

LAW & HEALTH CARE

IN THIS ISSUE:

Law & Health Care Program Faculty, Alums and Students Immersed in Health Care Reform	1
Alumni and Students Working in Health Care Reform.....	3
L&HCP Hosts “Health Care Reform: The State of the States” Roundtable.....	4
Professor Amanda Pustilnik Works at the Intersection of Chronic Pain and the Law	5
L&HCP and Student Health Law Organization Host Conference on FDASIA.....	6
Network for Public Health Law Continues to Grow Under Leadership of Professor Kathleen Hoke	7
L&HCP’s Health Care Ethics Committee Network Hosts MOLST Training Session.....	8
Faculty Highlights	9
L&HCP Hosts Health Law Regulatory & Compliance Competition	10
Fourth Annual Health Law Service Trip to Mississippi	10
Student Honors and Activities ...	11

LAW & HEALTH CARE PROGRAM FACULTY, ALUMS AND STUDENTS IMMERSSED IN HEALTH CARE REFORM

The State of Maryland is one of the most active and engaged states in implementation of the Patient Protection and Affordable Care Act (ACA) and Law & Health Care Program faculty, alumni and students are right in the middle of these massive reforms.

An active advocate of the state’s health care reform efforts in the area of mental health and substance use disorders is **UM Carey Law’s Ellen Weber**. Professor Weber teaches the Drug Policy and Public Health Strategies Clinic, which she created many years ago to address practices that inhibit the expansion of drug treatment in communities and discriminate against individuals with histories of drug dependence. Weber, who joined the faculty in 2002 after serving as the Senior Vice President for the Legal Action Center, has used the passage of the ACA as an opportunity to advocate for robust treatment benefits under the new law for individuals with mental health and substance use disorders. In 2010, Weber was awarded a \$350,000 grant from the Open Society Institute to ensure that the needs of this population were not ignored under the new reform payment and insurance models and that coordination and integration of addiction treatment and other health services would be a priority.



Professor Ellen Weber

To help carry out the work of the grant, Weber hired Paige Lescure. Having worked at the Maryland law firm Miles & Stockbridge, Ms. Lescure brought 20 years’ experience in health care law to her new position as Senior Health Law & Policy Fellow at the School of Law. Together with their clinic students, Weber and Lescure have become a remarkably successful team. They have partnered with health services providers, advocates, public leaders and legislators in an effort to guide public health policy reform to ensure greater access to addiction

Cont. on page 2

The *Law & Health Care Newsletter* is published by the Law & Health Care Program at the University of Maryland Francis King Carey School of Law
500 West Baltimore Street
Baltimore, MD 21201

L&HCP Faculty

Diane E. Hoffmann, JD, MS
Director, L&HCP and Professor of Law

Richard Boldt, JD
Kathleen Hoke, JD
Sara Gold, JD

I. Michael Greenberger, JD
Leslie Meltzer Henry, JD, MSc
Amanda Pustilnik, JD
Karen Rothenberg, JD, MPA
Ellen M. Weber, JD
Deborah J. Weimer, JD, LLM

Adjunct Faculty 2012-2013

Stephen Carney
Funk & Bolton, PA

Marc Charmatz, JD
National Assn. of the Deaf

James Doherty, Jr., JD
Pecore & Doherty, LLC

W. Lawrence Fitch, JD
Maryland Dept. of Health
and Mental Hygiene

Carl Jean-Baptiste, JD, MBA
MedStar Health, Inc.

Janet Klein Brown, JD
Office of the Attorney General

Janet Lord, LLB, LLM
Blue Law, LLC

Kevin McAnaney, JD
Law Office of Kevin G. McAnaney

Carol McCarthy, PhD, JD
Ober|Kaler

John S. Nugent, JD
Office of the Attorney General

Robert T.M. Phillips, MD, PhD
Forensic Consultation Association, Inc.

Frank Palumbo, PhD, JD
University of Maryland
School of Pharmacy

Jack Schwartz, JD

Sanford Teplitzky, JD
Ober|Kaler

L&HCP Managing Director
Virginia Rowthorn, JD

services in Maryland.

At a roundtable on health care reform held at the School of Law on March 1 (see article on page 4), Professor Weber spoke about the work she and her team have done in the area of mental health and substance use disorder benefits under the ACA. She noted that, prior to the ACA, some states already had state-level mandates regarding coverage for mental health and substance use treatment but these laws varied dramatically across states in many areas, particularly in terms of cost sharing, limits on duration of care and the scope of covered services. Inadequate insurance coverage of these medical conditions throughout the nation's history has led to a well-recognized denial of care for patients and a burden on the public health care system. Weber views the ACA as a long-overdue mechanism to address these wide gaps in service. She hopes that implementation of the ACA will lead to improved patient outcomes and lessen the burden on the health care system by allowing for earlier diagnosis of mental health and substance use issues, creating a more robust network of providers to treat these conditions in the public and private health insurance markets, and creating greater availability of services. She also hopes it will end the unfair practice of cost-shifting from insurance carriers to individuals and health providers as well as cost-shifting from private to public insurers.

