American citizens are increasingly being asked to see themselves in and through their genes. To the degree that Americans come to understand DNA as basic to humanity, the production, circulation, and management of genetic material will implicate our conception of the rights, duties, and interests of our citizens. As genetic information becomes more salient for assessing rights and duties, it becomes increasingly central to configuring new understandings of personhood and citizenship in the American polity (Dreyfuss; Nelkin). At all stages, the legal system in general, and intellectual property in particular, is playing a significant role in this process.

My current work explores the intersection of law, science, and the market as sources of knowledge and authority that frame and inform the management and commodification of human genetic material (Kahn JD 2000; Kahn JD forthcoming). As experts in the natural and social sciences produce knowledge that, in effect, Kingsley, the production, circulation, and management of genetic material will implicate our conception of the rights, duties, and interests of our citizens. As genetic information becomes more salient for assessing rights and duties, it becomes increasingly central to configuring new understandings of personhood and citizenship in the American polity (Dreyfuss; Nelkin). At all stages, the legal system in general, and intellectual property in particular, is playing a significant role in this process.

From the Director ...

Do Embryos Need New Protections?

By Jeffrey Kahn, PhD, MPH

Off in the distance, there are the growing rumbles of an approaching storm. Not of the meteorological variety, but a storm over increasing restrictions on biomedical research—both domestic and international—that may involve human embryos.

On the domestic front, the Bush administration recently announced the dissolution of a Clinton-era federal advisory committee that made recommendations on protection of human research subjects. The committee that will replace it, whose membership has not yet been named, has an additional responsibility in its charter. It is directed to consider "unborn human embryos" in the definition of human subjects as it proceeds with its work. Internationally, the United States recently announced it would not support an effort in the United Nations for a global ban on cloning for reproductive purposes, but would instead push for a wider ban on the use of cloning techniques for any purpose, including research, therapy, or reproduction. Do embryos deserve and need the sorts of protections being proposed, and what are the ramifications of these proposed changes in research policies?

Restrictions on federal funding for research that harms or destroy human embryos dates to the first Reagan administration. The perspective of subsequent administrations has ranged from vocal support...
constructs human identity at the molecular level, venture capital is making deals with these same professionals to manage and transform that identity into marketable products subject to patent rights (Krimsky). Genes are thus becoming sources both of identity and of property, concepts basic to historical constructions of American citizenship (Shklar 1991; Smith 1997).

**Few areas of the law** currently are as fully engaged in a pervasive management of genetic material and information as intellectual property law. Indeed, intellectual property characterizes the very nature of genetic material itself, for example, marking it as “natural” (hence beyond the reach of patent law) or “man-made” (and therefore patentable). Such designations have profound implications for our understandings of the status of the actual human beings who supply the material. Throughout the process of identifying and developing genetic material for use and commerce, intellectual property law is constructing (and sometimes deconstructing) powerful relationships between genetic material and a wide array of actors who encounter and/or manipulate it. These include the people who actually provide the material, laboratory research scientists, commercial biotech corporations, and the ultimate consumers or targets of genetic therapies or products. In examining the debates about the patentability of human genes, I aim to show how certain claims, supported by particular models of authoritative knowledge, gain recognition from and access to the power of the American legal and regulatory system while others are marginalized and denied.

**As my entry point** into this large area I explored recent debates before the United States Patent and Trademark Office (PTO) concerning the patentability of human genetic material (Kahn JD forthcoming). As part of the process of promulgating new rules for evaluating such patents, the PTO requested comments from the public. Ultimately, fifty-one sets of comments were submitted by mail and fax (available at www.uspto.gov/web/offices/com/sol/comments/utguides/index.html). The range of concerned parties ran the gamut from individuals and activist advocacy groups to major professional associations and large biotech corporations. As I analyzed the comments, I found they constituted sites for the articulation and debate of four diverse and powerful models of authority that are deeply implicated in ordering modern American political culture. In simplified form, these models may be briefly stated as follows. First, a dignitary model that focuses on the integrity of the individual human subject of genetic research and/or source of genetic material. This model argues against patenting genetic materials at any point as an affront to human dignity or the sanctity of life. Second, a scientific model that contrasts the ideal of free scientific inquiry to the monopoly-like restrictions of patent law. Third, a market-based model that seeks to extend patent protection far back into the research process (but not all the way upstream to the human subject of genetic material) as the most efficient means to produce both scientific knowledge and useful products. And fourth, an additional and distinct therapeutic dignitary model that focuses on the health and well-being of the human target or consumer of new genetic products or therapies. This last model accepts or rejects the extension of patent law instrumentally as it serves or undermines consumer access to significant health technology.

