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GENETIC INFORMATION AND THE IMPORTANCE OF CONTEXT: IMPLICATIONS FOR THE SOCIAL MEANING OF GENETIC INFORMATION AND INDIVIDUAL IDENTITY

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PART I – INTRODUCTION

Current genetic information laws are controversial and confusing.[1] Some people advocate stronger legal safeguards for any use of genetic information and others complain that current state and federal regulations are overly protective. The critics assert that the laws fail to adequately distinguish between clinical and research contexts.[2] They complain that new genetic privacy statutes make genetic research too onerous and will curtail important medical research. In the New England Journal of Medicine, representatives of

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1. Health law practitioners acknowledge confusion surrounding health information generally, commenting that, "No concrete scheme for regulating the collection, storage, use, and disclosure of human biological data presently exists, giving rise to much speculation and debate over how and by whom this information should be monitored and controlled." Karen E. Glover et al., *Collisions at the Intersection: Law and Bioinformatics*, 11 BNA HEALTH L. REP. 233, 233 (2002). State laws regulating medical privacy have been described as a "morass" and "erratic." *See* Andrew A. Skolnick, *Opposition to Law Officers Having Unfettered Access to Medical Records*, 279 JAMA 257, 257 (1998).

2. For a good critical overview of many of the issues surrounding medical research on human subjects, see Beverly Woodward, *Challenges to Human Subject Protections in US Medical Research*, 282 JAMA 1947 (1999). Woodward writes,

> In recent years, however, in discussions regarding consent requirements, expedited review, medical privacy, genetic studies, research with the mentally ill, and other topics, it has become common to read or hear statements by medical researchers that assert the primacy of the interests of science and society and that place the burden of justification on those who would put any obstacles in the way of scientific and societal goals. These assertions are often accompanied by an unwillingness to admit that there are any true conflicts between progress of science and the protection of human subjects.

Id. at 1948. *See also* Jocelyn Kaiser, *Researchers Say Rules Are Too Restrictive*, 294 SCI. 2070 (2001); L. Joseph Melton III, *The Threat to Medical-Records Research*, 337 NEW ENG. J. MED. 1466 (1997) (reviewing medical records research at the Mayo Clinic and discussing Minnesota's statute limiting access to medical records for research purposes).

the Association of American Medical Colleges ("AAMC") warn that genetic privacy rules that "restrict or prohibit the release of medical information for research purposes . . . . might marginally enhance patient privacy, but at a potentially steep cost to public health."[3] The Secretary of the Department of Health and Human Services received a letter in November of 2001 from the AAMC, various researchers and academic hospitals warning that regulations safeguarding genetic information severely threatened medical research.[4]

Most arguments for a distinction between research and clinical contexts are practical ones. The arguments fall into three general categories. The first is that genetic privacy statutes will lead to less research. The second is that genetic information in the research context is unlikely to lead to discrimination in the workplace or health insurance.[5] The third argument is that it is difficult to distinguish between genetic information and other medical information.[6]

In this article, I propose a theoretical position for developing legal safeguards that recognize a distinction between genetic information in the research and clinical contexts. The role of individual identity is central to my criticism of how current regulations over-protect all genetic information. Identity is also the keystone to my proposed alternative regulatory scheme for genetic information.

The analysis begins with a critique of the current regulatory approach to protecting all genetic information regardless of context or substance. Many legal safeguards designed to protect individuals from misuse of their genetic information focus only on the fact that the information is genetic instead of looking at the substantive content that the genetic information represents. This myopia detrimentally alters the social meaning[7] of genetic information by

3. Jennifer Kulynych & David Korn, *The Effect of the New Federal Medical-Privacy Rule on Research*, 346 NEW ENG. J. MED. 201, 201 (2002).

4. *Id.* Kulynych and Korn note that over 180 "leading research universities, medical schools, teaching and community hospitals, and medical specialty and scientific societies" signed the letter. *Id.* at 204 n.2. On March 27, 2002, Secretary Thompson proposed to modify the federal medical privacy rule. The AAMC submitted a formal comment letter on April 11, 2002. *See* Letter from Jordan J. Cohen, M.D., Association of American Medical Colleges, to Tommy G. Thompson, Secretary of U.S. Department of Health and Human Services (Apr. 11, 2002), *available at* http://www.aamc.org/advocacy/library/hipaa/corres/2002/041102.htm.

5. This statement is supported by various rationales, including that researchers do not disclose information that is easily connected to any particular individual. Another point is that the information from research is not useful to insurers or employers because research typically addresses small questions and the answers do not have clinical significance without extensive additional research.

6. *See* Lawrence O. Gostin & James G. Hodge, Jr., *Genetic Privacy and the Law: An End to Genetic Exceptionalism*, 40 JURIMETRICS J. 21 (1999).

7. There are many articles and books written on the subjects of social meaning, norms and social construction. *See, e.g.*, Lawrence Lessig, *The Regulation of Social Meaning*, 62 U. CHI. L. REV. 943 (1995); Cass R. Sustein, *Social Norms and Social Rules*, 96 COLUM. L. REV. 903 (1996); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the*

promoting the idea that a person's DNA is the essence of a person. Laws should instead regard genetic information as representing one attribute among many other important attributes, such as personality, ambition and character.

When the law protects information only because it is genetic, then the law encourages a shift in the social meaning of genetic information toward a "genetic essentialism." This change in social meaning alters our notions of identity. It is one thing to believe that our future health is heavily influenced by our individual genetic make-up. It is quite another thing to believe that we are "nothing more than our genes." This change in the social meaning of genetic information that our current regulatory scheme promotes has deleterious effects on our identity and our belief in autonomy.

Laws must consider the context within which genetic information arises to prevent erosion of beliefs in autonomy and identity. The law should protect genetic information in the clinical context since such information likely has concrete clinical meaning and might lead to discrimination.[8] In the clinical setting, a person's genetic information may form a substantial portion of their identity. However, even in the clinical setting, an individual's identity is more than a mere sum of genomic information, just as it is greater than a list of his or her physical ailments. Admittedly, genetic information may have attributes similar to race, religion, gender and other features of identity that might lead to discrimination and comprise an essential part of a person's sense of who he or she is. However, in the research context, genetic attributes are typically not yet tied to identity because the genetic information uncovered is unlikely to have clinical significance. In other words, why should the law grant a privacy interest to every individual's entire genetic information regardless of whether the information has any clinical significance or is likely to lead to discrimination? Why should the law grant a privacy interest to genetic information that says nothing meaningful about an individual's identity? If the law protects this kind of information only because it is genetic, this changes the social meaning of genetic information and individual identity.

I propose a way to recognize the context within which genetic information arises and a fluid means to evaluate when genetic information becomes sufficiently tied to individual identity to merit legal protection. This approach

Norms of Science, 94 NW. U. L. REV. 77 (1999). The author applies law and norms theory to scientific research and concludes that laws that "reinforce and reflect efficient norms" are superior. *Id.* at 80. One facet of many social norm theories is that the social meaning must remain uncovered to be effective. As soon as society's members become aware that the particular social meaning is socially constructed then the meaning changes. *See generally* ROBERTO MANGABEIRA UNGER, SOCIAL THEORY: ITS SITUATION AND ITS TASK (1987).

8. *But see* Colin S. Diver & Jane Maslow Cohen, *Genophobia: What is Wrong with Genetic Discrimination?*, 149 U. PA. L. REV. 1439, 1482 (2001) (concluding that a "regime of genetic transparency" rather than concentrating on genetic privacy is better on the grounds of fairness and efficiency).

focuses on the substantive character of the information instead of elevating information on the exclusive criteria of whether it is genetic (as many genetic privacy statutes do), thereby undermining traditional constructs of identity. For example, under the proposed approach genetic research that uncovers whether a person has a substantial risk for developing a serious neurological disorder would merit strong legal protections because the information reasonably impacts the individual's identity.[9] In contrast, research looking at genetic information that does not have clinical significance should not receive legal protections because it does not reasonably impact individual identity. The vehicle that will distinguish between these two contexts, as well as allow fluidity in the large area between these two examples, is the tort of misappropriation of identity.[10]

This article has two main points. The first part discusses how genetic privacy statutes that do not distinguish between the research and clinical contexts change the social meaning of genetic information. The second part addresses the proposed alternative approach, which borrows the tort of misappropriation of identity from tort law. Rather than protecting genetic information solely because it is genetic information, the tort of misappropriation of identity keeps our emphasis on traditional elements of individual identity, protecting those pieces of information that might reasonably impact identity. Instead of elevating genetic information and thereby adversely altering its social meaning, the tort of misappropriation of identity provides a way to more accurately describe the individual interests at stake in the use of genetic information. This proposed approach allows a distinction between research and clinical contexts as well as between different kinds of research contexts involving genetic information. Most importantly, it enables the law to take into consideration the context within which we collect and use genetic information. This reduces the adverse impact on identity promoted by the current law's effect on the social meaning of genetic information.

Part II discusses genetic exceptionalism and several writers' views about the risks of genetic exceptionalism, including how genetic exceptionalism

9. Interestingly, federal regulations ("CLIAA") require that a lab be accredited before any clinically significant lab results are passed on to the patient. Since most research labs are not CLIAA approved, the regulation prohibits the passing on of lab results to the patient or research participant.

10. *See* Jonathan Kahn, *Bringing Dignity Back to Light: Publicity Rights and The Eclipse of the Tort of Appropriation of Identity*, 17 CARDOZO ARTS & ENT. L.J. 213, 214 (1999) [hereinafter Kahn, *Bringing Dignity Back to Light*]; Jonathan Kahn, *Biotechnology and The Legal Constitution of the Self: Managing Identity In Science, the Market, and Society*, 51 HASTINGS L.J. 909 (2000) [hereinafter Kahn, *Biotechnology*]. Other commentators advocate using the tort of intrusion on seclusion to protect individual interests in genetic privacy. *See also* June Mary Z. Makdisi, *Genetic Privacy: New Intrusion A New Tort*, 34 CREIGHTON L. REV. 965 (2001).

leads to a reductionist view of identity. The section relies on the example of HIV exceptionalism for guidance. Part III elaborates on the difference between genetic information in the research and clinical contexts. Part IV discusses an alternative approach for genetic protection statutes that focuses on the substance of the genetic information. The proposal centers on a misappropriation of identity method. Part V offers a conclusion.

PART II - GENETIC EXCEPTIONALISM

> "You," your joys and your sorrows, your memories and your ambitions, your sense of personal identity and free will, are in fact no more than the [genetically determined] behavior of a vast assembly of nerve cells and their associated molecules.[11]

Francis Crick and James Watson described the double helix structure of DNA in the early 1950s.[12] Fifty years later, many people routinely ascribe quirks and family traits to "it's genetic." Although Crick's view about the extent of genetics in forming every aspect of our lives may be exuberant, many share his view of the power of genetics and its predominance in describing who and what we are. Legal commentators also describe genetic information as fundamentally different from other types of personal information.[13]

Many people are apprehensive about the potential for misuse of genetic information. Employers or health care insurers may use genetic information to discriminate against people because their genetic information indicates a greater risk of disease and expense.[14] A national survey in 1997 showed that two-thirds of respondents would refuse to participate in a genetic test if employers or health insurers could see the results.[15] Greater than eighty percent of the respondents favored prohibitions against employers or insurers having access to an individual's genetic information.[16] A genetics counselor at

11. FRANCIS CRICK, THE ASTONISHING HYPOTHESIS: THE SCIENTIFIC SEARCH FOR THE SOUL 3 (1994).

12. *See* J.D. Watson & F.H.C. Crick, *Genetic Implications of the Structure of Deoxyribonucleic Acid*, 171 NATURE 964 (1953).

13. *See, e.g.*, Lynda M. Fox & Barbara A. Kakenmaster, *The Genetic Privacy Act: Proposed Model Legislation*, 24 COLO. LAW. 2317, 2317 (1995). The authors write, "The major premise underlying the Act is that genetic information is different from other types of personal information and, thus, requires special protection." *Id.*

14. *See generally* Diver & Cohen, *supra* note 8. The authors advocate a legal strategy of "genetic transparency" to "enable our society to confront openly its phobias about genetic diversity and begin, at last, fully to appreciate its blessings." *Id.* at 1482. The authors use an economic analysis to reach their conclusion, maintaining that the prohibition of all genetic discrimination, although well-intentioned, would lead to significant welfare losses due to the "distortion of allocative efficiency." *Id.* at 1445.

