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NEWSLETTER

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FOCUS ON HEALTH LAW STUDENTS: PUTTING SKILLS INTO ACTION

UMDLAW STUDENTS STUDY HOSPITAL CHARITY CARE AND DEBT COLLECTION PRACTICES

In January, at the end of winter break, a group of 12 health law students and Law & Health Care Program (L&HCP) Managing Director Virginia Rowthorn traveled to Mississippi to work with the Mississippi Center for Justice (MCJ) on a number of health related initiatives (see details on page 4). In advance of the trip, MCJ attorneys asked the Maryland group to research the issue of hospital charity care and debt collection practices on both the national and state (Mississippi) level. In 2009, MCJ, in collaboration with the Mississippi Coalition for Citizens with Disabilities, created the Hospital Accountability Project to document hospital charity care and debt collection practices in Mississippi; study best practice models from across the country; and work with local hospitals to implement improved and consistent hospital charity care and debt collection practices. As a first step in this project, MCJ attorneys asked students to prepare a preliminary report on the issue and present it to key stakeholders in Jackson.¹ This article summarizes the group's findings.



L&HCP Students at the Mississippi Center for Justice.

Hospital charity care refers to medical care provided to low income and uninsured people by a hospital or other provider for which full payment is not expected. Although charity care is provided by for-profit hospitals, the practice is most closely associated with nonprofit hospitals. In order to maintain their nonprofit status, these hospitals must provide a benefit to the community which includes the provision of charity care. Unfortunately, what constitutes adequate charity care is

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not clear under the IRS code, a problem that has led some members of Congress to question whether nonprofit hospitals provide uncompensated care commensurate with the value of their tax exemptions.

The recently passed national health reform legislation includes provisions that will impose standards for the tax exemption of charitable hospitals for the first time. The legislation requires, among other things, that a hospital complete a community needs assessment once every three years, and adopt and publicize a financial assistance policy. In addition, the new law prohibits hospitals from billing those who qualify for financial assistance at the same rate they bill those who do not qualify for such assistance and from taking extreme collection actions if the hospital has not made reasonable efforts to notify patients of its financial assistance policy. Senator Chuck Grassley (R-Ia.) and Representative Bobby Rush (D-Ill.) have said that the provisions do not go far enough to ensure that nonprofit hospital centers provide adequate charity care and have promised to work together to examine the issue in the near future.

Hospital debt collection refers to the actions undertaken by hospitals to collect unpaid debts from individuals. Within certain guidelines (primarily state law), hospitals, like other businesses, have a toolbox of tactics available to them to collect debt including wage garnishment, foreclosure, and transfer of the delinquent accounts to credit agencies.

The two issues of charity care and debt collection are often discussed and studied hand-in-hand because many of the individuals who incur hospital debt would have—and arguably, should have—benefited from free or reduced price care. The two issues have received a great deal of attention in recent years at both the state and federal level because of the growing number of personal bankruptcies attributable to medical debt.²

Inconsistency at the State and Federal Level

Many hospitals consider the provision of charity care part of their core mission. However, as a result of the unclear and inconsistent patchwork of federal and state guidelines regarding charity care and debt collection, hospitals are not held to a clear and consistent definition of charity care. This allows hospitals to create their own policies and leads to hospitals in the same jurisdiction having vastly different practices.

While in the strictest sense, charity care is free care provided to patients who cannot afford to pay for their medical services, hospitals often lump the cost of free care in with other forms of “uncompensated care.” These other costs include liabilities such as bad debt, and expenses related to community benefits such as community health fairs, educational seminars and community donations that are not necessarily tied to patients’ inability to pay for health services.³ Therefore, when nonprofits report how much they spend on uncompensated care, that amount does not necessarily reflect the amount spent on the provision of free health care.

Inconsistent guidelines lead to systematic deficiencies that hamper delivery of charity care. For example, because there are no consistent rules to the contrary, hospitals often fail to adequately screen patients for public programs or the hospital’s charity care program; fail to notify patients of these programs; charge self-pay patients on average three times more for services than patients covered by private or public insurance; require large up-front payments; encourage aggressive collection practices; and sell patient accounts to third-party collection agencies that charge high interest rates.⁴

Many states include the concept of charity care in their laws relating to

hospitals, but these laws generally do not require hospitals to provide a particular level of charity care and many state guidelines are advisory.⁵ Additionally, hospitals that receive state funding are often required by law to operate as a safety net provider and provide charity care.⁶ However, these laws frequently fail to specify in detail how much free care is required.