Under the ACA, Weber noted at the roundtable, services for mental health and substance use disorders are one of ten categories of services considered part of the Essential Health Benefits (EHB) package. The EHB package is a core package of health care services and benefits that must be covered by state plans starting in 2014. The baseline and default EHB package is that of a typical small employer-sponsored health plan. Professor Weber, Ms. Lescure and her clinical students worked very hard – and successfully – to ensure that Maryland adopted a very comprehensive benefit for treatment of mental health and substance use disorders in its benchmark plan. While the State adopted the small group plan as the benchmark plan for medical services, her team worked closely with state officials on the EHB package and helped ensure that Maryland substituted the behavioral health benefit from the Government Health Employees Association (GHEA) plan as the state's benefit, as opposed to the default small group benefit. The GHEA behavioral health benefit is the most comprehensive among the ten benchmark plans and was incorporated based on the Clinic's analysis that it would comply with the Mental Health Parity and Addiction Equity Act (the Parity Act).

A main focus of Professor Weber's work is at the intersection of the Parity Act and the ACA which, working in tandem, may mark the advent of greater and more robust treatment services. The Parity Act prohibits insurance carriers from imposing quantitative treatment limitations and cost sharing burdens on patients in a way that is different from those imposed on medical and surgical patients. The Parity Act covers every aspect of mental health and substance use disorder treatment including non-quantifiable treatment limitations such as medical management standards, medical necessity standards, network adequacy standards, and provider reimbursement. Weber is very encouraged that regulations from the Department of Health and Human Services require benefits for treatment of mental health and substance use disorders under the ACA to be provided in compliance with the Parity Act. Weber's team has worked to make sure that Maryland's benchmark plan meets the requirements of the Parity Act.

Professor Weber has also looked at whether other states are using the Parity

Act to create robust drug and mental health treatment benefits. Although little detail is yet available, she noted that many state plans still include the historic limitations that Weber and her clinic have long fought against, including limitations on duration of care and wholesale exclusion of certain benefits like non-hospital residential treatment. Some states' EHB benchmark plans also require pre-authorization for treatment services, in clear contravention of Parity Act standards. To date, it is unclear whether state insurance departments will root out these inequities as they certify health plans to be offered in and outside the Exchange.

In addition to working on Maryland's EHB plan, Professor Weber's clinic was closely involved with the development of the Maryland Health Progress Act, the third bill passed by the Maryland General Assembly to implement health care reform. Her students evaluated the legislation and helped ensure that it provided for continuity

of care protections for consumers as they move between Medicaid and private insurance plans sold in the exchange.

In addition to the clinic's focus on coverage, Weber also spoke about her focus on the other legs of the health care system's three-legged stool – quality and access. A significant issue that Professor Weber has worked on is network adequacy and ensuring that carriers have included in their networks sufficient providers to meet the needs of all patients. She is working to ensure that, under the new benefit package, drug treatment programs can provide and be reimbursed for outpatient services, as they currently are in the State's Medicaid system. Weber and the clinic are encouraging regulators to allow for program reimbursement so that a broader range of drug treatment counselors may continue to provide services within the scope of their practice. This will ensure cost-effective care and wider availability of services for a historically underserved group of individuals.

ALUMNI AND STUDENTS WORKING IN HEALTH CARE REFORM

Rebecca Gwilt '10, Senior Consultant, ACA Exchanges and Medicaid Policy, CGI

I joined the Obama administration shortly after graduating in the fall of 2010, and worked for HHS on regulatory and operational policy under the Affordable Care Act (ACA). I spent nearly two years as part of a team at the Center for Consumer Information and Insurance Oversight (CCIIO) building the framework necessary for the implementation of Health Insurance Exchanges and the Medicaid expansion in 2014. I recently left to join the national health care team of a large company (CGI) which contracts with States and the federal government to build and provide IT and business solutions to effectuate the implementation of State-based and Federal Exchanges and the modernization of state Medicaid systems to prepare for the 2014 reforms.

Caroline Farrell '10, Attorney, U.S. Department of Health and Human Services Office of the General Counsel, Centers for Medicare & Medicaid Services Division

The Centers for Medicare & Medicaid Services (CMS) has had a tremendous amount of responsibility for implementing ACA. As an attorney in the CMS Division of the HHS Office of the General Counsel, my primary focus has been providing CMS legal advice as it implements the ACA. CMS Division attorneys work regularly with other attorneys in the HHS Office of the General Counsel and across the federal government to resolve novel, complex, high-profile legal questions and challenges arising from implementation efforts, which involve developing national programs to improve individuals' access to quality, affordable health care.