In justifying their arguments to the PTO, different groups invoke the powerful claims to authority based on the four models outlined above—the dignity of the human subject/source of genetic material, the ideals of free scientific inquiry, market efficiency, and the health of the consumer of genetic therapies or products. Each model relies for its justification on the implicit construction of a particular type of relation between the relevant actors and genetic material. How intellectual property law recognizes or dismisses claims from one or another model affects not only the parties directly engaged in the dispute but may also have significant implications for our understanding of the rights, standing, and status of genes and citizens more broadly throughout society.

Those who invoke the dignity of the human subject are trying to resist the incursion of property and commerce, as carried by patent law, into any area directly involving human genetic material. Their views are grounded in an understanding of human genetic material as inextricably bound up with the human subject or source of material. They view patents variously as the intrusion of the profane world of the market into the sacred world of the human essence, a property regime tantamount to slavery insofar as it confers ownership over constituent aspects of human identity, or the improper allocation of rights over the “common heritage of mankind” to distinct individuals or corporations. Here, the very concept of granting rights based on the “utility” of a gene seems to reduce human essence to a mere instrumentality.
Facility Profile
Jonathan Kahn, JD, PhD

Jonathan Kahn writes on a wide range of issues in history, politics, and law, with a special focus on the implications of biotechnology for our ideas of identity and citizenship. He is currently exploring the legal and ethical implication of how racial categories are produced and disseminated in the course of drug development. His recent work also examines how different areas of the law involving the management of information may be brought to bear on emerging problems presented by new developments in the field of human genetics. Genetics is rapidly becoming not only a vast commercial enterprise but also a powerful new way of thinking about individuals and their relation to society and the state. As the metaphors and practices of genetics proliferate, "genetic citizenship" is emerging as a critical new category for assessing and assigning legal rights and duties. Dr. Kahn thus views biotechnology as an arena where constitutional law and intellectual property are intersecting in new and important ways. Dr. Kahn holds a PhD in History from Cornell University and a JD from Boalt Hall School of Law, University of California. After graduating from law school, he practiced law for two years in Washington, DC with the firm of Hogan & Hartson. He then moved on to complete his PhD and began teaching at Bard College as Assistant and then Associate Professor of US History and Political Studies. Dr. Kahn came to the University of Minnesota from Harvard University where, from 1999 to 2001, he was a Visiting Associate Professor of Social Studies. He has also taught as an Adjunct Assistant Professor at Cornell University School of Law and as a Visiting Associate Professor at Western New England School of Law. He is the recipient of several awards and fellowships. Most recently, he was awarded a fellowship from the National Endowment for the Humanities to support his on-going project, "The Subject of Rights: Identity and Equality in American Law."

Selected Publications

Books

Articles


to explicit opposition, but with little change in policy over the intervening 20 years. A federal funding ban, however, leaves untouched any research that takes place with private funding. That has led to almost no rules related to privately funded embryo research, and that there is little information on what research is actually carried out involving embryos.

Including human embryos in research protection policies would bring much of this work into the open, but at the cost of new restrictions. Limits on research involving human embryos are not new, and their impact can be easily appreciated. Far fewer embryos are used in research than would have been the case if funding from federal sources like the National Institutes of Health were available, but because so little federal research could be conducted on human embryos, there has been limited understanding of human developmental biology.

Expanding definitions of “human subjects” to include embryos in the U.S. and banning any use of cloning technologies internationally will continue to slow such basic science. This seems especially ironic at a time that science seems to be on the cusp of breakthrough understandings of how embryonic stem cells go from their nearly unlimited potential to becoming specific types of target cells, and given the information that cells isolated from human embryos may be one of the few sources for studying this process.