As a result of the lack of state level policies specifying in any detail how much charity care hospitals must provide, it is up to hospitals to determine whether to implement a specific charity care policy and what it should include. Based on a limited telephone survey of Mississippi hospitals by Maryland health law students, it appears that the policies vary significantly from hospital to hospital. Similarly, a recent Maryland report that surveyed all Maryland hospitals concluded that “Maryland hospitals’ financial assistance policies vary considerably.”⁷

In the last decade, there have been several efforts on the state and national level to streamline and improve hospital charity care and to prevent abusive debt collection practices.

Initiatives on the National Level

Health care trade organizations, such as the American Hospital Association⁸ and the Healthcare Financial Management Association⁹, have published advisory guidelines to help hospitals implement effective charity care and debt collection policies. In addition, national healthcare advocacy groups have published white papers and advisory guidelines to bring attention to the problem of inadequate charity care and hospital debt collection practices. As an example, Families USA published an issue brief to highlight progressive reform measures that state policymakers have implemented and published a guide for consumers entitled “Guide to Coping with Medical Debt.”¹⁰

State Level Initiatives

With the downturn in the economy and the number of

bankruptcies attributable to medical debt growing, heart-wrenching stories of individuals struggling with the financial consequences of a hospital stay have appeared on the front pages of newspapers. This negative press has served as the impetus for state-wide investigations and legislative initiatives. For example, a 2009 *Baltimore Sun* investigation¹¹ discovered that the state’s 46 nonprofit hospitals had filed tens of thousands of lawsuits to collect unpaid bills while receiving surplus dollars from the state’s uncompensated care payment system.¹² Between 2003 and 2008, Maryland hospitals filed more than 132,000 suits, winning at least \$100 million in judgments and resulting in at least 8,000 home liens. This investigation spurred Governor Martin O’Malley to call on the Maryland Health Services Cost Review Commission (MHSCRC) to investigate the situation and on the Maryland General Assembly to pass legislation to remedy the issue. In 2009, Maryland passed legislation that strengthened hospital financial assistance programs as a result of the *Sun’s* initial investigations.

Six states have undertaken substantial efforts to overhaul the charity care and debt collection practices of hospitals within their boundaries – California, Connecticut, Illinois, Maryland, New Jersey, and New York.¹³ These states have implemented comprehensive legislation to inform patients about their payment options and protect and assist consumers with financial issues (see chart below).

Aside from the comprehensive legislation passed in these states, additional legal remedies have been pursued in other states to address hospital charity care and debt collection practices. To enforce price reductions in some states, Attorneys General in Minnesota, Wisconsin, and Mississippi have secured agreements with individual and groups of hospitals that mandate cost reduction for certain low-income patients. For example, in 2005, Minnesota’s Attorney General signed an agreement with 125 hospitals to charge

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Summary of Consumer Protections that Are Required by Law, By State¹⁴

	Establishes Income Thresholds for Hospital Charity Care	Hospitals Required to Notify Patients of Charity Care	Limits on Hospital Charges	Limits on Interest for Hospital Bills	Limits on Lawsuits Brought by Hospitals and Debt Collectors	Annual Limits on Collection
California	✓	✓	✓	✓	✓	
Connecticut		✓	✓	✓	✓	
Illinois		✓	✓	✓	✓	✓
Maryland	✓	✓	✓	✓		
New Jersey	✓	✓	✓			
New York	✓	✓	✓	✓	✓	

HEALTH LAW STUDENTS PRACTICE THEIR SKILLS DURING SERVICE TRIP TO THE DELTA REGION OF MISSISSIPPI

By Kaelyn Drumm 2L and Patricia Ramudo 2L

In the last week of winter break, 12 students from the School of Law had the once in a lifetime opportunity to explore the Delta Region of Mississippi and perform a needs assessment of three local communities to help identify issues of concern relating to Medicaid access, predatory lending, and school discipline. From this experience, we took with us unforgettable memories and, most importantly, an understanding of the way in which the law can provide hope and justice to a community devastated by economic downturns, systemic racism, and hopelessness.

