A story with international interest continues to unfold here at the University of Minnesota. Six-year-old Molly Nash and her family are awaiting the results of a test that will tell whether the stem cell transplant Molly received from her baby brother Adam was successful. The human drama of the Nash case has been nearly overshadowed by the steps that were taken to create Adam and make the stem cell transplant possible.

Molly was born with a genetic disease called Fanconi anemia, which results in a condition early in life that requires a bone marrow transplant to survive. Molly had no siblings, and neither of her parents was a close enough match to qualify as a donor. Rather than try to find an unrelated marrow donor, the Nashes decided to use an advanced genetic testing technique to help them have a child who wouldn't inherit Fanconi anemia, and who would also be a perfectly matched stem cell donor for Molly. Is this story an example of the genetic revolution going too far? Is it a case of creating one child to save the life of another? Or is it an example of using modern medicine to benefit everyone involved?

To make sure that the new baby would be a matched donor, doctors used in vitro fertilization to create embryos for the Nashes, and then did two kinds of genetic testing on them. First, the embryos were tested for Fanconi anemia, and only the unaffected embryos were tested a second time. The second test was used
sophisticated rules, as in the case of software filters that screen out objectionable Internet content. Such use of technological rules, rather than written laws, to govern behavior has been dubbed by Joel Reidenberg as “lex informatica.”

Until now, we have tended to rely upon written rules to govern the use of biological inventions. For example, a form of intellectual property called Plant Variety Protection encourages development of new varieties of sexually reproducing plants by granting the developer broad control over the growth, use, importation, and sale of a new plant. However, the Plant Variety Protection Act includes some important exceptions to such control, such as allowing farmers to save seed from a proprietary crop, or permitting agricultural research involving the plant. Plant variety owners might prefer that their control over the variety were not subject to such exceptions, and so as a condition of access to their seeds, they require that farmers contractually waive their rights to save seed or engage in other legally permissible uses. Often the terms of this contract are printed on the bag of seed; by using the seed, the contractual “fine print” purports that the farmer has agreed to the terms.

This description of seed licensing bears an uncanny resemblance to the history of content licensing in digital media. Owners of digital content, much like seed owners, have long wished to escape the consumer privileges afforded by copyright law. They have done so through the fiction of the “shrink-wrap” license, which purports to restrict a purchaser’s use of the accompanying product. The license takes its name from the legal fiction that the purchaser demonstrates agreement to the license terms by breaking the “shrinkwrap” cellophane on the product package.

However, courts in the United States have generally been reluctant to enforce such agreements because the purchaser may have no opportunity to review the license prior to opening the package. Additionally, it is extremely difficult for copyright holders to police such agreements. Consequently, copyright owners have begun deployment of sophisticated software “lock-out” systems that prevent access to digitized content except on the terms dictated by the owner. Such content management software may govern the number of uses, or their duration, or the payment schedule for additional access. The content management system may even permit the owner to shut off the software remotely if the user fails to make the required payment in a timely manner. This application of the “lex informatica” approach substitutes a self-enforcing set of software rules for the written rules of a shrinkwrap license.

Because seed owners face much the same problem, they have arrived at much the same solution. It is difficult to police the use of seed and to enforce the terms of “seed-wrap” licenses. However, newly available transgenic technology allows for the insertion of genetic elements that produce a toxin late in seed development. The toxin kills the seeds after the plant has matured; producing a viable crop for the farmer, but forcing him to return to the seed producer for new seed each year. Even in the absence of a contractual obligation not to save seed, the technology makes saving seed impossible. Thus, much as computer code can substitute for a license in digital media, genetic code can be substituted for a license in biotechnology.

Indeed, the terms of usage embedded in genetic code may be quite sophisticated. In one embodiment of the technology, it is possible to introduce into the seed a genetic “switch” that will repress, or turn off, the toxin production when the seed is exposed to a particular chemical. This in effect supplies a chemical “password” to seed germination that can be used to control the terms of seed usage from year to year. Yearly application of the control chemical, obtained from the seed owner for payment, would allow the owner to activate or deactivate seeds in much the same way that software can be remotely disabled for failure to make a payment.

The development of such technological use controls, whether in software or transgenic corn, is somewhat disturbing because it substitutes private technological rules for the public statutory rules declared by Congress in respectively the Copyright Act or Plant Variety Protection Act. Additionally, this instantiation of a proprietary rule in genetic code, following Reidenberg we might call “lex genetica,” is the first example of private regulation through genetic code, but is unlikely to be the last.