The field of reproductive medicine, where procedures like in vitro fertilization to create embryos are used in clinical applications, could also be affected. Expanded definitions of human subjects to include embryos would likely mean that new reproductive technologies would go through far greater oversight than is currently the case—offering patients increased protections, but at greater cost and slower-paced introduction into clinical practice.

So the possible changes would be milestones in research policy, with the significant ramifications of increased oversight along with new impediments for research, and a shift in the way we talk about the status of human embryos in the process. The two announcements by the Bush administration signal a change is at hand, and the question that remains is whether that distant rumble foreshadows a shower or a downpour.

A version of this article appeared in Dr. Kahn’s bi-weekly column, “Ethics Matters” on CNN.com

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**Center News**

**Starr Foundation Supports Resource Center Development**

The Center for Bioethics has received a three year leadership grant from the Starr Foundation. This funding will support the Center in developing and distributing educational materials about current bioethics issues, particularly those related to new technologies. Dianne Bartels, Associate Director, will lead the Center’s effort to conduct a needs assessment and develop resources to meet University and community educational needs. For information or requests, contact Elizabeth Chambers, Program Associate, at 612 624-3171 or email: chamb033@umn.edu.

**New Look for the Examiner**

The Bioethics Examiner gets an update and a new editor! Jonathan Kahn, JD, PhD, is the new editor and is featured in this issue. Please direct letters to the editor and announcements to him at kahnx015@umn.edu. We welcome your comments about our content and new look.

**Bioethics Institute for Life Science Faculty**

**University of Minnesota—Minneapolis, MN**

**June 14-19, 2003**

The Bioethics Institute sponsored by the USDA and NABC is a unique conference devoted to faculty in the life sciences and extension personnel. The Institute is designed to assist with the integration of ethics discussions into coursework. The 20th in a series of Institutes that have been held around the world, this workshop will be hosted by the Center for Bioethics and take place on the University of Minnesota campus in Minneapolis.

**Institute faculty** include Dennis Cooley, PhD, North Dakota State University; Nels Granholm, PhD, South Dakota State University; Kristen Hessler, PhD, Iowa State University; Jeffrey Kahn, PhD, MPH, University of Minnesota; Robert Streiffer, PhD, University of Wisconsin, Madison; and Gary Varner, PhD, Texas A & M University.

For more information, visit our website at www.bioethics.umn.edu or call 612-624-9440.
Those claiming to speak on behalf of the ideals of free scientific inquiry also seek to resist the incursions of patent law, but only into their labs. They are generally happy to have genetic material patented further downstream, once they are through with it. In justifying their claims, these scientists invoke the ideals of pure science unencumbered by patent law, commercial priorities or, less consciously, human rights.

Market-based arguments dovetail closely with the basic conception of patent law as the most efficient way to provide an incentive to innovate. Here good business is good science and vice versa. These arguments assert that there is nothing sacred or pure about the space of the laboratory. Indeed, they very consciously bring the lab into the realm of the market and argue that any DNA sequence that is useful to a researcher meets the utility requirement.

Finally, most commenters, regardless of their stand on patenting, also justify their claims by reference to the ultimate good of improving the health and well-being of the human target or consumer of the end-results of their endeavors.

As the PTO responded to the fifty-one sets of comments received, it effectively marginalized all dignitary concerns and responded primarily to contests among scientific and business experts. As the PTO dismissed such dignitary concerns it also dismissed their validation of the human being as a subject of rights and status in relation to genetic material. Instead, the PTO embraced and affirmed a construction of the human being as, at one end of the spectrum a passive repository of genetic raw material, and at the other end a reactive object or consumer of genetic products defined primarily in terms of individual genetic illness or disease (United States Patent and Trademark Office).

What we are left with from the PTO is a set of guidelines that affirm the power of scientific intervention to take genetic material out of nature, strip it of all affiliations with its human source, and reconstruct it in terms of a functional identity that values genetic material primarily in terms of its promise of ultimate commercial value in the marketplace. Here, patent law grants agency and transformative power only to science and commerce. The individual source of genetic material is denied any status in relation to the work of producing a valuable genetic product. Scientists and businessmen alone are deemed to create and develop genetic potential and so become the legal masters of relevant genetic material. The individual subject is denied any claims or connection to her genetic material once it enters the lab. The individual emerges from this eclipse only downstream from the process of genetic transformation and production, as a pathologized object or consumer of genetic therapies and products.