As background, students from the Law School have been traveling since early 2006 to the Gulf Region to help with the vast need for legal services created by Hurricane Katrina. Student groups have spent winter and spring breaks assisting with the rebuilding efforts of various Gulf Coast towns; working with the New Orleans Office of the Public Defender; and working with the Mississippi Center for Justice (MCJ) on civil legal matters, including the FEMA grant assistance system. In 2009, several health law students and L&HCP Managing Director Virginia Rowthorn approached MCJ about creating a trip that focused on health law. This request dovetailed nicely with a recent initiative that MCJ was beginning to build in the Delta Region of Mississippi.

Working out of their Jackson office, in 2009, Linda Rigsby and other MCJ attorneys were beginning to turn their sights to the vast unmet need for legal services in the Delta. One of those needs was access to Medicaid. MCJ wanted to perform an assessment of the area to determine specific deficiencies in access to Medicaid and asked if our group of health law students would be interested in survey-

ing the community. This was a perfect week-long project for our group and one that allowed us to get to know the community and learn about the slow, time-consuming, but ultimately very satisfying experience of grassroots organizing around an important issue.

Knowing that none of us had ever spent time in Mississippi, Rowthorn, Ms. Rigsby, and MCJ's Director of Training and Foundation Development Bonnie Allen created a schedule that first introduced us to Mississippi, the Delta, and health concerns at both levels. On our first day in Jackson, we met with State Representative John Hines, Sr. from the town of Greenville. He told us about the challenges his constituents face in accessing health care.

Ms. Rigsby was able to arrange a tour and meeting with one of Mississippi's foremost health care innovators, pediatrician Dr. Aaron Shirley. Dr. Shirley is the winner of a MacArthur Foundation "Genius Award," and creator of the "Dr. Aaron Shirley Medical Mall" in Jackson. We had the pleasure of sitting down and speaking with Dr. Shirley about the formation and history of the Mall. Dr. Shirley wanted to establish a central, easy to access location for low income individuals to take advantage of a full range of health care services. He found an abandoned shopping mall on a central bus line and the rest is history. We were lucky enough to get a tour of the facility from Dr. Shirley. We were very inspired by this visit because we saw first-hand the efforts the community was making, especially Dr. Shirley, toward helping other, less fortunate citizens in the area.

After our initiation to Mississippi, we buckled down and learned about the work we would undertake in the Delta. We were to conduct a community survey—a first for many of us. After some training, we decamped to Greenville and prepared for our first day of surveying. We split up into teams and interviewed at different locations including the Interfaith Ministries Soup Kitchen in the town of Greenwood. This kitchen seats and feeds approximately 50 people daily. Despite the adversities that these people encounter daily, they displayed a generous spirit and offered to share food from their plates. The Soup Kitchen in Greenwood served us with rich data and stories to take back to MCJ staff.

Another group interviewed students at Mississippi Valley State University. MVSU is located in the heart of the Delta in a small town called Itta Bena. This was clearly a different population and interview volunteers were not hard to come by. Within the first hour, students were approaching us, genuinely engaged and interested in what brought us to their home. Students voiced their concerns regarding a



L&HCP Managing Director Virginia Rowthorn (back row, left) and students in front of the B.B. King Museum

variety of issues such as child support and custody matters. Although we spent only a few hours with them, it was clear that these students are proud of where they are from and are truly invested in bettering their community. Most of the students were successfully enrolled in the state Medicaid program. We quickly noted that access to Medicaid was not a great concern in this educated population. This fact was in contrast to what we learned when we surveyed employees of the University who were struggling with the same basic needs as the rest of the Delta majority, the biggest being a lack of understanding about how to enroll in Medicaid and lack of adequate transportation to get to health care facilities.

We spent one afternoon at a health and legal clinic organized by MCJ in Indianola. The clinic was set up as a series of stations, including one at which we conducted more interviews. Aside from health care-related “stations,” there were legal stations to help individuals with foreclosure, health care and Medicaid, and family law. Members of our group were paired with MCJ attorneys.

During the trip our group truly began to appreciate the blues music that is so deeply rooted in the Delta soil. We had a private tour of the B.B. King Museum in Indianola, and had the amazing opportunity to visit the blues bar owned by B.B. King himself, Club Ebony. Local attorney and civil rights activist, and good friend of B.B. King, Carver Randall generously agreed to meet with us at the club, and give us the inside story on what growing up and living in the Delta was truly like. Randall candidly discussed delicate issues of race and politics with ease and understanding. He illustrated the importance of change in his community and what we, as future attorneys, could pursue to support the change the community seeks.