Sheena Tomar '12, Associate Director of Government and Regulatory Affairs, the University of Maryland Medical System

Health care reform is on the fast-track in Maryland and actually helped create my position as Associate Director of Government and Regulatory Affairs at the University of Maryland Medical System's (UMMS) Corporate Office last year. In my position, I track legislation in the General Assembly related to implementation of ACA requirements in Maryland, such as the Maryland Health Progress Act, and analyze its impact on UMMS as well as assess the hospitals' compliance with the new Federal and State regulations. With a movement toward patient-centered care and better outcomes, my focus is on identifying legislation that will facilitate access to care and improve quality of care. I also follow developments of the Maryland Health Benefit Exchange, assessing UMMS's feasibility and potential partnerships in becoming a connector entity to help enroll individuals into healthcare insurance plans starting January 1, 2014.

(Cont'd on p. 12)

L&HCP HOSTS “HEALTH CARE REFORM: THE STATE OF THE STATES” ROUNDTABLE

On March 1, UM Carey Law held a roundtable on the practical challenges and uses that states are facing in their implementation of the Patient Protection and Affordable Care Act. The roundtable was organized by Law & Health Care Program (L&HCP) faculty members Diane Hoffmann and Ellen Weber and built on a similar panel Professor Weber hosted at the 2012 ASLME Health Law Professors Conference. Professor Weber and the students in her Drug Policy and Public Health Solutions Clinic have been deeply involved in Maryland’s health care reform efforts in the area of mental health and substance use disorders. (See article on page 1.)

The roundtable brought together experts from a variety of fields to drill down into the details of implementation. Welcoming remarks were presented by Diane Hoffmann, Professor of Law and Director of the Law & Health Care Program, followed by introductions by Dr. Joshua Sharfstein, Secretary, Maryland Department of Health and Mental Hygiene, and Sonya Schwartz, Project Director of State Refor(u)m, National Academy for State Health Policy. Schwartz noted that the phrase “2014 Is Now” is frequently heard among people who are working furiously to implement health care reform at the state level by the start dates set forth in PPACA. The roundtable stimulated a great deal of information sharing on key issues currently being tackled by the states and created a framework for future collaboration.

Eight mini-sessions were held throughout the day, covering topics relating to implementation of health insurance exchanges and Medicaid expansion, and featured the following distinguished discussion leaders:

- Dr. Peter Bielsonson – Founder, Evergreen Health Cooperative
- Patricia Boozang – Managing Director, Manatt Health Solutions
- Brietta Clark – Professor of Law, Loyola Law School, Los Angeles
- Leonardo Cuello – Director of Health Reform, National Health Law Program
- Cheryl Fish-Parcham – Deputy Director of Health Policy, Families USA
- Bradley Herring – Associate Professor and Director, PhD Program in Health Economics & Policy, Johns Hopkins Bloomberg School of Public Health
- John Jacobi – Director, Dorothea Dix Professor of



(from l to r:) Dr. Joshua Sharfstein, Professor Diane Hoffmann, Professor Ellen Weber, and Paige Lescure

Health Law and Policy, Seton Hall University School of Law

- Kevin Lucia – Research Professor and Project Director, Georgetown University Health Policy Institute
- Ann Marie Marciarille – Associate Professor of Law, University of Missouri-Kansas City School of Law
- Susan McNally - U.S. Office of Personnel Management
- Judith Solomon – Vice President for Health Policy, Center on Budget and Policy Priorities
- Sallie Thieme Sanford – Assistant Professor of Law, University of Washington School of Law
- Sidney Watson – Professor of Law, Saint Louis University School of Law
- Elizabeth Weeks – Associate Professor of Law, University of Georgia School of Law
- Tim Westmoreland – Visiting Professor of Law, Georgetown University Law Center

An upcoming symposia edition of the L&HCP’s *Journal of Health Care Law & Policy* will be devoted to papers developed from talks presented at the roundtable.

The State of the States roundtable was supported with funding provided by the Rueben Shiling Mental Health Law Fund. Sonya Schwartz’s detailed overview of health care reform at the state level and a video of the roundtable are available at this link: <http://www.law.umaryland.edu/faculty/conferences/detail.html?conf=125>.

PROFESSOR AMANDA PUSTILNIK WORKS AT THE INTERSECTION OF CHRONIC PAIN AND THE LAW

L&HCP Professor Amanda Pustilnik is studying how chronic pain is treated in the law from two related perspectives -- disability and evidence. Pustilnik is currently working on an article that will be the follow-up to the article that she published last year titled “Pain as Fact and Heuristic: How Pain Neuroimaging Illuminates Moral Dimensions of Law,” (97 CORNELL LAW REV. 801). The new article takes the theoretical framework presented in the earlier piece and uses it to explore areas where emerging pain science, and particularly neuroimaging, can be used to improve and update specific areas of legal doctrine and practice. In the article she first presents the current science of chronic pain, building on extensive research, lab visits, and interviews with key researchers. She describes the contemporary scientific understanding of chronic pain as involving centralized neurological processes – not just the part of the body that hurts. She then contrasts the contemporary view of pain with the inadequate and outdated models of pain incorporated into the Social Security Disability regulations, the standards that federal judges apply to evaluate benefits decisions under those standards, to suggest reforms both in the regulations themselves and in the judicial practices of interpretation that have grown up around them. The paper then turns to the implications of contemporary pain science for evidence law, looking at both the narrative and the black-letter aspects of evidence.

