

2011-12
ANNUAL REPORT



Consortium on Law and Values
in Health, Environment & the Life Sciences™

Joint Degree Program
in Law, Health & the Life Sciences™

***Minnesota Journal of Law,
Science & Technology***

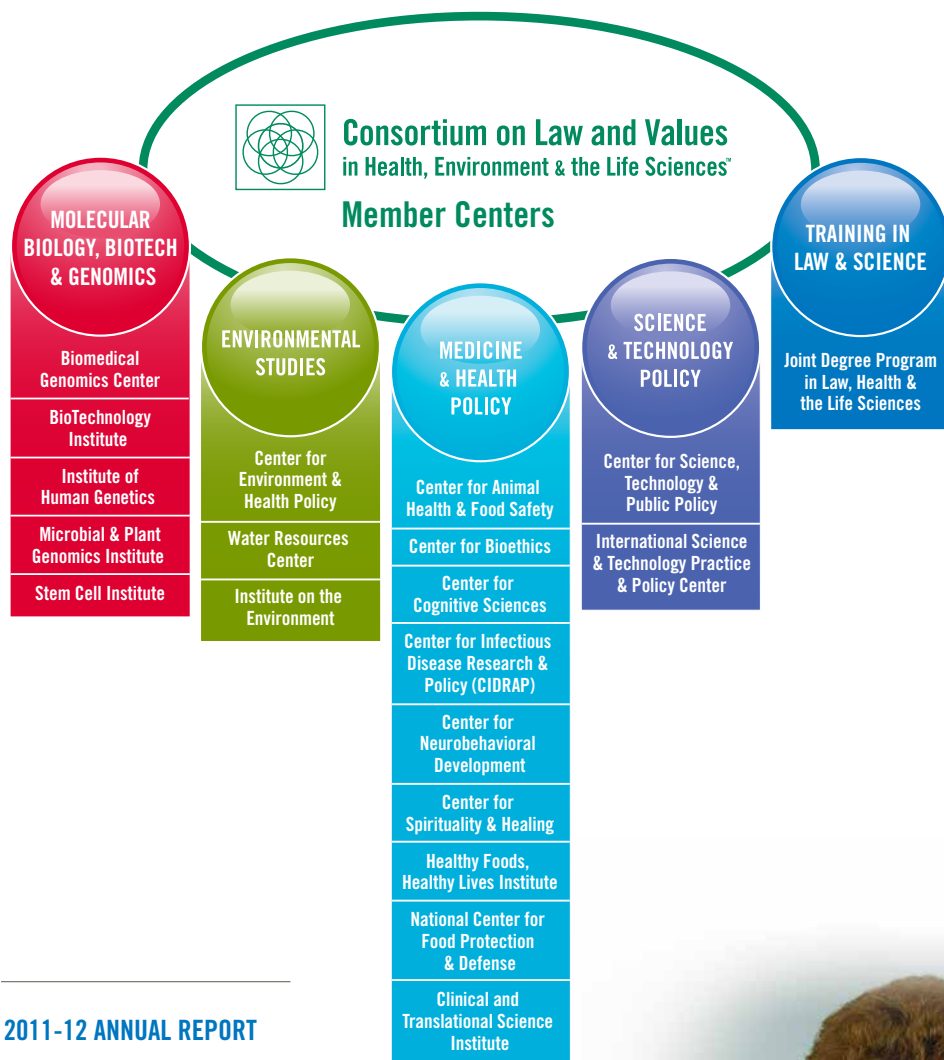


This year's highlights

- ▶ Supported by NIH funding, Consortium publishes:
 - **first** consensus recommendations on biobank responsibilities for return of results & incidental findings
 - **first** systematic and comprehensive recommendations on protecting human participants in nanomedicine products research
- ▶ Susan Wolf receives Robert Wood Johnson Foundation Investigator Award; goes on sabbatical for research & writing
- ▶ Consortium receives new NIH grant with Mayo on return of results to family and kin
- ▶ Joint Degree Program graduates 5 students
- ▶ *Minnesota Journal of Law, Science & Technology* ranks in top 10
- ▶ Consortium passes \$1 million mark in research awards to faculty and students

Who we are and what we do

The Consortium catalyzes work across the University of Minnesota on the societal implications of the life sciences, secures grant funding for original research, trains students in law and science, publishes a top interdisciplinary journal, and sponsors high-impact events each year, bringing to campus leading thinkers and scholars. **We link 20 leading centers and programs across 12 colleges** and are **one of only six University-wide centers**.



OUR LEADERSHIP

The Consortium is led by Founding Chair Prof. Susan Wolf, JD; Associate Director of Law, Geography & Environment, Prof. Hari Osofsky, JD; and Prof. William Toscano, PhD, Associate Director, Joint Degree Program. Our Executive Committee facilitates the work of the Consortium and Joint Degree Program, which both gain from the committee members' range of expertise. Our thanks go to the 2011-12 Executive Committee:

- Prof. Shaun Kennedy, BSE (Director, National Center for Food Protection and Defense)
- Prof. Mike Kilgore, PhD (Director of Graduate Studies, Department of Forest Resources)
- Prof. Michael T. Osterholm, PhD, MPH (Director, Center for Infectious Disease Research & Policy)
- Prof. Michael Sadowsky, PhD (Director, BioTechnology Institute)
- Prof. Brian Van Ness, PhD (Director, Institute of Human Genetics)

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Consortium on Law and Values in Health,
Environment & the Life Sciences
Joint Degree Program in Law, Health & the Life Sciences
University of Minnesota Law School
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To receive additional copies of this publication, send a request to jointdgr@umn.edu or call (612) 625-0055.

The University's mission, carried out on multiple campuses and throughout the state, is threefold: research and discovery, teaching and learning, and outreach and public service.

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▼ Mihail Roco, PhD, Senior Advisor for Nanotechnology at the National Science Foundation, spoke at the conference "Nanadiagnostics and Nanotherapeutics: Building Research Ethics and Oversight."

You can watch and listen to Dr. Roco deliver his remarks at z.umn.edu/roco



Mihail C. Roco, PhD
NATIONAL SCIENCE FOUNDATION

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2011-12 ANNUAL REPORT NOW ONLINE

This year, you'll be able to view our annual report at its own site—lawvalue.umn.edu/AR11. Please visit our web version to get expanded content, easy links, fast access to select pages, and the ability to forward information to others interested in our work.

OUR THANKS TO YOU

The Consortium's success would not be possible without the contributions of our tremendous students, staff, key administrators, faculty, and alumni, and the leadership of Provost Karen Hanson.

We're grateful to the individuals and programs that support us and to our collaborators in our community and around the world. Thank you for your role in making us a top interdisciplinary program at the University of Minnesota and a leading voice on law, values, and science.

Using a joint degree to solve environmental problems

Joe Dammel, JD, MS candidate in Science, Technology, and Environmental Policy

"As an undergrad, I worked at an oil refinery and got exposure to being a water quality compliance engineer," says Joe Dammel. "It was very interesting, but I realized it would be more interesting to focus on why the regulations were in place than trying to react to them. So I came to law school with the intention of doing environment and energy law."

Between college and starting law school, and with a BS in environmental engineering from Michigan Tech, Dammel worked for the Union of Concerned Scientists on carbon capture and storage. When he got to law school, he learned that Prof. Elizabeth Wilson at the Humphrey School's Center for Science, Technology and Public Policy (CSTPP) was working on that issue and was looking for a research assistant. Dammel applied and she hired him.

CSTPP supports an MS in Science, Technology, and Environmental Policy and is a JDP partner program. Dammel had been thinking of a joint degree and this particular JD/MS pairing seemed especially right for him. He joined the JDP in 2010 after his first year of law school, and is scheduled to graduate in 2013.