Continued on Page 4
Faculty Profile
Dan Burk, MS, JD, JSM

Professor Dan Burk is an expert in the law of intellectual property, and internationally recognized for his scholarship on cyberlaw and biotechnology. After visiting at the University of Minnesota during the 1999-2000 academic year, Professor Burk joined the University of Minnesota faculty in the Fall of 2000 and was appointed Vance K. Opperman Research Scholar. Professor Burk teaches in the areas of copyright, patent, and biotechnology law. He is the author of numerous papers on the legal and societal impact of new technologies, including articles on scientific misconduct, on the regulation of biotechnology, and on the intellectual property implications of global computer networks. Professor Burk holds appointments at both the Law School and the Center for Bioethics, and currently serves as Associate Director to the new Joint Degree Program in Law, Health, and the Life Sciences. He has also been closely involved in the development of the new Internet Studies Center at the University of Minnesota.

Prior to his arrival at the University of Minnesota, Professor Burk taught at Seton Hall University in New Jersey. He has taught as a visitor at George Mason University, Cardozo Law School, and the Ohio State University Programme at Oxford, and as a Teaching Fellow at Stanford Law School. He holds a BS in Microbiology (1985) from Brigham Young University, an MS in Molecular Biology and Biochemistry (1987) from Northwestern University, a JD, cum laude, (1990) from Arizona State University, and a JSM (1994) from Stanford University. He is a member of the Order of the Coif legal honor society and has served as a legal advisor to a variety of private, governmental, and intergovernmental organizations, including the American Committee for Interoperable Systems, the OECD Committee on Consumer Protection, and the United States State Department Working Group on Intellectual Property, Interoperability, and Standards.

Selected Publications

ARTICLES


to select only those embryos that were genetically compatible with Molly, since the plan was to use the baby’s cord blood for a stem cell transplant for her. The matched embryo was implanted, and nine months later Adam was born. The process was complete when the cells from Adam’s umbilical cord were used in a stem cell transplant for Molly.

The technology of pre-implantation genetic diagnosis (PGD) is about seven years old. It has been mostly used to help couples avoid passing on genetic diseases or illnesses — such as cystic fibrosis or Tay Sachs disease — to their future children. But this case applies PGD for a different purpose, and that raises new ethical issues.

By selecting an embryo based on whether it was a genetic match for Molly, genetic testing crossed an important line. For many people, there is a moral difference between choosing characteristics that are meant to protect the health of the child that will be born, and choosing characteristics that are based on the interests or desires of somebody else — whether it be the future child’s sibling, his or her parents — or for some other purpose. In Adam’s case, his compatibility with Molly had no impact, good or bad, on his health. But what about couples that may want to choose other, more controversial, characteristics for their children such as eye color, musical ability, height, or any number of others?

The only way to prevent couples from using PGD in unacceptable ways is either to create rules about what traits they can choose or to review every couple’s request for the use of PGD. But couples can have good reasons, bad reasons, or no reasons at all for having children, ranging from attempts to save a failing marriage, to create more hands for working on the farm, to merely by accident. We neither ask nor judge people’s motives for having children, a longstanding and understandable policy in most liberal societies. So it will take significant justification, such as risk of serious harms to future children, to change the presumption from reproductive liberty.

While we decide whether and what limits there ought to be on the use of PGD, many more couples will want to follow in the footsteps of the Nashes. But whether or not their motives are pure, PGD will be expensive, both monetarily and morally. The question is whether society is willing to pay the costs.

A version of this article appeared in an “Ethics Matters” column on CNN Interactive (www.cnn.com/health).

There is no particular reason, that such technology need be confined to plants. The constituent genetic control elements could equally well be added to the transgenic DNA cassettes contemplated for human gene therapy, allowing them to be activated or deactivated by administration of a regulatory pharmaceutical. We should as a society perhaps begin to consider whether withholding such a pharmaceutical for lack of payment is different than withholding any other pharmaceutical for lack of payment – or whether either action is acceptable.