Charity Care

Cont. from p. 3

a fair price for care and reduce their collection practices. In 2007, the agreement was extended for five more years.

Some states have passed laws against balance billing, i.e., billing the patient for costs that the insurer does not cover, that protect both insured and uninsured patients from falling into medical debt. A few states, such as California, Florida, and Maryland, have passed laws that require health plans to pay for out-of-network services in certain situations such as emergencies and prohibit providers from billing more than a patient’s copayment.¹⁵

Several states have tried to protect medical debtors’ incomes and assets from collection by, for example:

- Limiting the lifespan of medical debt to two years after the date the services were provided. (Arkansas)
- Prohibiting wage garnishment if the debtor has not been able to work for two weeks or more due to illness



*L&HCP Students with Dr. Aaron Shirley
(back row, 3rd from left)*

Our group of 12 concluded the week with a presentation to MCJ staff and other community leaders. Our report to the Center included a description of hospital charity care policies and debt collection practices that we prepared prior to our visit (see article p. 1). In addition, we were able to present a summary of the data we collected from our surveys which provided a snapshot of regional trends in access to Medicaid and other related issues.

The open discussion that followed our presentation was enlightening because ideas and personal opinions flowed freely back and forth. We had a great sense of accomplishment because the hard work we did prior to our week in the Delta and during our time there was genuinely appreciated by everyone at MCJ. Our time was too short but we truly look forward to working with the MCJ again in the future.

and delaying garnishment until two months after the debtor has recovered. (Kansas)

- Protecting homes of patients with catastrophic or terminal illnesses from foreclosure. (Louisiana)

Finally, patients and their advocates have used the courts to try to curtail abusive debt collection practices. In 2004, a number of hospital systems across the country were sued for providing insufficient levels of charity care, overcharging uninsured patients, and engaging in improper debt collection practices in violation of both tax exemption and consumer protection laws. While the plaintiffs were unsuccessful—Federal district courts unanimously and uniformly held that section 501(c)(3) of the federal tax code does not require free or discounted care to the uninsured—the lawsuits brought significant public attention to the issue.¹⁶

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DRUG POLICY CLINIC SECURES AMENDMENTS TO STATE DRUG PARITY LAW

Students participating in the School of Law's Drug Policy Clinic achieved victory in the final days of the 2010 session of the Maryland General Assembly with the enactment of a bill that increases the availability of addiction treatment and mental health services to individuals with commercial insurance plans. Drug Policy Clinic Professor Ellen Weber and third-year law student Delia Stubbs worked closely with the Maryland Insurance Administration (MIA) to support SB 57, a bill that would bring existing state law into compliance with the federal Mental Health Parity and Addiction Equity Act ("federal parity law"), as well as the recently enacted health reform legislation.

The federal parity law aims to end health insurance companies' discrimination against individuals with histories of addiction or mental illness by prohibiting group health plans from imposing separate or more restrictive treatment limitations on benefits for substance use disorder and mental health treatments than are imposed for physical illnesses.

Ms. Stubbs testified before the Senate Finance Committee and submitted testimony to the House Government Operations Committee that supported the proposed bill. Virtually all of the Clinic's proposed amendments to the bill were included in the final law signed by the Governor on April 20, 2010.

Maryland's original parity law prohibited health insurance companies from discriminating against individuals with mental illness or addiction by setting standards that would be deemed non-discriminatory for outpatient, inpatient and partial hospitalization services. SB 57 ensures better availability of treatment under certain health plans by eliminating tiered cost sharing requirements for outpatient mental health and substance abuse treatment, and preserving a floor for partial hospitalization services.

Under SB 57, Maryland will now prohibit certain health insurance plans from limiting behavioral health care services by using more restrictive standards to manage the behavioral health benefit than are used to manage other medical benefits. Such limitations—often couched in medical necessity criteria—often prevented individuals from accessing the treatment that they needed. The new limitations on managed care standards in SB 57 are a significant addition to state law. "I appreciated having the opportunity to work with the MIA and see how advocates, legislators, and state agencies can collaborate to promote the public's health," Ms. Stubbs commented, at the conclusion of the process. "I am grateful to have learned the value of public service so early in my career."