On the narrative aspects of evidence theory, the Pustilnik paper contends that courts often exclude and mis-evaluate relevant evidence because such evidence does not comport with the gate-keepers’ normative or narrative expectations of what chronic pain looks like and what actually causes it. Drawing on the literature on narrative in evidence law, and prior challenges to dominant narratives (like



Professor Amanda Pustilnik

what the “good victim” looks like), she argues that long-held psychosomatic assumptions about pain sufferers as malingerers or hysterics need to be challenged in and out of court. She then turns to black letter evidence law applications of new pain science. The paper presents a framework for analyzing when pain neuroimaging evidence ought to be admitted under the Daubert and Frye standards and when it ought to be excluded as either insufficiently reliable or insufficiently relevant.

The concepts discussed in this article will form the basis of a conference Professor Pustilnik is planning on pain and the law with David Semiowicz, a neuroscientist who is based in the UM School of Dentistry. Pustilnik and Semiowicz plan to convene an interdisciplinary group of primary neuroscience researchers, legal scholars, and legal practitioners (particularly judges and policy makers) to start a dialogue on, and come up with some set of best practices around, using pain neuroimaging to reform legal doctrines related to chronic pain.

L&HCP AND STUDENT HEALTH LAW ORGANIZATION HOST CONFERENCE ON FDASIA

The Law & Health Care Program and Student Health Law Organization, in conjunction with the University of Maryland School of Pharmacy's Center for Drugs and Public Policy and Arnold & Porter LLP, hosted a well-attended day-long conference in D.C., entitled "Emerging Issues in Food and Drug Law: Implementation of FDASIA," on Wednesday, April 17th. The Food and Drug Administration Safety and Innovation Act (FDASIA), was signed into law by President Obama on July 9, 2012.

While the Act is most known for reauthorization of user fees for brand pharmaceuticals and the addition of a user fee program for generics and biologics, the primary goal of Congress in passing the law was to provide FDA with new authorities to combat shortages of drug products in the United States and impose new requirements on manufacturers regarding early notification to FDA of issues that could lead to a potential shortage or disruption in supply of a product. Prior to FDASIA, only sole manufacturers of certain drug products for serious conditions were required to notify FDA of a discontinuance of those products. FDA received notifications from other manufacturers about potential shortages of other products on a voluntary basis. FDASIA provides FDA with enhanced authorities that:

- Broaden the scope of the early notification requirement by requiring all manufacturers of covered drugs to notify FDA of potential discontinuances.
- Require manufacturers to report discontinuances to FDA regardless of whether they intend to discontinue the product permanently or are facing only a temporary interruption of supply.
- Enable FDA to require, by regulation, mandatory reporting of shortages of biological products. The prior law excluded all biological products from the reporting requirements.
- Require FDA to issue a non-compliance letter to manufacturers who fail to comply with the drug shortage notification requirements and to make the letter and the company's response to the letter available to the public.

In addition to these provisions, the Act reauthorizes and amends several drug and medical device provisions that were scheduled to sunset and includes many new provisions

that bolster medical product regulation, including a breakthrough therapies designation, making permanent two programs that encourage pediatric drug development, and increased patient participation in regulatory decision-making. The law significantly changes the FDC Act and the PHS Act in several respects that will have considerable short- and long-term effects on the regulated industry.

This timely conference was the brainchild of James Valentine, MHS, President of the law school's Student Health Law Organization (SHLO) and an evening student at the law school. By day, James is a Program Analyst in FDA's Office of Health and Constituent Affairs. With his law school, law firm, and FDA contacts, James and other members of SHLO organized an impressive panel of experts to discuss the critical components of this important new law. This is the second conference that the Law & Health care Program has sponsored for food and drug law attorneys. The first, in 2009, covered topics including biologics, federal preemption, REMS, and generic drugs.

The Keynote Speaker for the event was Leslie Kux, JD, Assistant Commissioner for Policy at the FDA. The following law school alumni who work in food and drug law served as panelists or moderators:

- Dom Cirincione, JD, MPP, Regulatory Counsel, Office of Medical Policy, Center for Drug Evaluation and Research, FDA
- David Clissold, JD, MA, Director, Hyman, Phelps & McNamara PC
- Brian Kehoe, JD, Congressional Affairs Specialist, Office of Legislation, FDA
- Jeremiah Kelly, JD, MPP, Attorney for Medical Product Development & Regulation, Office of the Staff Judge Advocate (JAG), U.S. Army Material Command (USAMRMC)
- Delia Stubbs, JD, Associate, Hyman, Phelps & McNamara PC

The conference website: <http://www.cvent.com/events/emerging-issues-in-food-and-drug-law-implementation-of-fdasia/event-summary-3bb97324b1304384bbc5e5e8c919a54e.aspx> .