This year, Dammel received a Charles N. Nauen Award for Excellence in Environmental and Energy Scholarship for his Note on the regulation of hydraulic fracturing in the *Minnesota Journal of Law, Science & Technology* vol. 12, no. 2. Going forward, he wants to combine his expertise in engineering, the social sciences, and law to forge coherent policies that will help solve environmental problems.

"Industry generally wants to protect the environment, but it needs to be prodded at times," says Dammel. "I think the legal system is the best way we have—one of the only ways we have—to do that."

JOE DAMMEL



▲ JDP student Joe Dammel, JD, MS candidate in Science, Technology, and Environmental Policy, right, with JDP Advisory Board member Skip Humphrey, former Minnesota Attorney General and now head of the Office of Older Americans at the Consumer Financial Protection Bureau.



A MESSAGE FROM THE FOUNDING CHAIR

Dear Colleagues:

As I write this, scientists have just announced the first successful computer simulation of the inner workings of an entire organism, the nation continues to react to the Supreme Court's decision on health care reform, and much of the country is coping with record heat and drought, prompting yet more concern over climate change. The problems that we deal with at the University of Minnesota's **Consortium on Law and Values in Health, Environment & the Life Sciences** have never been more important—problems at the intersection of biomedicine, the life sciences, and society.

The 2011-12 academic year has been a big one for us. Our **NIH-funded project on "Managing Incidental Findings and Research Results in Genomic Biobanks and Archives"** published two blockbuster symposia: a collection of 20 articles in the April '12 issue of *Genetics in Medicine* and then nine more articles in the Spring '12 issue of the *Minnesota Journal of Law, Science & Technology (MJLST)*. The centerpiece of both efforts was a major article offering our project's consensus recommendations on how to handle the return of individual research results and incidental findings to individuals whose DNA and genomic data are archived in biobanks and used in research over time. Both *Nature* and *Science* carried news articles on this publication. The project was a collaboration with partners all over the country and Canada. And our work on return of results continues through a **new NIH-funded project with the Mayo Clinic on return of incidental findings to family members** and our participation in NIH's new **Return of Results (RoR) Consortium**. In addition, I am beginning work on a book and articles funded by a 2-year **Robert Wood Johnson Foundation (RWJF) Investigator Award in Health Policy Research**.

We also are now completing an **NIH-funded project on the ethics of nanomedicine research** in human beings. This ARRA Challenge grant is an opportunity for our project group to think systematically about when human subjects research on emerging technology calls for additional oversight beyond the baseline created by the DHHS Common Rule and FDA equivalent. The project also allows us to consider how concerns over occupational, bystander, and environmental exposures should bear on review of human subjects research.

Our events this year featured **Ezekiel Emanuel, MD, PhD, on health care reform**, as well as a **series on the international challenges of food safety**. In April, we competitively awarded more than \$100,000 to **University students and faculty** to catalyze campus-wide work on the

Professor Susan M. Wolf

McKnight Presidential Professor of Law, Medicine & Public Policy

Faegre Baker Daniels Professor of Law

Professor of Medicine

Founding Chair, Consortium on Law and Values in Health, Environment & the Life Sciences

Founding Director, Joint Degree Program in Law, Health & the Life Sciences

societal issues raised by biomedicine and the life sciences, pushing our historical total awarded well past \$1 million. When it came to the research based at the Consortium, we received more than \$2.7 million in grants this year, adding to the \$6 million we've received since our founding in 2000.

Our unique **Joint Degree Program in Law, Health & the Life Sciences** helped the University of Minnesota Law School again achieve a *U.S. News & World Report* **top-10 ranking for Health Law**. The JDP graduated five more students this year, for a **total of 45 alumni professionals** specifically educated to address the increasingly urgent social issues at the intersection of law, ethics, and science.

Our *Minnesota Journal of Law, Science & Technology* published a volume exploring issues as diverse as Internet-filtering in China, authentication of social-networking evidence in litigation, medical device regulation, and even what it means to be human in an era of synthetically created organisms and the possibility of human-animal chimeras. *MJLST* is now ranked by the Washington and Lee law journal ranking system as top-5 to top-10 in all four subject matter areas in which we publish.

These are just a few of the collaborations and accomplishments that marked the 2011-12 academic year, thanks to our spectacular staff, students, faculty colleagues, and collaborators around the world. As the new academic year begins, I prepare to go on my very first sabbatical, in order to focus on research and grants. We began building the Joint Degree Program and Consortium together in 1998-99. We have created a vibrant community dedicated to exploring the pressing issues posed by biomedicine and the life sciences and finding solutions. After more than a dozen years of working with you to build these programs, I look forward to concentrating on scholarship and projects, while welcoming new colleagues into administrative and leadership roles.

Our program continues to thrive. In the pages that follow, you'll find more about what we've accomplished together and what we plan for the coming year, including a new Consortium Forum on Health Care Reform and a national conference on energy and the environment. Thank you for the truly essential part you've played in our collaborative success. Every day brings new issues at the intersection of law and values, biomedicine, and the life sciences. We look forward to taking on the challenges ahead!

With warm gratitude,

Susan M. Wolf

2011-12 Events

Each year, we invite leading experts to the University of Minnesota to help us think in new ways about issues at the intersection of science, law, and society. The conferences and lectures we sponsor focus on emerging issues to help students, faculty, legislators, legal and medical professionals, and the public stay ahead of quickly evolving issues in biomedicine and the life sciences.



▲ Our annual conference in Fall 2011, **“Nanodiagnosics and Nanotherapeutics: Building Research Ethics and Oversight,”** tackled the challenge of protecting human participants in nano-medicine product research. **Samuel A. Wickline, MD**, Washington University Professor, Director of the Consortium for Translational Research in Advanced Imaging and Nanomedicine, and project member, opened the conference by addressing the **“Translation of Nanotherapeutics and Nanodiagnosics to Clinical Practice.”**



Full conference videos are archived for public access at lawvalue.umn.edu/nano

▼ **Ezekiel J. Emanuel, MD, PhD**, University of Pennsylvania Professor and one of the architects of the Affordable Care Act, provided an insider's view of efforts to improve health care delivery in his talk, **“Health Care Reform and the Future of American Medicine”** for the **Deinard Memorial Lecture on Law & Medicine** on January 25.



▼ For our two-part **Lecture Series on Law, Health & the Life Sciences**, we chose **“Food Safety: Coping with Domestic & International Challenges”** as this year's focus. **Robert Brackett, PhD**, Director and Vice President of the National Center for Food Safety and Technology, Illinois Institute of Technology, explained the workings of the Food Safety Modernization Act, the most comprehensive overhaul of U.S. food safety laws in over 70 years. **Jørgen Schlundt, PhD**, in photo below, Deputy Director of the National Food Institute, Technical University of Denmark, provided an international perspective on how to develop global food safety regulations.



Prof. Brackett's and Prof. Schlundt's lecture videos are archived for public access at lawvalue.umn.edu/foodsafety



► Consortium Associate Director of Law, Geography & Environment, **Hari Osofsky, JD**, brought together participants from around the country for the workshop, **New Directions in Environmental and Energy Law, Policy, and Geography** in May 2012. Exploring issues such as the challenge of integrating environmental, energy, climate, and economic policies and the question of who makes decisions in interstate energy transmissions, the workshop sets the stage for a major conference in Spring 2013—**“Legal and Policy Pathways for Energy Innovation.”**



Supporting our partners



This year's Consortium-sponsored lecture series, 'Food Safety: Coping with Domestic & International Challenges,' enabled our center to bring to campus two internationally known leaders in the food system: the former Director of the Department of Food Safety and Zoonoses for WHO (Jørgen Schlundt, PhD), and the former Director of the FDA's Center for Food Safety and Applied Nutrition (Robert Brackett, PhD). Their lectures supported the outreach and University community engagement goals of NCFPD, but even more valuable was the time each speaker spent with faculty members and students in support of our research and education programs.”