STUDENTS HELP SENIOR CITIZENS COMPLETE ADVANCE DIRECTIVES

This semester, health law students had the opportunity to help residents of a senior center complete advance directives as part of the Law School's popular Just Advice (formerly Legal Grind®) program. Just Advice, which functions under the auspices of the Law School's Clinical Law Program, hosts legal advice sessions in which Maryland law students and pro bono lawyers offer Baltimore citizens a cup of coffee and legal advice in various community settings outside of the law school. Recently, the Law & Health Care Program and Just Advice collaborated to include the preparation of advance directives into the arsenal of legal advice available to Just Advice clients. Prior to the first of two sessions at the Cherry Hill Nursing Home, Professor Jack Schwartz offered a training session in advance directives to interested students. Professor Schwartz, who wrote Maryland's Advance Directives form while serving as Director of Health Policy Development for the Maryland Attorney General, taught students how to help clients fill out the form and to understand the complex and often-sensitive issues underlying the different components of the form.

UMDLAW STUDENTS PARTICIPATE IN PATIENT MANAGEMENT COMPETITION

For the first time in the history of the competition, health law students joined students from other professional schools on the University of Maryland, Baltimore campus to take part in the Interdisciplinary Patient Management Competition. On April 7, five health law students joined medical, social work, nursing, physical therapy and pharmacy students to work together on a case to determine the best course of care for a patient. Written into the problem this year were three legal issues—consent to treatment, Medicaid fraud, and elder abuse. The five teams then presented their problem list and action plan to a panel of judges, which included Virginia Rowthorn, Managing Director of the Law & Health Care Program. The first place team, which included health law student Meghan Hatfield Yanacek, split a prize of \$300.

SPOTLIGHT ON FOOD AND DRUG LAW

LAW & HEALTH CARE PROGRAM HOSTS CONFERENCE ON EMERGING ISSUES IN FOOD & DRUG LAW

On November 16, the Law & Health Care Program, in conjunction with the law firm of Whiteford, Taylor & Preston, hosted a national conference that focused on emerging issues in food and drug law. The conference was the brainchild of Jeremiah Kelly, a former health law student who now practices food and drug law at Whiteford (profiled on page 9). Through this collaboration, Kelly and the Law & Health Care Program were able to bring together prominent food and drug law attorneys, pharmaceutical industry representatives, and government regulators to discuss four of the most cutting edge and controversial issues in food and drug law—follow-on biologics, preemption, risk evaluation and mitigation strategies (REMS), and the future of generic drugs.

The first panel, moderated by Francis B. Palumbo, PhD, JD (Executive Director of the University of Maryland Center for Drugs & Public Policy), was devoted to follow-on biologics (also referred to as biosimilars or follow-on protein products). The passage of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, gave rise to the modern generic drug industry. The Act also created a specialized form of patent litigation, known as Abbreviated New Drug Application (ANDA) litigation. While the Hatch-Waxman Act established an abbreviated approval process for generic versions of small-molecule drugs, it did not create a framework for the approval of follow-on biologics. The panelists—former FDA Chief Counsel Sheldon Bradshaw, JD (Hunton & Williams), Brian Wolfman, JD (Institute for Public Representation at Georgetown University Law, formerly of Public Citizen, and counsel for the respondent in *Wyeth v. Levine*), and Erika Leitzan, JD (Covington & Burling)—provided various perspectives on follow-on biologics, including the scope of FDA’s use of the 505(b)(2) approval process, immunogenicity, exclusivity periods, clinical trials and other essential issues in the field.

The panel members discussed whether Congress should create an abbreviated approval pathway for these products. Several bills have been introduced during this Congress that address follow-on biologics. They include HR 1427/SB 726, the “Promoting Innovation and Access to Life-Saving Medicine Act,” sponsored by Representative Henry Waxman (D-Ca.); and HR 1548, the “Pathway for Biosimilars Act,” sponsored by Representative Anna Eshoo (D-Ca.). These bills contain several provisions that, if enacted, are likely to create a specialized patent litigation framework that differs from the ANDA litigation developed under the Hatch-Waxman Act over the past 25 years.