References


Save the Dates

“Physician Assisted Dying: Assessing the State of the Debate” Conference
April 27 & 28, 2001

This conference will provide an update on the status of the debate over physician assisted dying from perspectives of public policy, medical and hospice issues, and religious and philosophical perspectives. A host of national speakers, including Connie Holden, David Mayo, Alan Meisel, Steven Miles, Timothy Quill, Estelle Rogers, and Susan M. Wolf, will present diverse perspectives in presentations including assessment of the impact of legislation in Oregon and the Netherlands, as well as ethical, legal, clinical, and religious considerations related to this controversial topic.

The conference is co-sponsored by the Center for Bioethics and the Death With Dignity National Center. More information is available on the Center website at www.bioethics.umn.edu or by contacting the Center for Bioethics.

Center News

AWARDS
Ronald Cranford, MD, and a group of colleagues were awarded a grant from the US Agency for Healthcare Research and Quality to conduct a three year project on the impact of ethics consultations on patients, families/intimate friends, physicians, nurses, treatments and charges in intensive care units. Hennepin County Medical Center was one of five sites chosen in locations across the United States.

Gregory Plotnikoff, MD, MTS, was listed on the 100 Most Influential People in Minnesota's Health Care in Minnesota Physician 2000; and received the CHIP (Council for Health Interdisciplinary Participation), University of Minnesota Medical School, Distinguished Alumni Award 2000.

FACULTY & ASSOCIATES
Debra DeBruin, PhD, has accepted a faculty position as Assistant Professor in the Center. Professor DeBruin's appointment will begin December 15, 2000.

Joan Liaschenko, RN, PhD, has accepted a faculty position as Associate Professor in the Center and in the School of Nursing. Professor Liaschenko's appointment will begin in January 2001.

Steven Miles, MD, is back at the Center after a bid for US Senate. The Republican incumbent he was challenging was unseated in one of the costliest races in the country, at $24 million. In November, Dr. Miles went to Sudan and Angola for the American Refugee Committee. In Sudan he designed improved HIV prevention programs to make them more attuned to local behaviors that potentially transmit HIV. His program model is now being used to design programs for United Nations and foreign aid funding. In Angola, he designed a nursing education program for a southern province and laid the foundation for programs of maternal health, mine injury prevention, polio surveillance, and HIV education in the north. This work is a continuation of Dr. Miles’ work in refugee relief that he began 20 years ago.

Mila Aroskar, RN, EdD, Faculty Associate in the Center, is retiring after more than 20 years on the faculty in the School of Public Health and in the School of Nursing at the University of Minnesota. As well as serving on a number of Center committees, she served on the advisory committee to create the Center for Bioethics prior to 1985, and was for many years the Center’s Director of Graduate Studies. Before joining the University of Minnesota faculty, she held positions in undergraduate and nursing programs at Villa Maria College, Erie, Pennsylvania and the State University of New York at Buffalo. She is a Fellow of The Hastings Center where she served as vice president, and participated in projects in nursing ethics education and the physician-patient relationship. She is a Fellow of the American Academy of Nursing; Chair, American Nurses Association Center for Ethics and Human Rights Advisory Board; and a member of the Editorial Board of the Bibliography of Bioethics. She is a co-author of the book, Ethical Dilemmas and Nursing Practice, now in its 4th edition. This textbook is widely used as a resource in nursing programs nationally and internationally.

VISITING FACULTY
Amy Haddad, PhD, Professor, Center for Health Policy and Ethics, Creighton University, will be a visiting faculty at the Center for Bioethics through Spring 2001. The focus of her research will be on Alzheimer’s disease and drug therapy.
Calendar of Events

JAN 22
Jeffrey Kahn, PhD, MPH, will be the keynote speaker on “The Ethics of Creation of Stem Cell Donors,” at the United Resource Networks’ (URN) 3rd Annual Evolving Science of Blood/Marrow Transplantation Conference, Naples, FL. For information, call 800-847-2050.

JAN 30
Jeffrey Kahn, PhD, MPH, will speak on “Implications of Pre-Implementation Genetic Testing,” for the VA Medical Center Biomedical Ethics Committee, Minneapolis, MN. For information, call 612-725-2000.

FEB 1
Jeffrey Kahn, PhD, MPH, will participate on a panel discussion “Governing GMO’s: Developing Policy in the Face of Scientific and Public Debate,” at the Cowles Auditorium, Hubert H. Humphrey Institute, University of Minnesota Law School. For information, call 612-625-0055.