—Shaun Kennedy, BSE
Director, National Center for Food Protection and Defense (NCFPD),
a Consortium member center
Associate Professor, Veterinary Population Medicine

Looking Ahead to 2012-13

This coming year we will delve more deeply into health care reform and continue our work on neuroscience and the law, as well as environmental and energy issues. Through our annual conference, lecture series, and informal forums, we hope to generate new insights and encourage collaborative thinking.



▲ Health care reform is exactly the kind of big, interdisciplinary issue that demands the Consortium's attention. In the photo above, people in Oklahoma City march to the state capitol building in support of the Affordable Care Act in 2009. In the three years since then, the issue of health care reform has remained controversial despite the Supreme Court ruling in June.

Health Care Reform Consortium Forum on Health Care Reform

Beginning on October 15, Law School Professors **Amy Monahan** and **Dan Schwarcz** will hold a series of meetings to encourage discussion and interaction among people across the University. Drawing faculty and staff from the School of Public Health, Carlson School of Management, Law School, Humphrey School of Public Affairs, and Medical School, the forum will strive to forge new collaborations and advance interdisciplinary work on the thorny issues of health care reform.

Deinard Memorial Lecture on Law & Medicine

Slouching Toward Health Reform: The Future of the Affordable Care Act

Thursday, January 31, 2013
11:30am–1pm
Cowles Auditorium, Humphrey School of Public Affairs

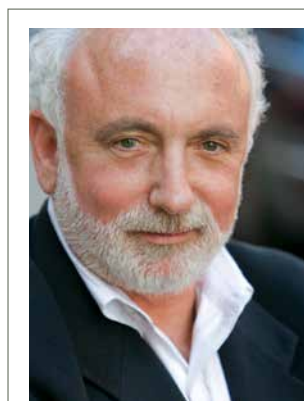
Sara Rosenbaum, JD, George Washington University's Harold and Jane Hirsh Professor of Health Law and Policy, will give this year's Deinard lecture on the battle over the Affordable Care Act and the array of system-based, practical, market, policy, political, and social challenges that lie ahead as the process of implementation moves toward January 1, 2014.

Neuroscience & Public Policy

Lecture Series on Law, Health & the Life Sciences

Should the Science of Adolescent Brain Development Inform Legal Policy?

Thursday, November 15, 2012
11:30am–1pm
Coffman Memorial Union Theater



▲ **Laurence Steinberg, PhD**, Distinguished University Professor and Laura H. Carnell Professor of Psychology at Temple University, will address whether burgeoning research on adolescent brain development should influence legal policy.

Neuroeconomics and the Governance of Choice

Thursday, February 28, 2013

11:30am–1pm

Cowles Auditorium,

Humphrey School of Public Affairs



▲ **Natasha Dow Schüll, PhD**, Associate Professor, Program in Science, Technology, and Society, MIT, will talk about the new field of neuroeconomics, how the brain makes choices, and whether the government can influence human decision making.

Energy & the Environment Consortium Forum on Energy & the Environment

Associate Director of Law, Geography & Environment, **Prof. Hari Osofsky, JD**, will continue to lead this University-wide gathering that fosters research partnerships and investigates issues of importance concerning energy and environmental policies.

Consortium annual conference—Spring 2013

Legal and Policy Pathways for Energy Innovation

Our annual conference will bring together leading scholars and key policymakers to focus on four areas of core concern—the future of clean energy infrastructure, environmental and energy governance, environmental and energy justice, and sustainable cities and metropolitan regions.

For information on these events, go to lawvalue.umn.edu or call our office at 612-625-0055.

Science into action



“No scientific result or study outcome makes any difference in improving the lives of humans, animals, plants, or the environment, if it can’t be used to produce consequential policies and actions. The Consortium represents one of the ultimate examples of ‘connecting the dots’ in a modern world. It’s the ground-zero intersection of science, law, and values. The Center for Infectious Disease Research and Policy was created to provide a place where front-line research of critical infectious disease issues of the day can quickly and effectively be translated into meaningful public policy. The Consortium is one of our most valued partners in supporting this process.”

—Michael Osterholm, PhD
Director, Center for Infectious Disease Research and Policy (CIDRAP), a Consortium member center
Professor of Environmental Health Sciences, School of Public Health
Adjunct Professor, Medical School

Consortium intramural research awards top \$1 million



This year we passed the \$1 million mark in Consortium funds awarded to University of Minnesota faculty and to graduate and professional students for intramural projects related to the societal implications of problems in health, environment, and the life sciences. In the past 10 years, more than a third of the projects addressed environmental issues, as does one of this year’s winners, ***What’s in the Frogs’ Water? Atrazine Concentration in Wetlands and Associated Landscape Factors***

in the Upper Midwest—Jennifer Olker, PhD student, Integrated BioSciences Graduate Program.

A selection of other 2011-12 awards:

Faculty award:

Ethical Expectations for Social Robots: A Cross-Sector Exploration—Steve Kelley, Leili Fatehi, Center for Science, Technology, and Public Policy (\$25,848)

Graduate and professional students awards:

Microturbines and “Cost-Free” Electricity in Rural Honduras: But for Whom...and For How Long? A Spatial Analysis of Marginalization and Empowerment—Jeff DeGrave, PhD student, Geography (\$7,850)

Genetic Counseling in South Africa: Comparison and Analysis of Session Goals between Patients and Genetic Counselors: A Two Part Investigation—Emily Sandberg, PhD, MS student, Genetic Counseling (\$9,962)

Frontline Youth Work with Street Children and Youth in Nepal: Edge Work, Boundary Work, Hard Work—Sheetal Rana, PhD student, Social Work (\$9,618)

View all awards at lawvalue.umn.edu/rfps

Consortium Research—The power of interdisciplinary collaboration

Some of the toughest questions in the 21st century are those posed by science and technology. A flood of innovations challenges our ability to make wise decisions. Meanwhile, global problems such as climate change beg for new answers. The Consortium, with its broad reach across disciplines, addresses the social, legal, and ethical implications of biomedicine, the life sciences, and environmental studies.

Our work helps the University of Minnesota fulfill its mission as a public, land-grant institution leading not just in science and biomedicine, but also in analysis of societal challenges. We are working to develop solutions. The Consortium has received multiple grants from NIH, NSF, and private foundations allowing us to conduct cutting-edge research and generate recommendations in four main areas in 2011-12:

- **Genetic and genomic research: return of results & incidental findings**
- **Oversight of nanobiotechnology and nanomedicine human subjects research**
- **Neuroscience and the emerging field of neurogenomics**
- **Environmental issues, and the legal and social challenges they pose**



Genetic and genomic research: return of results & incidental findings

“The return-of-results debate raises huge issues—how we conduct human subjects research, its relationship to clinical care, and what we owe the individuals generous enough to contribute their own specimens and data. What started as a small debate when we began our first funded project on this topic, has grown to be a world-wide conversation with big implications.”

—Susan Wolf, JD, Founding Chair of the Consortium on Law and Values in Health, Environment & the Life Sciences

The Consortium played a key role in beginning what is now a major debate over the return of individual research results and incidental findings to participants in human subjects research. NIH Director Francis Collins has called this issue “*one of the thorniest current challenges in clinical research.*” (Gina Kolata, “Genes Now Tell Doctors Secrets They Can’t Utter,” *New York Times*, August 25, 2012.)