15. Paul Steven Miller, *Genetic Discrimination in the Workplace*, 26 J.L. MED. & ETHICS 189, 189 (1998).

16. *Id.*

the University of California, Los Angeles (U.C.L.A.), reported that nearly 80% of people getting a genetic test for Huntington's disease would rather pay out of pocket than allow their insurance companies access to the information.[17] The dissemination of genetic information might also wreak havoc in other aspects of a person's life. For example, a potential spouse may change his or her mind about marriage or one's partner may decide against having children because of the other's genetic profile. Family and friends may pity, shun or avoid a person because of what they know, or think they know, about an individual's genes.

Others are fearful that genetic information might tell them some information about themselves that they would rather not know. For example, they might be told about the high probability of dementia after a certain age, an incurable disease, or a disease curable only with great suffering, time, monetary expense and familial burdens. Commentators cite many scenarios in support of the right not to know.[18]

Commentators also write about how genetic information is different than other types of information because it invokes the interests of the family as well as the individual. They ask about what rights and interests might protect genetic family members who do not want to know. Some argue that genetic information is different from family history because of the increased specificity and reliability of genetic results. When family members retell their family history, their memories are often inaccurate. They may be misinformed about what disease a relative had, or they may deny certain family propensities. Genetic information suffers from none of these human frailties. It is one thing to know that dementia runs in your family. It is quite another thing to know that you carry a gene that gives you a 75% chance of developing dementia by the time you are sixty-five years old.

Whether people view genetic information as more dangerous, more powerful or more complete, the belief that genetic information is different from other types of information is ubiquitous. This view has generated numerous legal commentators to argue that genetic information is fundamentally different and inherently requires additional protections. For example, George Annas describes genetic information as "a future diary."[19] Although he admits it is "in code and probabilistic," Annas argues that

17. Antonio Regalado, *Confidential! Genetics Research is Prompting Calls for New Privacy Laws*, WALL ST. J., Feb. 21, 2001, at R10.

18. *See, e.g.*, Richard S. Fedder, *To Know or Not to Know: Legal Perspectives on Genetic Privacy and Disclosure of an Individual's Genetic Profile*, 21 J. LEGAL MED. 557 (2000); Graeme T. Laurie, *Challenging Medical-Legal Norms: The Role of Autonomy, Confidentiality, and Privacy in Protecting Individual and Familial Group Rights in Genetic Information*, 22 J. LEGAL MED. 1 (2001).

19. George J. Annas, *Genetic Privacy: There Ought to Be a Law*, 4 TEX. REV. L. & POL. 9, 11 (1999).

"genetic information should be seen as private because it is in essence a reverse diary: it informs our younger selves about our aging selves."[20] Many state[21] and federal[22] genetic privacy statutes and regulations, as well as pending

20. *See id.* Professor Annas states, in full:

> But you can think about your DNA molecule as a "future diary." It is in code and probabilistic, but just as private. It is information about you, information about which you should have a right not to know, a right to say, "I don't want to know this." But even if you want to know it, you should have a right to say, "I don't want anybody else to know it. I don't want my employer to know it. I don't want the FBI to know it. I don't want my school to know it. I don't want my colleagues to know it. I don't want my spouse to know it. I don't want my children to know it."

Id. at 11. Professor Annas emphasizes that it is the fact that we treat genetic information as different from other types of information that supports special legal protections for genetic information. He argues that genetic information is different only in the sense that it should receive special legal protections because it involves three of the four different facets of privacy. Elsewhere, Professor Annas has also written that the issues raised by the Human Genome Project are not unique. Rather, they bring issues into focus. Whereas the issues might not be unique for Annas, he does advocate a property based right in genetic information. *See also* George J. Annas, *Mapping the Human Genome and the Meaning of Monster Mythology*, 39 EMORY L.J. 629, 640 (1990).

21. All states have legislation that restricts access to medical records. As of April 2002, thirty states had a statute that specifically addressed genetic information. Twenty-three states had laws requiring informed consent for disclosure of genetic information. Four states defined genetic information in terms of personal property. National Conference of State Legislatures, *State Genetic Privacy Laws, at* http://www.ncsl.org/programs/health/genetics/prt.htm (last updated Apr. 15, 2002). Another account claims that at least forty states have statutes that provide protections for genetic information, although the strength of the protections varies. Janet L. Dolgin, *Personhood, Discrimination, and the New Genetics*, 66 BROOK. L. REV. 755, 781 (2001) (indicating that the disparity is partially explained by the pattern of state laws addressing medical privacy, which has been described as a " morass" and "erratic."). *See also* Andrew A. Skolnick, *Opposition to Law Officers Having Unfettered Access to Medical Records*, 279 JAMA 257 (1998); Joy Pritts et al., *The State of Health Privacy: An Uneven Terrain: A Comprehensive Survey of State Health Privacy Statutes* (1999), *available at* http://www.healthprivacy.org/usr_doc/35309.pdf.

22. See, for example, Health Insurance Portability and Accountability Act of 1996 (HIPAA), which protects against genetic discrimination and invasion of privacy. Compliance with privacy concerns is the most important issue heading into 2002 according to an advisory board of health care attorneys put together by the Health Law Reporter. *See* M. Alexander Otto & Barbara Yuill, *Privacy Rule Still Dominates Health Practice; Attention Focuses on Bioterrorism Planning*, 11 BNA HEALTH L. REP. 5 (2002). Cost estimates for implementation of privacy rules under HIPAA, published in 2000, were $17.6 billion over ten years. *See Proposal Would Lower Price of Privacy Rule Under Research, Other Provisions, HHS Says*, MED. RES. L. & POL'Y REP., Apr. 3, 2002, at 36, 36. Recent proposed revisions of HIPAA's privacy rule is aimed at reducing researcher's burdens. *Id.* at 37. Other applicable federal laws include the Privacy Act of 1974, 5 U.S.C. § 552 (2000) (applicable to federal agencies); the Americans with Disabilities Act, 42 U.S.C. § 12112 (2000) (requiring confidential employee records); 42 C.F.R. § 482.24(b)(3) (1999) (Medicare regulations requiring hospitals to ensure confidentiality of medical records); and the common rule, where the federal regulation for the protection of human subjects in research places significant oversight with the Institutional Review Boards. *See* 45 C.F.R. § 46

legislation,[23] provide specific protections for genetic information and view genetic information as special. For instance, the Oregon Genetic Privacy Act includes a legislative finding that "genetic information is uniquely private and personal information." [24] Statutes like this one protect genetic privacy as a distinct form of medical information that merits protection separate from the already existing statutory protections for medical and research information. These statutes view genetic information as exceptional.

A. HIV exceptionalism and genetic exceptionalism[25]

The idea that certain types of information are exceptional is not new. For example, in the early 1990s, Ronald Bayer described our policy of treating HIV infection as an exceptional disease.[26] He termed this "HIV

(2000). In addition, there is pending federal legislation with ramifications on the use of genetic information included in one joint resolution, and ten bills in the Senate and House of Representatives. National Cancer Institute, *Genetic Privacy, Discrimination and Medical Information*, *at* http://www3.cancer.gov/legis/june02/genetic.html (last visited Sept. 19, 2002) (summarizing the pending legislation).

23. As of May 2002, pending federal legislation with some ramification on the use of genetic information included one joint resolution (H.R.J. Res. 38), and ten bills in the Senate and House of Representative. National Cancer Institute, *supra* note 24.

24. Statutes like Oregon's revised Genetic Privacy Statute, S. 114, codified at OR. REV. STAT. § 192.531, do distinguish between anonymous genetic information and other types of genetic information, but even anonymous genetic information is treated as exceptional and requires additional steps when a person agrees that their tissue may be used for genetic research. Commentators have pointed out that genetic information with only limited identifying information may adversely impact groups as well as individuals, but this is also true for other types of information such as race. A different approach from the one taken by genetic privacy statutes of focusing on all genetic information regardless of the substantive effects of the information, is arguably offered by the U.S. Supreme Court's interpretation of the Americans with Disabilities Act. *See* Laura F. Rothstein, *Genetic Discrimination: Why Bragdon Does Not Ensure Protection*, 3 J. HEALTH CARE L. & POL'Y 330 (2000). *But see* EEOC COMPL. MAN. § 902.8 (classifying asymptomatic genetic conditions as disabilities because persons with such conditions may be regarded as having a disability).

25. Others have looked to the HIV exceptionalism debate to gain insight into genetic exceptionalism. *See* Zita Lazzarini, *What Lessons We Learn From the Exceptionalism Debate (Finally)?*, 29 J.L. MED. & ETHICS 149 (2001). Lazzarini instructs that

> [t]he point is not whether genetic information or HIV should be treated as all other diseases are treated now, but how should we resolve that period of social negotiation that inevitably follows new discoveries or threats, and how will that response inform our ways of dealing with "old" information or threats.

Id. at 150. Lazzarini also asserts that "[a]s a society, we need to assess the real threats to privacy and dignity that genetics pose." *Id.* at 151. I undertake an examination of the real threat of genetics.

26. Ronald Bayer, *Public Health Policy and the AIDS Epidemic: An End to HIV Exceptionalism?* 324 NEW ENG. J. MED. 1500, 1500-04 (1991) [hereinafter Bayer, *Public Health Policy*]. *See also* Ronald Bayer et al., *HIV Antibody Screening: An Ethical Framework for Evaluating Proposed Programs*, 256 JAMA 1768, 1768-74 (1986) [hereinafter Bayer, *HIV*

exceptionalism" because our laws and health system treated HIV infection differently from other diseases.[27] Bayer painted the background of a traditional public health approach, which arose in the late nineteenth and early twentieth century, as a system that emphasized mandatory reporting to public health registries and compulsory testing.[28] HIV, he argued, stands in relief, emerging as exceptional.[29] This is evident by looking at how people were tested and screened for the disease, how the information was stored, and how our legal and health care systems implemented protections for the identity of HIV positive patients. Unlike other infectious diseases, HIV testing required specific consent, instead of the presumed consent accompanying most blood tests for infectious diseases.[30] The exceptional status of HIV infection is evident when a New York State court supported the state health commissioner in refusing to categorize HIV infection as a sexually transmitted and communicable disease.[31]

Bayer agreed that the justification for treating HIV infection differently lay largely in the great potential for stigmatization and discrimination.[32] According to Bayer, this civil liberties-sensitive approach was brought about by the relatively strong political power of gay men.[33] One of the reasons for the declining influence of HIV exceptionalism was the shift in risk of infection away from homosexual men and toward minority drug users.[34] Bayer remarked, "Not only do black and Hispanic drug users lack the capacity to influence policy in the way homosexual men have done, but also those who speak on their behalf often lack the singular commitment to privacy and consent that so characterized the posture of gay organizations."[35] For Bayer, HIV exceptionalism was largely a result of political forces.[36]

Antibody Screening]; Kevin M. De Cock & Anne M. Johnson, *From Exceptionalism to Normalisation: A Reappraisal of Attitudes and Practices Around HIV Testing*, 316 BRIT. MED. J. 290-93 (1998).

27. *See generally* Bayer, *Public Health Policy*, *supra* note 26.

28. *See* Lawrence O. Gostin et al., *The Law and Public Health: A Study of Infectious Disease Law in the United States*, 99 COLUM. L. REV. 59 (1999) (insightful article on the law, public health and infectious disease).

29. Bayer, *Public Health Policy*, *supra* note 26, at 1501.

30. *Id.*

31. N.Y. State Soc'y of Surgeons v. Axelrod, 572 N.E.2d 605, 607 (N.Y. 1991).

32. *See* Bayer, *HIV Antibody Screening*, *supra* note 26, at 1768.

33. Bayer, *Public Health Policy*, *supra* note 26, at 1503.

34. *Id.*

35. *Id.* Bayer notes other reasons for the end of HIV exceptionalism. These include the existence of more effective drugs for the treatment of HIV and the clinical understanding of the benefits of early treatment. *See* Ronald Bayer, *Clinical Progress and the Future of HIV Exceptionalism*, 159 ARCHIVES OF INTERNAL MED. 1042 (1999).

