutely essential." *Id.*

The Code was never officially adopted by the community of international lawmakers. *See* Shannon Benbow, Note, *Conflict & Interest: Financial Incentives and Informed Consent in Human Subject Research*, 17 NOTRE DAME J.L. ETHICS & PUB. POL'Y 181, 186 (2003).

57. NUREMBERG CODE, *supra* note 55.

58. *Id*. In the United States, this principle has been important to theoretical deliberations about the morality of human subject research. It has, however, not generally been followed in practice, largely because it would preclude research involving children and others incapable of giving consent. MICHAEL H. SHAPIRO ET AL., CASES, MATERIALS AND PROBLEMS ON BIOETHICS AND LAW 200 (2d ed. 2003). *See generally* DAVID ROTHMAN, STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING (1991).

59. Other abuses of human subjects of research in the United States included those revealed by Dr. Henry Beecher in a 1966 article in the *New England Journal of Medicine.* Beecher detailed twenty-two (of fifty) studies involving human subjects in the United States that involved unacceptable risks or other violations of ethics. *See* Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW. ENG. J. MED. 1354 (1966). Another set of revelations become public in 1986 with the release of a congressional subcommittee report (called *"American Nuclear Guinea Pigs"* and prepared for the House Subcommittee on Energy Conservation and Power). This report described unethical experiments on hundreds of people, carried out under the auspices of the federal government. *See* GEORGE J. ANNAS, SOME CHOICE: LAW, MEDICINE, AND THE MARKET 157-60 (1998).

60. *See, e.g.*, JAMES H. JONES, BAD BLOOD, THE TUSKEGEE SYPHILIS EXPERIMENT 1-2 (1981) (describing study of 400 African-American men run by the United States Public Health Service, involving observation, but not treatment, of men with syphilis over a forty year period).

information about the character of their illness, and more startlingly, were deprived of antibiotic treatment when it became available.[61] Media reports in 1972 on the history of the study led to the government's establishing a panel (Tuskegee Syphilis Study Ad Hoc Panel), commissioned to report on the study's moral and social implications.[62]

In the aftermath of revelation of the study and after the appearance of the panel's Report, Congress passed the National Research Act of 1974.[63] The Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.[64] The Commission was given the task of constructing principles for assessing the morality of human subject research. In 1979, the group presented a Report—referred to as The Belmont Report.[65] The Report detailed three "basic" ethical principles: "respect for persons, beneficence, and justice."[66] The first of these principles focused expressly on the significance of safeguarding individual autonomy. The "autonomous person," the Report explained, is one "capable of deliberation about personal goals and of acting under the direction of such deliberation."[67] "Respect for persons" was accordingly described as requiring "that individuals should be treated as autonomous agents," and that protection should be extended to "persons with diminished autonomy."[68] The Report further explained that in the research context, the concretization of respect for capable persons could be achieved through the institutionalization of the informed consent requirement.[69]

The Belmont Report served as more than a compilation of guidelines for researchers. As Albert Jonsen, one of the commissioners who created the Report, explained, the three "ethical principles"

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61. *See* JONSEN, *supra* note 8, at 146-48.

62. *See id.* at 148 (finding the study to have been immoral from the start and calling for the study's immediate end and for compensation to surviving victims of the study).

63. *See* National Research Service Award Act of 1974, Pub. L. No. 93-348, 88 Stat. 342 (1974).

64. *See id.*

65. *See* THE NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, (DHEW PUBLICATION NO. (OS) 78-0012) (1979).

66. *Id.* at 4.

67. *Id.* at 5.

68. *Id.* at 4-5. The report defined beneficence as the obligation to "do [no] harm," and beyond that, to "maximize possible benefits and minimize possible harms." It defined justice as an ethical matter addressed through fair answers to the following question: "Who ought to receive the benefits of research and bear its burdens?" *Id.* at 6, 8.

69. *See id.* The report explained that consent should be sought also from persons with limited capacity to understand, and that third parties should provide additional consent before such persons ("infants and young children, mentally disabled patients, the terminally ill and the comatose") should be permitted to participate in research. *Id.* at 13.

described in the Report have come to define not only the obligations of researchers to research subjects but the whole of contemporary bioethics.[70]

During more or less the same period that informed consent was being defined as one of the prerequisites of ethical research involving human subjects, the same notion was being shaped by courts and legislatures for application in clinical practice. As a result, lawmakers challenged the ancient Hippocratic precept ("do no harm") which often expressly precluded revelations from physicians to patients, and they challenged the much broader tradition of paternalistic care for patients to which physicians had been committed for many, many centuries.[71] In short, institutionalization of the informed consent requirement in application to clinic practice facilitated a dramatic reconstruction of the patient-physician relationship.

2. Development of the Informed Consent Doctrine in the Context of Clinical Care

By the middle decades of the twentieth century, patient autonomy began openly to replace physician authority as the central value by which society and the law judged the moral dimensions of relationships within the world of clinical health care as well as within the world of research and experimentation.[72] Development of the informed consent doctrine constitutes one of the central manifestations of this process.

For many centuries, English common law had frowned upon doctors treating patients who had not consented to treatment.[73] In the United States, the law's requiring patient consent prerequisite to patients' receiving health care dates back to the early twentieth century. The consent requirement was the central message of then-Judge Cardozo's famous pronouncement in *Schloendorff v. N.Y. Hospital* that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages."[74] Cardozo thus concluded that a

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70. *See* JONSEN, *supra* note 8, at 103-04 (noting that the three ethical principles "grew from the principles underlying the conduct of research into the basic principles of bioethics").

71. *See* William J. McNichols, *Informed Consent Liability in a "Material Information"Jurisdiction: What does the Future Portend?*, 48 OKLA. L. REV. 711, 715-16 (1995).

72. *See supra* notes 46-51 and accompanying text; *see also infra* note 99 and accompanying text.

73. *See* W. PAGE KEETON ET AL., PROSSER AND KEATON ON TORTS § 9 (5th ed. 1984).

74. *See* Schloendorff v. Soc'y of N.Y. Hosps., 105 N.E. 92, 93 (N.Y. 1914). Almost a decade before *Schloendorff,* the Minnesota supreme court suggested the outlines of an informed consent rule in *Mohr v. Williams. See* 104 N.W. 12 (Minn. 1905). The plaintiff had agreed to surgery on her

physician who treated a patient without her knowledge, and thus without her consent, had committed a legal wrong.

Cardozo's decision in *Schloendorff*, though clearly confirming a prohibition against treatment without consent, says nothing about providing patients with information about the implications of medical conditions from which they suffer or information about the nature and scope of proposed diagnostic or treatment responses.[75] The doctrine establishing that consent should be premised on information provided to the patient took shape almost a half century after *Schloendorff*, and has since been expanded and elaborated so as significantly to alter the character of the physician-patient relationship.[76]

In the years following *Schloendorff*, a variety of social and economic trends, including, in particular, the broad generalization of individualism within United States society after World War II, the development of expensive medical technology, new modes of access to information, articulation of an informed consent rule for application to research contexts, and the broad commercialization of health care, encouraged the widespread acceptance and expansion of the informed consent doctrine in clinical settings. This subsection will review the most straightforward aspects of the evolution of the *informed* consent doctrine in the decades following World War II.[77]

Within judicial arenas, the notion that consent must be predicated on information was first enunciated expressly, and the term "informed consent"[78] was first used, in *Salgo v. Leland Stanford Jr. University*, decided by the California First District Court of Appeals in 1957.[79] Martin Salgo, the plaintiff, was left paralyzed after he underwent a now-obsolete procedure, a translumbar aortography.[80] The court explained

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right ear. Instead, the surgeon operated on her left ear (which he had determined was diseased). The case was brought under an assault and battery theory. The court concluded that the surgery, absent the patient's consent was unlawful. Judge Brown explained:

> There is logic in the principle thus stated, for, in all other trades, professions, or occupations, contracts are entered into by the mutual agreement of the interested parties, and are required to be performed in accordance with their letter and spirit. No reason occurs to us why the same rule should not apply between physician and patient. If the physician advises his patient to submit to a particular operation, and the patient weighs the dangers and risks incident to its performance, and finally consents, he thereby, in effect, enters into a contract authorizing his physician to operate to the extent of the consent given, but no further.

Mohr, 104 N.W. at 15.

75. *See Schloendorf*, 105 N.E. at 92-95.

76. *See infra* notes 77-85 and accompanying text.

77. *See generally infra* Part IV (discussing elaboration and perversion of the doctrine).

78. Salgo v. Leland Stanford Jr. Univ., 317 P.2d 170, 181 (Cal. Dist. Ct. App. 1957).

79. *See id.* at 170.

80. The procedure involved puncturing the aorta from the rear and injecting a radio-opaque

that "[a] physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment."[81] However, the *Salgo* court, apparently uncomfortable with a sweeping rule demanding information as a prerequisite to consent, also stressed the physician's "discretion" to withhold information, "consistent, of course, with the full disclosure of facts necessary to an informed consent."[82]

Salgo thus represents an effort to amalgamate a new understanding of the physician-patient relationship with a traditional one. That effort was limited from the start by an inherent conflict between those two understandings. The first depends on the primacy of autonomous individuality; the second depends on the primacy of community and provides for hierarchy and paternalism, manifest in the figure of physician as decisor. Dr. Jay Katz has described *Salgo* as a fanciful attempt to render consistent two irreconcilable visions of the physician-patient relationship and two irreconcilable obligations of the physician.[83] Even more, *Salgo*, and the informed consent cases that followed it, reflect a transition from one understanding of personhood and community to a second, contrasting understanding.

In the next several years, the developing informed-consent doctrine was reinforced by a couple of judicial decisions that clearly required that a patient's consent be premised on information about the risks of recommended care.[84] Then, a decade and a half after *Salgo*, a federal court in Washington, D.C. presented a significantly broader interpretation of the emerging informed consent doctrine in *Canterbury v. Spence*.[85]

The case was initiated by Jerry Canterbury, who sued Dr. William Spence after surgery performed by Dr. Spence left Canterbury (then age nineteen) with a variety of permanent disabilities.[86] Before *Canterbury*, courts judged a physician's failure to disclose necessary information to a

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dye so that the aorta could be studied. *See* BERG, *supra* note 7, at 44.

81. *Salgo*, 317 P2d at 181.

82. *Id.*

83. *See* Jay Katz, *Informed Consent—A Fairy Tale? Law's Vision*, 39 U. PITT. L. REV. 137, (1977).

84. *See, e.g.*, Natanson v. Kline, 350 P.2d 1093, 1106 (Kan. 1960) (finding that the patient consented to radiation therapy but was not adequately informed about risk of burns from the therapy); Mitchell v. Robinson, 334 S.W.2d 11, 14-24 (Mo. 1960) (concluding that the patient consented to insulin shock and electroshock treatments but was not adequately informed about risks).

85. *See* Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972).

86. *See id.* at 777-78.

patient by rules forged in the context of malpractice litigation. Those rules looked to standard practice within the profession in order to assess a particular physician's failure to disclose.[87] In *Canterbury*, the court rejected that practice and concluded, instead, that assessment of the physician's failure to disclose would be judged with reference to the information that a reasonably prudent person would find "material" in deciding whether to consent to proposed treatment(s).[88]

The rule articulated in *Canterbury* broadly redefined the character of the physician-patient relationship. Indeed, that re-definition has likely been more consequential than, and was certainly not unrelated to, the decision's deep bow to patient autonomy in specific reference to informed consent.[89] Patient autonomy is less well served by the informed consent rule than is generally assumed. In part, this is because many patients (including those who are young, very sick, unconscious, or mentally challenged) are not fully autonomous.[90] In addition, competent patients, even when provided with adequate information, are often offered little more, as a practical matter, than an opportunity to choose or to reject recommended treatment.[91] Most patients remember comparatively little of what is communicated to them during pre-consent discussions with their physicians.[92] Finally, health care workers' descriptions of proposed treatments almost always differ from patients' actual experiencing of the treatment.[93]

In Onora O'Neill's term, consent is "opaque."[94] She explains:

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87. *See id.* at 783.

