The Evolution of Scholarship on the Cutting Edge

In the Fall of 2003, we devoted an issue of the Law & Health Care Program (L&HCP) newsletter to Scholarship on the Cutting Edge. In the introduction to that issue – which focused on the work of our faculty – we noted that “the field of health law offers a multitude of issues for thought-provoking scholarship ranging from whether or not to allow human cloning or whether to regulate IVF and genetic testing … to health insurance and fraud and abuse.” Over a decade later, these same issues continue to raise bedeviling and complex questions as science develops and the health care system evolves. As the L&HCP enters its 30th year of existence, cutting edge scholarship is still at the forefront of our program. This pursuit is enhanced by the synergistic effect that having a critical mass of health law scholars in one place creates. As our faculty...
has grown, so has the breadth of the health law topics we study. This has created valuable intersections that are reflected in our scholarship, teaching, and in our clinics. For instance, scholarship by some of our faculty members relating to how medical marijuana should be regulated dovetails with the work of our drug policy and public health law clinics. Research on the use of “big data” in health care naturally implicates the work of our faculty members who focus on human subjects research and policies surrounding the use of genetic and other health information. Professors who focus on mental health law have collaborated with faculty who are focused on neuroscience and addiction to explore issues surrounding adolescent decision making for health care decisions. We also find many opportunities to work with the L&HCP’s affiliated scholarly centers (including the Center for Health and Homeland Security and the Network for Public Health Law) as well as faculty members from the different professional schools on the University of Maryland campus. The L&HCP is more than the sum of its parts. Over time it has become a lively group of scholars who respond to and, equally as important, raise critical questions in health law that can often only be answered through a collaborative approach. This evolution over 30 years is reflected in the following update on the current work of L&HCP faculty members.

**Professor Diane Hoffmann**

Professor Diane Hoffmann has directed the L&HCP at the Carey School of Law since 1999. Since joining the faculty, her scholarship has primarily followed two strands: one focusing on legal and ethical issues in end of life care and the treatment of pain; the second on the use and regulation of new health-related technologies, products and procedures. These two areas of scholarship stemmed from joint appointments when she came to the law school—one with the campus Geriatrics and Gerontology Education and Research (GGEAR) Program, the other with the University’s Program on Public Issues in Biotechnology, which, at the time, was a program of the Maryland Biotechnology Institute.

Over the last decade her earlier focus on end of life care evolved into a focus on legal obstacles to the treatment of pain and arguments for more rational laws and enforcement of laws related to physician prescribing of opioids, see e.g. “Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws & Policies,” 1 St. Louis University Journal of Health Care Law and Policy 231 (2008). Her numerous articles on this topic led her to write a “Perspective” piece for the New England Journal of Medicine on medical marijuana and the law—both opioids and marijuana are scheduled substances under the Controlled Substances Act. In that piece, co-authored with Prof. Ellen Weber, the authors argued that moving marijuana from a Schedule I to a Schedule II substance would allow for a more rational approach to
advancing effective cannabinoid based medical treatment. As a result of the article, Hoffmann has given numerous talks at conferences around the country on the legal issues associated with state medical marijuana laws and continues to follow the growing state legislation on this topic.

Consistent with the second strand of her research, in 2009 Hoffmann received a three year grant from the NIH under the ethical, legal and social issues (ELSI) program of the Human Microbiome Project (HMP). The grant was awarded to Hoffmann, who was the Principal Investigator on the project, along with co-investigators at Maryland’s schools of law, medicine and pharmacy, to examine the current regulation of probiotics, i.e., substances containing live microorganisms that have a beneficial effect when taken in sufficient quantities by manipulating microbiome and host properties. Hoffmann formed a working group of scientists doing research on the human microbiome, food and drug law attorneys, health law professors, industry representatives, consumer advocates, and regulators from the Federal Trade Commission and the Canadian Health Products Directorate, to examine whether the current U.S. regulatory framework for probiotics adequately addresses issues of safety and effectiveness, provides sufficient information to consumers to make informed choices about probiotic products, and does not discourage research on potential therapeutic benefits of these products. The project resulted in a White Paper and articles in Science (“Probiotics: Finding the Right Regulatory Balance,” Oct. 2013), Beneficial Microbes (“Health Claim Regulation in the EU and the US: Which is the Better Approach,” 2013) and the Journal of Food & Drug Law (“Probiotics: Achieving a Better Regulatory Fit,” 2014). Hoffmann is also working, with colleague Jack Schwartz, on a fourth article resulting from this project on establishing a modified private right of action under the Federal Trade Commission Act for false or unsubstantiated health claims.

The ELSI project also led Hoffmann to co-author (with Dennis Fortenberry MD, MS and Jacques Ravel, PhD) another article about legal and ethical issues in human subject research generated by the HMP. The article was part of a special volume of the Journal of Law, Medicine & Ethics, guest edited by Carey Law Professor Leslie Meltzer Henry, on proposed changes to the federal Common Rule for conducting research on human subjects. In the piece, “Are Changes to the Common Rule Necessary to Address Evolving Areas of Research? A Case Study Focusing on the Human Microbiome Project,” Hoffmann and her co-authors explore ways in which research conducted under the HMP, like research conducted under the Human Genome Project, raises challenging issues for regulation of human subjects research, particularly issues related to subject selection and recruitment, group stigma, and information risks. She will be speaking on this topic at an upcoming meeting of the Institute of Medicine.

Next on Hoffmann’s research list is an examination of the potential regulatory frameworks for microbiota transplants.

Professor Richard Boldt

Professor Richard Boldt has been on the University of Maryland faculty since 1989. He teaches and writes in the areas of constitutional law, criminal law, mental disability law and torts and has a special research interest in legal issues surrounding mental health and drug use disorders. Professor Boldt has three recent articles, including two coming out in the next few months, which reflect his deep interest in these areas from both a research and advocacy perspective.