As we continue to explore the implications of human genetics, it is important to understand intellectual property law in general and the actions of the PTO in particular as directly implicating dignitary concerns.

References


February 27, 2003
The Minnesota Network of Healthcare Ethics Committees (MNHEC) is sponsoring, “Responding to Controversies: Using Organizational Ethics in Healthcare.” This conference will present models for ethical decision-making by healthcare organizations. It will be held at the Earle Brown Continuing Education Center, on the University of Minnesota, St. Paul campus. For more information, call 612-624-3171 or email: chamb033@umn.edu.
Recent Faculty Publications

**BOOKS**

**BOOK CHAPTERS**


**ARTICLES**


“… a powerful meditation — moving, sardonic, humorous, and startling by turns — on the role the “enhancement technologies” of American medicine have come to play in shaping our sense of who we are or wish to be.”

Clifford Geertz, Institute for Advanced Study, Princeton University

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**Monograph Available**

“Genetics in Primary Care: Clinical, Ethical, and Professional Challenges”

A monograph and website are the products of a Center-based research project on ethical challenges that primary healthcare professionals face when they see patients and families with genetic concerns. The project, led by Dianne Bartels and colleagues Bonnie LeRoy and Pat McCarthy Veach, offers continuing education credits free of charge to healthcare practitioners interested in the clinical, ethical, and professional challenges in genetics and health care. The report maybe obtained free of charge by contacting the Bioethics Resource Center at 612-624-3171, by email to chamb033@umn.edu, or by the web at [www.cme.programs.umn.edu/bestpractice](http://www.cme.programs.umn.edu/bestpractice).

The Center gratefully acknowledges the Josiah Macy Foundation for their support of this project.

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**Announcing New Center Reading Packet**

“Human Stem Cells: An Ethical Overview” presents a basic introduction to the science and ethical implications of human stem cell research including illustrations, a glossary, and a bibliography of additional readings pertaining to stem cells. All packets are available on the Center’s website at [www.bioethics.umn.edu](http://www.bioethics.umn.edu) or can be mailed upon request. For more information, contact the Center for Bioethics.

The Center gratefully acknowledges the Starr Foundation, in supporting this effort.
Calendar of Events

JAN 14
Carl Elliott, MD, PhD, will speak on “Amputees by Choice” at the University of Texas-Southwestern, Dallas, TX. For information, email: Jeffrey.Bishop@UTSouthwestern.edu.

JAN 20-22

JAN 28
Steven Miles, MD, will speak on “Refugee Resettlement” at the Minneapolis Women’s Club, Minneapolis, MN. For information, call 612-870-8001.

JAN 30, FEB 6, FEB 20, APR 3
The University of Minnesota Medical Student Committee on Bioethics Winter Lecture Series: 1/30 – Jeffrey Kahn, PhD, MPH, TBA, 2/6 – Steven Miles, MD, “The Role of the International Monetary Fund with Regard to Health Care around the World.” 2/20 – Trudo Lemmens, PhD, University of Toronto, TBA (co-sponsored by the Center for Bioethics). 4/3 – Joan Lischewski, RN, PhD, “The Ethics of Nurse-Physician Collaboration.” Lectures will be held from 12:10-1:00 pm on the University of Minnesota campus. For information, email: weis0206@umn.edu.

FEB 5
Jeffrey Kahn, PhD, MPH, will participate in a debate on “Limits of Living Donation” for the University of Minnesota Department of Surgery Transplantation Conference, Minneapolis, MN. For information, call 612-626-3576.

FEB 11
Debra DeBruin, PhD, will speak on “Informed Consent of Patients for Research Participation in ICU” for the American Association of Critical Care Nurses, sponsored by Abbott Northwestern Hospital, Minneapolis, MN. For information, email: chlan001@umn.edu.

FEB 13
Jeffrey Kahn, PhD, MPH, will speak at the University of Minnesota Department of Medicine Grand Rounds, Minneapolis, MN. For information, email: messm001@umn.edu.