The Consortium first tackled this issue in 2005 with an NIH/NHGRI grant, published our project’s recommendations in 2008, and quickly became a leading source of research and information on this subject.

In May 2011, our latest project group of top experts from the U.S. and Canada, including Isaac Kohane, MD, PhD, and Robert Green, MD, MPH, presented *the first comprehensive recommendations on return of results and incidental findings in biobank research* at our conference in Bethesda, MD, on “Should We Return Individual Research Results and Incidental Findings from Genomic Biobanks & Archives?”



Conference information and videos available at lawvalue.umn.edu/irrif.



Genetics in Medicine published the first comprehensive recommendations on return of results and incidental findings in biobank research, which were generated by a Consortium-led project.

In April 2012, we published our symposium in *Genetics in Medicine* and our high-impact consensus recommendations article garnered extensive news coverage, including on the *Science* and *Nature* websites. In May, we published a second symposium in the *Minnesota Journal of Law, Science & Technology*.

We're continuing to do leading work on this issue through an NIH-funded project with the Mayo Clinic on the question of whether an individual's results should ever be offered to their family and genetic kin. Thanks to that grant, we've joined NHGRI's new Return of Results (RoR) Consortium. In addition, Founding Chair Susan Wolf has been awarded a 2-year Robert Wood Johnson Foundation (RWJF) Investigator Award in Health Policy Research to produce a book and articles on the legal, ethical, public health, and policy implications of the debate over return of results.

OUR GENETIC & GENOMIC RESEARCH TRAJECTORY

2012-14

Translating Research Into Health Benefits: Returning Research Results & Incidental Findings
Robert Wood Johnson Foundation (RWJF) Investigator Award in Health Policy Research;
Susan Wolf, PI

2012 Spring

Debating Return of Incidental Findings and Research Results in Genomic Biobank Research—Law, Ethics, and Oversight
Symposium in the *Minnesota Journal of Law, Science & Technology*, vol. 13, no. 2;
mjlst.umn.edu

2012 April

Returning Incidental Findings and Research Results in Genomic Research with Biobanks & Archives
Symposium in *Genetics in Medicine*, nature.com/gim/journal/v14/n4/index.html

2011-16

Disclosing Genomic Incidental Findings in a Cancer Biobank: An ELSI Experiment
NIH/NCI/NHGRI # 1-R01-CA154517; Gloria Petersen, Mayo Clinic;
Barbara Koenig, UCSF; Susan Wolf, UMN, PIs

2011 May

Should We Return Individual Research Results and Incidental Findings from Genomic Biobanks & Archives?
Conference in Bethesda, MD

2009-11

Cutting-Edge Policy Issues in Reprogenomics: Revamping the Law, Ethics & Policy Governing Genomic Biobanks and Assisted Reproductive Technology
Robina LaPPS Research Funding, University of Minnesota Law School grant; Susan Wolf, PI

2009-11

Managing Incidental Findings and Research Results in Genomic Biobanks & Archives
NIH/NHGRI #2-R01-HG003178; Susan Wolf, PI; Jeff Kahn, Frances Lawrenz, Brian Van Ness, Co-Is

2008 Summer

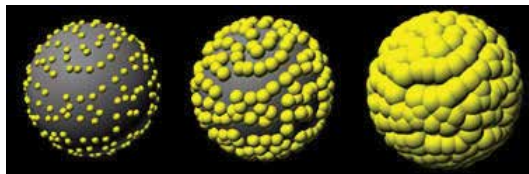
Managing Incidental Findings in Human Subjects Research
Symposium in the *Journal of Law, Medicine & Ethics*, vol. 36, no. 2

2005-07

Managing Incidental Findings in Human Subjects Research
NIH/NHGRI #1-R01-HG003178; Susan Wolf, PI; Jeff Kahn, Frances Lawrenz, Charles Nelson, Co-Is

Oversight of nanobiotechnology & nanomedicine in human subjects research

(Courtesy of Naomi Halas)



Small islands of gold are attached to tiny silica particles to form gold nanoshells. When injected into mice models, these nanoshells mark cancer micrometastases for imaging. Then when exposed to infrared light, they heat up and kill the tumors.

Nanotechnology holds tremendous promise in a wide range of fields. Our work has focused on nanobiotechnology and nanomedicine. In 2006, we received our first NSF grant to analyze oversight of nanobiotechnology. In 2009, we were awarded an ARRA Challenge grant from NHGRI at NIH to develop the first comprehensive recommendations on how to protect human participants in nanomedicine research involving nanotherapeutics and nanodiagnostics.

Our September 2011 conference, “Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight,” which grew out of the NIH grant, brought together top nanotechnology scholars and researchers, such as Mihail Roco, PhD, and Andrew Maynard, PhD, to explore questions such as:

- Does some nanomedicine research pose heightened risks?
- What are the special challenges in obtaining informed consent for nanomedicine research?
- How should occupational, bystander, and environmental risks be considered in deciding whether to authorize research protocols in nanomedicine?

In addressing those questions and others, we presented our project’s draft of the *first systematic and comprehensive recommendations on protecting human participants in research on nanomedicine products*.

These recommendations will be published in the Winter 2012 issue of the *Journal of Law, Medicine & Ethics*, as part of a larger symposium that our project has produced.



Full conference videos are archived at lawvalue.umn.edu/nano



“The one thing that does strike me as being genuinely different in the discussion here is the focus on occupational health and environmental issues as an aspect of nanomedicine risk assessment,” said R. Alta Charo, JD, a professor of law and bioethics at the University of Wisconsin Law School, at the conference in Minneapolis.

(As reported in *Nature* online, September 28, 2011) ▲

OUR NANOBIOTECHNOLOGY & NANOMEDICINE RESEARCH TRAJECTORY

2012 Winter

Symposium on the ethics of nanomedicine research in human beings
to be published in the *Journal of Law, Medicine & Ethics*

2011 September

Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight (Conference)

2011 April

Special Focus: Governance of Nanobiotechnology
Symposium in the *Journal of Nanoparticle Research*, vol. 13, no. 4,
springerlink.com/content/1388-0764/13/4/

2010 April

Governing Nanobiotechnology: Reinventing Oversight in the 21st Century (Conference)

2009-12

Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight
NIH/NHGRI ARRA Challenge grant #1-RC1-HG005338-01; Susan Wolf, PI;
Ralph Hall, Jeff Kahn, Jeff McCullough, Co-Is

2009 Winter

Developing Oversight Approaches to Nanobiotechnology: The Lessons of History
Symposium in *Journal of Law, Medicine & Ethics*, vol. 37, no. 4, onlinelibrary.wiley.com/doi/10.1111/jlme.2009.37.issue-4/issueetoc

2006-11

NIRT: Evaluating Oversight Models for Active Nanostructures and Nanosystems:
Learning from Past Technologies in a Societal Context
NSF #SES-0608791; Susan Wolf, PI; Efrosini Kokkoli, Jennifer Kuzma, Jordan Paradise,
Gurumurthy Ramachandran, Co-PIs

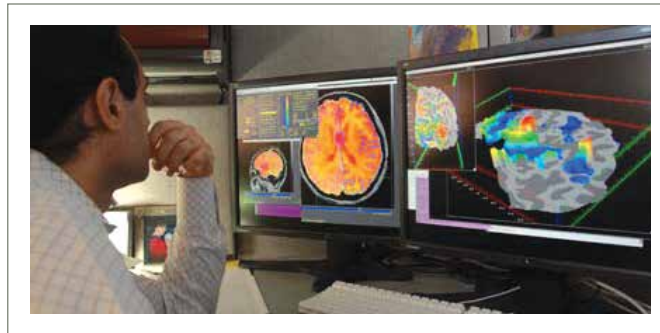
Neuroscience and the emerging field of neurogenomics

Recently, *Science* published research showing that judges given a hypothetical case to consider gave the perpetrator a shorter sentence if they heard evidence of “abnormalities in [his] brain function that may undermine the normal human aversion to inflicting harm on others.” (*Science*, vol. 337, no. 6093, August 17, 2012) According to the article, the finding surprised the researchers.