The first paper, “The ‘Voluntary’ Inpatient Treatment of Adults Under Guardianship,” which will appear in Volume 60, Issue 1 of the Villanova Law Review, tackles a gap in the laws that relate to hospitalization of adults under guardianship. Boldt’s interest in the issue was generated by an inquiry from a practitioner in Washington, DC and subsequently developed into
a full blown research project when Boldt realized that the answer was not only complicated but variable across states and jurisdictions. A number of states have adopted a preference for voluntary hospitalization over involuntary civil commitment for adults with severe mental illness who require inpatient treatment. Frequently, however, the disabilities that call for inpatient treatment also disrupt an individual patient’s capacity to participate fully in the decision-making process by which hospital admission is elected. The appointment of a guardian for some of these patients could provide a solution to this problem, but a range of statutory and case law limitations complicate matters. Boldt’s article provides a brief history of the law in this area, explores the role that informed consent plays in voluntary hospitalizations, provides an analysis of the interests in tension when a guardian is appointed, and offers a framework for an effective statutory approach that would allow guardians to arrange for voluntary hospitalization of a ward if the substantive standards and procedural requirements put in place by state law are adequate to insure that third-party decision-makers are acting with respect for the values held by these patients and, to the extent possible, are seeking to serve their best interests.

In Boldt’s recent article in the Maryland Law Review about problem-solving courts, he steps back from the mechanics of such courts to conclude that the practice is—to date—undertheorized and to urge that pragmatist theory be employed to guide the development of these courts.

In an article on a related theme, “Perspectives on Outpatient Commitment,” which will appear in Volume 49, Issue 1 of the New England Law Review, Boldt discusses research that he began as part of an initiative that he worked on with L&HCP Professors Diane Hoffmann and Amanda Pustilnik regarding outpatient civil commitment, also known as “assisted outpatient treatment” (AOT) or “mandatory outpatient treatment.” The initiative was convened to discuss whether stakeholders in Maryland might be able to reach consensus on a path to improving access to outpatient mental health care in Maryland. As part of this initiative, Professor Boldt studied legislative approaches to outpatient commitment. Boldt’s most recent article on the issue discusses proposed legislation at the federal level, including a bill introduced in

In Boldt's recent article in the Maryland Law Review about problem-solving courts, he steps back from the mechanics of such courts to conclude that the practice is—to date—undertheorized and to urge that pragmatist theory be employed to guide the development of these courts.

the fall of 2013 by U.S. Representative Tim Murphy entitled the “Helping Families in Mental Health Crisis Act of 2013,” which was fashioned to reform a number of existing policies and practices and included a controversial provision designed to encourage the states to make greater use of outpatient civil commitment. The Murphy reform bill was met in the House of Representatives by an alternative set of proposals developed by Representative Ron Barber to increase funding for community-based treatment. The Barber bill did not include provisions to encourage the use of outpatient commitment or other forms of enforced community-based care. Boldt’s article provides a brief history of the law governing involuntary civil commitment in the United States and reviews the available data on the outcomes of involuntary outpatient treatment, particularly with respect to subsequent hospitalizations and criminal system involvement, and concludes with a summary assessment of the considerations pushing for and against the greater adoption of outpatient commitment.

Professor Michael Greenberger

Professor Greenberger is the Director of the University of Maryland Center for Health and Homeland Security (CHHS), an academic and non-profit consulting entity with over 60 professionals on staff working on over 90 contracts worldwide. Among CHHS’ key areas of expertise are public health emergency preparedness and response, medical surge planning, mass fatality planning, training
and exercises, interoperability, cybersecurity, continuity of government, continuity of operations, critical infrastructure protection, and energy resilience. (More information about CHHS can be found at www.umdland.edu/healthsecurity/ and at www.mdhhs.com.)

Over the past year, Professor Greenberger has spoken on a number of issues related to biosecurity and dual use of research of concern. This research may provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety and national security. Earlier this year Greenberger spoke on this topic as a panelist at an AALS session entitled, “Risk and Regulation: Biosecurity and the Law.” In February, Professor Greenberger led CHHS’ efforts to coordinate with the Middle Atlantic Regional Center of Excellence for Biodefense and Emerging Infectious Diseases (MARCE) to host a conference on “Laboratory and Public Safety Preparedness for Dual Use Research of Concern.” The MARCE Conference brought professionals from emergency management, public health, the legal community, and federal, state and local governments together to address how to properly balance the ability to conduct biological research on potentially lethal pathogens with the implementation of appropriate protective biosafety mechanisms to prevent against the accidental or intentional release of such pathogens.

Professor Greenberger currently serves by appointment of the Governor of Maryland on the Commission on Maryland Cybersecurity Innovation and Excellence and is a member of the Baltimore Washington Cyber Task Force. Additionally, he was recently appointed to serve on the Editorial Board for the Disaster and Military Medicine journal; on the Committee on Science, Technology, and Law at the National Academy of Sciences; and previously served as the Chair of the Maryland Governor’s Emergency Management Advisory Council.

Recognized as a national expert in a number of areas, Professor Greenberger is called upon frequently to provide analysis and commentary on issues such as domestic and international responses to naturally-occurring and man-made emergencies; biosecurity and laboratory safety; counterterrorism strategies; and cybersecurity law and policy.

Professor Leslie Meltzer Henry

Professor Leslie Meltzer Henry joined the law school faculty in 2008. In addition to teaching at the law school, she is a faculty member at the Johns Hopkins Berman Institute of Bioethics. The focus of Professor Henry’s teaching and scholarship is constitutional law, bioethics, public health law and policy, reproductive justice, and research ethics.