88. *Id*. at 784, 786-87.

89. The Canterbury "reasonable person" standard remains the minority position among the states. Most states rely on the so-called "professional" malpractice standard in considering cases alleging a health care worker's failure to disclose. MARK A. HALL ET AL., HEALTH CARE LAW AND ETHICS 201 (6th ed. 2003); *see, e.g.*, Culbertson v. Mernitz, 602 N.E.2d 98, 103-04 (Ind. 1992) (relying on the professional malpractice standard and noting that the Code of Medical Ethics of the American Medical Association requires physician "to present the medical facts accurately to the patient").

90. *See* Robert F. Schopp, *Sexual Predators and the Structure of the Mental Health System: Expanding the Normative Focus of Therapeutic Jurisprudence*, 1 PSYCHOL. PUB. POL'Y & L. 161, 174 (1995); Michelle Oberman & Joel Frader, *Dying Children and Medical Research: Access to Clinical Trials as Benefit and Burden,* 29 AM. J.L. MED. 301, 314 (2003).

91. *See* Susan Adler Channick, *The Myth of Autonomy at the End-of-Life: Questioning the Paradigm of Rights,* 44 VILL. L. REV. 577, 624 (1999).

92. Alan Meisel & Loren H. Roth, *Toward an Informed Discussion of Informed Consent: A Review and Critique of the Empirical Studies*, 25 ARIZ. L. REV. 265, 292-95 (1983) (reporting a study revealing that patients remembered significantly less than half of what was told to them during informed consent interviews, and reporting other studies revealing that only sixty percent of patients about to undertake chemotherapy reported correctly what the therapy entailed despite having sat through informed consent interviews).

93. O'NEILL, *supra* note 6, at 38, 43.

94. *Id*. at 43.

> In [one] case I might consent to a medical procedure described in euphemistic and unthreatening ways, yet not see myself as consenting to another more forthright and equivalent description of that very treatment. In [a] second case I might consent to chemotherapy, and yet when as a result I fell desperately ill and weak may truthfully claim that I never consented to anything that would have *this* effect, even if these very effects were carefully described as among the normal effects of the treatment.[95]

For the most part, physicians are not expected, indeed they are no longer legally permitted, to effect choices about a patient's health care absent the informed consent of the patient.[96] Yet, patients are often not anxious or able to interpret medical data and participate actively in decision-making about health care.[97]

Canterbury and other decisions that have reinforced the physician obligation to disclose information about health care options[98] do not focus on diminishing physician authority and power even though that has been one consequence of the disclosure requirement they have defined. But a number of later judicial decisions that have dramatically augmented the scope of the informed consent doctrine, have focused almost explicitly on restricting physician authority and power in the context of the physician-patient relationship.[99] A few of those cases,[100] those that most obviously limit physician authority in that they require physicians to reveal information about their own limitations, are

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95. *Id*. at 43-44.

96. There are a few widely recognized exceptions to the informed consent requirement. For instance, patient consent is not required in an emergency situation that involves a patient unable to provide informed consent. Canterbury v. Spence, 464 F.2d 772, 788 (D.C. Cir. 1972). In addition, the disclosure obligation is waived if the physician believes that disclosure would present a "threat of detriment to the patient as to become unfeasible or contraindicated from a medical point of view." *Id*. at 789. This is the so-called "therapeutic" exception to the informed consent doctrine.

97. O'NEILL, *supra* note 6, at 28-48 (considering limitations of "informed consent" with regard to autonomy); Alan Meisel & Loren H. Roth, *supra* note 92, at 326 (referring to a study showing that most patients do not want to remain completely passive in the face of medical decisions but they do not want to bear full responsibility for their own medical decisions).

98. *See, e.g.*, Cobbs v. Grant, 502 P.2d 1, 10 (Cal. 1972) (holding physician to duty of reasonable disclosure).

99. *See infra* note 123 and accompanying text.

100. A variety of cases has extended the reach of the informed consent doctrine in other ways. For instance, in *Truman v. Thomas*, the Supreme Court of California obliged a physician to inform a patient about the risks of *not* agreeing to a suggested diagnostic test (in that case, a pap smear). The *Truman* court rejected the physician's argument that, "since a physician's advice may be presumed to be founded on an expert appraisal of the patient's medical needs, no reasonable patient would fail to undertake further inquiry before rejecting such advice." 611 P.2d 902, 906 (Cal. 1980); *see also* Conservatorship of Waltz, 227 Cal. Rptr 436, 442 (Cal. Ct. App. 1986) (holding that the "mere fact Waltz has been diagnosed as having a mental illness is not enough to deem him incapable of consent").

considered in Part IV.[101]

B. The Autonomous Patient in the Marketplace

The first Section of this Part provided background for the discussion in Part IV of the elaboration and perversion of the autonomous individuality in the world of health care. This Section provides background for the discussion in Part IV of the third excess, the generalization of autonomous individuality in the world of health care. The creation of a consumer marketplace for the treatment of infertility[102] will illustrate this third excess.

New understandings of patient and physician as putatively equal, autonomous partners support the appearance of forms of relationship and modes of decision making within the world of health care that resemble those in the commercial marketplace. Traditionally, the practice of medicine in the United States entailed a peculiar dichotomy. Medicine presented itself as a profession that ensured loyalty and justified trust. Yet, the practice of medicine has almost always been a business.[103] At one end, the practice of medicine entailed financial relationships and constraints. At the other end, neither doctors nor patients traditionally viewed themselves primarily as participants in a commercial marketplace. Rather, their relationships assumed physician authority, patient trust, and loyalty of each to the other. Those assumptions were grounded in social understandings of the physician-as-professional. George Lundberg, former editor of the *Journal of the American Medical Association*, relies on the metaphor of a rocking horse to describe a recent shift toward the business end of the continuum:

> [T]he balance between business and professional values has tipped dangerously toward the business side. [Writing in 1990,] I expressed this in a bell-shaped top and rocking-horse bottom, with money-grubbers and altruistic missionaries at opposite ends of the curve and businesspeople and professionals in the larger central portion of the curve . . . .

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101. *See infra* Part IV.

102. Other examples might have been considered instead. Among them is the changing relationship between pharmaceutical companies and patients. In particular, pharmaceutical companies increasingly rely on direct-to-consumer advertising to sell drugs, thus encouraging patients to ask their physicians for prescriptions for particular drugs. *See, e.g.*, Elizabeth C. Melby, *The Psychological Manipulation of the Consumer-Patient Population Through Direct-to-Consumer Prescription Drug Advertising,* 5 SCHOLAR 325 (2003); Meredith B. Rosenthal et al., *Promotion of Prescription Drugs to Consumers,* 346 NEW. ENG. J. MED. 498, 499-501 (2002).

103. *See* GEORGE D. LUNDBERG, SEVERED TRUST: WHY AMERICAN MEDICINE HASN'T BEEN FIXED 156 (2000).

> Unfortunately, we have always had money-grubbers, and probably always will. More alarming, however, has been the shift in the middle tilting physicians toward the business side. . . . My concern is that, if the rocking horse rocks too far toward the business side, it may tip over and the profession of medicine may be lost; all trust and respect will disappear.[104]

Lundberg wonders whether medicine may completely lose its professional persona during the course of the next decade and "become unequivocally dominated by business interests."[105] If that happens, he concludes, patients and physicians will grow further apart. One consequence may be an increasingly strong interest among patients in alternative forms of medical practice.[106] This possibility suggests the increasingly competitive character of the business of medicine for physicians.

Generally, however, even as the world of health care tilts toward the world of commerce, a number of factors, including especially, the presence of third-party payers, continues to distinguish the marketplace in health care from the larger commercial marketplace.[107] Moreover, patients do continue to respect their physicians and to accept their advice more trustingly than they accept advice from merchants. There are, however, a few areas of medical practice in which the process of commercialization has been especially overt. These have been, on the whole, areas that mostly operate without the mediation of third-party payers. The construction of a market in care for infertility is

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104. *Id.* at 164.

105. *Id.* at 165.

106. *Id.*

107. William White reviews several aspects that distinguish the health care industry from others:

> The health care industry has several important features that have combined to create a unique regulatory environment. First, the industry is characterized by major problems with uncertainty. Second, there are widely shared equity concerns. Third, the industry has been very dynamic; accompanied by rapid technological change, health care spending has been on a sharply rising trajectory since the early twentieth century.

William D. White, *Market Forces, Competitive Strategies, and Health Care Regulation*, 2004 U. ILL. L. REV. 137, 138 (2004). In particular, the presence of "uncertainly" in the world of health care has had important consequences for the shape of the health care marketplace. Among these consequences is "[a] pattern of skewed, hard to predict costs" that has resulted in a "demand for health insurance." *Id* at 139 (citing Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941 (1963)). The health care marketplace in the United States has further differed from the larger marketplace, in that society has been "unwilling to ration [health] care solely by price." *Id.* Finally, the health care industry in the U.S. has been characterized by a "dynamic pattern of growth," with more and more being spent on health care since the start of the twentieth century. *Id*. at 140.

illustrative.[108]

Infertility care has become a substantial business in the United States.[109] More than most patients, infertility patients resemble the putatively equal, autonomous actors who populate the commercial marketplace.[110] Infertility care can be very expensive,[111] and the panoply of possible "cures" can seem almost unending. Yet, patients often decide to "buy" the next cure, despite the fact that the emotional and financial toll (especially in the absence of insurance coverage) can be seriously burdensome.[112] Operation of this expensive health care marketplace depends in large part on the felt-*need* of patients, making autonomous choices that involve them in paying for more and more care, even when the odds of success are not encouraging.[113]

The marketplace in infertility care represents another sort of excess

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108. *See* Katherine T. Pratt, *Inconceivable?: Deducting the Costs of Fertility Treatment*, 89 CORNELL L. REV. 1121, 1123 (2004) (noting that most health insurance plans do not provide coverage for infertility care).

Sherrie A. Kossoudji reports that in 2001 there were more than 420 infertility laboratories in the United States and surrounding territories. *See* Sherrie A. Kossoudji, *The Economics of Assisted Reproduction* 28, IZA DP DISCUSSION PAPER NO. 1458 (Jan. 2005), http://ssrn.com/abstract=648057.

109. *See* Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 614 (2003) (citing Lori Andrews, *Reproductive Technology Comes of Age*, 21 WHITTIER L. REV. 375, 382 (1999)) ("[I]nfertility services have been transformed from a small medical specialty to a four-billion dollar annual industry. Couples seeking IVF now spend $44,000 to $200,0000 to achieve a single pregnancy."); Gina Kolata, *Fertility Inc.: Clinics Race to Lure Clients,* N.Y. TIMES, Jan. 1, 2002, at F1.

110. In addition to the comparative absence of third-party payers, other factors distinguish this area of health care from many others and facilitate the establishment of a commercial market in infertility care. Among these factors are the comparative absence of regulation of treatment for infertility in the United States, see Noah, *supra* note 109, at 648 (reporting a comparative absence of state and federal regulation and failure of tort law and professional self-regulation to control risky practices among infertility specialists); the deeply felt need, common among infertility patients, to continue care regardless of expense, see *supra* note 109 and accompanying text; and the wide set of increasingly technological treatment options typically offered to infertility patients who have not been successful with less expensive, less technological levels of care, see Carson Strong, *Too Many Twins, Triplets, Quadruplets, and So On: A Call for New Priorities*, 31 J.L. MED. & ETHICS 272, 277 (2003) (describing as dangerous the "attitude among infertility physicians" that "the desire of the couple to have a baby is more important than avoiding risks to the offspring").