36. Bayer, *Public Health Policy*, *supra* note 26, at 1502.

Bayer's objection to HIV exceptionalism was that it interfered with our ability to best prevent new infections and diagnose current ones.[37] He described recent trends with relief: "[T]he first decade of the epidemic came to an end, public health officials began to assert their professional dominance over the policy-making process and in so doing began to rediscover the relevance of their own professional traditions to the control of AIDS."[38] In Bayer's view, HIV exceptionalism was problematic because it represented a politically driven change in the social meaning of AIDS that had deleterious effects on the public health system's ability to effectively contain and treat the disease.[39]

How did HIV exceptionalism change the social meaning of the disease? The social meaning of "being HIV positive" was fundamentally different from "having syphilis" or "having heart disease." The difference in description of "having" verses "being" illustrates how HIV infection consumed an individual's identity to a greater degree. By categorizing HIV as exceptional, the social meaning of HIV infection took away some of the individual's ability to define his or her own identity. No matter what, once infected with HIV, people thought of themselves and were considered by others, HIV positive. Presumably, it was worse to be HIV positive than to be just about anything else, in part, because of the certainty of death in the relatively near future and, in part, because of the great risk of discrimination. It made sense that the legal protections for individuals with HIV should be stronger because of what it meant to be HIV positive. However, in doing so, the legal protections also impacted what it meant to be HIV positive.

More recently, Friedman Ross compared HIV with genetic information to address whether genetic information is exceptional.[40] She began with the proposition that HIV infection is not exceptional, as shown by the present day "normalization of HIV management."[41] She then examined whether differences between genetic information and HIV infection succeed in setting the former apart.[42] She discussed various attributes, including the potential for eugenics, the impact on family, and the probabilistic character of genetics.[43] Ross concluded that genetic information is not exceptional, relying on her analysis of the attributes mentioned, as well as on Gostin and Hodges, who

37. *Id.*

38. *Id.* at 1502.

39. *Id.* at 1503-04.

40. Lainie Friedman Ross, *Genetic Exceptionalism vs. Paradigm Shift: Lessons from HIV*, 29 J.L. MED. & ETHICS 141, 141 (2001).

41. *Id.* at 141-42.

42. *Id.* at 142-43.

43. *Id.* at 143.

argue against genetic exceptionalism largely on the basis of how closely genetic information melds with other medical information.[44]

Interestingly, Ross seeks the answer to whether genetic information is objectively different from HIV infection and other kinds of information, while implicitly assuming that we know.[45] Ross argues that if genetic information is not different, we should not treat it as exceptional.[46] One problem is that in many ways genetic information does seem different. Powerful techniques are associated with genetic information. From a cheek swab, a person's entire genetic sequence might be generated, with great amounts of potential and predictive information about the individual's future and her family, including children not yet conceived.

Scott Burris offers a different approach to the exceptionalism debate in his critique of Bayer.[47] His insightful conclusion is that society and the law's treatment of HIV is both similar and fundamentally different.[48] Burris argues that we never treated HIV differently.[49] Descriptions of HIV as exceptional rely on sentimental and inaccurate views of the past.[50] According to Burris, the "norm" that HIV must contrast against in order to attain exceptional status never existed.[51] Instead, HIV appears much like other "killer diseases of the past," and is similar to other politicized diseases like syphilis, tuberculosis and cholera.[52]

Burris argues the political, public health and societal reaction to HIV is part of a paradigm shift. The shift is toward a paradigm that places an emphasis on reducing the fear and stigma from certain "killer diseases." In the past, fear and stigma have stood in the way of more effective disease control. In contrast, our recent collective reaction to HIV and AIDS represents a movement to lessen the harmful effects of the fear and stigma as well as allowing more effective public health control of the disease itself. For example, many people expressed concern early on in the AIDS story about potentially infected patients who did not seek testing because they were worried about the possible effects of a publicized positive test result or even dissemination of the information that they had simply sought out a screening test for HIV. Increasing consent and confidentiality requirements lessened the

44. Gostin & Hodge, *supra* note 6, at 21.

45. Ross, s*upra* note 40, at 142-43.

46. *Id.* at 145.

47. *See* Scott Burris, *Public Health, "AIDS Exceptionalism" and the Law*, 27 J. MARSHALL L. REV. 251 (1994) [hereinafter Burris, *Public Health*]; Scott Burris, *Law and the Social Risk of Health Care: Lessons form HIV Testing*, 61 ALB. L. REV. 831 (1998).

48. Burris, *Public Health*, *supra* note 47, at 255.

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.*

fear and made it easier to treat and potentially prevent HIV. Burris concludes by stating that HIV was never exceptional. Instead, HIV represents a different and better approach to the way that law, medicine, and public health treat disease that threatens distinct groups and becomes inevitably politicized. For Burris, HIV is "unique but not exceptional."[53]

Although Burris and Bayer reach different conclusions about the benefit of HIV "exceptionalism" or "uniqueness," they both use the effectiveness of the public health system to control and treat the disease as the bellwether for their conclusions. However, Burris takes the argument a step further by considering the meaning of our belief that we treated HIV infection differently.

Burris' approach teaches us to ask not whether genetic information represents a new and exceptional threat to privacy, but to use the question, "Is genetic information exceptional?" as a starting point. We should, instead, ask the more informative question of what it means that many people, including many legislators and some judges, believe that genetic information is exceptional. Answering this question gives insight as to what might be a better legal approach for the protection of genetic information.

B. The Social Meaning Of Genetic Exceptionalism

The anthropologist Kaja Finkler describes today's world of "gene hegemony," writing:

> [E]verything about an organism's existence is predetermined and genetically programmed, including its variation, although geneticists recognize that the program may be affected by unknown and external factors in the environment, chance, or human manipulation. The sequence of our DNA reveals to us who and what we are; that is, what it means to be human. With DNA sequencing, some scientists have maintained that the riddle of life is close to being solved.[54]

The belief in the gene and belief in biological determinism go hand in hand. Perhaps it is the neatness of this fit that appeals to many people. Dorothy Nelkin and M. Susan Lindee expand on the widespread and profound effect of our belief in DNA. They describe a change in the social meaning of DNA:

> Just as the Christian soul has provided an archetypal concept through which to understand the person and continuity of self, so DNA appears in popular culture as a soul-like entity, a holy and immortal relic, a forbidden territory. The similarity between the powers of DNA and those of the Christian soul, we suggest, is more than linguistic or metaphorical. DNA has taken on the social

53. Burris, *Public Health*, *supra* note 47, at 261.

54. KAJA FINKLER, EXPERIENCING THE NEW GENETICS: FAMILY AND KINSHIP ON THE MEDICAL FRONTIER 48 (2000).

> and cultural functions of the soul. It is the essential entity—the location of the true self—in the narratives of biological determinism.[55]

Nelkin and Lindee illustrate the dangerousness and divisiveness of the cultural importance we have given the gene. The gene is powerful and deterministic. Nelkin and Lindee write, "[G]enetic explanations . . . construct difference as central to identity [and] definition of the self."[56] Differences attributed to genetic causes are powerful because they are immutable. An individual's genes, unlike behavior, cannot change during an individual's lifetime. Genetic explanations emphasize and formalize differences. Placing the causes for our differences within our DNA means that efforts to change our thinking and social programs to promote changes in attitudes are unlikely to bring effective changes because they will not eliminate genetically caused behavioral traits.

Not only do Nelkin and Lindee discuss the importance of genetic information in constructing our identity, but they also catalogue some of the results of genetic essentialism. They note how genetic essentialism appeals to those who want to emphasize individual responsibility and reduce governmental and societal responsibility for improving social conditions.[57] Although notions of the intrinsically individualistic character of each person's unique DNA supports individual responsibility, the idea that behavior is predominantly influenced by genetic factors leads to the rhetoric of the futility of improving social conditions.

This is the paradoxical element of genetic essentialism, which while fostering notions of individual responsibility, simultaneously undermines belief in autonomy.[58] Biologically determined actions are often excused, since they are apart from freely chosen actions.[59] The emphasis on the gene as the determinate force in our individual character leads to abolition of individual blame and responsibility.[60] Instead, responsibility shifts to the individual's genetic family.[61]

Finkler explored the shift from more traditional notions of family based on a complex network of obligations and a tradition to the genetic family's

55. DOROTHY NELKIN & M. SUSAN LINDEE, THE DNA MYSTIQUE: THE GENE AS A CULTURAL ICON 41-42 (1995).

56. *Id.* at 126.

57. The explanation for behavior lies in the individual DNA and there can be little collective responsibility for behavior caused by such a personal and individualistic source. *Id.* at 129. Social programs to improve living conditions are futile if personal attributes are not due to the interaction between one's environment and one's choices, but due to one's genetic makeup. Nelkin and Lindee provide examples stories in the popular press of individuals with "good genes" who transcend the difficult environment in which they grow up. *See id.* at 94-101.

58. See NELKIN & LINDEE, *supra* note 55, at 129.

59. *Id.*

60. *Id.*

61. *Id.*

emphasis on shared DNA alone.[62] Finkler writes, "To sense that one forms part of a family chiefly because one shares the same genes, requiring no social participation nor sense of responsibility to those who are related except to provide blood samples for testing purposes, removes the moral context of family relationships."[63] Similarly, Janet Dolgin shows how the construction of a "genetic family" is evolving, and she urges us to proceed carefully when considering how we will allow genetic information to change our views about personhood and the nature of our relationships. Dolgin sees the genetic family as a threat:

> The genetic family . . . is defined exclusively with reference to a genome. In consequence, the locus of social value shifts from the individual to groups of apparently fungible individuals, and the autonomous individual constructed through, and understood in terms of, Enlightenment values, ceases to be essential. Moreover, the view that genes are shared substance and information facilitates depersonalization. . . . A universe predicated on the notion of a genetic group would view the preservation of autonomy, and the protection of the individual, with indifference.[64]

And, later on, she concludes that central to the "emerging ideological construct" of the "genetic family" is "the obliteration of privacy," within the genetic family because the individuals are indistinguishable.[65]

The courts provide an example of this shift toward a genetic family. A New Jersey Superior Court decision in *Safer v. Estate of Pack*[66] shows the expanding role of the idea of the genetic family and its potential threat to individual privacy and autonomy. In *Safer*, the court expanded the scope of a physician's duty to warn about increased risk for cancer to include family members if one family member is diagnosed with a cancer that has a hereditary component.[67] Donna Safer, the daughter of a man who died twenty-six years earlier, sued her father's doctor for failing to inform her of her increased risk of colon cancer.[68] Since her cancer was the hereditary form, Donna Safer's risk of colon cancer was increased (most colon cancer is not hereditary in this sense). The New Jersey Superior Court found a duty to warn that extended to family members who were not the doctor's patients, by stating, "Further, it is appropriate . . . that the duty be seen as owed not only to the patient himself but that it also 'extend[s] beyond the interests of the patient to members of the immediate family of the patient who may be adversely affected by a breach of

62. FINKLER, *supra* note 54, at 48.
63. *Id.*
64. Dolgin, *supra* note 21, at 801.
65. *Id.* at 813.
66. 291 A.2d 1188 (1996).
67. *Id*. at 1191-1192.
68. *Id.* at 1190.

that duty.'"[69] The decision treated the patient/father with the hereditary form of colon cancer as primarily a member of a genetic family. The court focused on the daughter's status as a member of the same genetic family as her father to expand the physician's duty to inform to a person with whom the doctor has no patient-doctor relationship. Presumably, according to *Safer*, when a doctor now takes on a new patient, the doctor is also creating a doctor-patient relationship with the patient's entire genetic family.

This example illustrates how genetic information can limit not only the autonomy of the patient with colon cancer, but may also limit the individual autonomy of a family member who might not want to know that they have the "gene for colon cancer."[70] What if, in the example provided by *Safer*, the daughter did not want to know? Although most people may want to know about an increased risk of hereditary colon cancer because of available and effective screening methods, the problem is more apparent if the disease is one like Huntington's or Alzheimer's disease. A family member may not want to know about a disease whose onset is still years away and for which there is no effective treatment.[71] Arguably, such genetic information may profoundly impact an individual's identity. It may also limit individual choices by overly weighting one side of a decision, such as a decision about whether to have children.

This broad effect of genetic information is central to the problem. Genetic information implicates and potentially infringes autonomy rights whether the law expands the right to know to family members, as in *Safer*, or whether it shields genetic privacy.[72] The crux of the issue, and the point made by Dolgin,

69. *Id*. at 1192 (quoting Schroeder v. Perkel, 57 N.J. 53, 65, 432 A.2d 834 (1981)) (alteration in original).