Just how neuroscience, genomics, and the new field of neurogenomics will influence the law is still a big question, as technology develops even more sophisticated ways to identify and track how the brain works.

In 2007, the Consortium began to explore this new frontier with a grant from The Greenwall Foundation on **Emerging Problems in Neurogenomics: Ethical, Legal & Policy Issues at the Intersection of Genomics & Neuroscience**. From 2007 to 2010, Consortium Chair Susan Wolf participated in the MacArthur Foundation’s Project on Law and Neuroscience, based at UC Santa Barbara. Wolf received a subaward to study the use of neuroscience in the courts, as reflected in published decisions, and to compare the use of behavioral genetics.

In 2012-13, the Consortium’s annual Lecture Series on Law, Health & the Life Sciences will focus on the implications of neuroscience for public policy. Development of this year’s series has been led by Consortium members **Steve Kelley, JD**, Center for Science, Technology



◀ Functional magnetic resonance imaging (fMRI) measures brain activity by monitoring changes in blood flow.

& Public Policy, and **Profs. Michael Georgieff**, Center for Neurobehavioral Development, and **Akshay Rao**, Carlson School of Management.

In the first lecture, Temple University Professor **Laurence Steinberg, PhD**, an internationally known expert on psychological development during adolescence, will address whether brain science can, and should, inform debates about how adolescents should be

treated under the law. In the second lecture, cultural anthropologist and MIT Professor **Natasha Dow Schüll, PhD**, will talk about why humans value the present at the expense of the future and how that makes it difficult to put policies and regulations into place to govern decision-making.

OUR NEUROSCIENCE RESEARCH TRAJECTORY

**February 2013
November 2012**

Profs. Laurence Steinberg and Natasha Dow Schüll will address neuroscience and human behavior
Lecture Series on Law, Health & the Life Sciences

2008-09

How Should Neuroscience Change Law? Lessons from the Impact of Genetics and Emerging Convergence of Genomics and Neuroscience
Subaward from the MacArthur Foundation Project on Law and Neuroscience; Susan Wolf, subaward PI

2008

Emerging Problems in Neurogenomics: Ethical, Legal & Policy Issues at the Intersection of Genomics & Neuroscience (*Conference*)

2007-08

Emerging Problems in Neurogenomics: Ethical, Legal & Policy Issues at the Intersection of Genomics & Neuroscience
Greenwall Foundation grant; Susan Wolf, Jeff Kahn, Harry Orr, PIs

Environmental issues, and the legal and social challenges they pose

Facing the immense environmental challenges of this century, including climate change, energy supply and demand, and water use, calls for the interdisciplinary, collaborative thinking that is the Consortium's hallmark.

Our first Lecture Series on Law, Health & the Life Sciences in 2000-01 focused on ecology and biotechnology. We have actively addressed the legal, ethical, and scientific dilemmas involved in devising wise environmental policy ever since.

This past year, the Consortium's Associate Director of Law, Geography & Environment, **Hari Osofsky, JD**, initiated the **Consortium Forum on Energy & the Environment** where faculty from diverse fields explored issues and potential partnerships, including joint grant applications and writing projects.

In May 2012, Prof. Osofsky gathered leading thinkers from around the country, including **Dan Farber, JD**, UC Berkeley; **Ann Carlson, JD**, UCLA; **Rebecca Hardin, PhD**, University of Michigan; and

Victor Flatt, JD, UNC, for the workshop, **New Directions in Environmental and Energy Law, Policy, and Geography**. Participants examined topics such as climate change adaptation and building

new energy transmission lines. The workshop served as an incubator for future collaboration, including the spring 2013 conference, "**Legal and Policy Pathways for Energy Innovation.**"

OUR ENVIRONMENT & POLICY RESEARCH TRAJECTORY

Spring 2013

Legal and Policy Pathways for Energy Innovation (Conference)

2012 May

New Directions in Environmental and Energy Law, Policy, and Geography (Workshop)

2011-12

Prof. Hari Osofsky initiates Consortium Forum on Energy & the Environment

2010-11

From Climate Change to the Gulf Oil Spill: Law and Science in Times of Crisis, with lectures by Profs. Dan Farber, JD, and Daniel Bodansky, JD, Lecture Series on Law, Health & the Life Sciences

2005-06

Energy and the Environment: Science, Ethics & Policy
Lunch Series on the Societal Implications of the Life Sciences

2004

Environmental Threats to Children's Health: Legal and Policy Challenges (Conference)

2004

Intellectual Property Rights for the Public Good: Obligations of U.S. Universities to Developing Countries
Conference and symposium in the *Minnesota Journal of Law, Science & Technology*, focusing on agricultural and intellectual property

2003-04

Food, Animal Protection, and the Land
Lunch Series on the Societal Implications of the Life Sciences

2000-01

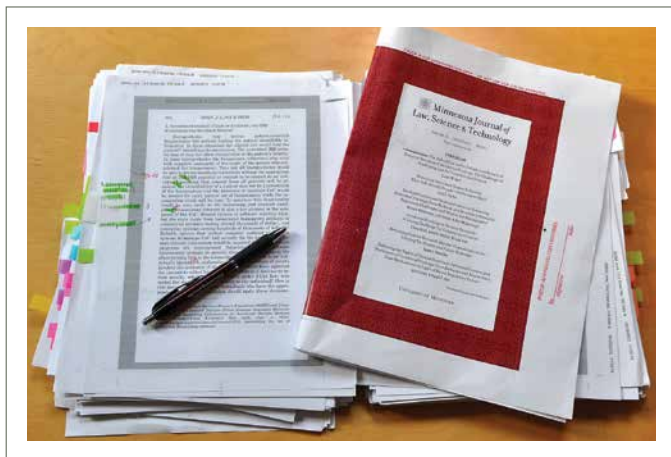
Ecology and Biotechnology
Lecture Series on Law, Health & the Life Sciences



▲ The Consortium explores issues such as federal and inter-state cooperation in alternative energy transmission.

Minnesota Journal of Law, Science & Technology

The Consortium oversees the **Minnesota Journal of Law, Science & Technology (MJLST)**—a top interdisciplinary journal publishing leading work on issues at the intersection of law, science, and technology. The journal is jointly edited by law students and by faculty from across the University of Minnesota.



This year, the journal welcomed **Prof. Ralph Hall, JD**, as Faculty Editor-in-Chief, and **Steven Kranz, JD**, as Managing Editor. The 2011-12 Student Editor-in-Chief was **Joe Dammel**; the Student Executive Editor was **Michelle Mercer**. To ensure accessibility and impact, *MJLST* is published simultaneously in print and online. Please visit mjlst.umn.edu to read the current issue. This year's volume featured articles tackling issues including:

- Should genomic researchers and biobanks offer individual research results and incidental findings to the people who contribute their specimens and data for research?
- How has social and environmental erosion following the BP blowout had an impact on the Louisiana Coast?
- How should policy makers balance the benefits of tracking online user data against its privacy costs?
- What standards should courts adopt to authenticate blog posts and other social media evidence during litigation?

In 2011, the *Minnesota Journal of Law, Science & Technology* was ranked **among the top ten journals** in each of its subject areas, according to the Washington and Lee University law journal rankings.