111. *See* Pratt, *supra* note 108, at 1135-36 (noting that the cost of one cycle of in vitro fertilization can be $10,000; intra-cytoplasmic sperm injection adds about $2,500 to the cost; use of donor eggs may cost $3,000 to $5,000 but can cost much, much more; and reliance on a surrogate usually costs between $10,000 and $25,000).

112. *See* Peter J. Neumann, *Should Health Insurance Cover IVF? Issues and Options*, 22 J. HEALTH POL. POL'Y & L. 1215, 1223-24 (1997) (citation omitted) (noting that survey respondents express readiness to spend "29 percent of their after-tax income for a 50 percent chance of having a child, and willing to risk a 20 percent chance of death in order to have a child").

113. The likelihood of success is small even among the average patient pool. *Id.* at 1221 (citation omitted) (reporting "that about 15 percent of initiated IVF cycles result in a successful delivery").

beyond those identified in rules about informed consent and about biomedical (including genomic) information. This mode of medical practice may foreshadow what medical care in general may look like if the medical profession as a whole tilts more fully toward what Lundberg refers to as the "business side."[114]

IV. THE APPEARANCE OF EXCESS: INFORMATION AND MARKETS

Relationships within the world of health care have been dramatically reshaped as patients and health care providers have increasingly been defined through the attributes of autonomous individuality. This section describes and analyzes a set of *excesses* that has accompanied the expansion of the notion of autonomous individuality within the world of health care. This Article assumes that these excesses, as that label clearly suggests, are among the less felicitous consequences of the shift toward the valuation of autonomous individuality in the world of health care. However, this assessment is not intended to gainsay the significant benefits for both patients and health care providers that have resulted from rules requiring respect for patient autonomy.[115]

By definition, the changes detailed in this Part are at the margins of the broader ideological changes that have redefined relationships among patients and health care providers in the last several decades. However, even changes at the social and legal margins of the process that have led to the valuation of individual autonomy in health care settings must be accounted for when assessing the whole. Among other things, changes that are marginal when they appear may become the mainstream over time.

This Part examines three different kinds of excesses that have followed the social and legal commitment to safeguarding individualism in health care settings. The first two kinds of excesses, at least in part concretized through the arm of the law, involve information. The first of

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114. *See supra* notes 102-103 and accompanying text.

115. In reviewing the moral justification for the informed consent doctrine, Ruth Faden and Tom Beauchamp write: "[r]espect for autonomy . . . [in the literature on informed consent] is conceived as a principle rooted in the liberal Western tradition of the importance of individual freedom and choice, both for political life and for personal development." FADEN & BEAUCHAMP, *supra* note 6, at 7. Faden and Beauchamp continue:

> The moral demand that we respect the autonomy of persons can be formulated as a *principle of respect for autonomy*: Persons should be free to choose and act without controlling constraints imposed by others. The principle provides the justificatory basis for the right to make autonomous decisions, which in turn takes the form of specific autonomy-related rights.

Id. at 8-9.

these, referred to here as the *elaboration* of autonomous individuality has developed as a result of courts' expanding the reach of the informed consent doctrine.[116] The second, referred to as the *perversion* of autonomous individuality, follows from the informed consent doctrine as it affects and is effected by rules of confidentiality in reference to genetic information.[117] And the third example, referred to as the *generalization* of autonomous individuality, is illustrated by the developing market in infertility care.[118] This third example, unlike the other two, has resulted more from the absence than from the presence of legal constraints. Each excess will be considered in turn.

A. The Elaboration of Individualism: Informed Consent

The legal constructions considered in this section portray an elaboration of the informed consent doctrine that suggests a new mode of leveling the relationship between doctor and patient. This elaboration reflects the increasing significance paid by society and the law to patient autonomy.[119] In addition, though less directly, it has followed from the transformation of "information" in the era of the Internet.[120]

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116. *See infra* Part IV.A.

117. *See infra* Part IV.B.

118. *See infra* Part IV.C.

119. *See supra* note 100.

120. The Internet has made once-arcane bits of medical knowledge (as it has made virtually every other kind of knowledge) widely accessible. This has altered the character of dialogue between patients and physicians. *See* Lynn Neary, *How the Internet has Changed the Way Doctors and Their Patients Interact and Communicate*, NRP, July 14, 2003 (reviewing the consequences of patient access to health information through the Internet on the relationship between patient and physician).

Equally, the Internet has transformed the tone and influenced the direction of legal deliberations about the informed consent doctrine and about medical information more generally. *See, e.g.*, Nicolas P. Terry, *An eHealth Diptych: The Impact of Privacy Regulation on Medical Error and Malpractice Litigation*, 27 AM. J.L. & MED. 361, 384-94, 394-410 (2001) (examining consequences of eHealth for malpractice litigation and suggesting privacy regulations intended to protect electronically stored health information will alter the informed consent doctrine).

No longer does possession of "information" distinguish experts from everyone else. *Id*. (reporting on-line survey showing that with regard to certain kinds of practical information the Internet can be more useful than direct queries to one's doctor).

As information has proliferated, the value of information has changed. Within health care contexts, information is often more valuable in that patients who seek, uncover, and use information relevant to health and to health care, can rely on that information to question their health care providers and to direct their own health care choices. Both patients and health care providers (who have also benefited by the accessibility of Internet resources) are more informed than they were two decades ago. *See, e.g.*, Sevan Lawson, *Bitter Pill for 'Cyberchondriacs'*, BBC NEWS, http://news.bbc.co.uk/1/hi/technology/3736653.stm (last visited Oct. 15, 2005) (referring to Health on the Net Foundation survey that reported that about half of all people rely on the Internet for second opinions).

However, as information has proliferated, it has also become less valuable. People

This Section analyzes two cases involving suits by patients against their doctors. In both cases, *Johnson v. Kokemoor*[121] and *Howard v. University of Medicine and Dentistry of New Jersey*,[122] a physician was obliged to have informed, but, in the view of the respective courts, did not adequately inform, a patient about the physician's own comparative lack of experience or the physician's lack of certain professional credentials. Although these cases follow from *Canterbury* and other cases resembling *Canterbury*,[123] they suggest a new message for physicians and patients, that patients are entitled to be told by their doctors about the limitations of the *doctor as doctor*.

In *Johnson v. Kokemoor*, Wisconsin's highest court considered a physician's obligation to reveal to a patient information about the physician's own limited experience with a particular surgical procedure.[124] Dr. Kokemoor, who operated on an aneurysm at the back of Donna Johnson's brain, failed to disclose, in seeking Johnson's consent for the surgery, that he was comparatively inexperienced in clipping the sort of aneurysm from which Johnson suffered. He also failed to inform Johnson that he was not board certified in neurosurgery.[125]

The surgery left Donna Johnson with incomplete quadriplegia. However, the court did not attribute that result to malpractice on the part of Dr. Kokemoor. Rather, the court, holding for Johnson, explained that "[w]hen different physicians have substantially different success rates, whether surgery is performed by one rather than another represents a choice between 'alternate, viable medical modes of treatment' under [Wisconsin statute] § 448.30."[126] In particular, expert testimony introduced by the plaintiff indicated that "the morbidity and mortality rate expected when a surgeon with the defendant's experience performed

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increasingly rely on bits of uncategorized, un-contextualized information gathered from unknown (and sometimes unknowable) sources that may or may not be reliable. *See, e.g.*, *id.* (suggesting that information gained online by patients cannot always be trusted and suggesting that information obtained by patients relying on the net may result in "confusion and unnecessary alarm").

121. *See* Johnson v. Kokemoor, 545 N.W.2d 495, 505 (Wis. 1996).

122. *See* Howard v. Univ. of Med. & Dentistry, 800 A.2d 73, 83-85 (N.J. 2002).

123. *See, e.g.*, Cobbs v. Grant, 502 P.2d 1, 10 (Cal. 1972) (placing on the treating doctor the duty "of reasonable disclosure of the available choices with respect to proposed therapy and of the dangers inherently and potentially involved in each").

124. *See Johnson*, 545 N.W.2d at 505. Other courts have refused to recognize an informed consent cause-of-action in cases involving physicians who misrepresented or failed to reveal "personal" information. *See, e.g.*, Duttry v. Patterson, 771 A.2d 1255, 1259 (Pa. 2001) (suggesting that plaintiff whose physicians misrepresented "personal" information might have a cause-of-action for misrepresentation or in negligence but could not rely on the informed consent doctrine with regard to the misrepresented personal information).

125. *See Johnson*, 545 N.W.2d at 499.

126. *Id.* at 507.

the surgery would be significantly higher than the rate expected when a more experienced physician performed the same surgery."[127] The court reported that articles reviewed by Dr. Kokemoor prior to the surgery, established that even the most accomplished posterior circulation aneurysm surgeons reported morbidity and mortality rates of fifteen percent for basilar bifurcation aneurysms. Furthermore, the plaintiff introduced expert testimony indicating that the estimated morbidity and mortality rate one might expect when a physician with the defendant's relatively limited experience performed the surgery would be close to thirty percent.[128] The court concluded that these statistics might well have convinced "a reasonable person in the plaintiff's position" to forego surgery under Dr. Kokemoor's hand and to seek a more experienced neurosurgeon. Thus, the Wisconsin court further concluded that Dr. Kokemoor had failed adequately to inform Donna Johnson about the risks of the surgery to which she consented.[129]

The assumption behind *Johnson* was that had Donna Johnson been fully informed, she would have selected a different surgeon, not that she would have foregone the surgery altogether. The court noted plaintiff's having introduced evidence showing that the "a reasonable physician in the defendant's position" would have referred Donna Johnson to a more experienced surgeon.[130] Johnson was able to show that she was left disabled as a result of the surgery. She was further able to present statistics showing that the risk of being left disabled was significantly increased because surgery on her was performed by a comparatively inexperienced surgeon. She was not, however, able to show that the bad result would not have occurred if a more experienced surgeon had performed the operation.[131] In fact, plaintiff's evidence suggested that there was more than a ten percent mortality and morbidity rate associated with the sort of surgery plaintiff underwent, even when that surgery was performed by a surgeon deemed among the best in the

127. *Id*. at 506.

128. *See id.* at 506.

129. *Id*. at 506-07.

130. *Id*. at 499-500 (noting, in addition, that the patient should have been sent to a tertiary care center and that such a center, the Mayo Clinic, was but ninety miles away).

131. *See id.* at 506. Informed consent doctrine requires a plaintiff to show a causal connection between the undisclosed risk and the harm that resulted. If one presumes that Donna Johnson, if informed about Dr. Kokemoor's comparative inexperience, would not have foregone the surgery but would have selected a more experienced surgeon, then she is required to show that the harm that befell her was the result of her not having been privy to the information (in this case about Dr. Kokemoor's inexperience) that would have led her to select a different surgeon. *See also* Howard v. Univ. Med. & Dentistry 800 A.2d 73, 79-80 (N. J. 2002) (summarizing analysis of damages in such cases).

world.[132] Thus, the court in *Johnson*, relied on estimates of comparative risk.[133] Although it was virtually assumed that the bad result could be attributed to Dr. Kokemoor's inexperience, there was a significant risk, as reported by the *Johnson* court, of a bad result even had Kokemoor been rejected in favor of a more experienced doctor.[134] In short, it is difficult to ascertain whether the risk in question occurred or not.