(from l to r) Dr. Andrew von Eschenbach, Jeffrey Senger, L&HCP Director Diane Hoffmann and Jeremiah Kelly '08

A second panel, moderated by Jeremiah Kelly, included Shawn Brown (Vice President for State Government Affairs at the Generic Pharmaceutical Association), John E. Calfee, PhD (Resident Scholar at the American Enterprise Institute for Public Policy Research), and Kay Holcomb (Genzyme Corporation). These panelists discussed the impact of the *Riegel* and *Wyeth* cases on drug and device labeling. These two Supreme Court cases, one involving a medical device and the other a drug, have altered the landscape for the preemptive effect of medical device and drug labeling. In 2008, in *Riegel*, an eight-justice majority of the Supreme Court ruled that state suits concerning injuries caused by medical devices are barred because state law in the area is preempted by federal law. In March 2009, the Court in *Wyeth* addressed implied pre-emption, a different legal standard, and held that state juries may award damages for harm from unsafe drugs even though their manufacturers had complied with federal regulations. *Wyeth* argued that its compliance with FDA’s labeling requirements should immunize it from lawsuits. The panel discussed these seminal decisions and their impact on state tort claims as well as the policy and legal implications of these decisions from a regulatory and patient perspective.

The third panel, moderated by Diane E. Hoffmann, JD, MS (Director of the Law and Health Care Program at UMDLaw), addressed the challenges of REMS. The FDA Amendments Act of 2007 (FDAAA) gave FDA the authority to require REMS from manufacturers to ensure that the

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benefits of a drug or biological product outweigh its risks. While most REMS fall into the category of medication guides, others are more restrictive and impose obligations such as a communication plan for healthcare providers and other processes to assure safe use of the product. REMS were intended to usher in a new era of drug safety and post-market drug surveillance but FDA's implementation of REMS and the industry's consternation about these provisions of FDAAA have caused substantial debate about the requirements. The panelists—Sheila Weiss Smith, PhD (Professor, University of Maryland School of Pharmacy), Maya Florence (Skadden, Arps, Slate, Meagher & Flom), and former FDA Chief Counsel Gerald Masoudi (Covington & Burling)—discussed the regulatory process of implementing a REMS and the principal hurdles facing the industry in complying with the law.

The panel also addressed related provisions of FDAAA that were designed to enhance the effect of REMS and considered the case of opioids. In 2009, FDA announced that it had contacted the manufacturers of opioid pain medications, including fentanyl, morphine, and oxycodone, requiring them to have REMS in place for their products. Letters went out to manufacturers of brand-name and generic products with either approved new drug applications (NDAs) or approved abbreviated NDAs, most of them extended-release products or transdermal systems. In explaining their action, FDA stated that REMS would be required because opioid manufacturers have taken steps to prevent misuse, abuse, and accidental overdose of these drugs, including warning labels, risk-management plans, and direct communications to prescribers and patients with little success. Opponents of FDA's actions noted that these drugs are already highly regulated through the Drug Enforcement Agency as scheduled drugs and many (but not all) states monitor their use through Prescription Monitoring Plans (PMPs). Panelists also raised other concerns such as the effect of the regulations on providers in group settings who may not be able to comply with the REMS (e.g., hospice or nursing homes) and whether the burden of complying with the REMS may lead physicians to prescribe medications which also have serious side effects or which are less effective in managing pain.

The final panel, moderated by Lawrence Sung, JD, PhD (Director of the Intellectual Property Law Program at UMDLaw), addressed the issue of generic drugs, including patent exclusivity and litigation. Generic drugs provide a bioequivalent substitute for more expensive innovator drug products. Some critics have argued that the exclusivity periods granted to pharmaceutical companies under Hatch-Waxman essentially maintain a pharmaceutical company's ability to sell branded medications at a monopoly price

for an extended period of time. Supporters of the current system have suggested that an alternative system would be deleterious to research and safety, permitting pharmaceuticals of unknown effectiveness into the market. FDA requires a lengthy approval process before a generic prescription drug enters the marketplace, and Hatch-Waxman has been criticized for its weaknesses in facilitating a more timely entry of generic drugs onto the market.

The panelists—former Commissioner of Patents & Trademarks Bruce Lehman (Whiteford, Taylor & Preston), Robert A. Dormer (Hyman, Phelps & McNamara), and Elizabeth H. Dickinson (Associate Chief Counsel for Drugs in the Office of the Chief Counsel at FDA)—

discussed the effectiveness of Hatch-Waxman and whether the exclusivity periods under the Act inhibit competition in the pharmaceutical market or appropriately promote drug safety research.