NETWORK FOR PUBLIC HEALTH LAW CONTINUES TO GROW UNDER LEADERSHIP OF PROFESSOR KATHLEEN HOKE

The Network for Public Health Law, funded by the Robert Wood Johnson Foundation (RWJF), was launched in September 2010 to provide technical legal assistance to state and local public health officials, legislators and community groups working to secure evidence-based public health policy. Maryland Carey Law is home to the Network's Eastern Region, serving the Mid-Atlantic and New England states. When the original funding ended in March of 2013, RWJF agreed to extend the Network's operations for another two years, awarding Maryland Carey Law nearly \$1 million to continue the work in the Eastern Region.

L&HCP Professor Kathleen Hoke directs the Center and integrates her Public Health Law Clinics into the Network's operations. The Eastern Region also employs three attorneys who are alumni of the law school: Kerri Lowrey (Deputy Director); Cristina Meneses (Senior Staff Attorney); and Mathew Swinburne (Staff Attorney); as well as Program Manager, Megan Griest. Together the team produces issue briefs, webinars, blogs, and much more. Recently clinic students developed a 50-state survey of state law regulating the use of epinephrine in schools and prepared a companion issue brief suggesting that state and local governments could prevent harm to children by permitting schools to "stockpile" epi pens and train staff to use them in cases of suspected anaphylactic shock even in children not yet diagnosed with allergies. Because young children may have been exposed to a particular allergen—i.e. a bee sting—until an unfortunate event occurs during the school day, access to an undesignated epi pen could prevent injury and death in schools with very little risk of harm. Students have also prepared briefs on issues as far reaching as teen driving and blogged about arsenic in rice, hospital liability for superbugs and electronic cigarettes.

This summer Network Eastern Region staff will present as a panel on childhood safety at the Safe States Alliance/SAVIR Annual Conference; comment on denialism as an industry dynamic in public health at the annual American Society of Law, Medicine & Ethics' Health Law Professors Conference; and host the full Network staff from all regions at the law school. In the coming year, Hoke and the Network hope to identify schools of law that are interested in exploring the creation of a public health law clinic to provide students the opportunity to practice public health law under the supervision of experienced faculty. This will not only benefit the students in searching for public health law jobs but it will expand the pool of lawyers educated and trained to assist in developing sound public health policy.



Professor Kathleen Hoke

UM Carey Law Participates in Interdisciplinary Institute for a Healthiest Maryland

UM Carey Law's Legal Resource Center (LRC) for Maryland Public Health Law and Policy, formerly the LRC for Tobacco Regulation, Litigation and Advocacy, is participating in an interdisciplinary project under the aegis of the Institute for a Healthiest Maryland (IHM), a joint venture of the University of Maryland, Baltimore, and the Maryland Department of Health and Mental Hygiene. The LRC is participating in the IHM, along with representatives from the UM Schools of Medicine, Pharmacy, Dentistry, and Nursing, as well as faculty from the University of Maryland, College Park; the University of Maryland, Baltimore County; and the Johns Hopkins Bloomberg School of Public Health. The campus-wide effort is funded by the CDC under the Community Transformation Grant Program. The main focus of the IHM is to reduce the public health burden in Maryland associated with tobacco use, obesity and hypertension. From supporting programs that allow pharmacists to provide more extensive counseling to patients with hypertension, to facilitating the adoption of smoke-free policies in multi-unit housing and helping local school boards increase physical activity and improve nutrition in schools, the interdisciplinary team works collaboratively to identify evidence based, legally sound policies that will reduce the morbidity and mortality associated with tobacco use, obesity and hypertension in Maryland.

The LRC is directed by **Professor Kathleen Hoke** and supported by two attorney alumni, Managing Director Rita Vera and Staff Attorney Will Tilburg. Students in Hoke's Public Health Law Clinic assist with the LRC work,

Cont'd on page 11

L&HCP'S HEALTH CARE ETHICS COMMITTEE NETWORK HOSTS MOLST TRAINING SESSION

Maryland health care providers who work with patients and families at the end-of-life assembled April 2nd at UM Carey Law for a day-long training session on how to use the new “medical orders for life-sustaining treatment” (MOLST) form for medical orders directing life-sustaining measures. The Maryland Health Care Ethics Committee Network (MHECN), an initiative of the Law & Health Care Program, sponsored the session. The Maryland MOLST form was proposed in 2011 and replaces the state’s DNR form.

MOLST or POLST (“physician orders for life-sustaining treatment”) forms represent a significant paradigm change in advance care policy by standardizing provider communications through a plan of care in a portable way, rather than focusing solely on standardizing patients’ communications via advance directives. These forms require providers and patients or their surrogates to accomplish two core tasks:

- First, a health care professional initiates a discussion with a patient (or the patient’s authorized surrogate) about treatment options in light of the patient’s current condition.
- Second, the patient’s preferences for end-of-life treatments are incorporated into medical orders, which are recorded on a highly visible, standardized form that is kept at the front of the medical record or with the patient if the patient lives in the community.