Six years later, in *Howard v. University of Medicine & Dentistry of New Jersey*,[135] the New Jersey Supreme Court entertained a case that raised similar questions. The New Jersey court reached a decision that modified the broad obligation on the physician suggested by *Johnson*, but that, nonetheless, held a physician responsible for having failed accurately to inform a patient (who consented to surgery) about the physician's qualifications.[136]

In 1997, Dr. Robert Heary performed neck surgery on Joseph Howard, who had been injured as a result of two separate automobile accidents, one in 1991 and a second in 1997. The surgery left Howard with quadriplegia. Howard, who had consented to the surgery, sued Dr. Heary for negligence.[137]

Howard and his wife (who had attended pre-surgery consultations between her husband and the physician) claimed that they discovered only as a result of Dr. Howard's deposition testimony that he had not accurately informed them about his experience and professional credentials—that, among other things, he was not, in fact, board certified in neurosurgery.[138] Howard then moved to amend his complaint by adding a fraud claim. The state supreme court, overturning the decision

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132. *See Johnson*, 545 N.W.2d at 499.

133. The court found that Dr. Kokemoor was obliged to inform Donna Johnson about his comparative inexperience with the surgery he recommended, that he was obliged to report "comparative risk evidence," and that Johnson should have been informed about a tertiary care center where her surgery could have been done by a surgeon more experienced than defendant. *Id.* at 507-09.

134. *See id.* at 499. The court premised its decision on the importance of the patient's not having received information about the defendant's comparative success rate as compared with a more experienced surgeon. However, it should also be noted that, if plaintiff's testimony was correct, Dr. Kokemoor had in effect lied to her when he told her that he had previously performed the recommended surgery "dozens" of times. *Id.* In fact, he had performed many (about thirty) operations involving aneurysms during his residency and about six times after his residency, but these operations involved a different (and more easily treatable) sort of aneurysm than that from which the plaintiff suffered. *Id.* at 499-500. It is not possible to know to what extent, if any, this evidence that the defendant had lied influenced the court's view of the case.

135. 800 A.2d 73 (N.J. 2002).

136. *See id.* at 83.

137. *See id.* at 76.

138. *See id.* at 76-77 (noting that Dr. Heary had given deposition testimony to the effect that he was not board certified when he operated on Joseph Howard and that he had done "a couple dozen" operations of the sort he did on Howard "during his career").

of the court below, refused to allow Howard to base his amended case on a cause-of-action in fraud.[139] However, the court found Howard had a cognizable claim that Heary had failed adequately to provide information on which Howard premised his consent to surgery.[140] The court, declining to obligate physicians to document details about their "background and experience as part of the required informed consent disclosure,"[141] concluded that "significant misrepresentations concerning a physician's qualifications can affect the validity of consent obtained."[142]

Finally, the New Jersey court in *Howard* noted that the plaintiff would be faced with a heavy burden in proving both that his risk of harm was "substantially increased" as a consequence of defendant's limited experience and credentials *and* that a "reasonably prudent person" would not have consented to Dr. Heary's performing the surgery in question had that "reasonably prudent" person known about the doctor's comparative inexperience and lack of credentials.[143] If Howard was able to meet that burden, then, the court concluded, he "may be compensated for that injury caused by [the neck surgery] irrespective of whether defendant deviated from the standard of care in performing the surgical procedure."[144]

Thus the decision in *Howard* resembles that in *Johnson* in allowing an injured patient/plaintiff to succeed even though the physician/defendant did not commit malpractice and even though the patient was aware of the broad risks of the procedure to which he or she consented.[145] In both cases, the plaintiff's cause-of-action related to provider-specific information.

In this regard, *Johnson* and *Howard* represent an elaboration of the doctrine laid down in cases such as *Canterbury*.[146] They also represent a shift in focus. In *Canterbury*, the center of the court's concern was the *patient* and his right to information about the risks of a proposed

139. *Id*. at 82.
140. *Id*. at 86.
141. *Id.* at 82.
142. *Id.* at 83.
143. *Id*. at 84-85.
144. *Id*. at 85.
145. Other courts have declined to follow the model laid down in *Johnson v. Kokemoor*. For instance, the Court of Appeals of Washington concluded that a surgeon was not obliged, as part of the informed consent process, to tell his patient that he had only recently learned how to perform the procedure (a laparoscopic cholecystectomy) that he proposed performing on her or that he had never performed one on a human (though he had practiced the procedure during a two-day course). Whiteside v. Lukson, 947 P.2d 1263, 1264 (Wash. Ct. App. 1997).
146. Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972); *see supra* notes 85-89, 96 and accompanying text (discussing *Canterbury*).

treatment (surgery on the plaintiff's back).[147] In contrast, in both *Johnson* and *Howard*, unrevealed or inaccurate information about the limitations of the doctors' experience and qualifications constituted the essential issue.

To say this somewhat differently, *Canterbury* reflects a court focused on empowering the patient while *Johnson* and *Howard* reflect an effort to disempower the physicians. *Canterbury*, on the one hand, and *Johnson* and *Howard* on the other, reflect different aspects of a broader process that has redefined the physician-patient relationship during the last several decades. *Canterbury* presumes the centrality of the patient's autonomy and thus works to equalize the relationship between physician and patient. *Johnson* and *Howard*, in contrast, stress the physician's limitations. Together, the two perspectives, both justified with reference to the notion that consent to health care should be predicated on the communication to patients of information about that care, represent a broad re-shaping of the traditional physician-patient relationship that once prized hierarchy and assumed paternalism.[148] However, the stress in *Johnson* and *Howard* works to minimize (and perhaps even to undermine) physician autonomy far more than the stress in *Canterbury.*

B. The Perversion of Individualism: Genetic Information

A different set of concerns about patient autonomy and medical information has arisen with regard to genetic information.[149] In this context, the possibility of distorting the meaning of autonomous individuality is striking. This Section reviews that possibility and suggests its implications.

There is widespread concern about discriminatory uses of genetic information.[150] Life and health insurers have denied coverage on the basis of genetic test results;[151] employers have conditioned offers of

147. *Id.*

148. *See supra* notes 121-144 and accompanying text.

149. *See* Mark A. Rothstein, *Policy Makers Need to Address Genetic Issues*, EMP. TESTING: L. & POL'Y REP., Mar. 1998, at 41 (distinguishing genetic information from other sorts of information in that genes reveal information about families and larger social groups as well as information about future health risks; genetic information is "transgenerational" and thus implicates "self-identity" and "individuality;" moreover, "stigma" is often attached to genetic information). Rothstein notes that genetic information is distinguishable from other sorts of medical information largely because "it is regarded as unique." *Id*.

150. *See, e.g.*, Colin S. Diver & Jane Maslow Cohen, *Genophobia: What is Wrong with Genetic Discrimination*, 149 U. PA. L. REV. 1439, 1443 (2001) (noting concern that genetic information can be used for disadvantageous purposes).

151. *See, e.g.*, Robyn B. Nicoll, Comment, *Long-Term Care Insurance and Genetic*

employment and continued employment on genetic testing.[152] Schools,[153] blood banks,[154] prisons,[155] and adoption agencies[156] have similarly limited services as a result of genetic test results. Moreover, the uses and abuses of genetic information have multiplied as a result of Internet access which dramatically expands the potential for the proliferation of genetic information.[157] State legislatures[158] and Congress have begun to respond.[159]

Many genetic tests are now available.[160] Whether genetic tests are performed on embryos in vitro,[161] on fetuses in uteri,[162] on children[163] or

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Discrimination—Get it While You're Young and Ignorant: An Examination of Current Discriminatory Problems in Long-Term Care Insurance Through the Use of Genetic Information, 13 ALB. L.J. SCI. & TECH. 751, 762-63 (2003) (detailing how insurers gain access to genetic information).

152. *See* David J. Wukitsch, *New York's Legal Restrictions on Employer's Collection and Use of Employee's Genetic Information*, 9 ALB. L.J. SCI. & TECH. 39, 40-41 (1998) (reporting employers' uses of employees' genetic information).

153. Kourtney L. Pickens, *Don't Judge Me by My Genes: A Survey of Federal Genetic Discrimination Legislation*, 34 TULSA L.J. 161, 162 n.5 (1998).

154. *The Potential for Discrimination in Health Insurance Based on Predictive Genetic Tests: Hearing Before the H. Subcomm. On Commerce, Trade and Consumer Prot. of the Comm. on Energy and Commerce*, 107th Cong. 11 (2001), *available at* http://www.access.gpo.gov/congress/house (last visited Oct. 15, 2005).

155. Rochelle Cooper Dreyfuss & Dorothy Nelkin, *The Jurisprudence of Genetics*, 45 VAND. L. REV 313, 328-29 (1992).

156. *See* Diver & Cohen, *supra* note 150, at 1443.

157. *See* Frances H. Miller, *Forward: Phase II of the Genetics Revolution: Sophisticated Issues for Home and Abroad*, 28 AM. J. L. AND MED. 145, 149 (2002) (recognizing the importance of regulations safeguarding privacy from revelation of genetic information on the Internet under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936, 2023 (codified in scattered sections of 26, 28 and 42 U.S.C.)).

158. *See, e.g.*, GA. CODE ANN. § 34-54-1 (2004) (discussing genetic testing).

159. In October 2003, the Senate passed a bill prohibiting insurers from denying medical coverage or setting premiums on the basis of genetic information. The bill also prohibits employers from using genetic information in making decisions about hiring and firing employees. Genetic Information Nondiscrimination Act of 2003, S. 1053, 108th Cong., (as passed by U.S. Senate, Oct. 14, 2003). A similar bill was passed in the Senate (98 to 0) in 2005, but was held up in the House. *See* Ronald Kotulak, *Genes: Your Body's Crystal Ball*, CHI. TRIB., June 26, 2005, at C1 (attributing the response in the House to "strong objections from the health insurance industry and the U.S. Chamber of Commerce").

160. *See* David Wessel, *Capital: Wanted: Public Policies to Help Genetic Testing Fulfill Its Promise*, WALL ST. J., June 19, 2003, at A2. (reporting availability of about 900 genetic tests). The predictive value of genetic tests is variable. Genetic testing in an a-symptomatic patient may indicate the possibility or likelihood that the patient will become ill or disabled. Some conditions associated with genetic alterations can be either prevented or treated; others, such as Huntington's Disease, cannot be prevented or treated. Testing for certain genetic alterations (for example, that associated with Huntington's Disease) has very high predictive value. Testing for other conditions does not. For instance, up to fifteen percent of women who test positive for BRCA1, associated with breast cancer, and who, furthermore, have close family members with breast cancer, will not develop the condition. LORI B. ANDREWS ET AL., GENETICS: ETHICS, LAW AND POLICY 225-26 (2002).

on adults, the information the tests provide is viewed differently than other medical information. Most information discerned from medical testing relates to the person tested. If testing reveals that a person has a broken leg, an appendicitis, or an ulcer, that information will generally have little direct relevance to discerning the physical condition (present or future) of anyone but the affected person. If a person tests positive for a genetic alteration associated with an illness or disability, however, that information is immediately *perceived*[164] as relevant to the health status of the patient's family members and possibly to members of his or her ethnic, racial, national or religious group as well.[165]

Genetic information has a usual combination of attributes. It is the most individualistic of all information. An individual's genome is unique. Yet, genomic characteristics are shared among family members and among members of larger groups defined through reference to ancestral groups, including groups that society views as ethnic or racial.[166]

Genomic medicine harmonizes remarkably well with a society concerned for over two centuries with safeguarding autonomous individuality. Even more, the social dangers that inhere in the use and dissemination of genomic information resemble a set of social dangers that have long inhered in Western society. This Section is devoted to detailing, and exploring the implications of, these claims.