Professor Henry is working with colleagues at Johns Hopkins on a project about the concept of dignity in law and medicine. The project, funded by a grant from the Gordon and Betty Moore Foundation, is designed to study and make recommendations regarding the loss of dignity that patients may experience in intensive care units (ICU). The first phase of the grant came to a close this summer. Henry was the team lead for the component of the grant that involved conceptualizing the meaning of dignity in the ICU. Based on the conceptual model the team created, Henry co-wrote an article entitled, “Respect and Dignity: A Conceptual Model for Patients in the ICU,” in Narrative Inquiry in Bioethics (forthcoming 2014). The article notes that, although the concept of dignity is commonly invoked in clinical care, there is not widespread agreement—in either the academic literature or in every-day clinical conversations—about what dignity means. This makes it difficult to determine what threatens patients’ dignity and, conversely, how to honor commitments to protect and promote
Professor Henry is working with colleagues at Johns Hopkins on a project about the concept of dignity in law and medicine. The project, funded by a grant from the Gordon and Betty Moore Foundation, is designed to study and make recommendations regarding the loss of dignity that patients may experience in intensive care units.

The article presents the first conceptual model of dignity for patients in the ICU based on the notion that there are three sources of patients’ dignity—shared humanity, personal narratives, and autonomy—each of which independently warrants respect. The article describes each source of dignity and draws on examples to illustrate how clinician attitudes, actions, and behaviors can either contribute to, or detract from, expressions of respect for patient dignity.

Professor Henry is also continuing her work on ethical and legal protections for human research subjects. Last summer, she edited a symposium issue of The Journal of Law, Medicine & Ethics entitled “Revising the Common Rule: Prospects and Challenges.” This symposium issue of the journal grew out of a roundtable the L&HCP sponsored with the Berman Institute to address an Advance Notice of Proposed Rulemaking (ANPRM) that was circulated for comment to every federal agency regarding updates to the Common Rule—the regulations governing use of human subjects in government-funded research. In addition to discussing the topic areas identified in the ANPRM as focal points for change, participants also considered mechanisms for enhancing research protections that might require amending the Common Rule beyond the ANPRM’s proposals. The conversations and presentations at the Roundtable resulted in seven papers in the symposium issue of the journal. Henry wrote an article published in that issue about why the United States has not developed a no-fault compensation system for injured research subjects. That article is called “Moral Gridlock: Conceptual Barriers to No-Fault Compensation for Injured Research Subjects.” In relation to this scholarship, Professor Henry has made presentations to the staff of the Presidential Commission for the Study of Bioethical Issues, at the Health Law Professors’ Conference, and the Johns Hopkins Berman Institute of Bioethics Seminar Series.

On another front, Professor Henry is a team member on an NIH-funded grant entitled “PHASES—Pregnancy and HIV/AIDS: Seeking Equity Study.” The project aims to understand and remedy the underinclusion of pregnant women, women of childbearing potential, and women who are lactating from HIV/AIDS clinical trials. Stemming from this initiative is an article she is co-authoring with the team that explores how the current legal and regulatory framework for human subjects research may contribute to the underinclusion of women. The research team is holding a meeting in November with legal stakeholders (general counsels from the pharmaceutical industry and major research institutions, former FDA regulators, and food and drug lawyers) in this area to inform the team’s work.

In a different but related vein, Professor Henry has been doing some writing about the ethical and legal aspects of the Facebook Study that was recently in the news. Facebook generated anger among some members of its social network after a study was published based on manipulations of its users’ news feeds. The study involved altering the news feeds of roughly 689,000 users to determine whether positive or negative content would affect their emotions and subsequent Facebook updates. Henry was quoted in the Wall Street Journal and ABCNews.com commenting on the study, and with UM Carey Law faculty member James Grimmelman, she co-authored several impact letters to the involved parties that aim to improve research protections for consumers of social media.

Professor Kathleen Hoke
Professor Kathleen Hoke directs the Legal Resource Center for Public Health Policy, funded by the Maryland Department of Health and Mental Hygiene, and the Network for Public Health Law’s Eastern Region, funded by the Robert Wood Johnson Foundation. Hoke teaches the Public Health Law Clinic through which she engages law students in the work of the
Network and the Center.

Through the Legal Resource Center (LRC) (www.law.umaryland.edu/programs/publichealth), Hoke provides technical legal assistance to Maryland state and local health officials, legislators, and organizations working in tobacco control, obesity reduction, and injury prevention. Recent work has focused on the regulation of cigars and electronic cigarettes, the development of sound policies to create smoke-free multiunit housing, legislation to prevent injury by requiring seatbelts for all vehicle occupants, and legislative mandates that childcare facilities serve only healthy beverages.

The Network for Public Health Law (www.networkforphl.org) provides technical legal assistance to national, state and local public health professionals, their attorneys, legislators, researchers, and advocates working to develop sound public policy to improve public health. This assistance often results in the creation of fact sheets, issue briefs, 50-state surveys, webinars, and other useful tools on emerging and persistent public health issues. Under Hoke’s direction, the Network’s Eastern Region deliverables have focused on environmental health, food safety and injury prevention.

In addition to contributing to, and supervising LRC and Network products, Hoke writes about emerging issues in tobacco regulation. Hoke has authored legal synopses published by the Tobacco Control Legal Consortium, including "Regulating Tobacco Advertising and Promotion: A ‘Commerce Clause’ Overview for State and Local Governments," and filed petitions with the Food and Drug Administration requesting the agency take a more flexible approach to regulating nicotine replacement therapy and to expanding regulatory power over cigars.

Hoke has authored legal synopses published by the Tobacco Control Legal Consortium, including "Regulating Tobacco Advertising and Promotion: A ‘Commerce Clause’ Overview for State and Local Governments," and filed petitions with the Food and Drug Administration requesting the agency take a more flexible approach to regulating nicotine replacement therapy and to expanding regulatory power over cigars.

**Professor Frank Pasquale**

Professor Frank Pasquale joined the Law & Health Care Program in 2013 and teaches Administrative Law, Health Care Law and Policy, and the Health Information Privacy and Innovation seminar. These courses, as well as numerous note and comment supervisions, allow Pasquale to share his deep interest and background in information law with our students. In classes and research, they explore how technology is changing the role and impact of information in our lives.

While Pasquale’s past legal scholarship has explored ways of advancing the use of technology in health care, his new book *The Black Box Society* explains how principles of health care policy should inform internet regulation. For example, Pasquale argues that consumers should be able to access all data held about them, not just health data, because health status can be inferred from data not covered under HIPAA.