70. Most colon cancers, and most human cancers, are not genetic in the sense that they are passed from one generation to the next. Cancers are genetic in the sense that they are caused by genetic mutations, but current understanding is that the genetic mutations giving rise to most cancer are not passed from parent to child. Instead, most cancers are caused by a series of genetic mutations that accumulate over time and survive in a population of cells that grows into a cancer. For example, most colon cancer arises in older people and involves a series of genetic mishaps. Genetic mutations are relatively common and there is a risk for a mutation every time a cell divides. Most of the mutations are caught by the cell's machinery and either fixed or the cell is killed or dies. Over time, the risk that these safety mechanisms fail increases, partially explaining that many cancers are more common in older persons. *See generally* RAMZI S. COTRAN ET AL., ROBBINS PATHOLOGIC BASIS OF DISEASE (6th ed. 1999).

71. *See* MATT RIDLEY, GENOME: THE AUTOBIOGRAPHY OF THE SPECIES IN 23 CHAPTERS 63 (1999). Some estimate that only 20% of people would chose to know their fate if they could. *Id.*

72. The court in *Safer* recognized the potential conflict, stating, "It may be necessary, at some stage, to resolve a conflict between the physician's broader duty to warn and his fidelity to an expressed preference of the patient that nothing be said to family members about the details of the disease." *Safer*, 677 A.2d at 1192-93. The same predicament occurs within the setting of genetic research, where an individual who chooses not to participate may be affected by

is that the profound shift in the social meaning of genetic information occurs once decision makers begin balancing the interests of the individual with the diagnosed genetic attribute against the interests of genetic family members.[73] Although the genetic family members may or may not have the genetic attribute, the decision maker values both groups (the person with the genetic attribute and that person's family members) similarly because the decision maker has elevated genetic information to an essential defining attribute. Genetic information begins to define us at the point where the focus is on the genetic character of the information rather than on the individual and his or her right to make a decision within the setting of traditional familial responsibilities and relationships.

In *Safer*, the court allowed the genetic character of the information to change the meaning of the patient-doctor relationship and the daughter-father relationship. Why should not the law respect the confidentiality of the patient-doctor relationship and leave it up to family members to share the information if they choose? If a doctor diagnoses a patient with syphilis, the general rule is that the doctor is under no obligation to tell the patient's spouse.[74] Why should the fact that the information is genetic change the legal responsibilities of keeping medical information confidential?

Genetic information begins to define who we are when we look primarily at the fact that information is genetic rather than look at the substance of the genetic information. Similar to the example of "being HIV positive," we view

information derived from genetic family members. *See* Henry T. Greely, *The Control of Genetic Research Involving the "Groups Between,"* 33 HOUS. L. REV. 1397, 1411 (1997).

73. This balancing approach is used by The American Society of Human Genetics in their official statement about Professional Disclosure of Familial Genetic Information. Am. Soc'y of Human Genetics Subcommittee on Familial Disclosure, *ASHG Statement: Professional Disclosure of Familial Genetic Information*, 62 AM. J. HUM. GENETICS 474 (1998). The statement notes the case law established by *Tarasoff v Regents of the University of California*, 551 P.2d 334 (Cal. 1976), placing a general duty on third parties for foreseeable, serious and identifiable risks. *Id.* The statement also notes that foreign bodies, such as the World Health Organization and others, support limited disclosure to at-risk relatives provided the harm is grave and imminent and effective intervention is available. The statement summary includes the following, "Moreover, where the harm is serious . . . and likely, and where prevention or treatment is available, the health-care professional may have a privilege to warn at risk relatives, *irrespective of the patient's wishes.*" *Id.* at 476 (emphasis added).

74. *See generally* Judy E. Zelin, *Physician's Tort Liability for Unauthorized disclosure of Confidential Information About Patient*, 48 A.L.R. 4th 668 (1986) (discussing unauthorized disclosure by a physician of confidential information). Various theories exist, including invasion of privacy, breach of the confidential doctor-patient relationship and malpractice. A physician's obligation to reveal confidential information to warn a third party was recognized in *Tarasoff v. Regents of the University of California*, 551 P.2d 334 (Cal. 1976). The case involved a psychotherapist whose patient killed Tarasoff. The court restricted the duty to a foreseeable, serious injury to a reasonably identifiable victim. *Id.* at 342. The rule for psychotherapists is codified in CAL. CIV. CODE § 43.92 (West 1997).

genetic traits as powerfully defining who an individual is, overriding the ability of individuals to treat genetic information as one piece of information to which we are able to give differing degrees of value and meaning. Rather than allowing individuals to define themselves, we begin to allow genetic information to define the individuals. In other words, a person's genetic information that his or her eyes are green should be no different than other information that verifies the green color of his or her eyes, like a photograph of the person's eyes or a testimonial that his or her eyes are green. The law should protect this information if it is in a medical record because the law protects confidential information but not solely because the information is genetic. In certain situations, the use of a photograph depicting someone is legally protected. Similar standards might be used to protect information that is genetic, as I will discuss.

PART III - THE DIFFERENCES BETWEEN THE CLINICAL AND RESEARCH CONTEXTS OF GENETIC INFORMATION

A. The Importance of Context in Genetic Information

Genetic privacy statutes create a protective area around our genetic information. Many of these statutes extend the zone of privacy around genetic families, which, as discussed above, concomitantly weakens the protections around individuals.[75] Moreover, many genetic privacy statutes fail to adequately recognize the importance of context.[76] These statutes do not adequately distinguish between the research and clinical contexts, between different kinds of research, and whether genetic information is collected in medical or employment settings. Interestingly, many statutes implicitly recognize context by creating exceptions for genetic information collected for the government's benefit, reducing the strength of the genetic protections for individuals when the information is collected and used by the state.

Although most genetic privacy statutes distinguish between genetic information that is easily linked to an identifiable individual and anonymous

75. For example, the Oregon Genetic Privacy Act explicitly extends its protections to include not only the individual but also the individual's genetic family. Oregon's Senate Bill 114, codified at OR. REV. STAT. § 192.531 (2001), passed into law and effective beginning January 2001, contains the legislative finding that "an analysis of an individual's DNA provides information not only about the individual, but also about blood relatives of the individual, with the potential for impacting family privacy, including reproductive decisions." *Id.*

76. *See, e.g.*, S. B. 114, 71st Leg. Assem., Reg. Sess. (Or. 2001). The bill does create different categories of genetic information depending on the degree to which the genetic information can be linked to a particular individual. Nevertheless, the statute mandates that individuals be notified that their genetic material is used for research even if the genetic information is completely anonymous (it is impossible to link the information to the individual). *Id.*

genetic information, the focus of the protective scheme remains on the genetic information and not on the context. The distinction between linked and anonymous genetic information is different from recognizing context because the distinction makes no attempt to consider the substantive quality of the genetic information.

The failure to recognize the contexts within which researchers uncover genetic information elevates genetic information to an "essential entity" and distorts the meaning of identity by placing too much value on the genetic character of information, instead of looking at how the substantive information might impact individual identity. Ironically, protecting all genetic information just because it is somehow derived from DNA brings us closer to the harms Nelkin, Lindee, Finkler and others warn against, and brings us closer to formalizing the kind of "we are nothing more than our genetics" view promoted by Crick. Legal protections of genetic information should recognize that genetic information obtained in the research context may not have the same impact as genetic information within clinical contexts. Legal protections should also acknowledge that not all research is the same. The legal protections should incorporate an understanding that different kinds of research involve different kinds of individual interests in genetic information.

Legal protections for genetic information in the clinical setting make sense for the same reasons that legal protections exist for other confidential medical information; there is significant risk that such information might lead to discrimination or adversely impact individual autonomy, privacy or identity. The distinction between genetic and non-genetic information is often difficult.[77] However, if the law effectively protects all important confidential medical information in the clinical setting, there is little need to distinguish between genetic and non-genetic information, at least for the purposes of protecting privacy and autonomy. Admittedly, the legal protections for confidential medical information are not as strong and effective as they might be. Notwithstanding these deficiencies, implementation of stronger protections for the difficult to define category of genetic information will not strengthen the confidentiality protections of other medical information.[78]

77. *See* Gostin & Hodge, *supra* note 6, at 21 (arguing against genetic exceptionalism on various grounds including the inherent difficulty in distinguishing between genetic and non-genetic medical information). *See also* Diver & Cohen, *supra* note 8, at 1451 (discussing the difficulty in defining what sources comprise legally protected genetic information, and noting that medical history and direct observations can divulge much genetic information).

78. *See* Gostin & Hodge, *supra* note 6, at 23. The authors point out that laws emphasizing the difference between genetic information and other kinds of health information foster genetic exceptionalism, which they do not think is appropriate for a number of reasons. *Id.* One reason is that it is "unfair to persons with non-genetic conditions by excluding them from the protection of private interests which they would otherwise be entitled if their condition has a genetic origin." *Id.* at 23-24.

The legislative failure to distinguish between the research and clinical contexts, and between different kinds of research, reflects a lack of understanding about the kinds of genetic information research typically involves. A brief explanation of the different contexts might lend clarity to the argument advocating such distinctions.

B. Tissue in the Bank

There is a difference between research on tissue used primarily by physicians for routine diagnostic and therapeutic purposes and research done by researchers on tissue removed explicitly as part of prospective clinical trials. Tissue removed as biopsy tissue, or as part of a therapeutic operative procedure, like taking out a segment of colon for colon cancer, is used primarily for therapy and diagnosis. Typically, a pathologist looks at this tissue and gives either an initial diagnosis or confirms an existing one. After the removed tissue serves its diagnostic or therapeutic purpose, a laboratory routinely stores the tissue or parts of the tissue. One can think of this tissue as "banked," held safely for possible future use. Occasionally, researchers return to this "banked" tissue to conduct studies to learn about a certain disease, particularly cancer. They may perform tests uncovering genetic information.[79] As a part of these tests, researchers may de-identify the information in an effort to protect patient confidentiality. They would give the tissue and the accompanying clinical information a number with access limited to a few researchers.

In contrast, researchers in prospective clinical research take tissue for the primary purpose of doing research on the tissue, although oftentimes, the sample of tissue also serves diagnostic purposes. Notwithstanding, in many cases, this tissue would not be removed if not for the research. Subjects in this kind of research give specific informed consent. An Institutional Review Board typically reviews this kind of research to ensure that the research is generally worthwhile and that research subjects are adequately protected. An obvious potential conflict exists for the physician involved in this kind of

79. *See* Ellen Wright Clayton et al., *Informed Consent for Genetic Research on Stored Tissue Samples*, 274 JAMA 1786 (1995) (consensus statement); Karl T. Kelsey, *Informed Consent for Genetic Research*, 275 JAMA 1085 (1996) (voicing concern that consent requirements for research use of stored tissue will cause a reduction in the numbers of samples available for research); Wayne W. Grody, *Molecular Pathology, Informed Consent, and the Paraffin Block*, 4 DIAGNOSTIC MOLECULAR PATHOLOGY 155 (1995) (voicing concern that consent requirements for research use of stored tissue will cause a reduction in the numbers of samples available for research); Rebecca D. Pentz et al., *Research Letter: Informed Consent for Tissue Research*, 282 JAMA 1625 (1999) (finding no reduction in accrual of tissue samples after adding two questions to the informed consent; one specifying that the tissue will be banked and the other asking whether the patient would want to be informed if the research uncovers any medically useful information).

research because it takes place in a clinical setting.[80] The doctor has an interest in the research, yet must maintain his obligations as the research subject's physician. A recent Harris pole concluded that only about one-third of adults in the United States are "very confident" that patients in clinical trials receive "very good" medical care, although more than 80% of the poll respondents believed that such trials were "essential" or "very important."[81] An example of prospective clinical research trials is testing of a new drug to treat leukemia. A researcher divides a group of people who have a particular type of leukemia into two groups. Researchers/physicians collect blood samples and bone marrow biopsies and perform various imaging studies to measure the disease course. Researchers perform various tests, including genetic tests, on the collected samples.

Not all genetic information is the same, even within the same research protocol. Some of the collected genetic information, such as whether a patient has a subtype of the disease associated with a worse or better prognosis might reasonably impact patients and might be used by third parties to the detriment, or benefit, of the patient. Other genetic information, such as identification of a section of DNA encoding a protein not previously associated with the type of leukemia, would not reasonably impact clinical outcome or serve any clinical purpose because too little is known about the protein. Third party insurers or employers would be unlikely to use this information, since they would not know what it means. The legal safeguards in these different scenarios should recognize the different contexts to closely correlate the degree of legal protections with the degree of risk to an individual being harmed by dissemination of genetic information.