Deeply committed to the preservation of equality and liberty, post-Enlightenment ideology has also provided for the development of racism. Racism suggests a profound opacity at the center of Western culture. Yet it is predicated on an ideological shift that developed early in the history of egalitarianism. To quote the French anthropologist Louis Dumont, "once equality and identity bear on the individual *souls*,

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161. *See* Jeffrey R. Botkin, *Prenatal Diagnosis and the Selection of Children*, 30 FLA. ST. U.L. REV. 265, 280-83 (2002).

162. *See id.* at 159-60.

163. Lainie Friedman Ross & Margaret R. Moon, *Ethical Issues in Pediatric Genetics*, *in* GENETICS IN THE CLINIC: CLINICAL, ETHICAL, AND SOCIAL IMPLICATIONS FOR PRIMARY CARE 153 (Mary Briody Mahowald et al. eds., 2001).

164. The claim being made here is not that genetic information is genuinely different from other sorts of medical information. Rather, it is that it is seen as being different in the manner specified in the accompanying text.

165. *See* Mark Levin, *Screening Jews and Gentiles: A Consideration of the Ethics of Genetic Screening Within the Jewish Community: Challenges and Responses*, 3 GENETIC TESTING 207 (1999) (noting potential of genetic testing for group stigmatization). *See generally* Anita LaFrance Allen, *Genetic Testing, Nature, and Trust*, 27 SETON HALL L. REV. 887 (1997) (discussing the vulnerability of American Blacks to discriminatory use of genetic information).

166. *See* Rothstein, *supra* note 149, at 41.

distinction could only be effected with regard to the *bodies*."[167] "What is more," continues Dumont, "discrimination is collective, it is as if only physical characteristics were essentially collective where everything mental tends to be primarily individual."[168]

Gunnar Myrdal noted a similar link between egalitarianism and racism in the U.S.:

> The dogma of racial inequality may, in a sense, be regarded as a strange fruit of the Enlightenment . . . . The race dogma is nearly the only way out for a people so moralistically equalitarian, if it is not prepared to live up to its faith . . . . [R]ace prejudice is, in this sense, a function [a perversion] of egalitarianism.[169]

In short, racism can be understood as a perversion of individualism and egalitarianism. Moreover, it is a perversion that develops not outside, but firmly *inside* a society that prizes individualism and egalitarianism. Racism, in Dumont's view, is *not foreign* to a society committed to Enlightenment values. Rather, racism in the United States emerged as an exception (a reflection of hierarchy) that co-exists with the society's self-conscious endorsement of equality.

Dumont and Myrdal are suggesting in this regard that racism *grew out of and is a perversion of* individualism and egalitariansim. This Section suggests that certain applications of rules about the disclosure of genetic information reflect a similar grounding in and perversion of individualism and egalitarianism.

A 1996 New Jersey case, *Safer v. Estate of Pack*,[170] is illustrative. The case is presented here as a cultural document, not a rule of law.[171] The legal case was commenced by Donna Safer against Dr. George Pack.[172] In 1990, Donna Safer, then thirty-six years old and newly

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167. *See* LOUIS DUMONT, APPENDIX, HOMO HIERARCHICUS 255 (Mark Sainsbury trans., 1970).

168. *Id.*

169. GUNNAR MYRDAL, AN AMERICAN DILEMMA, THE NEGRO PROBLEM AND MODERN DEMOCRACY 89 (20th Anniversary ed. 1962) (citing and quoting DUMONT, *supra* note 167, at 256).

Although the issue is beyond the scope of this Article, it should be noted that Myrdal and Dumont differ in their understanding of caste. For Dumont, caste is the essence of a social system (such as that in traditional India) that prizes holism and hierarchy. In such a system, each caste is viewed as an integral part of a structured whole. *See generally* DUMONT, *supra* note 167, at 19. Myrdal, on the other hand, (who was not a student of traditional India in particular) sees the caste system as akin to racism because both oppress people identified with specific groups. *See id.* at 239-58 (analyzing Myrdal's understanding of caste).

170. 677 A.2d 1188 (N.J. Super. Ct. App. Div. 1996).

171. In 1996, the same year that the case was decided, the state legislature passed a law that places limits on physicians' communication of genetic information to third parties. Genetic Privacy Act, N.J. STAT. ANN. § 17B:30-12 (West 1996). *See infra* note 251 and accompanying text.

172. More detailed discussions of this case and its implications can be found in Janet L.

married, was diagnosed with a hereditary form of colon cancer. At the time of Donna's diagnosis, the disease had already metastasized.[173] Twenty-six years earlier, when Donna was ten, her father, Robert Batkin, had died of the same form of colon cancer.[174]

In 1992, Donna commenced suit against Dr. George Pack,[175] who had cared for her father during the seven years of Batkin's illness.[176] Dr. Pack had never treated Donna. Yet, Donna's suit implied that Dr. Pack had provided her with negligent medical care.[177] Donna Safer, and her husband, himself a physician, claimed that Dr. Pack violated his professional duty in failing to warn Donna that her health was at risk.[178]

The trial court dismissed the Safers' petition, concluding that a doctor was under no duty to warn a patient's child of a genetic risk.[179] The trial court further distinguished Donna Safer's case from others in which courts had imposed a duty on physicians to warn relatives of patients suffering from infectious diseases of the risk that they also had been exposed to the condition from which their relative suffered.[180] The trial court explained that with genetic conditions "the harm is already present within the non-patient child . . . . The patient is taking no action in which to cause the child harm."[181]

On appeal, the New Jersey appellate court disagreed with the trial court and ordered that the case be sent back to the lower court for trial.[182] Due to the posture of the case when it reached the appellate court, that court assumed that plaintiffs were correct in claiming that the hereditary

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Dolgin, *Personhood, Discrimination, and the New Genetics*, 66 BROOK. L. REV. 755, 802-16 (2001); Janet L. Dolgin, *Choice, Tradition, and the New Genetics: The Fragmentation of the Ideology of Family*, 32 CONN. L. REV. 523, 552-58, 562-65 (2000).

173. *See Safer*, 677 A.2d at 1190.

174. *See id.*

175. Dr. George Pack died in 1969. Donna Safer and her husband brought suit against the estate of Dr. Pack. *See id.*

176. *See id.* at 1189-90.

177. *See id.* at 1190.

178. Presumably the warning should have come through Donna's mother or in some sort of unorthodox memorandum sent to Donna's own doctor because Donna was only ten years old when her father died. *Id*.

179. *See id.*

180. *See id.* at 1191; 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, 132-34 (1997) (analyzing "duty to disclose" cases).

181. *Safer*, 677 A.2d at 1191. The trial court's explanation reflects widespread confusion about the categorization of predispositions to illness based on genetic alterations in the absence of symptomatology. *See* Katskee v. Blue Cross/Blue Shield, 515 N.W.2d 645, 651-52 (Neb. 1994) (deciding plaintiff's familial history of breast and ovarian cancer categorized her as ill, even though she had no symptoms or signs of cancer, and thus entitled her to insurance coverage for removal of her uterus, ovaries, and fallopian tubes).

182. *See Safer*, 677 A.2d at 1189.

nature of the disease was known at the time Dr. Pack was treating Mr. Batkin and that the physician was required, by medical standards then prevailing, to warn those at risk so that they might have the benefits of early examination, monitoring, detection and treatment, that would provide opportunity to avoid the most baneful consequences of the condition.[183]

In addition, the appellate court defined a duty to warn about genetic predispositions because "[t]he individual or group at risk is easily identified."[184] Judge Kestin, writing for the court, explained: "[T]he duty [is appropriately] seen as owed not only to the patient himself but . . . it also 'extend[s] beyond the interests of a patient to members of the immediate family of the patient who may be adversely affected by a breach of that duty.'"[185]

Safer was not unprecedented in eliminating the traditional requirement that a professional is responsible only to one with whom he or she is in a relationship of privity.[186] Other courts had imposed liability on doctors for failing to warn non-patients at risk of contracting a contagious disease from the physician's patient;[187] for failing to warn individuals known to be at risk of harm from a mentally ill patient;[188] and for failing to warn a patient's relative about a foreseeable, non-contagious condition (from which the physician's patient suffered and for which the relative was at risk).[189]

In a 1995 Florida case, resembling *Safer*, Florida's highest court imposed a duty to third parties on physicians whose patients suffered

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183. *See id.* at 1191.

184. *See id.* at 1192.

185. *Id.* (quoting Schroeder v. Perkel, 432 A.2d 834, 839 (N.J. 1981)).

186. Among other things, *Safer* and cases that resemble it pose a duty to warn third parties against a physician's obligation to protect patient confidences. That obligation has long been viewed as fundamental. BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 317 (5th ed. 2004). However, the legal source of the confidentiality is less clear. Most states have a testimonial privilege, protecting patient confidences from disclosure in court. *Id*. at 323. Certain sorts of medical information are protected specifically, see, Alcoholism Prevention, Treatment, and Rehabilitation Act, 42 U.S.C. §§ 290dd-3 (West 1982 & Supp. 1986) (cited in FURROW, *supra*, at 324), and state licensing laws often imply that physicians must protect patient confidences. *See* FURROW, *supra*, at 323-25 (reviewing other possible sources of physician obligation to protect patient confidences).

187. *See, e.g.*, Tracy A. Bateman, *Annotation, Liability of Doctor or Other Health Practitioner to Third Party Contracting Contagious Disease from Doctor's Patient,* 3 A.L.R. 5th 370 (1992).

188. *See, e.g.*, Tarasoff v. Regents of Univ. of Cal., 551 P.2d 334, 353 (Cal. 1976) (concluding that a therapist is obliged to warn a third party about a known risk of harm from therapist's patient).

189. *See, e.g.*, Bradshaw v. Daniel, 854 S.W.2d 865 (Tenn. 1993) (obliging physician to have warned wife of patient who suffered from Rocky Mountain Spotted Fever that she was also at risk of coming down with the condition because she and her husband had walked in an area that exposed them to the tick that causes Rocky Mountain Spotted Fever).

from genetic conditions.[190] In 1990, Heidi Pate, who had recently been diagnosed with medullary thyroid carcinoma, brought suit against the health care providers who had treated her mother for the same condition three years earlier. The defendants responded that a physician's duty should not be extended to "third party non-patients."[191] Florida's highest court disagreed, concluding that:

> [W]hen the prevailing standard of care creates a duty that is obviously for the benefit of certain identified third parties and the physician knows of the existence of those third parties, then the physician's duty runs to those third parties. Therefore . . . we hold that privity does not bar Heidi Pate's pursuit of a medical malpractice action . . . . [U]nder the duty alleged in this case, a patient's children fall within the zone of foreseeable risk.[192]

The court recognized Heidi Pate's standing to bring the suit.[193] It did not, however, permit Pate to premise the case on the doctor's failure to warn *her*.[194] Rather, the *Pate* court recognized Heidi Pate's right to argue that her mother's doctor was responsible for warning his patient that her children and certain other relatives were at risk of developing the disease from which she suffered. The court explained:

> To require the physician to seek out and warn various members of the patient's family would often be difficult or impractical and would place too heavy a burden upon the physician. Thus, we emphasize that in any circumstances in which the physician has a duty to warn of a genetically transferable disease, that duty will be satisfied by warning the patient.[195]

In contrast, the New Jersey court that decided *Safer* concluded that Dr. Pack, who treated Donna Safer's father, was under a duty to warn not only his patient, but his patient's children and presumably certain other close relatives as well, about the risk that they, too, carried the genetic alteration associated with colon cancer. The implications of the holding are staggering.