The book was cited in the White House Report on Big Data, and Pasquale will be giving book talks at Yale,
SUNY-Buffalo, the University of Virginia, and several other institutions.

In addition to his new book, Pasquale addressed data policy in the health care industry in several venues over the summer. In June, Pasquale and Professor Melissa M. Goldstein of George Washington University’s School of Public Health presented a report on a panel titled “Exploring Legal Challenges to Fulfilling the Potential of mHealth in a Safe and Responsible Environment,” to members of the American Association for the Advancement of Science (AAAS) Working Group on mHealth (the use of mobile communications in health care). The panel focused on regulation, guidelines, and policies relating to mHealth which raise questions about the type of regulatory framework that will both facilitate innovation and deployment of new technologies, and protect patients.

Professor Pasquale also presented on data policy at the Health Privacy Summit at Georgetown Law Center in June. The Summit brought together national and international privacy experts from academia, along with healthcare providers, information technology specialists, industry representatives, and government officials to hear insights, ideas, and analysis from leaders in the health privacy community. The Summit focused on patient identification issues, mobile application privacy, international cybersecurity, and research data. Pasquale spoke on a panel titled “Privacy, Big Data, and Mobile: Technologies Operating Outside HIPAA Protection.”

In addition to these projects, Pasquale was appointed to a University of Maryland committee exploring the ethical, legal, and social implications of big data research. He has also joined the Council for Big Data, Ethics, and Society, a national committee of academics in data science, law, informatics, and social science, supported through a grant by the National Science Foundation as part of the National Big Data Initiative. The Council meets four times a year and publishes reports in order to help researchers, practitioners, and the public understand the social, ethical, and legal issues that underpin the "big data" phenomenon.

In addition to his work in the area of big data, Professor Pasquale has written and presented on other topics. His article “Private Certifiers and Deputies in American Health Care” was recently published in the North Carolina Law Review. At the Privacy Law Scholars Conference in June, Pasquale and UM Carey Law Professor Danielle Citron’s paper “The Scored Society: Due Process for Automated Predictions,” was selected out of the over 60 papers presented for an award from the International Association of Privacy Professionals for “overall excellence and relevance to the profession of privacy.” Another Pasquale proposal on automation and the professions was selected by Triple Canopy, an arts and culture organization based in New York, as one of seven commissions chosen from over 350 applications in 2014. The paper includes sections on legal and medical automation. Pasquale published an early draft version of part of the paper as a blog post, which was praised by the President of the American Association of Law Schools (Dan Rodriguez) as “an extraordinarily thoughtful, informed perspective on the ‘machine v. lawyers’ ” debate.

**While Pasquale’s past legal scholarship has explored ways of advancing the use of technology in health care, his new book The Black Box Society explains how principles of health care policy should inform internet regulation. For example, Pasquale argues that consumers should be able to access all data held about them, not just health data, because health status can be inferred from data not covered under HIPAA.**

---

**Professor Amanda Pustilnik**

Amanda C. Pustilnik is an Associate Professor of Law at the University of Maryland School of Law, where she teaches Criminal Law, Evidence, and Law & Neuroscience. Her current research includes work on models of mind in criminal law, evidentiary issues presented by neuroscientific work on memory, and how neuroscience can help the law reconceptualize its approaches to questions involving physical and emotional...
pain in legal domains ranging from tort to torture. As part of her ongoing scholarship in the area of neuroscience and the law, in April of this year, Professor Pustilnik organized two L&HCP events. The first event was the L&HCP’s annual Rome Lecture which was given this year by Stanford Law Professor Hank Greely on the topic of “Neuroimaging, Mindreading, and the Courts.” Professor Greely’s talk was a kick off to the interdisciplinary roundtable that took place the following day on the topic of “Imaging Brains, Changing Minds: Chronic Pain Neuroimaging and the Law.” The roundtable was designed to create a dialogue between the fields of law and neuroscience and to make legal actors aware of recent breakthrough work in neuroimaging that has led to a paradigm shift in understanding chronic pain. Professor Pustilnik look at questions that arise as science, law, finance and public policy intersect such as whether brain imaging can distinguish truth from falsehood or predict who will become violent and determine how to prevent it. The Center addresses these issues by monitoring relevant brain discoveries; promoting neuroscience that is responsible, ethical and scientifically sound; and discouraging premature or inappropriate use of scientific findings.

**During the Spring 2015 semester, Professor Pustilnik will serve as the first Senior Fellow in Law and Neuroscience at the Center for Law, Brain & Behavior at Massachusetts General. As a Fellow, Pustilnik will pursue original research, mentoring, and public engagement related to issues of pain and the law.**

organized and moderated the roundtable in collaboration with Dr. David Seminowicz from the Department of Neural and Pain Sciences at the University of Maryland School of Dentistry, and with the support of the American Association for the Advancement of Science’s Scientific Responsibility, Human Rights and Law Program. Prominent legal academics, scientists and judges attended the roundtable. Pustilnik is currently working with several of the participants in the roundtable on articles that will appear in an upcoming symposium issue of the L&HCP’s *Journal of Health Care Law & Policy* next year.

During the Spring 2015 semester, Professor Pustilnik will serve as the first Senior Fellow in Law and Neuroscience at the Center for Law, Brain & Behavior at Massachusetts General. As a Fellow, Pustilnik will pursue original research, mentoring, and public engagement related to issues of pain and the law. The Center is a collaboration between Massachusetts General Hospital and Harvard Law School and was created to look at questions that arise as science, law, finance and public policy intersect such as whether brain imaging can distinguish truth from falsehood or predict who will become violent and determine how to prevent it. The Center addresses these issues by monitoring relevant brain discoveries; promoting neuroscience that is responsible, ethical and scientifically sound; and discouraging premature or inappropriate use of scientific findings.

**Professor Karen Rothenberg**

Professor Karen Rothenberg, the founding director of the L&HCP, is currently on leave from the L&HCP, serving as Senior Advisor on Genomics and Society to the Director of the National Human Genome Research Institute (NHGRI) and a visiting scholar at the National Institutes of Health Department of Bioethics.