The differences between prospective clinical research and retrospective research on banked tissue collected in the usual course of medical care are important. First, the informed consent requirements differ. In the tissue bank case, the principal reason for the invasive procedure is therapeutic or diagnostic with the primary benefit hopefully flowing to the patient. The patient gives informed consent for the invasive biopsy or operation knowing that there is a direct therapeutic benefit. Informed consent may require that the physician inform the patient of the possibility of research on the removed tissue, but the primary purpose of the procedure remains therapeutic or diagnostic. In the past, informed consent likely did not include an explicit statement that genetic research might be done, since genetic research fell under the more general category of research, which is included in the informed

80. *See* Frances H. Miller, *Trusting Doctors: Tricky Business When It Comes to Clinical Research*, 81 B.U. L. REV. 423 (2001) (part of a symposium about Trust Relationships).

81. *See Public Uneasiness About Patient Care in Clinical Trials Revealed in Harris Poll*, 1 MED RES. L. & POL'Y 48, 49 (2002).

consent.[82] Prospective research, in contrast, is unlikely to produce any direct benefit to the patient or research subject. The principles of informed consent require that the patient explicitly consent to the use of their tissue for relatively well-defined research purposes. Specific informed consent is essential because the patient would not undergo an invasive procedure if not for the research. This is one way in which research on previously banked tissue is fundamentally different from prospective research where small amounts of tissue are taken only for research purposes.

Another difference lies in tradition. In the United States and England, tissue removed for diagnostic purposes following the patient's informed consent for an invasive procedure was historically available for research once the diagnostic purposes of the tissue were fulfilled.[83] It was considered potential waste[84] and property of the hospital or pathology laboratory.[85] For

82. Admittedly, tissue-banked retrospective research potentially effects patient interests if it uncovers relevant clinical information. However, federal regulations do not allow the release of clinically relevant results unless it is from an accredited clinical laboratory and most research labs are not clinical labs. *See* William Grizzle et al., *Recommended Policies for Uses of Human Tissue in Research, Education and Quality Control*, 123 ARCH. PATHOLOGY & LABORATORY MED. 296, 297 (1999); Genetic Testing Under the Clinical Laboratory Improvement Amendments, 65 Fed. Reg. 25,928-34 (May 4, 2000).

83. *See* Peter N. Furness, *Research Using Human Tissue—A Crisis of Supply?*, 195 J. PATHOLOGY 277, 277 (2001). Furness refers to the Nuffield Council of Bioethics in 1995, which concluded that it was reasonable to believe that patients have abandoned their tissue once they have consented to its removal for diagnostic or therapeutic purposes. *Id.*

84. *See* Julia D. Mahoney, *The Market For Human Tissue*, 86 VA. L. REV. 163 (2000) (discussing the need to recognize the ubiquity of commercial activity in transfers of human tissue in order to evaluate and better regulate the activity, particularly as new uses are uncovered with advancing biotechnology). Mahoney writes, "[U]ntil the medical advances of the past century, however, human tissue from a living body was of use, almost exclusively to its original possessor." *Id*. at 170.

85. *See* Jonathan I. Epstein, *Pathologists and the Judicial Process: How to Avoid it*, 25 AM. J. SURGICAL PATHOLOGY 527 (2001). A "Letter to the Editor" from a physician in Argentina expressed surprise at Epstein's statement that tissue received for diagnostic purposes does not belong to the patient. The Argentinean doctor wrote that in Argentina such tissue belongs to the patient, since the patient paid for the work done on the tissue. Richard Drut, Letter to the Editor, *Who is the Owner of the Slides, Blocks and Fixed Tissues?*, 26 AM. J. SURGICAL PATHOLOGY 274, 274 (2002) (citing Moore v. Regents of the Univ. of Cal., 271 Cal. Rptr. 146 (1990); Cornelio v. Stamford Hosp., 717 A.2d 140 (Conn. 1998)). Jonathan I. Epstein & Richard Kidwell, Authors' Reply, *Who Is the Owner of the Slides, Blocks, and Fixed Tissues*, 26 AM. J. SURGICAL PATHOLOGY 274, 274 (2002). The authors, a pathologist and a lawyer, interpret *Cornelio* as holding that the patient "possessed no property right in her cells, contained in pap smear specimen slides." *Id.* They point out that the lower court found that the patient did not expect to retain possession of the cells after their removal and that the pap smears constituted part of the medical record. *Id.* Issues that Epstein and Kidwell do not discuss include what if the patient does have an expectation of retaining a right, such as a privacy right, in the cells or tissue? Possession does not necessarily include every stick in the bundle of property rights and as public

example, a patient consented to having a lung tumor removed. After the surgeon and the pathologist examine the tissue, the tissue is stored as required by federal law.[86] Researchers may then use the stored tissue for research on lung tumors.

The often-cited case, *Moore v. Regents of the University of California*, affirmed that the patient did not retain a property right in tissue or cells removed for diagnostic or therapeutic purposes.[87] The precise parameters of informed consent in cases like *Moore*, which involve tissue removed for diagnostic or therapeutic purposes and the subsequent commercial benefit for the physician or researcher, remain problematic. Until recently, most pathology departments in the United States never questioned whether there might be any problem with doing research on bits of tissue retained after the tissue had served its diagnostic utility.

Recently, however, pathology departments now understand that in many cases approval by the Institutional Review Board is required before anyone conducts research on banked tissue even though this kind of research is not "clinical research" in the sense of the traditional prospective clinical trial.

This relatively recent shift in the practice and understanding of pathologists and researchers is largely the result of heightened legal, public and institutional awareness about the special concerns regarding genetic information. In Oregon, for example, the Oregon Privacy Act requires that patients provide their specific informed consent for genetic research done on their tissue samples unless the research is anonymous research.[88] If the

expectations and understanding changes (improves?), so too might the outcome of a case like *Cornelio*.

86. One federal regulation requires that a clinical laboratory "retain stained slides at least ten years from the date of examination and retain specimen blocks at least two years from the date of examination." 42 C.F.R. § 493.1259(b) (2002). The slides referred to are glass slides upon which thinly cut sections of tissue are placed and stained. A pathologist looks at these under a microscope to give a diagnosis. The tissue comes from the specimen blocks, which contain the biopsy tissue or portions of a tumor removed.

87. *See* Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990) (recall that the final holding in the case was about the fiduciary aspect of the patient-doctor relationship and what this meant in the context of the physician fulfilling her obligations to the patient while obtaining informed consent); Christopher Scott Pennisi, Note, *More on* Moore: *A Novel Strategy for Compensating the Human Sources of Patentable Cell-Line Inventions Based on Existing Law*, 11 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 747 (2001) (exploring some of the property aspects of *Moore* and proposing the shop rights doctrine; recommending changing informed consent so that patients retain interests in inventions derived from their tissue); William Boulier, Note, *Sperm, Spleens, and Other Valuables: The Need to Recognize Property Rights in Human Body Parts*, 23 HOFSTRA L. REV. 693 (1995).

88. OR. REV. STAT. § 192.531 (2001) (defining anonymous research as "research conducted in such a manner that the identity of an individual who has provided a sample, or the identity of an individual from whom genetic information has been obtained or the identity of the individual's blood relatives, cannot be determined").

research will be anonymous (individual identity cannot be determined), the statute requires that someone notify patients that their tissue may be used for anonymous genetic research. In addition, the patient or research subject may request that the tissue sample not be used for anonymous research.[89]

This heightened awareness of researchers and the general public signifies a change in the social meaning of genetic information. Resulting in part from regulations and statutes, the heightened awareness of the special character of genetic information and the apparent increased privacy safeguards are changes in the right direction. However, a better understanding of genetic research might help protect individual identity without moving toward genetic essentialism and expanding, as Kaja Finkler would say, genetic hegemony.

C. Informed Consent Is an Awkward Fit for Genetic Information in the Context of Retrospective Research on Banked Tissue

Genetic information in the clinical context is governed by pre-existing theories for informed consent and general confidentiality requirements. For example, the typical informed consent for a clinical genetic test would involve someone telling the patient about the risks of the invasive procedure, the meaning of the genetic test results, including the disease for which the genetic assay is testing, and about alternatives other than the test. The patient may visit with a genetic counselor who may discuss a variety of additional issues, including the impact on family members. Similarly, for prospective research, the research subjects will be required to give informed consent before the research project begins because investigators will have an idea about what the genetic test is looking for. For prospective research, however, the researchers will not have a good understanding of what the results of a genetic assay will mean because a better understanding of, for example, expression of a particular gene and its relationship to disease is exactly what the research is trying to clarify.

In retrospective research, the patient or research subject cannot give true informed consent for specific research at the time their tissue is removed because, typically, there will be little information about the research. New

Federal regulations also distinguish between anonymous tissue samples and identified samples. Distinctions are made between anonymous, signifying that no identification was ever attached, and made anonymous, signifying that any link between identity and the tissue is irreversibly removed. 45 C.F.R. § 46.102(f)(2) (2001).

89. OR. REV. STAT. § 192.537(2)(a) (2001) ("A person may use an individual's DNA sample or genetic information for anonymous research only if the individual was notified the sample or genetic information may be used for anonymous research and the individual did not, at the time of notification, request that the sample not be used for anonymous research."); OR. REV. STAT. § 192.53 (2001) (the required informed consent for genetic information is different from what the statute terms "blanket informed consent" because the informed consent required for genetic research must specify that the tissue sample might be involved in genetic research).

techniques and new hot research topics arise in the time between tissue procurement and the initiation of research. Often at the time the patient gives informed consent for tissue removal, the diagnosis is not known. Therefore, at the time of consent neither the patient nor the researcher will know basic facts about the research (for example, does the research involve benign or malignant tissue?). For these reasons, it is more appropriate that patients or research subjects in the setting of retrospective research give their authorization for the future use of their tissue for possible and unspecified genetic research rather than their informed consent. This is recognized by the various state and federal privacy rules that require authorization for possible future use of patients' tissue. These provisions recognize the poor fit between traditional theories of informed consent and retrospective research on banked tissue.[90] Another advantage of the authorization approach is that it allows patients or potential research subjects the chance to change their minds. Once they have given authorization and are aware that their tissue might be used for genetic research, they can return to the institution and withdraw their authorization for subsequent research.[91]

Another reason for this poor fit is that typically the primary reason for the invasive procedure is therapeutic or diagnostic. Patients are likely focused on this primary reason rather than the secondary chance that some yet unidentified researcher may do research on the tissue. Even if the consent could be specific enough to be informed, the patient giving consent may not fully understand the scope of their consent regarding possible future research. An alternative is that the law could require researchers to go back to patients for specific consent for well-characterized research. However, this approach would be onerous because of the difficulties and expense of tracking down patients years after the biopsy or operation.

Despite the practical difficulties with using informed consent to authorize retrospective research on banked tissue, the underlying purpose of informed

90. Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations endorsed by President Clinton and President Bush include requirements that research subjects sign an authorization statement for the use and disclosure of their private medical information. The HIPAA requirements for valid authorization include a specific and meaningful description of the information, an expiration date and a statement that the patient or research subject has a right to revoke authorization. *See* George J. Annas, *Medical Privacy and Medical Research—Judging the New Federal Regulations*, 346 NEW ENG. J. MED. 216 (2002) (citing Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462 (Dec. 28, 2000)). In a response to a letter to the editor, Annas noted that the Bush administration may modify the privacy rules and that the Department of Health and Human Services invited comments on some of the privacy rules. *See* George J. Annas, Author's Reply, *Medical Privacy and Medical Research*, 346 NEW ENG. J. MED. 1674, 1674 (2002).

91. This may become problematic when human tissue is transferred to other research institutions and biotechnology companies. *See* Mahoney, *supra* note 84, at 167-96 (discussing the ubiquity of commercial dealings involving human tissue and the issues raised).

consent (to protect patient self-determination and autonomy) remains. The theoretical foundation of informed consent, originally articulated by Justice Cardozo in *Schloendorff v. Society of The New York Hospital* as the right to self-determination, has evolved over the years, but the emphasis on the patient's autonomy remains.[92] Although many genetic privacy acts seek to protect individual rights in autonomy and privacy, genetic information does not always affect autonomy and privacy. Because there is harm in overprotecting genetic information, the key becomes developing a method to distinguish between when the law should and should not protect genetic information.