FEB 28
Carl Elliott, MD, PhD, will speak on “Better Than Well” at the University of Memphis, Memphis, TN. For information, email: hsmith@memphis.edu.

MAR 12

MAR 14
Genetics and Disability Insurance: Ethics, Law & Policy Conference, sponsored by the Center for Bioethics, University of Minnesota. For information, visit www.bioethics.umn.edu.

MAR 19
Jeffrey Kahn, PhD, MPH, will speak at the Fairview University Medical Center Annual Conference, “Cutting Edge 2000,” Minneapolis, MN. For information, call 612-273-5607.

MAR 20
Carl Elliott, MD, PhD, will speak on “Better Than Well” at the University of Maryland School of Medicine, Baltimore, MD. For information, email: hsilverm@medicine.umaryland.edu.

APR 2
Carl Elliott, MD, PhD, will speak at the University of Michigan, Program in Psychiatry and Life Sciences, Ann Arbor, MI. For information, email: jmetzl@med.umich.edu.

APR 10
Jeffrey Kahn, PhD, MPH, will speak on “Ethics, Policy, and the Challenges of the New Biology” at the University of California–San Diego, San Diego, CA. For information, call 612-624-9440.

APR 24
Carl Elliott, MD, PhD, will speak at the Washington University, Department of Internal Medicine Grand Rounds, Seattle, WA. For information, email: smoorhea@im.wustl.edu.

APR 28
Jeffrey Kahn, PhD, MPH, will speak at the Program in Ethical Reflection, at Carleton College, Northfield, MN. For information, email: zpruitt@carleton.edu.

MAY 5-8
5/7 – Debra DeBruin, PhD, will speak on “Research Involving Vulnerable Populations” at the Integrity and Accountability in Clinical Research Conference, sponsored by National Patient Safety Foundation (NPSF), Washington, DC. For information, contact the Center for Bioethics.

MAY 16
Jeffrey Kahn, PhD, MPH, will speak on “Swinging on the Pendulum: Protection vs. Access in Research On Human Subjects” at the Park Nicollet Symposium, Minneapolis, MN. For information, call 953-993-3005.

JUNE 14-19
Bioethics Institute for Life Science Faculty will be host-end by the Center for Bioethics and held on the University of Minnesota campus. The workshop is sponsored by the USDA and NABC. For information, visit www.bioethics.umn.edu or call, 612-624-9440.

Center for Bioethics Seminar Series

All lectures will be held from 12:15-1:30 pm on the University of Minnesota campus, Minneapolis, MN. For information, contact the Center for Bioethics.

FEB 14 “Health Care and International Financial Organizations,” by Steven Miles, MD.

MAR 28 “Genetic Determinism and Criminal Behavior: Why Biologists Need Sociology 101,” by Robert Dingswall, PhD.

APR 11 “Ethical and Policy Challenges in the Study and Use of DBS for Parkinson’s Disease,” by Raymond de Vries, PhD.

MAY 9 “Where are We Going in the Human Genome Project?” by Jeffrey Kahn, PhD, MPH.

JUNE 13 “Psychiatry and Feminist Virtue Ethics,” by Andrea Nicki, PhD.
The University of Minnesota Center for Bioethics and the Joint Degree Program in Law, Health & the Life Sciences will sponsor a day-long conference to address the understanding of the ethical, legal, and policy challenges arising in disability insurance as a result of emerging genetic technologies.

**topics include:** Disability in the Genetic Age; Disability Insurance: Private and Public; Predictive Medical Information and Underwriting; The Moving Target of Disability; Genetic Exceptionalism, Privacy and Confidentiality; and Health, Life and Disability Insurance: Understanding the Relationships.

**Speakers include:** David Christianson, John Dodge, MD; Robert Jerry, II, JD; Jeffrey Kahn, PhD, MPH; Nancy Kass, ScD; Paul Miller, JD, Mark Rothstein, JD; Kathryn Sedo, JD; Anita Silvers, PhD; Karen-Sue Taussig, PhD, and Susan M. Wolf, JD.

*This conference is supported by Grant #NHGRI/NIH/1RO1-HG02089. For more information, contact the Center for Bioethics at 612-624-9440 or see our website at www.bioethics.umn.edu or www.jointdegree.umn.edu.*