As we noted in the Spring 2014 edition of the L&HCP newsletter, in addition to her work on a variety of genetic policy issues, Professor Rothenberg’s current research focuses on the use of theatre as an innovative tool to identify and encourage discussion of the unique ethical, legal and social issues posed by emerging technologies in health care. This year, Rothenberg and her colleague Dr. Lynn Bush of Columbia University Medical Center, published a book, *The Drama of DNA: Narrative Genomics*. The book uses excerpts from Rothenberg and Bush’s original plays and plays by other authors to examine the implications of genomic technologies in today’s soci-

**In April, Rothenberg moderated a discussion at the Smithsonian in Washington, DC with several contemporary playwrights who have used theatre to examine the ethical, legal, and social issues that genomics have introduced into our lives, as well as to stimulate conversations about biomedical research.**
ety as well as to foster a greater understanding of how genomic information should be evaluated, processed, and shared. The book links readers to online versions of their original plays and is designed to serve as a resource to health care providers, researchers, patients, and their families.

Rothenberg’s collaboration with Dr. Bush, which began when Rothenberg spent academic year 2009-2010 on sabbatical as a Scholar-in-Residence at Columbia Law School, has been a fruitful one. They have co-authored many short plays to help convey the complexity of ethical issues raised by genomic research. Their plays were presented at an Ethical, Legal, and Social Issues (ELSI) Congress sponsored by NHGRI and have been performed by interdisciplinary groups of professionals in Australia, the Netherlands, and London and at the annual meetings of the American Society of Human Genetics, the American Society for Bioethics and Humanities, National Society of Genetic Counselors, Public Responsibility in Medicine and Research (PRIM&R), and several institutes within NIH. Recently Rothenberg engaged the staff of the Presidential Commission for the Study of Bioethical Issues in reading one of the plays aloud.

In April, Rothenberg moderated a discussion at the Smithsonian in Washington, DC with several contemporary playwrights who have used theatre to examine the ethical, legal, and social issues that genomics have introduced into our lives, as well as to stimulate conversations about biomedical research. Playwrights Dorothy Fortenberry (The Good Egg), Lisa Loomer (Distracted), Cassandra Medley (Relativity), and Anna Ziegler (Photograph 51) discussed why and how they used complex topics rooted in genetics—including issues of identity, the power of genetic information, and the impact of health decisions on family dynamics—in their work. The program was designed to complement the National Museum of Natural History exhibition “Genome: Unlocking Life's Code,” which is co-sponsored by NHGRI and for which Rothenberg was asked to conduct public outreach. Rothenberg is planning future programs in conjunction with the exhibit which will travel to science museums around the country and Canada over the next few years.

In addition to her theatre-related work, Rothenberg recently co-authored a paper in the *Georgetown Law Journal* titled “Finding Fault? Exploring Legal Duties to Return Incidental Findings in Genomics Research,” which deals with the issue of incidental findings that come up when the whole genome of an individual is sequenced.

**Professor Ellen Weber**

Professor Ellen Weber created and teaches the Drug Policy and Public Health Strategies Clinic in which she and her clinic students focus on policy development to expand access to substance use treatment services and represent clients who face discrimination based on their history of drug dependence. Over the past four years, Weber has focused her clinic work and scholarship on the implementation of the Affordable Care Act in Maryland and the Mental Health Parity and Addiction Equity Act. The Clinic has received two multi-year grants from the Open Society Foundation to support this work with the goal of ensuring that Maryland’s consumers benefit from the significant expansion of drug treatment services under the ACA.

One component of Weber’s health care reform implementation projects grew out of her 2013 article on the Parity Act, “*Equality Standards for Health Insurance Coverage: Will the Mental Health Parity and Addiction Equity Act End the Discrimination*,” published in the *Golden Gate University Law Review*. The article explored the Parity Act’s expansive non-discrimination standards which, according to Weber, could address many of the health plan design features that have historically limited access to substance use and mental health treatment through private insurance.

**Looking ahead to the second year of ACA implementation, Professor Weber and her Clinic students will help develop strategies to ensure that persons entering and leaving local jails are enrolled in health insurance plans and that individuals maintain insurance coverage and have effective appeal rights.**
In the article, Weber recommended strategies that would ensure more effective enforcement of the Parity Act by state insurance departments. Weber has tested her recommendations for achieving enforcement of the Parity Act in Maryland through her clinic practice. Over the past three years, Weber’s students have advocated for legislation in the Maryland General Assembly that would require insurance carriers to report key data points to the state insurance administration to facilitate the State’s review of plans for parity compliance. This would address one of the key barriers to consumer enforcement of the Parity Act. Most recently, Weber’s clinic students investigated whether the roughly eighty individual health plans offered in 2014 through Maryland’s marketplace complied with the Parity Act. The students identified significant gaps in the carriers’ assessment of plan features for parity compliance and the State’s review of plan compliance. As a result of this work, the Clinic has asked the Centers for Medicare and Medicaid to intervene to ensure that the State’s 2015 health plans meet the ACA’s standards for mental health and substance use benefits. Weber and her students have also provided extensive community education about the expanded drug and mental health treatment that is available under the ACA and have compiled a set of “Frequently Asked Questions” that responds to provider and consumer questions about those services under private and public insurance. Looking ahead to the second year of ACA implementation, Professor Weber and her Clinic students will help develop strategies to ensure that persons entering and leaving local jails are enrolled in health insurance plans and that individuals maintain insurance coverage and have effective appeal rights. Weber plans to address the lessons she is learning through the Clinic’s ACA implementation work in her future scholarship.

In relation to her work, Weber has given several recent presentations recently to the Tuerk Conference (sponsored by the National Council on Alcoholism and Drug Dependence of Maryland), the Maryland Mental Hygiene Administration’s Annual Conference, and the Preventing and Treating Substance Use Disorders 2014 Conference (sponsored by Community Catalyst).