D. Not All Tissue Genetics Is the Same—Tumor Genetics vs. Germline Mutations

An individual's interests in his or her genetic information depends upon the kind of tissue used in the genetic research. Some commentators note that genetic research is considered sensitive because it often involves highly predictive germline mutations in bad diseases like breast or ovarian cancer.[93] This kind of germline research is likely to uncover genetic information that implicates family members in addition to the individual whose tissue is examined (the proband, in the language of genetics). However, when the research is on tumor mutations, not germline mutations, it is often not predictive of family risk (depending on the type of tumor). Much research performed on tissue-banked material is research looking at tumor genetics and not germline mutations.

Admittedly, all cancer may be genetic, but it is to varying degrees heritable.[94] The risk of any person of getting cancer, including sporadic tumors, is influenced by various hereditary and environmental factors. For example, most lung cancer is strongly related to cigarette smoking, but the mortality rates of people with lung cancer are greater among non-smoking relatives of smokers than among non-smokers who do not have any smokers in

92. Schloendorff v. Soc'y of the N.Y. Hosp., 105 N.E. 92 (N.Y. 1914). In *Schloendorff*, Justice Cardozo wrote: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages." *Id.* at 95-96. For a brief account of how the informed consent theory evolved from Cardozo's common law battery-based approach to the recent negotiated terms that depend fundamentally on patient-doctor discourse, see Ken Marcus Gatter, *Protecting Patient-Doctor Discourse: Informed Consent and Deliberative Autonomy*, 78 OR. L. REV. 941 (1999).

93. Laura M. Beskow et al., *Informed Consent for Population-Based Research Involving Genetics*, 286 JAMA 2315 (2001).

94. *See* FINKLER, *supra* note 54, at 58 (examining the impact of a genetic basis of cancer means for some people and maintaining that the emphasis on genetics turns some healthy people into people who believe they are sick, yet without any of the signs or symptoms for which they are at increased risk).

their extended family.[95] The influence of genetics on the development of cancer in individuals is likely a continuum. On one side of the continuum are the clearly inherited cancer syndromes like childhood retinoblastoma, where carriers of the gene are 10,000 times at greater risk and the tumor is usually in both eyes. At the same end of the continuum are certain breast and ovarian cancers that present at a younger age than most breast and ovarian cancers and are linked to the genes BRCA-1 and BRCA-2.[96] These are non-sporadic tumors.

At the other end of the continuum is the kind of colon cancer that presents in a seventy-year-old man, or chronic myelogenous leukemia (CML), a cancer of the blood and bone marrow, presenting in a fifty-year-old individual. These "sporadic" or "spontaneous" cancers do not run in families. Although researchers may ultimately find a hereditary component to the degree of risk for particular cancers in every individual, the particular genetic event studied by scientists does not have any known hereditary component. For example, CML involves a translocation of a piece of chromosome nine and a piece of chromosome twenty-two. This translocation is neither present at birth nor in the person's non-leukemic cells. Perhaps there is a genetic clue in the germline genetics of patients who later on develop CML that we do not yet know about, and a researcher would not find it if studying the leukemia cells. Therefore, even if there is an undiscovered hereditary component to a sporadic tumor, research looking at the sporadic tumor genetics is some distance away from identifying genetic information of the individual from whom the cancer arises.

Although many researchers believe that genetic predisposition contributes to most "spontaneous" tumors,[97] the degree of increased risk in the colon cancer in the seventy-year-old man that is represented by genetic predisposition is significantly less than the risk that is represented by the presence of the retinoblastoma gene in the five-year-old boy. Should the legal protections be the same for the "relevant" genetic information in the five-year-old boy and the statistically insignificant genetic information in the seventy-year-old man? Similarly, why should the law protect genetic information that represents, for example, a statistically insignificant increase in colon cancer risk in a seventy-year-old man and not protect information that indicates that if a fifty-year-old individual eats nothing but fatty fast food, that individual is likely to have a much greater risk of a heart attack? Perhaps both pieces of

95. COTRAN ET AL., *supra* note 70, at 275.
96. *Id.* at 276.
97. *Id.*

information deserve privacy protections (and should be medically confidential) as pieces of information that comprise the whole of personal identity.[98]

E. Most Research Produces Genetic Information with Little Impact on Individual Identity

Another reason why the research context is important is that most scientific research addresses small questions with little or no impact on individual identity. Not only do researchers rarely ask questions that are clinically significant by themselves, but the research seldom answers the questions without requiring additional research.[99] This is not to say the research is clinically insignificant, but this research serves as only a small piece of a larger puzzle. Moreover, scientists must generally verify the results and conduct additional research because the results give rise to new questions. Non-verified pieces of genetic information that lack clinical significance should not impact individual identity. Admittedly, however, a risk remains that insurers, employers, researchers, participants and families may use the information improperly and erroneously interpret the results if the information is linked to an individual or a group. The accuracy of the conclusions drawn from the genetic information is largely irrelevant when genetic information is linked to an individual or a group and therefore suffers harm from improper use.

F. Identifying Information

The problem is that genetic information about tumors and normal tissue means little unless genotype can be correlated with phenotype. Researchers need to correlate genetic information with clinical information to reach any meaningful conclusions.[100] For example, discovering that a particular tumor expresses a new protein is only valuable if a researcher has access to information about how the new protein may be related to clinical information. Relevant clinical information includes such things as the tumor and patient

98. The recent explosion in Internet personal data has lead to many articles discussing informational privacy issues. *See, e.g.*, Pamela Samuelson, *Privacy as Intellectual Property?*, 52 STAN. L. REV. 1125 (2000) (discussing various approaches, including the property rights model and a market-oriented system that uses a system with a default licensing of personal data provision); Paul M. Schwartz, *Privacy and Democracy in Cyberspace*, 52 VAND. L. REV. 1609 (1999) (arguing that privacy norms are important for democracy).

99. For example, a recent issue of BLOOD published the following articles: Olivier Giet et al., *Increased Binding and Defective Migration Across Fibronectin of Cycling Hematopoietic Progenitor Cells*, 99 BLOOD 2023 (2002); Letetia C. Jones et al., *Expression of C/EPPβ from the C/ebp$\propto$ Gene Locus is Sufficient for Normal Hematopoiesis In Vivo*, 99 BLOOD 2032 (2002). Admittedly, not all titles are so esoteric, however, isolated study results mean little to an individual study participant and the results are unlikely to lead to identification of the study participants without further identifying information.

100. *See generally* Beskow et al., *supra* note 93.

behavior, how long and how well did the patient live, what kind of treatment was given, how far the tumor had spread (stage), what the tumor looked like (grade and type) and the age and strength of the patient. Once a researcher has access to sufficient patient-identifying information, then the researcher, research subject or some other person might be able to identify the individual.

It is when the individual's identity can be discovered that the legal protections of the individual and the individual's genetic family become important. Even if the genetic information derived from research is not enough to draw valid scientific conclusions, legal protections are warranted when the information and the identity of the individual might be linked. Once the individual is indentifiable, there is a risk that the information may be improperly used by insurers or employers, or that researchers, participants, families or others may erroneously interpret the results.

The law properly protects linked information because it is medical information, not because it is genetic information. Both the genetic information and the clinical information deserve legal protection. An individual's legal rights should be implicated depending on the substantive attributes of the information, rather than the single attribute of the information being genetic. For example, genetic information that impacts identity would include something like the retinoblastoma gene, because this reasonably affects how individuals think of themselves. Certainly, many patients with cancer undergo a significant change in their identity. Lance Armstrong, who won the Tour de France bike race four years in a row (as of winter 2003) after he had cancer, apparently underwent a significant change in the way he viewed himself and life because of his high stage cancer and his close brush with death. Similarly, people who learn that they carry a gene that significantly increases their risk for a particular cancer also feel an impact on their identity. Genetic information that reveals that a person and her family have an increased risk for an autoimmune disease impacts the identity of the individual and the whole family.

It is when the genetic information reasonably impacts identity that the law should implement increased protections. This can be accomplished without leading to deleterious change in the social meaning of genetic information.

PART IV—THE TORT OF MISAPPROPRIATION OF IDENTITY APPLIED TO GENETIC INFORMATION

A. Identity as the Touchstone for Legal Protection of Genetic Information

Treating all research contexts identically because they involve any aspect of genetic information is an example of genetic essentialism that alters the social meaning of genetic information. To avoid these pitfalls, legal protections for genetic information in the research context should focus on the

substantive content of the information to assign the appropriate degree of protection for the genetic information. I propose that legal protections are appropriate for genetic information that reasonably impacts individual identity. The focus on the impact on individual identity allows the law to better recognize the context and substantive content of the genetic information.

For example, this approach would mandate legal protections for genetic information that uncovers a significant risk for the development of a neurodegenerative disorder because this is genetic information that reasonably impacts identity. In contrast, genetic information arising in the research context that has minimal clinically significant repercussions for the individual, while still confidential and legally protected because it is confidential medical information, would not merit legal protection as specifically protected genetic information because it does not reasonably impact individual identity.

The law would still require general consent before researchers could use the patient's tissue for research. However, by taking into consideration the context and focusing on the substance of the genetic information, the legal protection for genetic information would not treat all genetic information the same based only on the seemingly overriding fact of the information being genetic. Moreover, identity provides a more solid theoretical foundation for the protection of genetic information. This approach would require that special legal protections for genetic information derived from retrospective research performed on banked tissue, and would apply only when the genetic information reasonably impacts individual identity.

The initial threshold for implementing legal protections for genetic information should be that the genetic information is linked to a patient or group. Commentators generally agree that research using non-linkable data, or anonymous data, does not invoke consent requirements.[101] Recall, however, that even anonymous genetic information, if it is linked to a group, can have adverse consequences for all members of the group. For example, many researchers have looked specifically at Ashkenazi Jews. Professor Dolgin states that the disproportionate research attention paid to Ashkenazi Jews has led to a disproportionate number of genetic alterations being associated with Ashkenazi Jews, thereby reinforcing public perceptions that this group is more likely to suffer from genetic alterations, and, thus, furthering historical anti-Semitic attitudes of Jewish people as more sickly.[102] Dolgin's description of the adverse impact of genetic information on group identity reinforces the appropriateness of identity as the touchstone for legal protection of genetic

101. *See* Patricia (Winnie) Roche et al., *The Genetic Privacy Act: A Proposal for National Legislation*, 37 JURIMETRICS J. 1 (1996); George J. Annas, *Rules for Research on Human Genetic Variation—Lessons from Iceland*, 342 NEW ENG. J. MED. 1830 (2000).

102. Dolgin, *supra* note 21, at 790-794.

information rather than the reliance on a privacy right for the theoretical foundation.

The second question to be reached before deciding if legal protections should attach to genetic information should be whether the particular genetic information will reasonably impact individual identity. For example, information from a clinical test result that identifies an individual as carrying a gene for hemochromatosis deserves protection because a person's identity is reasonably impacted by knowing that one has the disease and its likely sequelae. However, a genetic research result discovering an esoteric tumor protein, while still legally protected as confidential medical information (if linked to an individual person), should not invoke special legal protections.

Many genetic privacy statutes are over broad in that they ignore the question of context and fail to delineate different kinds of genetic information. These shortcomings foster a genetic essentialism that undermines the value we traditionally place in individual autonomy.[103] A small and clinically insignificant bit of an individual's genetic information is no more private and should enjoy no more legal protections than the color of her hair or the size of her foot. When enough bits of information come together, like enough pixels on a screen can become a recognizable face, then an individual's identity may be discovered and legal safeguards should apply. Similarly, if a truly unique bit of information is uncovered, then it too should enjoy legal safeguards. In both the quantitative and the qualitative versions, the focus is on what the information means rather than simply the single attribute of the information's genetic character. This approach avoids the definitional difficulties of what constitutes genetic information. It also avoids fostering a climate of genetic exceptionalism and provides a theoretical framework for the complex task of organizing and regulating the collection, storage and use of genetic information.