MOLST and POLST forms record several treatment decisions common to seriously ill patients: cardiopulmonary resuscitation; the level of medical intervention desired in the event of an emergency (comfort only, limited treatment, or full treatment); and the use of artificial nutrition and hydration. As technology and treatment options change, the forms will also continue to evolve. Also unique to these forms is the fact that they are designed to transfer across treatment settings, so that the information in the form is readily available to medical personal, including EMTs, emergency physicians and nursing staff. MOLST and POLST Programs rely on a coordinated health care system to ensure preferences are honored throughout the course of a patient’s treatment.

Maryland adopted a MOLST – rather than POLST – form because a nurse practitioner as well as a physician can sign the form. According to the Maryland MOLST Training Task Force which is made up of more than 70 organizations, associations, facilities, providers,



Participants at L&HCP's MOLST Training

professionals, and consumers, the Maryland MOLST order form is designed to:

- Consolidate important information into orders that are valid across the continuum of care;
- Standardize definitions across end-of-life care forms;
- Remind patients and providers of available treatment options; and
- Increase the likelihood that a patient’s wishes regarding life-sustaining treatments are honored throughout the health care system

The proposed regulations were recently updated by the Maryland Department of Health and Mental Hygiene to extend the date until July 1, 2013 for when assisted living programs, home health agencies, hospices, kidney dialysis centers, nursing homes, and hospitals (for certain patients) must complete MOLST forms for newly admitted patients.

The workshop was designed for health care providers who interact with patients and families regarding end-of-life decision making. Attendees learned how to use the Maryland MOLST form and their obligations and requirements under the MOLST regulations. Professor Diane Hoffmann, Director of the Law & Health Care Program, worked with MHECN Coordinator Dr. Anita Tarzian to organize the program. Dr. Patricia Tomsko Nay, Medical Director, Maryland Office of Health Care Quality, and Paul Ballard, Assistant Attorney General, led the training session.

FACULTY HIGHLIGHTS

Karen Rothenberg

- Professor Rothenberg's article "Finding Fault? Exploring Legal Duties to Return Incidental Findings in Genomic Research," was accepted for publication by the *GEORGETOWN LAW JOURNAL*.

Diane Hoffmann

- Professor Hoffmann's work was cited recently in the *New York Times* in an article by Laurie Edwards entitled "The Gender Gap in Pain." The NYT article stated "The oft-cited study 'The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain' found that women were less likely to receive aggressive treatment when diagnosed and were more likely to have their pain characterized as 'emotional,' 'psychogenic' and therefore 'not real.'" Hoffmann's article, co-authored by Dr. Anita Tarzian, appeared in the *Journal of Law, Medicine & Ethics* (29 (2001): 13–27). The NYT article can be found at http://www.nytimes.com/2013/03/17/opinion/sunday/women-and-the-treatment-of-pain.html?pagewanted=all&_r=0.
- Professor Hoffmann was appointed to the Maryland Stem Cell Research Commission as one of the Commission's two bioethicists. The Commission is an independent unit within the Maryland Technology Development Corporation and establishes criteria, standards and requirements to ensure that stem cell research financed by the Maryland Stem Cell Research Fund complies with state law.

Leslie Henry

- Professor Leslie Henry's article, "The Jurisprudence of Dignity," 160 *U. PENN. L. REV.* 169 (2011) was described as a "must read" in a very glowing review by Jonathan Simon, Adrian A. Kragen Professor of Law at Berkeley Law. You can find the full review at <http://crim.jotwell.com/dignity-is-coming/>.
- Professor Leslie Henry has worked with several students (now recent alums) to help them publish several articles that were developed from seminar and independent study papers:
 - Max Siegel, "The Future of Family," 23 *GEO. MASON U. C.R. L.J.* 2 (2013)
 - Max Siegel, "Surviving Castle Rock: The Human Rights of Domestic Violence," 18 *CARDOZO JOURNAL OF LAW & GENDER* 727 (2012)
 - Rebecca Spence, "Abandoning Women to their Rights: What Happens When Feminist Jurisprudence Ignores Birthing Rights," 19 *CARDOZO JOURNAL OF LAW & GENDER* 101 (2012)

- Mike Ulrich, "With Child, Without Rights?: Restoring an HIV+ Pregnant Woman's Right to Refuse Medical Treatment," 24 *YALE J.L. & FEMINISM* 303 (2012)

- Mike Ulrich, "Researchers Without Borders?: Limiting Obligations of Ancillary Care Through the Rescue Model," 3 *HEALTH LAW & PUBLIC POLICY FORUM* 28 (2011)

- Mike Ulrich, "Resource Restraints: Rethinking Disclosure of Individual Genomic Findings," *MICH. ST. J. MED. & L.* (forthcoming, 2013)