Co-sponsored by Greenleaf Health, LLC and the University of Maryland School of Pharmacy's Center on Drugs & Public Policy, the conference also featured Dr. Andrew von Eschenbach, the former FDA Commissioner of Food and Drugs, and Jeffrey Senger, Deputy Chief Counsel of FDA, who served as the conference's keynote speakers. Papers from the conference will be published in a forthcoming issue of the law school's *Journal of Health Care Law & Policy*.



Dr Frank Palumbo addresses conference participants.

UMDLaw Graduates at FDA

A number of UMD Law graduates work in policy and legal positions at the FDA:

Office of Legislation

Brian Kehoe and Lauren Cohen

Office of the Chief Counsel

Claudia Zuckerman, Shoshana Hutchinson, Julie Finegan, Shannon Chilcoate Singleton, Ann M. Oxenham, Abigail Brandel, Deborah Biswas, Melissa Sviatko Mendoza, and Deepti Kulkarni

CBER

Diane Maloney

ALUMNI PROFILE: JEREMIAH J. KELLY '08

Two things we know about L&HCP alum Jeremiah Kelly: he isn't afraid of hard work, and he instinctively sees the value of collaboration. Throughout law school, Jeremiah worked in the Commissioner's Office at the U.S. Food and Drug Administration (FDA) in the Office of Legislation, where he analyzed proposed legislation that would impact FDA's authority to regulate food and drugs and responded to questions arising out of often-sensitive Congressional oversight investigations. He also served in FDA's Office of the Chief Counsel, where he assisted in advising FDA's multiple centers. During his years at FDA, he earned a Masters of Public Policy from the George Washington University School of Business & Public Management and a JD from UMDLaw, both as an evening student.

While he was a student, Jeremiah created an externship opportunity for law students in the FDA Office of Legislation, and paved the way for regular externships. After graduation, Jeremiah joined the law firm of Whiteford, Taylor & Preston (WTP) as an Associate in their Specialty Litigation Section. In private practice, Jeremiah has litigated several complex cases in Federal Court and briefed a matter in the Court of Appeals of Maryland. In addition, he has assisted a specialty-needs food manufacturer in conducting a Class 1 international food recall; advised members of a sophisticated plastic surgery practice on the applicability of FDA's human cell, tissue, and cellular and tissue-based product regulations to the autologous use of pluripotent stem cells;

and had an article published in the *Food and Drug Law Journal* related to his passion, follow-on biologics.

As busy as Jeremiah is in his position at WTP, his impulse to collaborate has not waned. He approached his former professors Diane Hoffmann and Frank Palumbo last summer and asked if they would be willing to collaborate with WTP on a Conference on Emerging Issues in Food and Drug Law (see article, p. 7).

Jeremiah worked tirelessly with Law & Health Care faculty and his colleagues in the food and drug bar to organize the conference. WTP Managing Partner Martin Fletcher remarked that, "because of his work at the FDA, Jeremiah knows many of the top leaders in the field. I think it says a lot about his reputation that so many of them agreed to come speak at the conference when he asked them." UMDLaw Dean Phoebe Haddon praised Kelly, saying, "I am tremendously appreciative of the assemblage of experts that [Jeremiah] helped to bring together as well as [his] leadership in creating the opportunity for the School of Law to partner with [WTP]."



Jeremiah J. Kelly '08

FACULTY WORKING ON FDA-RELATED ISSUES

Regulating Tobacco Cessation Medications

Professor Kathleen Dachille has taken her first steps into the field of food and drug law with the filing of a Citizen's Petition seeking changes in the manner in which the agency regulates tobacco cessation medications. (Petition No. FDA-2010-089-0001). Filed on behalf of the Society for Research on Nicotine and Tobacco (SRNT) and the Association for the Treatment of Tobacco Use and Dependence (ATTUD), the petition urges FDA to provide smokers with more flexible pathways towards becoming tobacco-free. Current law has resulted in instructions and warnings on nicotine replacement therapy products (NRT) that overstate the risks, and do not allow for the most efficacious use of NRT. For example, current required warnings on NRT indicate that a smoker not use the nicotine patch and gum at the same time. However, research shows smokers who successfully quit using NRT often use the patch all day and night and chew the gum when a particularly urgent or deep craving strikes, and that such use is safe. Not only do studies support the efficacy and safety of longer term use, there is no question that continued use of NRT is far safer

than continued smoking. The petition remains pending at the agency and public comments continue to be added to the docket.