B. Appropriation of Identity

Jonathan Kahn advocates the tort of appropriation of identity as a way for the law to protect individual dignity interests and maintain "a legally sanctioned space that places control over the self beyond the reach of the market."[104] In a recent article, Kahn advocates using the privacy-based tort of

103. *See generally id.*

104. Kahn, *Bringing Dignity Back to Light*, *supra* note 10, at 214. He aims to "disentangle publicity and privacy" because he is concerned that the more common publicity right, based on property, has hidden the other important concerns that appropriation of identity protects, such as privacy and dignity. *Id.* Whereas publicity rights involve commercial interests, courts have also protected personal interests in dignity and integrity of the self. To illustrate that courts recognize the difference, Kahn cites various cases, including *Onassis v. Christian Dior-N.Y., Inc.*, 472 N.Y.S.2d 254 (N.Y. Sup. Ct. 1984). In this case, Jacqueline Onassis sued Christian Dior, Inc. because Christian Dior used an advertisement with a look alike of her without permission. *Id.* at

appropriation of identity to resolve the often-cited and often-discussed case of *Moore v. Regents of the University of California*.[105] He maintains that the current principles of intellectual property law and informed consent do not resolve the complex issues of biotechnology represented in *Moore*.[106] Instead, Kahn argues that appropriation of identity, discussed by the California Court of Appeal in *Moore*,[107] provides the basis for a better resolution of the problems raised by *Moore.*

Kahn's insight is valuable because it illustrates a way to provide legal recognition of a right in genetic information that is not derivative of an underlying property right in tissue and does not exclusively focus on the genetic attributes of the information. Moreover, his approach recognizes a continuum of legal interests based on the degree of the impact on individual identity.

Kahn's focus on the relationship between object (cells in *Moore*, genetic information in the present case) and identity allows him to implement a spectrum, or continuum, of legal protections. He is able to do this because he does not simply look at the relationship between the object and the physical body or simply focus on the object or information. Kahn describes his

256. She sought an injunction rather than monetary damages because she was not asserting an infringement of her commercial right to publicize her image. *See id.* Instead, she wanted to protect her identity as a person who does not engage in the commercialization of her image.

105. Kahn, *Biotechnology*, *supra* note 10, at 910-11. *See also* Charlotte H. Harrison, *Neither Moore nor the Market: Alternative Models for Compensating Contributors of Human Tissue,* 28 AM. J.L. & MED. 77 (2002); Peter Halewood, *Law's Bodies: Disembodiment and the Structure of Liberal Property Rights,* 81 IOWA L. REV. 1331 (1996); Laura M. Ivey, Moore v. Regents of the University of California: *Insufficient Protection of Patients' Rights in the Biotechnological Market,* 25 GA. L. REV. 489 (1991); Stephen Ashley Mortinger, *Spleen for Sale:* Moore v. Regents of the University of California *and the Right to Sell Parts of Your Body,* 51 OHIO ST. L.J. 499 (1990); Jeffrey A. Potts, Note, Moore v. Regents of the University of California: *Expanded Disclosure, Limited Property Rights,* 86 NW. U. L. REV. 453 (1992).

106. Kahn, *Biotechnology*, *supra* note 10, at 911. In *Moore*, the patient, John Moore, had treatment of his hairy cell leukemia at the University of California, Los Angeles, Medical Center (UCLA-MC), where Dr. Golde confirmed the diagnosis, and John Moore's spleen was removed as part of the then accepted treatment for hairy cell leukemia. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 480-81 (Cal. 1990). After the procedure, the doctors and researchers at UCLA-MC encouraged John Moore to return for follow-up, in part so that they could get more of Moore's hairy leukemia cells. *Id.* at 481. After approximately three years, Golde and a researcher established a cell line and the Regents of the University of California applied for a patent. *Id.* at 481-82. When Moore discovered this, he sued, claiming a property-based right in a share of profits. *Id.* at 482. He did not claim that his dignity, privacy, or identity had been legally harmed. The California Supreme Court held that Moore's doctor had breached his fiduciary duty and that informed consent was not adequate, but further rejected Moore's conversion claim. *Id.* at 485, 488. The Court of Appeal's discussion about appropriation of identity was not seriously considered by the majority in the California Supreme Court decision.

107. Moore v. Regents of the Univ. of Cal., 249 Cal. Rptr. 494, 507-08 (Cal. Ct. App. 1988).

approach as "a legal regime for the management of information . . . . in this case, information regarded as intimately bound up with a subject's identity."[108]

In explaining appropriation of identity, Kahn explains that it is the improper use of another's name or image, rather than the physical property or body, that historically gave rise to the tort.[109] There must be a connection between the image or name and a person's identity. Kahn comments about how remarkable it is that the law recognizes such an "amorphous concept as 'identity'"[110] and notes that courts have expanded the right to include improper use of another's voice[111] and objects that invoke a person's identity but may be separate from their physical person, as in *Motschenbacher v. R.J. Reynolds Tobacco Co.*[112]

In *Motschenbacher*, a racing car driver sued R.J. Reynolds Tobacco Company for improperly using his recognizable racing car in an advertisement without his permission.[113] The case concerned an advertisement starring Motschenbacher's race car, which Motschenbacher uniquely identified with special markings.[114] Although Motschenbacher was not recognizable in the advertisement, words promoting the defendant's cigarettes were indirectly attributed to Motschenbacher because words in a text balloon were placed next to the unrecognizable racing car driver sitting in the recognizable car.[115] The plaintiff established that many people recognized the car as Motschenbacher's, but the trial court dismissed the case because the plaintiff was not directly identified and the racing car was, in effect, too far removed from the plaintiff.[116] The Ninth Circuit Court of Appeals disagreed, reasoning that the use of the distinctively Motschenbacher car implied Motschenbacher as the driver.[117] The court, therefore, recognized the car as a constitutive part of Motschenbacher's identity. Alternatively, the court recognized that Motschenbacher imprinted parts of the car with aspects of his identity.[118] The court's implicit holding was that the constitutive object is connected to the individual's identity.

Moore's case is problematic because of the difficulties in characterizing Moore's legal rights in his tissue. The history of the case, from the diversity of the decisions and opinions of the three courts that dealt with the facts to the

108. Kahn, *Biotechnology*, *supra* note 10, at 911.
109. *Id.*
110. *Id.* at 917.
111. *See* Midler v. Ford Motor Co., 849 F.2d 460 (9th Cir. 1988).
112. 498 F.2d 821 (9th Cir. 1974).
113. *Id.*
114. *Id.*
115. *Id.*
116. *Id.* at 822-23.
117. *Motschenbacher*, 498 F.2d at 827.
118. *See id.*

different views offered in the extensive commentary on the case, highlights the difficulty of defining individual interests in information derived from human tissue. Moore wanted monetary compensation and eschewed any identity aspects of his claim, despite the California Court of Appeal's sympathy for a claim that Moore's identity was misappropriated. He wanted to share in the profits from the cell line derived from his cells and centered his claim on conversion of his personal property (his cells). The trial court dismissed the claim, but the California Court of Appeal reversed, writing that, "a patient must have the ultimate power to control what becomes of his or her tissues. To hold otherwise would open the door to a massive invasion of human privacy and dignity in the name of medical progress."[119] The California Court of Appeal expressed interest in allowing Moore's claim, but was concerned about commercialization of the human body and the potential detrimental effects on human dignity.[120] It is this concern with dignity and the effects on identity that likely influenced the California Court of Appeal to advocate an appropriation of identity claim, and influenced the reasoning that DNA deserved the same protections as a name or image because DNA was constitutive of a person's identity.

In the end, the California Supreme Court rejected the Court of Appeal's appropriation of identity approach and Moore's conversion claim.[121] In part, the California Supreme Court dismissed the appropriation argument because Moore insisted on the property aspects of his claim. Quickly dismissing the appropriation argument as "irrelevant to the issue of conversion,"[122] the Supreme Court settled instead on the doctor's breach of fiduciary duty. Because Moore's physician was also the researcher who used Moore's cells, the court reasoned that the physician failed to fulfill his fiduciary duty when he did not tell Moore the whole story about his interests in obtaining Moore's cells.[123] Thus, the California Supreme Court sidestepped the more difficult issue of characterizing Moore's legal interest in his cells. The California Supreme Court decided that there is no property right in one's cells, but that

119. Moore v. Regents of the Univ. of Cal., 249 Cal. Rptr. 494, 508 (Cal Ct. App. 1988).

120. Kahn, *Biotechnology*, *supra* note 10, at 918-19.

121. Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1990).

122. *Id.* at 490. There is extensive commentary on the property right issue in *Moore*. *See* Peter Halewood, *Law's Bodies: Disembodiment and the Structure of Liberal Property Rights*, 81 IOWA L. REV. 1331 (1996); Laura M. Ivey, Moore v. Regents of the University of California: *Insufficient Protection of Patients' Rights in the Biotechnological Market*, 25 GA. L. REV. 489 (1991); Stephen Ashley Mortinger, *Spleen for Sale:* Moore v. Regents of the University of California *and the Right to Sell Parts of Your Body*, 51 OHIO ST. L.J. 499 (1990); Jeffrey A. Potts, Moore v. Regents of the University of California: *Expanded Disclosure, Limited Property Rights*, 86 NW. U. L. REV. 453 (1992).

123. *Moore*, 793 P.2d at 486.

somehow legal interests attach to these cells because it is important that the doctor or researcher tells patients what will happen to them.

The California Supreme Court did implicitly recognize a connection between the patient or research subject and the cells after they are removed from the body, although the adequacy of the conventional informed consent (consent for removing the spleen in the first place) was not at issue. However, it is unclear whether the parameters of the informed consent requirements were influenced by the physician or researcher's intentions or by the fact that the patient retained some uncharacterized interest in the cells after removal from the body.

The case remains controversial because of its failure to give Moore much of anything. The case is cited by some science researchers for the idea that patients do not retain any interests in their tissue once they have given conventional informed consent.[124] The case is instructive because it introduces issues that remain largely unsettled today. Many commentators advocate, and rare state statutes maintain, that genetic information is a property right.[125] One of the core provisions in the model genetic privacy act written by Professor Annas, is that, "DNA is the property of the individual from whom it is obtained."[126] Oregon's initial Genetic Privacy Act characterized a person's genetic information as property, stating, "An individual's genetic information and DNA sample are the property of the individual . . . ."[127] Subsequently, the Oregon legislature revised the statute and characterized the individual's right in genetic information as a privacy right. Although most state and federal approaches allow a privacy right in genetic information, the difficulty in characterizing the right precisely remains. One advantage of using the tort of appropriation of identity is that it combines aspects of property and privacy[128] law and its inherent fluidity is well suited to the difficulty of characterizing genetic information.

Kahn makes an important distinction between the privacy-based tort of appropriation of identity, which relies on the individual's interest in maintaining "integrity of identity," and the more common property-based right

124. *See, e.g.*, discussion *supra* note 87.

125. *See, e.g.*, Thomas E. Colonna, *Protection of Privacy in Personal Genetic Information*, 2 W. VA. J. L. & TECH. 2.1, ¶ 47 (June 10, 1998), *at* http://www.wvu.edu/~wvjolt/Arch/Colonn/Colonn.htm. ("Providing individuals with control over their personal genetic information is accomplished first by establishing that an individually identifiable DNA sample is the property of the individual who is the source of the DNA sample.").

126. Roche et al., *supra* note 101, at 4.

127. *See* OR. REV. STAT. §§ 659.036, 659.227, 659.700, 659.705, 659.710, 659.715, 659.720, 659.990, 746.135 (1997). For an internet site explaining some of the legislative history, see *What's Going on Now? Oregon Genetic Privacy Act*, *at* http://www.geneforum.org/learnmore/gp/or_gpa.cfm (last visited Sept. 13, 2002).