Professor Deborah Weimer
Professor Weimer has directed the Health Care Delivery and HIV/AIDS Clinic at the University of Maryland Carey School of Law since 1988. She developed the HIV Clinic - as it is known - as an interdisciplinary effort and has worked with medical providers and social work staff at the Evelyn Jordan Clinic, as well as the Pediatric HIV Clinic at the University of Maryland Medical System (UMMS), for many years. She and her students have successfully represented clients living with HIV in a wide range of civil cases since the early years of the epidemic. She and her students have also been involved in legislative advocacy on the state level to improve conditions for individuals and families living with HIV illness. The HIV Clinic receives annual grant support from the Maryland Legal Services Corporation and the Ryan White Foundation and also works closely with the campus-wide JACQUES Initiative which provides medical, social, and legal services to individuals living with HIV.

Professor Weimer’s scholarship has focused on the value and challenges of interdisciplinary practice. She has also advocated for legislative reform to respond to the needs of families impacted by HIV. In 2011, she co-authored a book chapter titled “Patients and Families Living with HIV/AIDS,” that appeared in Poverty, Health and Law Readings and Cases for Medical-Legal Partnership (Elizabeth Tobin Tyler et al. eds.). This book is the first of its kind to comprehensively describe the role of law and lawyers in helping to address and mitigate social disparities in health care in

Cont. on page 18
ALUMNI NEWS

MICHAEL R. ULRICH NAMED SENIOR FELLOW IN HEALTH LAW AT YALE LAW SCHOOL

2011 L&HCP graduate Michael Ulrich was recently named Senior Fellow in Health Law and Research Scholar in Law at Yale Law School. Michael was a very active member of the L&HCP, acting as President of the Student Health Law Organization, participating in the first health law service trip to the Mississippi Delta, and serving as the Manuscripts Editor for the Journal of Health Care Law & Policy. For all his accomplishments at the law school, he earned the Public Service Award. Before joining the Yale Law School, he worked as a bioethicist in the Division of AIDS at the National Institutes of Health, where he reviewed clinical research protocols and grants, and performed ethics consultations. Other projects included identifying ethical issues in HIV cure research, addressing problems with international specimen sharing, and ways to improve tailoring HIV research to vulnerable populations. He also earned an M.P.H. from the Harvard School of Public Health in their Law and Public Health program. His articles have been published in the Yale Journal of Law & Feminism, Michigan State University Journal of Medicine & Law, and American Journal of Bioethics, among others.

DELORA SANCHEZ SELECTED FOR PRESTIGIOUS MARSHALL MEMORIAL FELLOWSHIP

Delora Sanchez, who graduated from the law school with the Health Law Certificate in 2006, was recently selected by the German Marshall Fund of the United States to be a Marshall Memorial Fellow. Founded in 1982, the Marshall Memorial Fellowship provides a unique opportunity for emerging leaders from the United States and Europe to build an understanding of politics, business, innovation, and culture on the other side of the Atlantic. For Fellows, it is an intensive learning and networking experience that begins with six months of preparations and ends with 24 days of immersion across the Atlantic. The German Marshall Fund selects 75 Marshall Memorial Fellows each year from 35 nations. The fellows are selected from business, government, and civil society. Delora is Associate Director of State Affairs at the Johns Hopkins Health System Corporation in Baltimore and an active contributor to the L&HCP. She will leave on October 16th and spend time in Brussels, Freiburg, Rome, Tirana, and Paris. To learn more about the health care system in Europe, she has arranged to meet with leaders in the health care industry in Belgium, Italy, and Germany. In Tirana, she plans to investigate the “concrete mushroom” project which aims to repurpose concrete bunkers that were built when Albania was in isolation. According to Sanchez, a Baltimore native, “I am hoping to take some ideas and apply them to Baltimore’s over 16,000 vacant buildings.”
At a breakfast reception held on May 14, a record 48 students were awarded the Health Law Certificate. Professor Diane Hoffmann, Director of the Law & Health Care Program (L&HCP), and L&HCP faculty members presented the certificates to the students and spoke about each student individually to the crowd of friends and family. This tradition of honoring each individual student who gets the certificate has become an institution at the law school. The comments—written by faculty members who get to know the students through classes, clinics and externships—range from laudatory to comical but never fail to impress the visiting guests with the incredible breadth of activities the students undertake in their three years at the law school. The picture that emerged at the reception was that of a group of students who will become vibrant and valuable members of the professional world of health lawyers. In her comments at the reception, Hoffmann called the 2014 class of health law students "the most dynamic, brilliant, and just plain fun group of health law students that I can remember in recent history."

This ceremony marked the 17th year that the L&HCP at the University of Maryland Carey School of Law has been awarding the Health Law Certificate to those students who have concentrated their legal studies in the area of health law. Each student pursued his or her interest in health law in a unique way and each student's story is worth recounting but, given the limits of space, in this article we focus on five certificate students whose various backgrounds and career aspirations highlight the breadth of health law and its future practitioners.

Wandaly Esther Fernández
Everyone at the law school knows about Wandaly Fernandez. Her contribution to the law school was exemplary. In addition to earning the Health Law
Certificate and serving as Manuscripts Editor of the *Journal of Health Care Law and Policy*, Wandaly was the President of the 2014 class. She was also the only student member of the Dean’s Search Committee this year and played a key role in selecting the law school’s new dean – Donald Tobin. She participated actively in the high powered group of faculty, alumni, university officials and community leaders who made up the search committee, and her judgments were influential in shaping the thinking of the group. Wandaly was also a member of the Moot Court Board, a semi-finalist in the Myerowitz Moot Court Competition, Co-Captain of the National Trial Team, Peer Advisor, Admissions Ambassador and Rose Zetzer Fellow. She impressed faculty and staff across the law school with her unique leadership skills and judgment. Wandaly, who earned her undergraduate degree at the University of North Carolina, is now an Associate at Epstein Becker Green in Washington DC where she joins many other wonderful L&HCP alums who remain active and involved in the program as competition judges, mentors, and speakers at the law school.