- Health, Medicine, Psychology, and Psychiatry
5th out of 71
- Science, Technology, and Computing
7th out of 67
- Environment, Natural Resources, and Land Use
7th out of 88
- Intellectual Property
10th out of 80

Washington and Lee also named *MJLST* as **the top subscription value** among journals in those same categories, measured by the number of times the journal is cited annually compared to the cost of a subscription.

The journal's interdisciplinary range is due to our roster of contributors, which combines established scholars at the top of their field with emerging authors presenting fresh perspectives.

Looking ahead to the coming year, *MJLST* will publish articles on the limits of bureaucratic control of cyber-threats, whether the possibility of two genetically distinct "chimeric" cell lines in a single organism can thwart DNA identification of criminals, and the danger of applying the precautionary principle to information technology. Full-volume subscriptions are \$20 (two issues per volume). You can subscribe at mjlst.umn.edu or email the journal at mjlst@umn.edu.

Daily dose

The reach and impact of the journal was recently extended when *MJLST* joined the world of social media. With the launch of its LawSci Blog and Twitter feed, the journal now brings its innovative perspectives to its audience on a daily basis.

To access the LawSci Blog, Twitter feed, and the new LinkedIn Alumni Group, visit mjlst.umn.edu/SocialMedia.



From *MJLST's* LawSci Blog:

FBI Face Recognition Concerns Privacy Advocates
by Rebecca Boxhorn, JD, Consortium Research Associate,
Former *MJLST* Staff & Editor

Helen of Troy's face launched a thousand ships, but yours might provide probable cause. The FBI is developing a nationwide facial recognition database that has privacy experts fretting about the definition of privacy in a technologically advanced society. The \$1 billion Next Generation Identification initiative seeks to harness the power of biometric data in the fight against crime. Part of the initiative is the creation of a facial photograph database that will allow officials to match pictures to mug shots, electronically identify suspects in crowds, or even find fugitives on Facebook.

Link to the continuation of FBI Face Recognition Concerns Privacy Advocates at mjlst.umn.edu/SocialMedia.

Consortium Faculty Directors

The Consortium links 20 leading centers and programs at the University of Minnesota to address the legal, ethical, and policy implications of biomedicine and the life sciences. Nationally recognized scholars from across the University comprise the faculty of the Consortium. Select Consortium faculty include:



Biomedical Genomics Center

Prof. Kenneth B. Beckman, PhD, Director
*Department of Genetics, Cell Biology,
and Developmental Biology*



Center for Environment & Health Policy

Prof. William Toscano, Jr., PhD, Director
*Professor of Molecular Toxicology
Head, Environmental Health Sciences
Head, Global Health Initiative
Associate Director, Joint Degree Program
in Law, Health & the Life Sciences*



BioTechnology Institute

Prof. Michael Sadowsky, PhD, Director
*Professor, Department of Soil, Water
and Climate*



Center for Infectious Disease Research & Policy

Prof. Michael Osterholm, PhD, MPH, Director
*Professor, Environmental Health Sciences
Adjunct Professor, Medical School
Director, NIH-supported Center of Excellence
for Influenza Research Surveillance*



Center for Animal Health & Food Safety

Prof. Jeffrey Bender, DVM, MS, Dipl. ACVPM, Director
*Professor, School of Public Health,
College of Veterinary Medicine*



Center for Neurobehavioral Development

**Prof. Michael Georgieff, MD, Director
and Founder**
*Professor, Medical School
Professor, Institute of Child Development*



Center for Bioethics

Prof. Debra DeBruin, PhD, Co-Director
*Director of Graduate Studies, Assistant
Professor, Center for Bioethics
Assistant Professor, Medical School*



Center for Science, Technology & Public

Senior Fellow Steve Kelley, JD, Director
Hubert H. Humphrey School of Public Affairs



Prof. Mary Faith Marshall, PhD, FCCM, Co-Director
*Professor, Center for Bioethics
Professor, Medical School*



Center for Spirituality & Healing

Prof. Mary Jo Kreitzer, PhD, RN, FAAN, Director
Professor, School of Nursing



Center for Cognitive Sciences

Prof. Apostolos P. Georgopoulos, MD, PhD, Director
*Director, Brain Sciences Center
Regents Professor
American Legion Brain Sciences Chair
McKnight Presidential Chair in
Cognitive Neuroscience
Professor of Neuroscience, Neurology and
Psychiatry*



Clinical and Translational Science Institute

Prof. Bruce R. Blazar, MD, Director
*AHC Associate Vice President for Clinical and
Translational Science Programs
Director, Center for Translational Medicine
Regents' Professor of Pediatrics, Andersen
Chair in Transplantation Immunology, and
Chief of the Pediatric Blood and Marrow
Transplantation Program*



Healthy Food, Health Lives Institute

Prof. Mindy Kurzer, PhD, Director
Professor, Food Science and Nutrition



Institute of Human Genetics

Prof. Brian Van Ness, PhD, Co-Director
Professor, Department of Genetics,
Cell Biology, and Development



Prof. David Largaespada, PhD, Co-Director
Professor, Depts. of Genetics, Cell Biology,
and Development and Pediatrics



Institute on the Environment

Prof. Jonathan Foley, PhD, Director
Professor and McKnight Presidential Chair,
Department of Ecology, Evolution and Behavior



International Science and Technology Practice and Policy Center

Prof. Phil Pardey, PhD, Director
Professor of Science and Technology
Policy, Department of Applied
Economics



Joint Degree Program in Law, Health & the Life Sciences

Prof. Susan M. Wolf, JD, Director
McKnight Presidential Professor of Law,
Medicine & Public Policy
Faegre Baker Daniels Professor of Law
Professor of Medicine
Chair, Consortium on Law and Values in
Health, Environment & the Life Sciences



Prof. Hari Osofsky, JD
Consortium Associate Director of Law,
Geography & Environment
Associate Professor of Law



Microbial and Plant Genomics Institute

Prof. Nathan Springer, PhD, Director
Associate Professor, Department of Plant
Biology



National Center for Food Protection and Defense

Prof. Shaun Kennedy, BSE, Director
Director of Partnerships and External
Relations, College of Veterinary Medicine
Assistant Professor, College of Veterinary
Medicine



Stem Cell Institute

Prof. Jonathan Slack, PhD, Director
Tulloch Chair in Stem Cell Biology,
Genetics & Genomics
Professor of Genetics and Cell Biology



Water Resources Center

Prof. Deborah Swackhamer, PhD, Co-Director
Charles M. Denny Chair in Science,
Technology, and Environmental Policy,
Hubert H. Humphrey School of Public Affairs
Professor, Environmental Health Sciences