The decision suggests a stunning reinterpretation of autonomous individuality that displaces focus on the individual person with focus on a genetic whole that includes any number of separate, essentially

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190. Pate v. Threlkel, 661 So. 2d 278 (Fla. 1995).

191. Answer Brief of Appellees Shands Teaching Hospital and Clinics, Inc. and Florida Board of Regents at 7-8, *Pate*, 661 So. 2d 278 (Fla. 1995) (No. 84289).

192. *Pate,* 661 So. 2d at 282.

193. *Id.* at 281-82.

194. *See id.* at 282.

195. *Id.*

undifferentiable people. The whole is itself understood according to the metaphor of the individual. That is, from the perspective of the genetic whole, the basic unit of social value contains an unspecified number of units, all identical insofar as they are viewed with reference to *shared genes*. Individuals who form the larger whole are not important as such[196] but only because they replicate the genetic pattern (whatever it is) presumed to define the whole.

The social consequences of this view are enormous.[197] Among them is a far-reaching shift in the meaning of privacy. *Safer*, for instance, eviscerates the notion of *individual* privacy as it has existed in the West for several hundred years. *Safer* defines the unit to which privacy is owed, not as the individual person, but as some larger genetic whole within which any individual is rendered substitutable for any other.[198]

This result is inherent in the notion of autonomous individuality, but as a perversion of that notion. Conceptually, the genetic family, or presumably the genetic ethnic group or racial group, replicates its units, each of which replicates each of the others.[199] That understanding of a genetic group presumes that each unit (each person) within the larger whole enjoys no privacy vis-a-vis the other units. Each is presumptively fungible for each of the others, and thus the privacy of each is the privacy of all. In that vein, the patient in *Safer*, Robert Batkin, and his daughter, Donna Safer, were envisioned by the court as two parts of one whole. The court defined the doctor's obligation to extend to the whole, not only to the parts (i.e., the particular people composing the genetic whole). That is, Robert Batkin's doctor owed a duty to his patient as well as to his patient's child because from the perspective of the genetic family the two were not differentiable.[200]

Safer leaves a wide variety of questions unanswered: How far does the obligation extend? Does it include a patient's siblings, parents, cousins, third cousins? What is the physician's obligation to locate such

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196. *See* KAJA FINKLER, EXPERIENCING THE NEW GENETICS: FAMILY AND KINSHIP ON THE MEDICAL FRONTIER (2000) (describing ideology of genetic inheritance). The postulates of an ideology of genetic inheritance make sense from within a perspective that focuses on groups presumed to share genetic traits.

197. An analysis of these consequences from a somewhat different perspective can be found in Dolgin, *Personhood, Discrimination, and the New Genetics*, *supra* note 172, at 802-12.

198. *See* Robert Wachbroit, *Rethinking Medical Confidentiality: The Impact of Genetics*, 27 SUFFOLK U. L. REV. 1391, 1401-02 (1993) (noting that "a health professional's duty might be to respect the privacy" of some whole viewed in genetic terms, such as the family).

199. *See id.* at 1402.

200. Clearly, the court understood that even from the perspective of genomic information Robert Batkin and Donna Safer were differentiable. However, by focusing on one relevant genetic alteration, presumptively shared by Batkin and his daughter, the court appropriated a view of the genetic family that rendered its individual members indistinguishable.

people? Does the obligation to reveal genetic information overcome the patient's desire to keep the information confidential? The court expressly noted this last conundrum but left it for the trial court, when reconsidering the case[201] to decide whether, "there are or ought to be any limits on physician-patient confidentiality, especially after the patient's death where a risk of harm survives the patient, as in the case of genetic consequences."[202] But at present, *Safer* and the questions it raises are more important as illustration and warning than as law. After the New Jersey appellate court rendered its decision, the state legislature significantly limited a doctor's duty to reveal information about a patient's genetic condition to relatives.[203]

Thus, *Safer* serves primarily as a cultural document that reflects a troubling understanding of the relationship between the individual person and a larger, genetically defined group of people. *Safer's* message is reflected as well in a 1998 Statement of the American Society of Human Genetics (ASHG).[204] The ASHG Statement proposed giving health care providers discretion to contravene usual rules of privacy in certain situations involving genetic information. Those situations include cases,

> where attempts to encourage disclosure on the part of the patient have

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201. In 1999 the case was tried. The jury held for the defendant, Dr. Pack, apparently on the ground that there was evidence that Donna Safer had, in fact, known about the risk to herself of becoming ill with the disease from which her father died. *See* E-mail from Connie Lenz, Assistant Director, Maurice A. Deane Law Library, Hofstra University School of Law, to author (Oct. 6, 1999, 16:38 CST) (summarizing discussion with Gary Maher, attorney for the plaintiff) (on file with author). The author is grateful to Gary Maher for supplying briefs in the case.

202. Safer v. Estate of Pack, 677 A.2d 1188, 1193 (N.J. Super. Ct. App. Div. 1996).

203. Genetic Privacy Act, N.J. STAT. ANN. § 10:5-45 (West 2004). The statute, passed in 1996, limits a health care provider's obligation to disclose genetic information to third parties to cases in which the patient has consented to the revelation or the patient has died.

Federal law now imposes strict rules on a physician's right to disclose information about patients. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 (codified in scattered sections of 18, 26, 29 and 42 U.S.C.); 42 U.S.C. § 1320d-6 (West 2005) [hereinafter HIPAA]. However, HIPAA does not safeguard genetic information in any special manner. Thus, it does not provide complete privacy for genetic information, as it does not provide complete protection for any medical information. For instance, HIPAA does not protect genetic test results obtained during research, and it does not protect DNA samples. Allison Ito, *Privacy and Genetics: Protecting Genetic Test Results in Hawaii*, 25 HAWAII L. REV. 449, 461-62 (2003). Moreover, the regulations provide an exception that may cover the sort of situation at issue in *Safer*. "Covered entities" under HIPAA (including "(1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form . . . ."45 C.F.R. 164.104 (2004)), may disclose "protected health information" to someone who is either at risk of becoming ill or of spreading an illness as long as some other law provides for transmission of the relevant information. 45 C.F.R. 164.512 (2004).

204. *See generally* The American Society of Human Genetics Social Issues Subcommittee on Familial Disclosure, *ASHG Statement: Professional Disclosure of Familial Genetic Information*, 62 AM. J. HUM. GENET. 474 (1998) [hereinafter ASHG *Statement*].

> failed; where the harm is highly likely to occur and is serious and foreseeable; where the at-risk relative(s) is identifiable; and where either the disease is preventable/treatable or medically accepted standards indicate that early monitoring will reduce the genetic risk.[205]

The ASHG Statement differs from *Safer* in that the Statement proposes *discretionary* revelation of genetic information whereas the *Safer* court concluded that in certain cases revelation of genetic information should be mandatory. Both, however, depend on a similar understanding of family. The genetic family presumed by *Safer* and by the ASHG is defined through reference to shared DNA. Individuals and the larger genetic whole from which they cannot be distinguished are defined exclusively in terms of the genome they are presumed to share.[206] This understanding of family is rarely explicit. Yet, it harmonizes with traditional understandings of family that stress the unity effected through shared "blood."[207]

As a practical matter, the notion of the genetic group raises difficult questions within the world of health care. Most important, the notion of "patient" is transformed. Indeed the ASHG Statement characterizes genetic information as a "family possession rather than simply a personal one."[208] That perspective conflicts sharply with the usual understanding of medical information in contemporary society (at least in relation to competent adult patients).[209]

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205. *Id.* at 474. The ASHG Statement proposed further limiting revelation of otherwise confidential information to cases in which "[t]he harm that may result from failure to disclose should outweigh the harm that may result from disclosure." *Id.*

206. These issues are described in greater detail in Dolgin, *Personhood, Discrimination, and the New Genetics*, *supra* note 172, at 808-12.

207. *See* David M. Schneider, AMERICAN KINSHIP: A CULTURAL ACCOUNT (1968) (deciphering the cultural assumptions underlying American families before family life was widely redefined, beginning in the early 1970s).

208. ASHG *Statement*, *supra* note 203, at 476 (quoting Dorothy Wertz et al., GUIDELINES ON ETHICAL ISSUES IN MEDICAL-GENETICS AND THE PROVISION OF GENETIC SERVICES (1995)).

209. Older understandings of medical information and of who has the right to learn about such information differ from both the contemporary understanding and from that suggested by *Safer*. As the so-called "traditional" family was displaced by the modern "family-of-choice," an older understanding of medical information as belonging to the family, or more accurately to the *pater familias* (the head of family), was displaced by an understanding of medical information as the possession only of the individual being tested or treated.

Within the world of traditional families, the family as a unit was viewed by the law as autonomous. *See, e.g.*, McGuire v. McGuire, 59 N.W.2d 336, 342 (1963) (refusing to intervene to protect interests of a wife who alleged that her husband failed adequately to provide for her). However, the understanding of genetic information as a family possession (as presented in the ASHG Statement) differs fundamentally from nineteenth-century and early twentieth-century understandings of medical information as a "family" matter. This difference reflects the fundamental difference between the so-called "genetic family" and the traditional family. In the context of the traditional family, understood broadly as a small universe of fixed, hierarchically

In short, *Safer* and the ASHG Statement similarly suggest a novel and rather discomforting view of genetic groups. For each, the individual person is eviscerated by the greater significance of the genetic whole. Genetic groups (such as the genetic family) represent a peculiar involution of individualism. They displace the interests of the individual in favor of the interests of the whole, while defining the whole through the metaphor of the individual. The French social theorist Louis Dumont described this possibility as the consequence of an "attempt, in a society where individualism is deeply rooted and predominant, to subordinate it to the primacy of the society as a whole."[210]

As a theoretical matter, that possibility, central to social fascism, is antithetical to an order that values autonomous individuality; yet, at the same time, it is a transformation of that order, and can develop from it.

C. The Generalization of Individualism: The Patient as Consumer in the Marketplace of Infertility Care

This Section suggests a third consequence of the importation of the notion of autonomous individuality into the world of health care, the appearance of the patient as consumer in a marketplace of health care options.

For most of the nineteenth and twentieth centuries, health care remained separate, at least conceptually, from the marketplace of consumer goods.[211] Moreover, until the last decades of the twentieth century, medical practice was shaped through a set of professional rules and obligations that differed from the rules generally assumed in the

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structured roles, husbands were given medical information about their wives, and parents about their children. *See* Tooley v. Provident Life & Accident Ins. Co., 154 So. 2d 617, 618 (La. Ct. App. 1963) (finding a doctor not bound by the duty to safeguard a woman's medical records from her husband). *See* Deftos, *supra* note 180, at 113 (discussing *Tooley*). For the most part, however, those lower in the status-based pattern of hierarchically structured family roles (wives and children) were not privy to medical information about husbands and parents.

Thus, the assumptions behind the ASHG *Statement* suggest a family unit quite different than that identified with the traditional family. The Statement relies on the work of Robert Wachbroit to explain the implications of the claim that genetic information is a "family possession." The Statement explains that Wachbroit presents "a family-health model that contemplates the physician's patient as the entire family; 'family' is understood to refer to a genetic network rather than a social institution. Therefore, the physician's duties pertain to the genetic family as a whole." ASHG *Statement, supra* note 204, at 476 n.2 (citing Robert Wachbroit, Genetics *Rethinking Medical Confidentiality: The Impact of Genetics*, 27 SUFFOLK U.L. REV. 1391 (1993)).