**Brian Hall**

Brian was a member of the L&HCP who became a favorite of the faculty of the program. Professor Kathi Hoke called him her “go-to student” in her Public Health Law Clinic because of his insight and attention to detail. He was also recognized as an incredibly knowledgeable member of the team that represented the law school at the Loyola University Chicago Health Law Transactional Competition. With Brian’s help, the team made a presentation at the competition that one judge commented was so good it matched the degree of difficulty he hoped to meet in his own presentations. This deep knowledge of health law was fostered by a Masters of Health Administration degree Brian obtained from Cornell University. This gave Brian a head start in health law that served him very well. During law school, he served as a law clerk at the Johns Hopkins Health System Legal Department, a clerk in the office of U.S. Senator Lindsey Graham working on issues relating to implementation of the Affordable Care Act, and a health policy intern at the American Society of Nuclear Cardiology. Like Wandaly, Brian is also a first year Associate at Epstein Becker Green where he promises to impress his colleagues with a degree of expertise in health law rarely seen with recent health law graduates.

**Pari Rashmi Mody**

Pari was one of many students in our program whose science background drove their interest in the intersection of law and biotechnology. Pari graduated from Oberlin College with a BA in Biopsychology and a concentration in Cognitive Science in 2006. Prior to coming to the law school, she worked as a researcher at Johns Hopkins and the University of Pennsylvania. Her work in these labs resulted in co-authoring two scientific articles, “Rats Subjected to Chronic-Intermittent Hypoxia (CIH) have Increased Density of Noradrenergic Terminals in the Trigeminal Sensory (Sp5) and Motor (Mo5) Nuclei” (505...
Neuroscience Letters 176–79 (2011)) and “Central but not Basolateral Amygdala is Critical for Control of Feeding by Aversive Conditioned Cues” (29 Journal of Neuroscience 15205-12 (2009)). Pari pursued her interest in science and the law at the law school and, as a research assistant, was a very important part of L&HCP Professor Amanda Pustilnik’s work on neuroscience and the law for two years. Upon graduation, Pari was named to the Order of the Coif. She is now an associate at Squire Patton Boggs LLP.

James E. Valentine

James, who graduated in December 2013, was (and still is) a critical member of the L&HCP notwithstanding the fact that he was an evening student with a demanding day job at the FDA. As Co-President of SHLO during his second year, James helped organize the inaugural Health Law Regulatory and Compliance Competition. This competition was a great success and has since grown into a national competition. James also spearheaded an L&HCP conference in partnership with Arnold & Porter in Washington, DC, titled Emerging Issues in Food and Drug Law: Implementation of FDASIA. The conference focused on the Food and Drug Administration Safety and Innovation Act (FDASIA) and was geared to food and drug law practitioners. The conference was a huge success. Now, as a recently minted lawyer and Associate at Hyman, Phelps, and McNamara PC, James continues to have more hours in the day than his peers. He is helping to organize the 4th annual regulatory competition that he helped start in 2012 and is part of the planning committee for the third Emerging Issues in Food and Drug Law conference that will focus on the Drug Quality and Security Act. The Act was passed by Congress to respond to the October 2012 outbreak of fungal meningitis that was traced to the poor drug compounding practices of the New England Compounding Center in Framingham, Massachusetts. We are grateful for his continued participation in our program and look forward to many years of partnership.

Blake Walsh

Blake arrived at the law school with a BA in History of Science and Medicine from Yale University. Her undergraduate degree proved to be a perfect entry into
Blake’s tireless dedication to her work was discussed during the May 14 celebration breakfast. L&HCP Professor Sara Gold told the attendees that Blake had to spend her last Spring Break during law school combing through over 1300 pages of medical documentation and reorganizing exhibits for an upcoming trial. Her sacrifice was rewarded in the end when she was able to help her client gain full custody of his younger brother. Blake continues to devote her boundless energy to health law at Waller Lansden Dortch & Davis LLP in Nashville.

2014 HEALTH LAW CERTIFICATE RECIPIENTS

Golnaz Alemousavi
Leila J. Ameli-Grillon
Lucy Brierly Bansal
Angelica Carliner
Travis Franklin Chance
Ian M. Clark
Melanie Dang
Aharon Dinovitz
Kristen Driggers
Wandaly Esther Fernández
Austin Foxwell
Patricia Greenwell
Martin Brian Hall, IV
Mario Hernandez-Gerety
Tereza Hess
Darby Hull
Megan Ix
Michalina Janik
Marta Kikena De Matto
Dana M. Krohn
Johanna Lister
Joanne Micheline Lucas
Nathan Whitmore McCurdy
Pari Rashmi Mody
Mallory Montgomery
Cindy Ann Nguyen
Bradley Nolet
Stephanie B. Noronha
Nkechi N. Nwaogu
Minyoung Park
Chelsea Person
Lauren Patrice Peterson
William Rader
Sara Rigdon
Jorge E. Rodriguez
Casey Rojas
Philip H. Scharper, Jr.
Crystal D. Schroeder
Stacy Lynn Siegel
Eugene Albert Knight Simms
Patrick Stewart
Allan Robert Thorson
Amond Robert Thorson
Amond Uwadineke
James E. Valentine
Abigail P. Walker
Blake Lauren Walsh
Darren H. Webb
Viola Anna Woolums
L&HCP Professor Kathi Hoke aka Iron Woman

L&HCP Professor Kathi Hoke, whose scholarly accomplishments are detailed in this newsletter, has some equally impressive accomplishments that take place outside of the law school. On September 20, Hoke completed the Ironman Maryland triathlon. Her finishing time was 13 hours, 41 minutes, 37 seconds. The race consisted of a 2.4 mile swim in the Choptank River; a 112 mile bike ride that took her through the Blackwater Wildlife Refuge on the Eastern Shore; and a 26.2 mile run through Cambridge, MD. The total mileage is 140.6. This was the inaugural Ironman Maryland and Hoke’s first full Ironman. She has always been a long distance runner but started doing triathlons to celebrate turning 40 in 2007. She started with a sprint distance at IronGirl and gradually built up to Olympic distance and Half Iron races before tackling the full Ironman. She has done races in Maryland, Pennsylvania, Delaware, New Jersey, New York, and New Hampshire. Hoke said about completing the event, “I feel incredibly grateful that my body and mind are strong enough to indulge in these adventures and that my family, friends, students, and colleagues are supportive of the insanity. I went skydiving in May and did Ironman in September; who knows what adventure lies ahead?”