Faye Sleeper, MA
Co-Director

Joint Degree Program in Law, Health & the Life Sciences

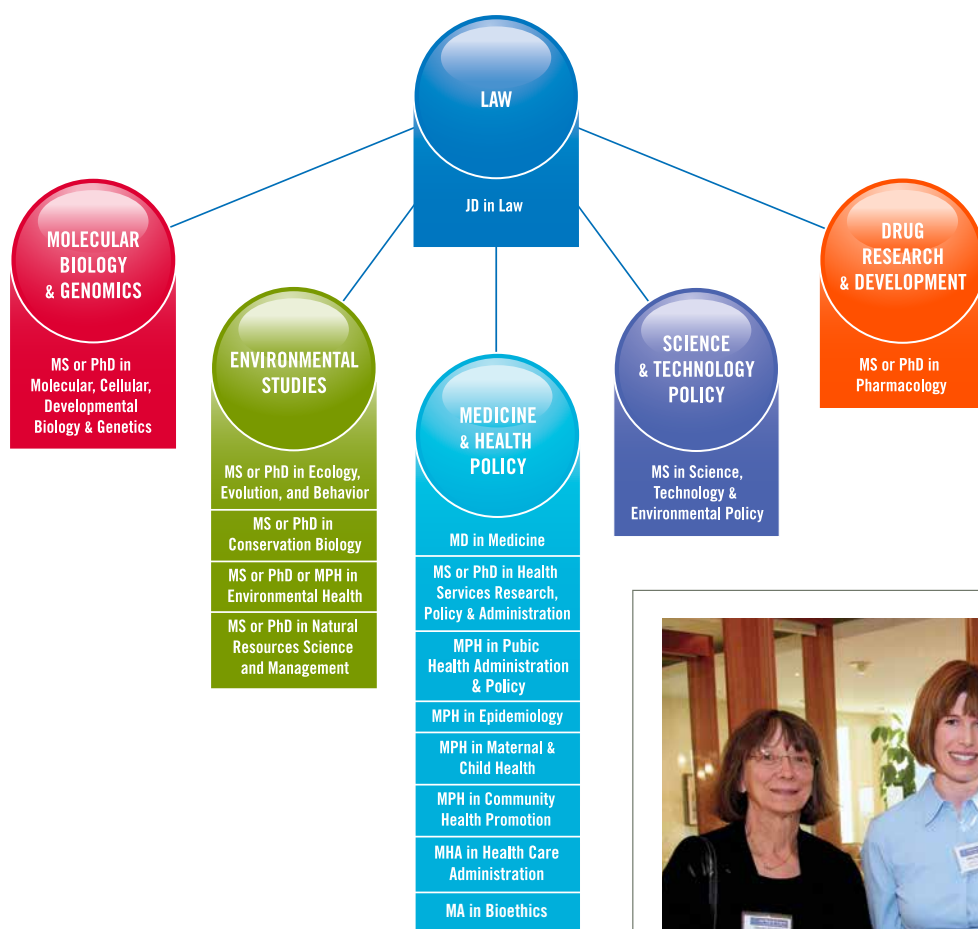
Equipping students to work at the intersection of law and science

The scholarship and success of JDP students, the strength of the program's faculty, and the Consortium's trailblazing research helped the University of Minnesota Law School again achieve a *U.S. News & World Report* top-10 ranking for Health Law in 2012.

The Consortium's Joint Degree Program in Law, Health & the Life Sciences (JDP) is ***the most interdisciplinary and integrated program of its kind in the country***. It allows students to earn a JD and companion degree in the sciences concurrently, in less time, and with more academic support and potentially more financial support than if the students were to pursue the two degrees separately.

We serve more than 40 students directly each year with our Joint Degree Program, JDP Student Fellows program, research assistant positions, and Concentration in Health Law and Bioethics program. To achieve this, we count on the expertise and involvement of more than 400 faculty colleagues across eight colleges at the University of Minnesota.

In Fall 2011, we welcomed three new JDP students and celebrated our graduates. JDP students are prepared to work at the intersection of law and science and to see emerging issues from myriad perspectives. In addition to pursuing rigorous training, they distinguish themselves by winning awards, publishing, and volunteering.



ESSENTIAL GUIDANCE

The Joint Degree Program benefits from the dedication and big-heartedness of our committee members who provide guidance for the program and mentor our students. Our gratitude goes out to our Advisory Board, Governing Committee Consortium members, Consortium Executive Committee, and program faculty.



▲ From left to right: JDP Advisory Board member Margo S. Struthers, JD, Oppenheimer Wolff & Donnelly LLP; JDP students Sally Holthouse and Anne Dwyer, both JD, MPH candidates in Public Health Administration & Policy; and JDP Advisory Board member Judith Walker, JD, Vice President Blue Cross and Blue Shield of Minnesota.

“During the hiring process [at Goodwin Procter], my JD and MS in Molecular, Cellular, Developmental Biology & Genetics were regarded as valuable credentials for patent litigation. As an associate, the additional scientific fluency I cultivated through the Joint Degree Program has regularly proven useful for analyzing prior art publications and working with science advisors and expert witnesses.”

—Laurel Kilgour, JD, MS Molecular, Cellular, Developmental Biology & Genetics ('09)
Associate Attorney, Goodwin Procter

2011-12 honors and achievements include:



▲ Heather Baird

JD, MPH candidate in Public Health
Administration & Policy

Selected as Articles Submissions Editor
for the *Minnesota Law Review*

Awarded a Walter H. Judd International Graduate & Professional Fellowship and an Upper Midwest Human Rights Fellowship to spend a month at medical sites in Nepal to help with data collection, quality initiatives, and community outreach



▲ Lindsay Carniak

JD, MPH candidate in Public Health
Administration & Policy

Awarded a Minnesota Justice Foundation Clerkship to work as a Social Security Law Clerk at the Minnesota AIDS Project

Received a Robina Public Policy Fellowship to work at the Minnesota Department of Human Service (DHS) on the “Roadmap to a Healthier Minnesota,” a report to the Governor and legislature

Joined *Law and Inequality: A Journal of Theory and Practice* as a staff member

Anne Dwyer

JD, MPH candidate in Public Health
Administration & Policy

Received a Book Award as the highest-scoring student in the Law School's Health Insurance & Health Care Reform seminar

Selected to join the *Minnesota Law Review* Board of Editors

Grace Fleming

JD, MA candidate in Bioethics

Received the Upper Midwest Human Rights Fellowship for her work on HIPAA compliance at the Center for Victims of Torture

Selected to join the *Minnesota Law Review* staff

David Hanna

JD, MS candidate in Chemistry

Chosen as Lead Articles Editor for the *Minnesota Journal of Law, Science & Technology*

Received a Charles N. Nauen Award for Excellence in Environmental and Energy Scholarship for his Note to be published in *MJLST* vol. 14, no. 1, “Do Educational Institutions Score High on Their Sustainable Efforts?: A Case Study (and Grade) on Chemical Waste Minimization and Reduction in Teaching and Research Laboratories at the University of Minnesota”

Keli Holzapfel

JD, PhD candidate in Molecular, Cellular, Developmental Biology & Genetics

Selected as Student Editor-in-Chief of the *Minnesota Journal of Law, Science & Technology*

Received the Milne-Brandenberg Travel Award and a Consortium travel award to present a poster at the 6th International Conference on CD1/NKT cells in Chicago



▲ Pari McGarraugh

JD, MPH candidate in Public Health
Administration & Policy

Selected as Managing Editor of the *Minnesota Law Review*

Received Book Awards as the highest scoring student in Administrative Law and Professional Responsibility

Will publish her Note, “Up or Out: Why Sufficiently Reliable Statistical Risk Assessment is Appropriate at Sentencing and Inappropriate at Parole,” in the *Minnesota Law Review*

Sarah Schenk

JD, MPH candidate in Environmental Health

Selected as a staff member of the *Minnesota Law Review*

Won first place in the ABA's 29th Annual Smith-Babcock-Williams Student Writing Competition for her paper about the intersection of CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act) and Chapter 11 bankruptcy. It will be published in *The Urban Lawyer* and *The Federal Lawyer* in 2013.



▲ Rick Weinmeyer

JD, MA candidate in Bioethics

Selected as Editor-In-Chief of the *Journal of Law & Inequality: A Journal of Theory and Practice*

Awarded a summer bioethics intern position at the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Disease, National Institutes of Health



▲ Ashley Zborowsky

JD, MPH candidate in Public Health Administration & Policy

Selected as Note and Comment Editor for the *Minnesota Journal of Law, Science & Technology*

Will publish her Note, "Rethinking Off-Label Regulation in the Wake of *Sorrell v. IMS Health*: Can State Involvement Compensate for Waning FDA Authority to Curb Commercial Free Speech?" in *MJLST* vol. 14, no.2

“The interdisciplinary education I received through the Joint Degree Program enabled me to develop a strong foundation in health law, as well as gain exposure to issues at the forefront of the intersection of law and public health. It provided me with the resources to acquire the skills and information necessary to succeed in my career as a health care regulatory attorney.”