210. DUMONT, *supra* note 167, at 250.

211. Even when medicine was largely a cottage industry, health care was rendered in exchange for money. However, the relationship between patient and health care providers did not resemble the relationship between merchant and consumer so much as that between ministers and congregants.

marketplace.[212] The advent of managed care, sophisticated technology, high costs, and the "informed" patient in the second half of the twentieth century, displaced old models of the patient-physician relationship and provided for the emergence of the patient as consumer.[213] Moreover, the notion of the "informed patient" merges with the notion of the "informed consumer."[214]

Patients have begun to see themselves as consumers. This transformation is particularly evident in the context of infertility care. This domain of health care has become an expensive marketplace of consumer choices: IVF clinics advertize widely in print media[215] and on the Internet; health insurance is less likely to pay for infertility treatment than for most other forms of health care;[216] patients using third-party gametes "shop" for donors;[217] and when one treatment does not produce the desired end—as when a new hair product or a new make of automobile fails to satisfy the consumer—there will almost invariably be even "newer" and "better" options available soon.[218] Some infertility clinics even forgive payment if a pregnancy does not result or offer patients the opportunity to receive treatment at lower prices if they agree to participate in clinical trials.[219] Moreover, the variety of treatment

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212. *See* STARR, *supra* note 4, at 25 (describing physicians as "one of the few occupational groups in the twentieth century able to resist the current that has drawn self-employed artisans and craftsmen of all kinds into the orbit of industrial and bureaucratic organization").

213. *See supra* notes 5-6, 212 and accompanying text.

214. ROY PORTER, THE GREATEST BENEFIT TO MANKIND 660 (1999) (noting development of various consumer groups that "challenged the [medical] profession's monopoly").

215. *See* ELIZABETH BARTHOLET, FAMILY BONDS: ADOPTION AND THE POLITICS OF PARENTING 187-88 (1993) (noting the presence of advertisements for IVF clinics more than a decade ago).

216. Only about one-fifth of large companies in the United States provide health insurance that covers infertility treatments. Julie Appleby, *Pricey Infertility Care Sparks Insurance Clash*, USA TODAY, Dec. 18, 2001, *available at* http://www.usatoday.com/money/covers/2001-12-19-bcovwed.htm. About a quarter of the states mandate some form of infertility coverage. Randy Diamond, *Insurance Coverage Mandated for Infertility*, THE RECORD (Bergen County, N.J.), Sept. 1, 2001, at A17. A few other states (e.g., California, New York, Connecticut, Texas) require health insurance companies to offer infertility coverage but do not require employers to buy it. *See* Appleby, *supra*.

217. *See* Irene Sege, *A $50,000 Dilemma on Campus*, BOSTON GLOBE, Mar. 6, 1999, at A1 (describing an advertisement placed in student newspapers seeking tall, smart ova donors and offering to pay up to $50,000 for the ova).

218. Over a decade ago, Elizabeth Bartholet described the difficulty for infertility patients of giving up on care, even after long periods of unsuccessful care. After spending a decade trying to become pregnant and eight years being treated by doctors for infertility, Bartholet "constrained by . . . limited funds and the fact that there was then no insurance coverage for IVF" decided to stop seeking treatment. BARTHOLET, *supra* note 215, at 198. But, she adds, "[i]f I could have gone on, I might well have 'chosen' to do so." *Id.*

219. *See generally* Antonio Regalado, *Clinical Trials Offer In-Vitro at a Discount*, WALL ST. J., Jan. 13, 2004, at D1.

options constantly being developed and offered to infertility patients resembles the variety of new and better products offered to consumers by stores and manufacturers.

In short, since 1978 with the birth of the first child conceived in vitro, a profitable and largely unregulated market in treatments for infertility has developed in the U.S.[220] One commentator, echoing many others, has described reproductive technology as "a multibillion dollar industry based solely on consumer demand."[221] Even more, developments in genetics, combined with developments in reproductive technology[222] increasingly encourage prospective parents to see the baby as a product. Here too choices proliferate.[223]

The marketplace for reproductive options, much as the marketplace for shampoo, furniture, cars, or eateries, operates by presenting a variety of choices and, at any point in time, defining *one* choice as more fulfilling, more real, more satisfying than the others. The *one* appropriate choice, however, changes quickly.[224] Advertisements rely on and

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220. The issue of regulation often arises in connection with an allegation of abuse within the world of fertility treatment. One recent allegation involved Richard Gladu's claim that Boston IVF did not have his permission to impregnate his estranged wife with an embryo produced from her egg and Gladu's sperm. Gladu brought a $3 million lawsuit in which he claimed financial ruin as a result of a child support obligation and emotional troubles due to his conflicting responses to the child produced as a result of the insemination. *See* Doreen Iudica Vigue, *Boston Clinic Sued Over Use of Embryo*, BOSTON GLOBE, Aug. 20, 1998, at A1.

In February 2004, a Massachusetts trial court ordered Boston IVF to pay $98,000 to Gladu for the cost of bringing up his then-seven-year old daughter, and it awarded him $10,000 for emotional distress. *See Legal Issues: Man gets $108,000 from Fertility Clinic for Breach of Contract,* HEALTH INS. L. WKLY., Feb. 22, 2004, at 41.

221. *See* Lisa Belkin, *The Made-to-Order Savior: Producing a Perfect Baby Sibling,* N.Y. TIMES, July 1, 2001, § 6, at 36, *available at* http://www.nytimes.com/2001/07/01/magazine /01FANCON1.html (quoting Susan M. Wolf, Professor of Law and Medicine, University of Minnesota).

222. This combination is referred to as "reprogenetics." *See, e.g.*, Dana Ziker, *Appropriate Aims: Setting Boundaries for Reprogenetic Technology*, 2002 DUKE L. & TECH. REV. 11.

223. For several decades, chromosomal testing during pregnancy has routinely been used to allow women to abort babies suffering from a variety of chromosomal conditions, including Down's Syndrome. More recently, prospective parents have relied on pre-implantation genetic diagnosis for a variety of purposes. Some have used the process to select embryos of only one gender. *See* Editorial, *Choosing the Sex of Your Baby*, N.Y. TIMES, Sept. 30, 2001, at § 4, at 12. Others have used the process to select against embryos diagnosed with a variety of genetic alterations linked with illness or disability. In 2002, the Journal of the American Medical Association considered the case of a thirty-year old woman with a gene for early-onset Alzheimer's. Anxious to have a child free of the gene (likely to result in Alzheimer's by age forty), the woman relied on preimplantation genetic diagnosis to select against the genetic alteration. *See generally* Jerome Groopman, *Designing Babies*, WALL ST. J., Mar. 4, 2002, at A14.

224. *See* STEVE BARNETT & MARTIN G. SILVERMAN, IDEOLOGY AND EVERYDAY LIFE 66 (1979) (describing "[e]veryday life" as "the domain of the substitution of one element for another within limited universes of meaning (e.g., our supposed choices among toothpastes, cars, fashions, modes of leisure, etc.)).

illustrate this dynamic.[225] Consumers are presented with a new form of shampoo or a new automobile model. Accompanying images suggest that use of the product will change the user's everyday life by making that person attractive and competent. When the product—the shampoo, the car, the toothpaste—does not, in fact, produce those ends, a "new, improved" version is available to be tried.[226]

Reproductive technology is being marketed similarly. Advertisements for IVF and other reproductive technologies appeal to the potential buyer's sense of incompleteness and incompetence. The advertisements suggest that everyday life will be rendered joyful and the buyer attractive and competent, if the clinic or provider's advertized offer is accepted. A search on Google.com leads to a panoply of illustrative presentations on various infertility clinics' websites. Only a few examples, randomly selected, are described here; many others exist. Fertility Neighborhood, labeled on its website as a Service of Freedom Drug and Priority Health care, offers a link to "Treatment Options."[227] The link presents several additional options: "Medications for Infertility; Procedures for Women; Procedures for Men; Assisted Reproductive Technology; Lifestyle & Emotions; Choosing a Clinic; Choosing a Pharmacy." Clicking on any one of the seven brings one to another long list of links; clicking on any of these, in turn, produces a registration form that enables one to become a member of Fertility Neighborhood.[228]

Abington Reproductive Medicine is described on its website as proud of providing "close, caring relationships . . . with our patients" and as offering "cost-effective and cost-conscious care, without sacrificing personalized attention."[229] A link presenting "patient comments" is punctuated by photographs of attractive young couples and one woman alone (perhaps pregnant). One patient thanks the doctor who treated her and her husband for a "second chance."[230] She explains:

> It is by no small act of fate that less than six months [after arriving at

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225. *See* HENRI LEFEBVRE, EVERYDAY LIFE IN THE MODERN WORLD (Sacha Rabinovitch, trans., 1971) (asserting that "ideology of consumption is based" on "the advertizing ideology").

226. *Id.* at 104-09 (symbolizing the operation of advertisements thusly: "'Be a well-groomed man. Every morning become a tremendous guy who appeals to himself and to women. Use this After-Shave, or you will be nobody and know it . . . .'" *Id*. at 106-07.).

227. Fertility Neighborhood, http://www.fertilityneighborhood.com (last visited Nov. 5, 2005).

228. Membership is billed as providing "free access to medical experts," "a supportive community," and "helpful articles that explain infertility and its treatment." *Id*. (follow "Join Now" hyperlink) (last visited Nov. 5, 2005).

229. Abington Reproductive Medicine, http://www.abington-repromed.com/our_practice /our_philosophy.html (last visited Nov. 5, 2004).

230. *Id*. *at* http://abington-repromed.com/our_practice/patient_comments3.html (last visited Nov. 5, 2005).

> your office, my husband] and I are expecting our first child. You and your office helped create this miracle. You are a credit to your profession. In a time where [sic] medical malpractice has risen to scary heights, it is comforting to know that there are doctors like you who still realize that successful results come from truly caring and listening to your patients.[231]

Another patient reported that she had "given up hope" until she became pregnant at the clinic:

> In your office, the doctors were accessible, and spent long hours making me feel that I deserved the number of children I wanted, while the nurses supported my moods, answered my questions, and were genuinely thrilled when we saw our twins on the ultrasounds. One year later, we still feel a part of your practice with our own little miracles, and that your practice remains a part of our family.[232]

The promise reflected in these comments is of self-worth and fulfillment at the level of everyday (family) life. The promise described in the patients' comments is actualized through a business arrangement between patients and the clinic. The statements quoted and other patient comments on the website reflect a combination of market forces[233] and family sentiment that characterizes involvement in infertility care for many patients. The patients' comments blur the boundary between commerce and family. Presumably designed to compete successfully in the marketplace of infertility care by enticing new patients to use the clinic, the presentation defines the relation between patient and clinic (buyer and seller) in language that suggests friendship and family. For instance, the patient who describes the clinic's practice as "part of our family" expressly conflates a family created through the birth of what she refers to as her "own little miracles" with her relationship to the clinic.[234]

Other clinics' websites resemble advertisements for spas, fitness centers, and bucolic vacations. The homepage of the website of the Arizona Center for Reproductive Endocrinology and Infertility, for instance, is headed by a picture of daisies, partially covered by the

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231. *Id.*

232. http://www.abington-repromed.com/comments.html (visited Jan. 5, 2004).

233. Abington Reproductive Medicine's website includes links to a newsletter, "Reproductive Medicine Matters." The summer 2005 issue announced a program allowing qualified patients to receive a seventy-percent discount if treatment (including three IVF cycles) is "unsuccessful." *Shared Risk IVF Treatment Refund Program Now Available to Patients*, REPROD. MED. MATTERS (Abington Reproductive Medicine), Summer 2005, at 1, *available at* http://www.abington-repromed.com/newsletter/pdfs/summer05NL.pdf.