Maryland Healthcare Ethics Committee Network (MHECN) News

MHECN Grant Award to Study MOLST Program

In September the Law & Health Care Program received word that the Maryland Office of Health Care Quality (OHCQ) had awarded funding to MHECN to evaluate the Maryland Medical Orders for Life-Sustaining Treatment (MOLST) program. MHECN is a membership organization for ethics committees at health care institutions in Maryland and an initiative of the Law & Health Care Program. The Maryland MOLST evaluation study will determine whether MOLST forms in Maryland health care institutions are being used correctly and what impact the MOLST program has had on end-of-life care for Marylanders since the MOLST program went into effect statewide in 2011.

Recognized as a “next generation” advance directive, MOLST programs have caught the attention of communities around the country seeking to improve end-of-life care. Currently more than 26 states have implemented MOLST-like orders. The MOLST Program works by transforming life-sustaining treatment preferences into medical orders that can be followed by emergency medical technicians, nursing facility staff, and other health professionals in times of crisis and transition from one setting to the next. However, the program’s success is dependent on appropriate implementation. Evaluating how the MOLST form is being used allows for identifying areas for improvement to achieve the goal of improving end-of-life care.

This evaluation study will address the following questions:

1. What is the rate of hospital compliance with the MOLST-on-discharge obligation?
2. Is there evidence of some process underlying completion of the MOLST form?
3. What is the MOLST form completion error rate?
4. Is completion of the MOLST form complementing or replacing advance directive completion?

Data collection will take place this academic year and results should be available by next fall.
November 10 Conference
“Religious, Medical, Ethical and Legal Perspectives on End of Life Issues”

The Law & Health Care Program’s Maryland Healthcare Ethics Committee Network (MHECN) is holding a conference on November 10 in conjunction with the Institute for Jewish Continuity and the University of Maryland Schools of Medicine, Nursing, Pharmacy, and Social Work. The conference, “Religious, Medical, Ethical and Legal Perspectives on End of Life Issues,” will bring together faith representatives, bioethicists, ethics committee members, and others to identify religious and ethical questions that arise in the care of patients at the end of life and discuss strategies to help patients, family members, and health care providers navigate the complexities of end of life decision-making. In addition to a discussion on “Religious Perspectives on ‘God's Will,’” conference organizers will facilitate two interprofessional panels that will tackle these complex issues from different professional perspectives. The conference is being organized by MHECN Program Coordinator, Dr. Anita Tarzian, an Associate Professor at the University of Maryland School of Nursing in the Department of Family and Community Health.

Evolution of Scholarship
Cont. from p. 11

a variety of settings. It is designed as both a teaching tool and a resource for those interested in medical-legal partnerships. Professor Weimer’s chapter describes the relationship between HIV, social determinants of health such as poverty, race and sexual orientation, and the law. It illustrates how an effective medical legal partnership can—and has—addressed the many barriers to care faced by people living with HIV. It describes legal protections that have been enacted to protect individuals and families affected by HIV that at the same time can play a role in encouraging people to be tested for HIV.

In the last three years, Professor Weimer has initiated a new clinic to focus particularly on housing issues faced by people living with HIV. Substandard housing in Baltimore poses a major health risk to individuals with chronic health problems including HIV and asthma. These issues are described in a recent op-ed piece written by Professor Weimer and published by the Baltimore Sun in June titled “Justice Eludes Ten-

ants.”

Professor Weimer’s newest research focuses on the impact that access to legal services can have on the health and welfare of people living with HIV illness. While an interdisciplinary approach to patient care in the context of HIV is well accepted, little data exists to measure the impact of integrating legal services into an interdisciplinary care setting. Effective treatment for HIV is now available but among low income people of color, poor health outcomes and deaths from HIV-related causes still occur.
FALL 2014 ROME LECTURE

ABBE GLUCK
PROFESSOR, YALE LAW SCHOOL

The Challenges of the ACA in the Courts, the Congress and the States: The Legal-Political Twists and Turns of the Most Controversial Statute in Modern Times

NOVEMBER 20, 2014
5 PM

CEREMONIAL MOOT COURT ROOM
UNIVERSITY OF MARYLAND FRANCIS KING CAREY
SCHOOL OF LAW

RECEPTION FOLLOWING EVENT

4TH ANNUAL HEALTH LAW REGULATORY & COMPLIANCE COMPETITION: CALL TO COMPETE

The Health Law Regulatory & Compliance Competition is a unique and innovative competition that challenges law students to navigate through the complex regulatory landscape of health care law, including compliance with health care regulations and FDA law. It will be held on Saturday, February 21, 2015, from approximately 8:00 a.m. until 3:00 p.m. at the University of Maryland Francis King Carey School of Law in Baltimore, MD.

About the Competition:
The Competition requires teams of 2-3 students to analyze a hypothetical fact pattern involving various interactions between health care stakeholders and entities participating in several health care activities that necessitate regulatory and compliance oversight. The fact pattern will be given to teams the day of the competition, and students will have approximately 1.5 hours to analyze the problem. Teams will then present their findings and recommendations to a panel of practicing regulatory and compliance attorneys. The 4th Annual Competition will focus on several interactions between various health care stakeholders, including hospitals, physicians, drug and device manufacturers, and related third parties.

Call to Compete:
If you would like to have a team from your law school participate in the Competition, you can find additional details and information about how to register at www.law.umaryland.edu/health/events/hlrc_competition.html.
Comments and letters should be forwarded to the above address.