FEB 22

MAR 29-APR 1
“Exploring Organ Transplantation: Current Issues, Emerging Technologies and Innovative Approaches” conference sponsored by the United Resource Networks. On 3/29 — Jeffrey Kahn, PhD, MPH, will speak on “Ethical Issues in Living Donation”; and on 4/1 — Professor Kahn will speak on “Creation of a Donor: An Exploration of Ethical Issues in the Future of Transplantation.” The conference will be held in Scottsdale, AZ. For information, call 612-797-4831.

APR 5-7
The University of Nijmegen, The Netherlands, will hold an Advanced European Bioethics Course, “Death Without Suffering.” For information, call 0031-24-3615320, or email: n.steinkamp@efg.kun.nl.

APR 13
Young-Rhan Um, RN, PhD, Visiting Faculty, Center for Bioethics, will speak on Korean nursing ethics, 12:15-1:30 pm on the University of Minnesota campus. For further information contact the Center.

APR 27-28
“Physician Assisted Dying: Assessing the State of the Debate,” conference, co-sponsored by the Center for Bioethics and the Death with Dignity National Center will be held in Minneapolis, MN. Contact the Center for Bioethics for more information.

APR 30-MAY 1
Steven Miles, MD, will speak on “Geriatrics for the Primary Care Provider: A Clinical Perspective — A Personal Approach,” at the Geriatric Research, Education, and Clinical Center (GRECC)/Department of Veterans Affairs, Minneapolis, MN. For information, call 612-725-2051.

MAY 3-5
Steven Miles, MD, will speak on “Drug Lords: The Politics of Medication Coverage in the US,” at the American Philosophical Association Central Meeting, Minneapolis, MN. For information, call 704-687-3542.

Student Committee on Bioethics (CHIP) Annual Winter Lecture Series

This year’s lecture series features distinguished scholars in bioethics as well as researchers and practitioners from the cutting edge of their fields.

Speakers Include:

JAN 18
Michael Osterholm, PhD, MPH, icanc, INC.

JAN 25
*Jeffrey Kahn, PhD, MPH, University of Minnesota

JAN 30
*Steven Miles, MD, University of Minnesota

FEB 6
*Eric Juengst, PhD, Case Western Reserve University

FEB 15
*Tod Chambers, PhD, Northwestern University

FEB 22
*Daniel Callahan, PhD, The Hastings Center

MAR 1
Mark Leenay, MD, Fairview Health Services

MAR 8
*Susan M. Wolf, JD, University of Minnesota

MAR 15
*Rebecca Dresser, JD, Washington University

MAR 29
*Paul Wolpe, PhD, University of Pennsylvania

Lectures will be held at 12:15 p.m. on the University of Minnesota campus. Locations to be announced. Please contact the Center for a detailed schedule or for additional information, e-mail: tric0009@umn.edu.

*Lectures are cosponsored by the Center for Bioethics Annual Seminar Series.
Faculty Publications

BOOKS

ARTICLES/REVIEWS

Center Publications

READING PACKETS
Center packets contain an overview of legal and ethical issues, key articles, and a bibliography.
No. 1: Organ Transplantation (August 1997)
No. 2: Withholding or Withdrawing Artificial Nutrition and Hydration (July 1997)
No. 3: Termination of Treatment of Adults (September 1997)
No. 5: Distributing Limited Health Care Resources (April 1997)
No. 6: Resuscitation Decisions (June 1997)
No. 7: The Determination of Death (May 1997)
No. 8: New Frontiers in Genetic Testing and Screening (August 1999)

MANAGED CARE AND END-OF-LIFE CARE PACKETS
A Center program addressing ethical issues in managed care has led to the publication of annotated bibliographies on end-of-life care.
• Ethical Issues in Managed Care (1997) — articles addressing ethical issues in managed care.
• Advance Directives (1995) — focuses on empirical research related to the dissemination, clinical use, and effects of advance directives.
• Palliative Care (1995) — articles describing clinical, legal, and ethical issues in pain control for terminally ill persons and articles describing and comparing hospice care to conventional care for terminally ill persons.

Reading packets are available for $5 each. All orders must be prepaid. To order reading packets or reports, make checks payable and mail to:
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University of Minnesota
Suite N504 Boynton
410 Church Street SE
Minneapolis, MN 55455-0346

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