128. *See generally* Kahn, *Bringing Dignity Back to Light*, *supra* note 10; Kahn, *Biotechnology*, *supra* note 10.

of publicity, which involves the commercial value of one's likeness. For example, when Jacqueline Onassis sued Christian Dior, Inc. because the fashion design company used an advertisement with a look alike of Onassis without Onassis' permission, she based her claim on a privacy-centered appropriation of identity claim because she did not want to be known as someone who allowed her likeness to be used for selling things.[129] Her action relied on a broad interpretation of the New York Civil Rights law, which prohibited a "person, firm or corporation" from using for commercial purposes the "name, portrait or picture of any living person" without prior written permission.[130] Christian-Dior did not use a picture of Onassis or make any direct reference to her name. In its decision, the New York court focused on the word "portrait" in the statute and traced case law back seventy years to conclude that "[t]he principle to be distilled from a study of the statute and of the cases construing it is that all persons, *of whatever station in life*, from the relatively unknown to the world famous, are to be secured against rapacious commercial exploitation."[131] The statute, the court reasoned, was "intended to protect the essence of the person, his or her identity or *persona* from being unwillingly or unknowingly misappropriated for the profit of another."[132] Interestingly, Onassis and the court emphasized the dignity aspects of the underlying right. Onassis did this by seeking an injunction rather than monetary damages, and the court stressed that the right belonged to every person, to the poor and unknown, and to the rich and famous. Notwithstanding this emphasis on dignity, the court and the statute limit the legal protections to infringements of individual dignity to the commercial context. This result, Kahn claims, is from courts failing to distinguish properly between the two separate torts of publicity and appropriation of identity.[133]

As mentioned before, an important aspect of the tort of appropriation of identity is its reliance on the relationship between the individual identity and the image, or voice or part of an individual's identity that was appropriated. The fact that everyone's fingerprints are unique does not merit legal protections for the fingerprint unless it reasonably impacts the individual's identity. A stranger might lift my fingerprint from a public handrail and publish its image without me suffering any harm. If the stranger attaches my

129. Onassis v. Christian Dior-N.Y., Inc., 472 N.Y.S.2d 254, 256 (N.Y. Sup. Ct. 1984).

130. *Id*. at 258 (quoting Section 50 and 51 of the New York Civil Rights Law, including the following passage from Section 50: "A person, firm or corporation that uses for advertising purposes, or for the purpose of trade, the name, portrait or picture of any living person without having first obtained the written consent of such person . . . is guilty of a misdemeanor.")

131. *Id.* at 260 (emphasis added).

132. *Id.*

133. Kahn, *Bringing Dignity Back to Light*, *supra* note 10, at 233. According to Kahn, "appropriation cases are driven in significant part by a logic of privacy rights even as they employ the rhetoric of publicity." *Id.*

picture to the fingerprint, then I may have a legal claim that my identity has been unreasonably impacted, but the focus of the claim would be on how publishing the picture impacts my identity rather than the fingerprints. If the stranger added a caption proclaiming my appreciation for a commercial product, then I have a stronger legal claim because the impact on my identity is increased. However, the underlying claim remains based on the recognizable picture rather than the fingerprint.

Is genetic information more like the unique fingerprint or the unique picture? The answer, of course, depends on the type of genetic information and how intimately the information addressed by the genetic information connects to an individual. If over time my fingerprint becomes associated with me and my fingerprint becomes recognizable by a significant number of people (whatever that number may be), then a connection exists between my fingerprint and my identity. It is only after a sufficient connection exists that the use of my fingerprint alone may reasonably impact my identity, like how Motschenbacher's car impacted Motschenbacher's identity. Therefore, the use of a single fingerprint that does not reasonably impact my identity does not merit special legal safeguards because a piece of genetic information that does not impact identity should not invoke special legal protections. Genetic information in the research context that has uncertain, unverified and no clinically accepted meaning is unlikely to reasonably impact an individual's identity.

This brief scenario illustrates two points. The first is the importance of the relational aspects. Kahn recognized this and wrote, "[I]t is the relationship between an individual and a particular image that establishes whether her identity is bound up in the image. The court's opinion overlooks this relational aspect of identity, simply asserting the material basis of identity in DNA."[134] A short strip of DNA, lacking any unique features, will not impact identity even if it is linked to an individual. Analogously, my identity is not impacted if some stranger collects a fingerprint, which ends up being mine, as part of an art project, unless my fingerprint was somehow, like Motschenbacher's car, well known as my fingerprint. Only by establishing a connection between the individual and a unique piece of genetic information (and not all genetic information is unique) will there be an impact on identity.

The second point is how the tort of appropriation of identity relies on social norms and community standards. Kahn, contrasting publicity with appropriation, notes that determining if something constitutes appropriation is governed by local community standards, social norms and democratic control:

> Publicity rights demand accountants and other relevant experts from the realm of celebrity and marketing to determine damages. Appropriation calls upon the local community to consider whether an outrage or affront to relevant

134. Kahn, *Biotechnology*, *supra* note 10, at 927.

> social norms has occurred. The former involves the virtues and vices of expert management. The latter similarly involve the virtues and vices of local democratic control.[135]

Allowing social norms and community standards to determine when one's identity is impacted introduces reasonableness. Under this rubric, one can envision how a research subject might successfully claim that her identity was appropriated when researchers used the subject's genetic information in, for example, fetal research without telling the subject. Such use would reasonably impact the research subject's identity. It might violate relevant social norms. Similarly, this approach allows the conclusion that Moore's identity was impacted by knowing that a cell line, which was essentially a clone of a piece of him, was distributed around the country.

The reliance on social norms and community standards used by the tort of appropriation of identity would permit researchers to use genetic information derived from routinely-banked tissue (with routine informed consent) provided the genetic information did not impact an individual's identity. The determination of whether use of genetic information reasonably impacts identity would depend on community standards and social norms. The researcher's decision whether to go ahead with the research would necessitate a judgment about the prevailing community standards and social norms.[136] For example, a researcher might use banked tissue for genetic research on a tumor gene that has no significant impact on identity without getting additional consent to that routinely obtained prior to invasive procedures. These consents often include a general provision for the use of tissue for research.

Another facet of relying upon social norms and community standards is that what is considered reasonable changes over time and varies by region. In one jurisdiction, patients may be surprised to know that any genetic research might be performed on their tissue and that any genetic information might reasonably impact identity (for example, that genetic information used in fetal tissue or cloning research might impact identity). One envisions, perhaps, a rural hospital where tissue collected during diagnostic and therapeutic procedures is, after diagnosis, sent to a far-away research laboratory for stem cell research. In this kind of community, it makes sense to place the onus on researchers or physicians to inform patients or research subjects of the potential future use of their tissue. They might do this as part of the routine informed consent form. It would also behoove researchers in this setting to

135. Kahn, *Bringing Dignity Back to Light*, *supra* note 10, at 215.

136. The proposed system would likely need either notice or regulatory provisions, or both. The determinations would likely be made on a case-by-case basis by the various institutional review boards (IRBs) as much as by individual researchers. Public notice provisions could also be used to provide an additional layer of protection if IRSs fail to judge prevailing community standards accurately. These issues are complex and beyond the confines of this article.

engage in an aggressive publicity and public education program, with the hope of changing the community perceptions about what reasonably impacts identity. In contrast, there may be other jurisdictions where people do not believe that every bit of genetic information impacts identity and patients who consent to having their tissue used for research would not be surprised to discover that researchers conduct future genetic research on this tissue.

In both jurisdictions, the advantage of the proposed approach is that it would allow researchers an opportunity to explain how the pixel of genetic information does not reasonably impact identity. Ultimately, the community will decide whether the researcher made a correct judgment about the impact of the genetic information on the individual's identity. Moreover, the risk-adverse researcher and institution would likely err on the side of obtaining specific consent and make efforts to bring debate into the public arena.

There are risks to this approach. One risk is that this approach would not offer an easy-to-follow, bright-line rule. But there are risks with bright line rules too. Bright line rules can seem to simplify complex issues and, as in the case of many genetic privacy rules, draw the line in the wrong place leading to over-broad protections. Notwithstanding, a risk exists that an emphasis on the prevailing community standards may not adequately protect individual variations about what makes up a person's identity. What may impact the identity of one person may not impact another person's identity.

For example, in *Bitsie v. Walston*, the Court of Appeals in New Mexico concluded that a picture of an eighteen-month-old Navajo girl in a newspaper article about a cerebral palsy fundraising project was not an invasion of privacy as a matter of law, because the facts did not offend persons of "ordinary sensibilities."[137] The court reached its conclusion despite accepting that the evidence showed that traditional Navajo beliefs held that the use of the picture of the toddler, a healthy girl without cerebral palsy, in association with the disease was bad luck and increased her chances of getting a disease like cerebral palsy.[138] The court emphasized that "traditional" beliefs were different from the "ordinary sensibilities" of "the developed society on which the interest in privacy is based."[139] Although acknowledging that 20,000 Navajos lived in New Mexico with "traditional" beliefs, the court used a unique concept of time and concluded that the tort of invasion of privacy did not extend to these "traditional" beliefs because it only applied to the customs

137. 515 P.2d 659, 663 (N.M. Ct. App. 1973). Walston took a picture of eighteen-month-old La Verne Bitsie with the consent of La Verne's father. *Id.* at 661. Later, a newspaper article about note cards by local artists that were sold to benefit the cerebral palsy fund included a picture taken by Walston of La Verne Bitsie. *Id.*

138. *Id.* at 662 ("The evidence then is that the newspaper story was offensive to traditional Navajos.").

139. *Id.* (The court reminded the reader that the interest in privacy is one that "appears only in comparatively highly developed state of society.")

of New Mexico at the time the case was decided.[140] It did not matter that 20,000 people held these traditional beliefs at the time court published its decision. It would seem that 20,000 people with a shared belief system are enough to qualify as a community and formulate social norms. The dissent recognized the error, writing, "It is erroneous to say that traditional Navajo Indians are not people with 'ordinary sensibilities.' The same could then be said of Irish-Americans, Mexican-Americans, Chinese-Americans, black people, Catholics, Protestants and Jews."[141]

Bitsie raises important concerns. The Navajo view toward the increased risk resulting from the association of the toddler's picture with cerebral palsy is similar to the majority view about genetic information. Many people fear the potential of genetic information to predict the future and believe that this information reasonably impacts identity. The association of DNA sequences with the development of subsequent disease are cast in terms of increased risk. Some might argue that it is the mathematical likelihood of the subsequent event that affects the degree that one's identity is reasonably impacted. Some might argue that the Navajo's claim is invalid because there is no rational connection between the picture and the development of disease. However, a better approach is that the reasonableness is measured in terms of the relevant community's belief in how the individual's identity will be impacted. Applying the tort of appropriation of identity to the context of genetic information means that we must be sensitive to the fact that different people will have different ideas about what reasonably impacts identity. But it is this variation in views that makes a common-law based remedy applicable.

PART V—CONCLUSION

In summary, two important points make appropriation of identity well suited to genetic information. First, it recognizes the importance of the relationship between the individual and the object. The tort, therefore, recognizes a continuum of proper legal protections based on the context within which genetic information is collected and used and on the substantive content of the genetic information. A legal system that conveys a recognition of the prevailing importance of individual identity from DNA will look at the substantive content of genetic information rather than only focusing on the fact that the information is genetic. Because the context within which genetic information is collected, studied, stored, and otherwise used will effect the impact genetic information has on individual identity, the degree of legal protection should be tailored to the context. Recognition of context is one critical method for the law to reflect further understanding that the degree of

140. *Id.*

141. *Id.* at 667 (Sutin, J., dissenting).

protection rests on the extent to which the genetic information impacts individual identity.

Second, reliance on identity as the keystone in this proposed system of governing how to best protect individual genetic information is a better fit than privacy law. Identity is constantly created by ourselves and those around us. This process happens in the privacy of our homes, in the public arena of the workplace, the schoolyard, the classroom, the athletic arena, and the public square. It is both conscious and accidental, active and passive. The underlying right to privacy is different from publicity because the right to publicity emphasizes the marketplace and one's commercial worth. Identity, like privacy, is in part a dignity interest that all of us possess, but identity more directly implicates the result of choices made by individuals. Many of us to varying extents can choose our profession, spouses, friends, and acquaintances. The misuse of genetic information impacts one's identity and the ability to create, or influence, one's identity. Ironically, legal protections that treat all genetic information as synonymous with identity reduce individual opportunity to actively participate in forming an identity.[142] Such legal protections change the social meaning of all genetic information by exclusively looking at the genetic attributes of the information instead of examining the substantive content and the context of the information. Despite good intentions, these kinds of genetic privacy acts encourage the kind of genetic reductionism echoed by Crick's words quoted earlier.

Certainly, there should be legal protections against genetic discrimination and reasonable safeguards for privacy and confidentiality, but these must be done rationally. The tort of appropriation of identity offers a fluid, community-based tool that incorporates changing social norms and recognizes the contexts within which genetic information arises. Whether adopted or not, the emphasis on identity is a better starting point for us to analyze the difficult and unanswered issues of genetic information.

142. *See supra* notes 21-22 and accompanying text.