- Christine White, "Let IVF Take its Course: Reconciling Procreative Liberty for the Twenty-First Century," 35 *WOMEN'S RTS. L. REP.* (forthcoming 2013–2014)

Michael Greenberger

- University of Maryland's Center for Health and Homeland Security, directed by L&HCP faculty member Michael Greenberger, has recently begun developing two public health toolkits for the Association of State and Territorial Health Officials (ASTHO). These toolkits, which will be developed in collaboration with the Olson Group, will identify key legal barriers that arise in common public health situations. The toolkits are designed to help public health officials nationwide improve their understanding of, and ability to navigate through, common issues encountered in public health emergency preparedness and response, such as shortages of medical resources and privacy of individuals' personal health information. The toolkits, on the topics of altered standards of care and emergency drug shortages respectively, will be completed by late May 2013.

Ellen Weber

- Ellen Weber and students in her Drug Policy and Public Health Strategies clinic successfully advocated for a bill in Maryland that would create a program to make naloxone, a drug used to reverse an opioid overdose, more readily available to persons trained to identify opioid overdose symptoms and administer the medication. The bills (SB 610/HB 890) that were approved by both houses of the Maryland General Assembly would create a program similar to programs in other states. The CDC has documented that naloxone access programs save lives. In 2010, a CDC Harm Reduction Coalition study of 48 naloxone distribution programs in 15 states and the District of Columbia found that these programs led to 10,171 opioid overdose reversals over a 14-year span, with a distribution of naloxone to an estimated 53,000 individuals.

STUDENTS COMPETE IN HEALTH LAW REGULATORY & COMPLIANCE COMPETITION

On February 16, 2013, the University of Maryland Francis King Carey School of Law held the 2nd Annual Health Law Regulatory and Compliance Competition. The Competition is designed to put students in the shoes of health law attorneys and regulators who handle complex regulatory and compliance questions. This year, thirteen teams from around the country participated in the competition. In addition to a home team from UM Carey Law, teams participated from Loyola Beazley, Saint Louis University, Temple, Seton Hall, Widener, American, University of Virginia, Hamline, Temple, Penn State, Washington University in St. Louis, and Southern Illinois University. Loyola's team won first place honors with University of Virginia and Washington University coming in second and third place.

During the competition, teams of three students analyzed a fact pattern using federal health regulations, rules, and agency documents, and presented a legal and policy solution and/or recommendations to a panel of regulatory and compliance attorneys. This year's competition focused on the life sciences industry, food and drug law, and compliance with fraud and abuse laws related to companies that manufacture products regulated by the Food and Drug Administration (FDA).

The competition judges represented lawyers from some of the country's most prominent health law firms



*UM Carey Law Team (left to right):
3L John Glass, 3L Rebecca Hall, 1L Neha Patel, Virginia Rowthorn, Managing Director, Law & Health Care Program, and Diane Hoffmann, Director, Law & Health Care Program.*

including Arnold & Porter, Ober|Kaler, Epstein Becker Green, and Hyman, Phelps & McNamera, as well as FDA officials, health care executives, and the President of Bayer Healthcare LLC.

The competition was generously supported by the law firms of Ober|Kaler and Epstein Becker & Green.

FOURTH ANNUAL HEALTH LAW SERVICE TRIP TO MISSISSIPPI

By Abby Walk, Connie Lee, Liz Rinehart and Vicki Chihos

The Maryland Carey Service Corps Health Law Trip had another successful time in Mississippi in January. This is the fourth consecutive year that students from the law school have spent their final week of winter break working with the Mississippi Center for Justice (MCJ) on health-related service projects.

The group of nine Maryland students worked with MCJ on several projects involving the Affordable Care Act (ACA) and legal issues facing individuals with HIV/AIDS. The group split their time between MCJ's offices in Jackson and the Delta and, in their free time, made trips to

the BB King Museum and the Catfish Museum. This year's trip leaders were health law students Liz Rinehart and Vicki Chihos who had both been on the previous year's trip.

The ACA team focused on Medicaid expansion, which is a hotly contested issue in Mississippi. In addition to meeting with stakeholder patients and clinicians, the team compiled data about the accessibility of Medicaid outstations (office where people can apply and re-apply for Medicaid) and created fact sheets regarding how Medicaid expansion would benefit different groups, such as children and those with pre-existing health conditions. MCJ will use



UM Carey Law Students During Winter Break Service Trip to Mississippi

the group’s work product to help educate legislators and the general public.

People living with HIV/AIDS in Mississippi face tremendous legal obstacles because of stigma and misperceptions about how the virus is spread. The law students put together a database of pro-bono legal providers in the state, developed a fair housing training program, and created legislative fact sheets on the benefits that Medicaid expansion would provide to people living with HIV/AIDS. The team also met with community advocates while in the Delta and took a tour of Taborian Hospital in the town of Mound Bayou. This historic hospital was the first hospital in the South to treat African American patients and was being renovated and reopened as an urgent care center. The experience was memorable and the team felt lucky to be included in the celebration.