234. *See supra* note 232.

words: "Helping You to Achieve Your Dreams!"[235] Infertility, the site explains, "can create [e]motional, [p]hysical, & [f]inancial hardships."[236] The clinic promises to dissipate each hardship.[237]

Contrasting images of infertility treatment abound in stories told by unsuccessful patients and many academic commentaries.[238] The British anthropologist Sarah Franklin writes that "[a]lthough ART's are often celebrated as an expansion of reproductive choice, all the women interviewed for this study described not having any choice—they 'had to try' IVF."[239] Franklin, who did anthropological fieldwork in an IVF clinic in Britain, contrasts media depictions of IVF with the experiences of women going through the process:

> In contrast to the extensive media depiction of women choosing IVF because they are "desperate" for a child, this study found that women were in fact often already resigned to the likelihood of not having children *before* undergoing IVF . . . . Ironically, it is the experience of undertaking IVF that may *produce* the very "desperateness" that it is often represented as helping to relieve.[240]

Thus, the IVF industry also resembles the larger commercial marketplace in attempting to create a need it then presents itself as able to satisfy.

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235. Arizona Center for Reproductive Endocrinology and Infertility, http://www.infertility-azctr.com (last visited Oct. 15, 2005).

236. *Id.* This site also presents a second theme present on many of the websites describing infertility treatments—the power of science. Arcane terms are defined; reproductive procedures are explained, and success is described. *See generally* Institute for Reproductive Health, http: www.cinncinnatifertility.com (last visited Jan. 5, 2004); Jones Institute for Reproductive Medicine, http://www.jonesinstitute.org (last visited Oct. 15, 2005).

Describing themselves through the language of advertising, infertility clinics stress the panoply of treatment choices available to patients. For instance, the website of the Arizona Center for Reproductive Endocrinology and Infertility describes eleven forms of treatment for infertility, including intrauterine insemination, ovarian stimulation, IVF and embryo transfer, and intracytoplasmic sperm injection. Arizona Center for Reproductive Endocrinology and Infertility, http://www.infertility-azctr.com/art.html (last visited Jan. 5, 2004). Other methods listed are: gamete intrafallopian transfer, gender selection, testicular biopsy, assisted hatching, preiimplantation genetic diagnosis, gamete donation, and cryopreservation of sperm, embryos, and oocytes. *Id*.

237. The clinic's care is described as "cost-effective." Moreover, the clinic promises to "creat[e] a well informed patient" so that "a successful partnership is forged." Finally, the website stresses the importance of "an open and ethical relationship" between the clinic and each patient." Arizona Center for Reproductive Endocrinology and Infertility, *supra* note 235.

238. *See supra* note 218 (describing Elizabeth Bartholet's description of her decision to stop infertility treatment).

239. Sarah Franklin, *Making Miracles: Scientific Progress and the Facts of Life in* REPRODUCING REPRODUCTION: KINSHIP, POWER, AND TECHNOLOGICAL INNOVATION 102, 107 (Sarah Franklin & Helena Ragoné eds., 1998).

240. *Id.* at 112.

At least as troubling to many bioethicists as the market in infertility treatment is the developing panoply of choices-in-babies offered to infertility patients.[241] Prospective parents are selecting for and against traits that will characterize their children.[242] Infertile couples have advertised for tall ova donors with SAT scores of at least 1400.[243] Gender selection is another option available to prospective parents.[244]

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241. Leon Kass, former chair of President George W. Bush's Council on Bioethics describes IVF and embryonic genetic testing as the beginning of a process that threatens to "transform[] begetting into making" and "procreation into manufacture." LEON R. KASS, LIFE, LIBERTY AND THE DEFENSE OF DIGNITY 201-02 (2002). He sees cloning as a frightening extension of the process:

> With cloning, not only is the process in hand, but the total genetic blueprint of the cloned individual is selected and determined by the human artisans. To be sure, subsequent development is still according to natural processes, and the resulting children will be recognizably human. But we would be taking a major step into making man himself simply another one of the manmade things.

Id. at 201-02. Kass differentiates cloning from other forms of reproductive technology in that with cloning "we give existence to a being not by what we are, but by what we intend and design." *Id*. at 202.

242. At present, cloning represents the extreme edge of prenatal selection. Leon Kass locates what he takes to be the essential problem with cloning: It is not that the cloned child is produced with the assistance of technology. Rather, the problem for Kass is that the cloned child, produced as the result of "human design," is inferior to the one who designed the child:

> As with any product of our making, no matter how excellent, the artificer stands above it, not as an equal but as a superior, transcending it by his will and creative prowess. In human cloning, scientists and prospective "parents" adopt a technocratic attitude toward human children, as their artifacts. Such an arrangement is profoundly dehumanizing, no matter how good the product.

KASS, *supra* note 241, at 202.

Other commentators are less troubled than is Kass by the prospect of reprogenetics and cloning. Professor Lee Silver wrote:

> Advanced reproductive technologies will be used to provide infertile couples and individuals with the opportunity to have biological children in the context of loving families. Reprogenetic technologies will be used to provide children with increased chances of physical and mental health and increased longevity. If standard medical practice is followed, no technology will be applied until its safety and efficacy is demonstrated . . . . If standard medical practice is followed, the benefits will outweigh the risks.

Lee M. Silver, *How Reprogenetics Will Transform the American Family*, 27 HOFSTRA L. REV. 649, 656-57 (1999).

A human has not yet been cloned, though human embryos have been. Advanced Cell Technology, a Massachusetts biotechnology company, cloned a human embryo to the 16-cell stage. Kristen Philipkoski, *Human Clone Produces Stem Cells*, Wired News, Feb. 11, 2004, http://www.wired.com/news/0,1294,62254,00.html. Researchers in South Korea claimed to have cloned human embryos from which they derived stem cells. *Id.* In December 2005, the head of the South Korean group, Hwang Woo-suk, responded to accusations that he had falsified data. He asserted that his findings were accurate but asked to have his research report withdrawn. The report was published by the journal Science in May 2005. Kwang-Tae Kim, *Seoul University Probes Stem Cell Research*, NEWSDAY, Dec. 18, 2005, *available at* http://www.newsday.com/news/health/sns-ap-stem-cell-accusations,0,249967.story.

243. *See, e.g.*, Sege, *supra* note 217.

244. *See, e.g.*, Belkin, *supra* note 221; *Choosing the Sex of Your Baby, supra* note 223.

Moreover, through preimplantation genetic diagnosis or prenatal testing followed by abortion if test results prove disappointing, it is possible to select for or against a wide range of other traits.[245]

The generalization of marketplace individualism is further evident in the practice of infertility care insofar as it may involve third parties, negotiated arrangements, and money exchange. Reliance on gamete donors and surrogates reflects a form of interaction once viewed as antithetical to the creation of the parent-child bond.[246] Thus, assisted reproduction suggests a shift in understandings of family relationships, as it suggests a shift in understandings of the world of health care. This is not accidental. Just as the last several decades of the twentieth century witnessed an explicit transformation of the family away from a hierarchically structured universe identified with unremitting loyalty,[247] so a similar shift has begun to transform the world of health care from one essentially separate from the world of the commercial marketplace to one increasingly hard to distinguish from the world of commerce.

V. CONCLUSION

The three kinds of excesses described in this Article may be unavoidable consequences of rules fashioned through the lens of an ideology steadfastly committed to safeguarding autonomous individuality. Yet, these excesses diminish the very benefits to patients that the rules from which they flow were intended to effect.

The excesses described in this Article are likely to interfere with the sort of physician-patient relationship most productive of good health care. These excesses facilitate the construction of a health care system that redefines patients as consumers and doctors as employees—accountable to a complex assortment of commercial interests and state administrators.

Shifts in the scope of the patient-provider relationship and in the meaning of "patient" have been facilitated by what William Sage refers to as the "lawyerization of medicine."[248] That process is not a first cause

245. *See, e.g.*, CHRISTIAN MUNTHE, PURE SELECTION (1999) (considering the moral dimensions of preimplantation genetic diagnosis); R. Ashcroft, *Bach to the Future: Response to: Extending Preimplantation Genetic Diagnosis: Medical and Non-Medical Uses*, 29 J. MED. ETHICS 217 (2003), *available at* http://www.jmedethics.com. (considering medical and non-medical uses of preimplantation genetic diagnosis).

246. *See* JANET L. DOLGIN, DEFINING THE FAMILY 245-53 (1997) (summarizing transformation of families in the United States in the second half of twentieth century and noting the place of third-party participation in the reproductive process in that transformation).

247. *Id.*

248. William M. Sage, *The Lawyerization of Medicine*, 26 J. HEALTH, POL., POL'Y & L. 1179 (2001).

of the ideological changes described in this Article. Rather it is a modus vivendi for incorporating new understandings and values into the world of health care. Nevertheless, it is now incumbent on lawmakers to serve, once again, as a modus vivendi for change. This time, the task requires lawmakers to tame the excesses that have flowed from earlier efforts to safeguard patient autonomy. The aim is to temper the excesses without sacrificing rules that protect autonomous individuality.

For instance, elaborations of the informed consent doctrine that diminish physician authority without clearly enhancing patient welfare, such as the requirement in *Johnson* that the physician inform a surgery patient about the physician's own comparative inexperience, should not be encouraged by lawmakers.[249] The rule in *Johnson* precludes the development of trust between patient and physician. Yet, trust seems to play a central part in the healing relationship.[250]

Similarly, the value of providing people with information about their future health risks must be balanced against the dangers inherent in defining patients with reference to their DNA. Those dangers include the social risk of conflating identity with genetic alterations and the correlative risk of imagining genetic groups as undifferentiated wholes. The New Jersey legislature recognized these risks and precluded their most likely manifestations.[251] Other states should follow that example.

Finally, the third excess delineated in this Article, the generalization of autonomous individuality (illustrated through reference to the creation of a commercial market in reproductive care) threatens widely to re-shape the physician-patient relationship. Uses of reproductive technology should be more consistently and carefully regulated than is currently the case in the United States.[252] At present, states lack comprehensive regulatory schemes that could provide for infertility care, while precluding or at least limiting the

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249. Johnson v. Kokemoor, 545 N.W.2d 495 (Wis. 1996); *see supra* notes 121-134 and accompanying text.

250. It should not be assumed that trust is inevitably a good thing, only that it can be and often is a good thing. A number of commentators have noted that trust can be the basis for immoral as well as moral relationships. *See, e.g.*, Annette Baier, *Trust and Antitrust*, 96 ETHICS 231, 231-32 (1986). Trusting relationships may exclude some parties to their detriment, and trusting relationships may, in effect, silence one party to the relationship in the name of "trust."

251. Genetic Privacy Act, N.J. STAT. ANN. § 17B:30-12 (West 1996).

252. Other countries now have comprehensive regulatory schemes, limiting and channeling the uses of reproductive technology. *See, e.g.*, Human Fertilisation and Embryology Authority (HFEA), 1948, SI 2004/1511 § 2 (U.K.). That legislation was enacted soon after the completion of the Warnock Report in 1984. The report was named for Mary Warnock, who headed the commission (formed in 1982) that provided direction for the British Parliament in regulating reproductive assistance. *See* MARY WARNOCK, A QUESTION OF LIFE: THE WARNOCK REPORT ON HUMAN FERTILISATION AND EMBRYOLOGY (1984).

commercialization of such care. It is time that states respond to that challenge.

None of these responses is dramatic. All are comparatively easy to effect. They should be undertaken in order to safeguard the goals that, in fact, underlie legal rules mandating respect for patient autonomy.