—Taylor Pierce, JD, MPH Public Health Administration & Policy ('11)
Staff Attorney, Cleveland Clinic

Our 2012 Graduates

We are very pleased to announce the 2012 graduating class of the JDP. We are proud of their hard work and scholarship and look forward to their future successes! We congratulate:



Rachel Herder, JD, PhD

- Chris Harvey, JD, MS Conservation Biology. Current position: Intern for the Office of the Solicitor at the U.S. Department of the Interior in Minneapolis
- Rachel Herder, JD, PhD Molecular, Cellular, Developmental Biology & Genetics. Current position: Associate at Wilson Sonsini Goodrich and Rosati in the Life Science Patent Group, Palo Alto, CA
- Elizabeth Karan, JD, MPH Public Health Administration & Policy. Current position: David A. Winston Health Policy Fellow in Washington, DC
- Catherine London, JD, MPH Public Health Administration & Policy. Current position: Associate at Fredrikson & Byron in the Health Law Group, Minneapolis
- Christopher Pinahs, JD, MS Plant Biological Sciences. Current position: Law Clerk for the Honorable David S. Doty, Sr., in U.S. District Court



Elizabeth Karan, JD, MPH



▲ Chris Pinahs, JD, MS, right, with JDP Advisory Board member and University of Minnesota General Counsel, Mark Rotenberg.



▲ Catherine London, JD, MPH, right, with her mother, Barbara London, at the JDP graduation reception.

Program and Scholarship Support

Because of the Consortium and Joint Degree Program, the University of Minnesota has become a leading institution pioneering interdisciplinary training and research on the societal implications of the life sciences. Private contributions allow us to expand our unique programming, research, and scholarship. We invite you to participate in our success.

Where your gifts are needed:

Joint Degree Program Student Support

Although the JDP saves students money by streamlining the route to two degrees, total tuition costs per student can range from \$110,000 to \$175,000, depending on what degree a student pairs with a JD. Scholarship funding can ease a student's debt burden, help us attract top students, and allow the JDP to be accessible to those from diverse financial backgrounds. Please consider contributing to the **JDP Student Scholarship Fund**, or establishing your own fund.

PHYLLIS KAHN



▲ JDP student Erik Nyre, right, with Minnesota State Representative Phyllis Kahn, who established the Kahn Scholarship in Law & Science with her husband, Donald Kahn. Rep. Kahn has been a member of the JDP Advisory Board and is a strong supporter of our unique law and science program.



Conferences & Lectures

Consortium events offer debate on pressing issues in science, law, and medicine and are open to the public free of charge or at very low cost. Our events are videotaped and archived for public access on our website. By supporting the **Consortium Fund for Conferences and Lectures**, you will allow us to bring national scholars to the University, give students a broader view of issues at the intersection of law and science, and help us offer continuing education credits—CLE and CME—and Responsible Conduct of Research credits to professionals across the University and Twin Cities.

Minnesota Journal of Law, Science & Technology (MJLST)

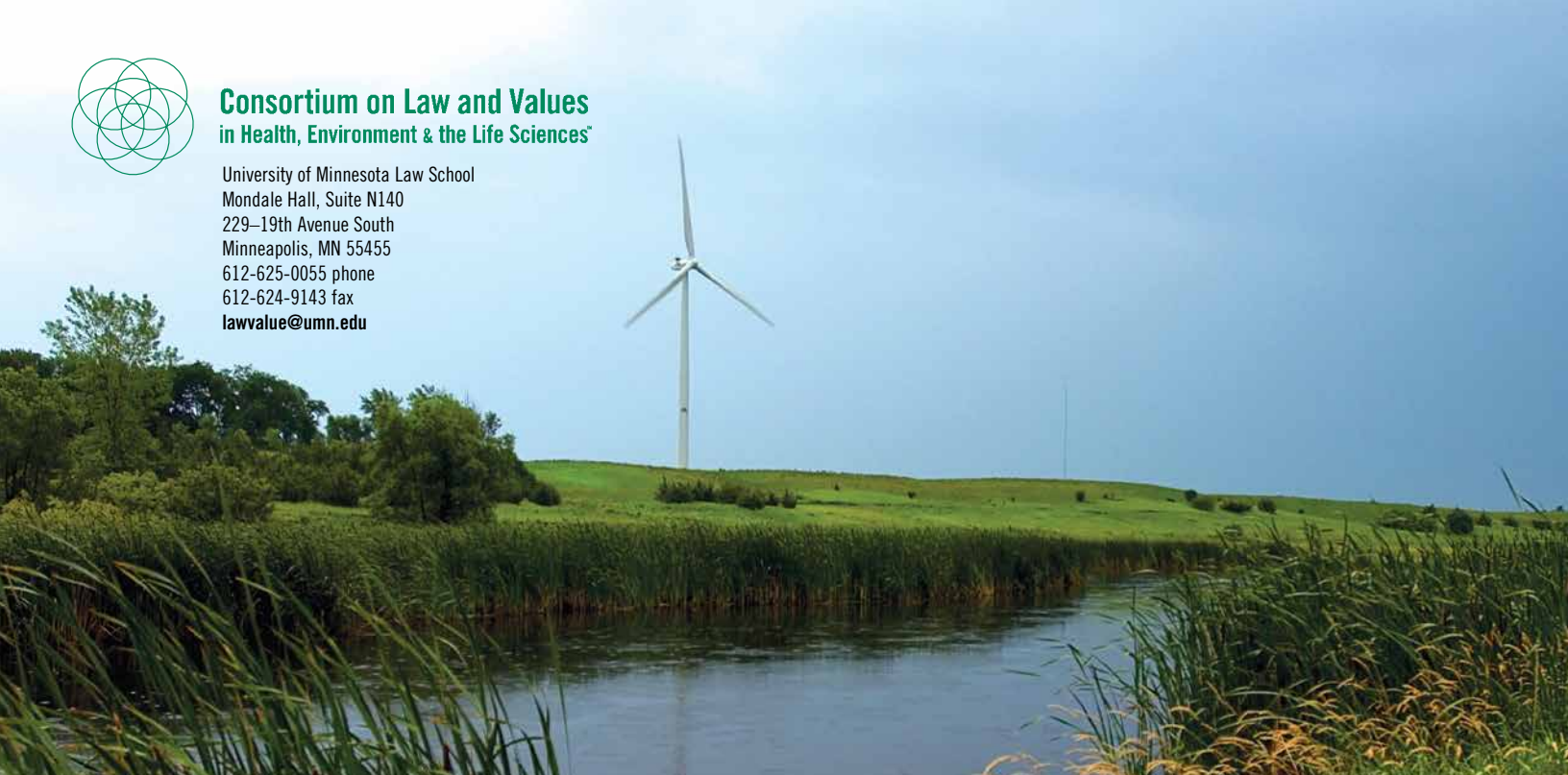
The *Minnesota Journal of Law, Science & Technology* is fast becoming a leading interdisciplinary publication and, in 2011, was ranked a top-10 law journal in each category in which we publish. The support of donors is vital in helping *MJLST* further its commitment to excellence.

To learn more about supporting the JDP, Consortium, or *MJLST*, please contact Associate Program Director Carol Rachac at 612-625-3356 or at crachac@umn.edu



Consortium on Law and Values in Health, Environment & the Life Sciences*

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2011-12 ANNUAL REPORT

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Environment & the Life Sciences and Joint Degree Program in Law,
Health & the Life Sciences, University of Minnesota.

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catalogs, brochures, newsletters, conference materials, or publications) please contact us.