The students participated in a community meeting in Humphreys County organized by MCJ to discuss access to health care. A photo of the Maryland team at the community meeting and a description of their service project appeared in the *Belzoni Banner*.

Plans for next year’s Health Law week are already underway as the group looks forward to continuing the law school’s partnership with MCJ.

Network for Public Health

Cont. from p. 7

tracking state and local legislation on the covered issues, identifying potential policy options to address tobacco use and obesity in Maryland and reaching out to relevant local officials to discuss policy options.

STUDENT HONORS AND ACTIVITIES

- George A. Neyarapally 2L, Pharm.D., M.P.H., published the paper “A Review of Recent Federal Legislative and Policy Initiatives to Enhance the Development and Evaluation of High Value Drugs in the United States,” 14 DEPAUL J. HEALTH CARE L. 503 (2013).
- Abe Gitterman 3L has had a number of papers selected for honors and publications:
 - Runner up in the 2012 ABA Health Law Section Writing Competition for his paper “Executives Should Think Twice Before Accepting Pleas ‘Relating to Fraud’: The Expansion of Exclusion Under the Park Doctrine.” The paper will be published in an upcoming edition of *The Health Lawyer*.
 - “Manufacturing a Solution: How the U.S. Food and Drug Administration Can Ensure the Safety and Security of a Globalized Drug Supply Chain” won second place and a \$1,000 prize in the Food and Drug Law Institute’s H. Thomas Austern Memorial Writing Competition and will be published in an upcoming issue of FDLI’s *Food and Drug Law Journal*.
 - “What is the Best Way for Manufacturers and Physicians to Apply Sunscreen to Avoid Being Burned by the Final Sunshine Act Regulations?,” 3 FOOD AND DRUG POLICY FORUM 1 (no. 4, 2013).
- Jane (Yevgeniya) Kalinina, PharmD/JD student, was named an Express Scripts Scholar, a prestigious \$10,000 award to a PharmD student in a joint degree program. The Express Scripts Foundation created the award to support the efforts of academic pharmacy to educate students with diverse interests.
- James Valentine 3E, was instrumental in creating and launching the new FDA Patient Network Website as part of his job as a program analyst in FDA’s Office of Health and Constituent Affairs. The Website is an interactive tool for educating patients, patient advocates, and consumers about their medications—prescription and over-the-counter—and medical devices. James appears in a video clip advertising the new website.
- Hannah Levinson 3L spoke at the Health Care Compliance Association’s Compliance Institute on April 23 as part of a panel titled “The Future of Compliance: Where Law Students and New Attorneys Fit In.”

LAW & HEALTH CARE PROGRAM

500 West Baltimore Street
Baltimore, MD 21201
www.law.umaryland.edu/healthlaw

Comments and letters should be forwarded to the above address.

ALUMNI AND STUDENTS WORKING IN HEALTH CARE REFORM (CONT'D)

Josh Greenfield 3L, Extern at CMS Center for Consumer Information and Consumer Oversight

Interning at the Centers for Medicare and Medicaid Services (CMS), has allowed me to appreciate the many complexities of healthcare reform and the ACA. We have been working to ensuring that many privacy safeguards and other protection standards are met for those who apply for coverage through the marketplace. It is exciting to see the behind-the-scenes work going into the federally-facilitated and state-based exchanges and to be a part of this massive undertaking. Even amidst the sequester, many talented and dedicated individuals are working tirelessly to ensure that deadlines are met and the marketplace “go-live” date goes as smoothly as possible.

Blair Inniss 3L, Extern at the Hilltop Institute (a health research organization at the University of Maryland Baltimore County)

At the Hilltop Institute, my supervisor and I worked for the Maryland Health Benefit Exchange. Everything I did was with the purpose of helping Maryland prepare for open enrollment on the Exchange, which will go live on October 1, 2013. Some of my projects included following bills that my supervisor and the Exchange staff wrote, tracking policy guidance from the federal government and making sure that nothing Maryland is doing contradicts federal guidance, and helping to write draft regulations. Through the internship, I was deeply entrenched with healthcare reform and saw first-hand what it takes to implement such a massive, sweeping reform. It was one of my greatest learning experiences in law school.

Ian Clark 2L, Student Attorney, Drug Policy and Public Health Strategies Clinic

As a Student Attorney for the Health Care Reform Team of the Drug Policy and Public Health Strategies Clinic, I reviewed and commented on amendments, interim policies, and regulations regarding the Maryland Health Progress Act of 2013 and Maryland Health Benefit Exchange Acts, focusing on substance use disorder benefits. Over the course of the year, I participated in the stakeholder committee process and communicated with healthcare advocacy groups on projects involving Continuity of Care, the Maryland Essential Health Benefit and Benchmark Plan, Provider Network Adequacy, and the Health Information Exchange. I now have a greater understanding of the administrative and legislative lawmaking processes, and am honored to have had the opportunity to affect policy change and to help guide Maryland’s implementation of the ACA.