Professor Dachille is also engaged in matters that stem from the passage of the Family Smoking Prevention and Tobacco Control Act (FSPA) in June 2009, which gave FDA jurisdiction to regulate tobacco products. After the bill passed, Professor Dachille spent significant time with colleagues around the country assessing the potential impact of the legislation, identifying and answering legal questions raised by the law, and advising state and local health departments about new powers made available to them under the statute. More recently, Professor Dachille worked with members of the Maryland General Assembly to seek passage of legislation that mirrors many provisions of the FSPA and allows for state and local enforcement of those provisions. Currently students in Professor Dachille's Tobacco Control Clinic are preparing a citizen's petition related to flavored cigars, and assisting the Maryland

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Department of Health and Mental Hygiene with a proposal to secure federal funds to conduct enforcement of the new FDA statute and regulations. As provisions of the FSPA and related regulations go into effect, and as FDA continues to study how best to exercise its important power, there is no doubt that Dachille and her students will remain busy with FDA-related work for quite some time.

Medical Marijuana and the Law

In a recent issue of the *New England Journal of Medicine*, Director of the Law & Health Care Program Diane Hoffmann and Professor Ellen Weber commented on the U.S. legal landscape surrounding medical marijuana. States have led the medical marijuana movement largely because federal policymakers have consistently rejected petitions to authorize the prescription of marijuana. Currently fourteen states—California, Alaska, Oregon, Washington, Maine, Hawaii, Colorado, Nevada, Vermont, Montana, Rhode Island, New Mexico, Michigan, and most recently New Jersey—have passed laws eliminating criminal penalties for using marijuana for medical purposes. A recent Department of Justice memo indicating that the DEA would no longer prosecute individuals who use marijuana in states that permit its use for medical purposes may spur additional states to pass similar laws. Because states have taken on the issue, medical marijuana is regulated by a patchwork of different state laws and regulations.

Hoffmann and Weber's article analyzed the fourteen state laws in terms of possession limits, individuals allowed to possess medical marijuana, and qualifying medical conditions. They also looked at what state laws don't regulate, including the quality of the marijuana and ways of ob-

taining the drug. Most states explicitly permit patients or caregivers to cultivate marijuana, but are silent on whether patients or their caregivers may buy or sell marijuana or whether dispensaries are permitted. The article also noted many state laws are missing a requirement that physicians recommending medical marijuana to adult patients provide even a rudimentary disclosure of risks and benefits, although such disclosure is generally required for patients who are minors.

Reliance on state legislatures to implement medical marijuana has led to a hodgepodge of laws and regulations that, while providing relief to some patients, are inadequate to advance effective treatment. The article notes that medical experts emphasize the need to reclassify marijuana as a Schedule II drug to facilitate rigorous scientific evaluation of the potential therapeutic benefits of cannabinoids and to determine the optimal dose and delivery route for conditions in which efficacy is established. Professors Hoffmann and Weber argue that this research could provide the basis for regulation by FDA but concede that current roadblocks to conducting clinical trials make this more rational route of approval unlikely and perpetuates the development of state laws that lack consistency or consensus on basic features of an evidence-based therapeutic program. They also point to another downfall to the state-based approach—it may leave patients and physicians in a precarious legal position. Although the current Justice Department may not prosecute patients if they use marijuana in a manner consistent with their states' laws, the federal law prohibiting possession of marijuana remains unchanged, and future administrations could return to previous enforcement practices.

Charity Care

Cont. from p. 5

References

1. The report prepared for MCJ was authored by Michelle Brunner (1L), Aaron DeGraffenreid (1L), Caroline Farrell (3L), and Maya Uppaluru (1L) under the supervision of Virginia Rowthorn, Managing Director of the Law & Health Care Program.
2. According to an *American Journal of Medicine* study, in 2007, 62.1% of all American bankruptcies have medical causes. In 34.7% of these cases, the family medical bills were greater than \$5,000/month or more than 10% of the family income. Himmelstein, D., et. al., "Medical Bankruptcy in the United States, 2007: Results of a National Study," *The American Journal of Medicine*, Vol. 20, No. 8 (August 2009).
3. Bennett, L., "It's All in the Numbers: Beginner's Guide to Charity Care Analysis," Consumers Union of U.S., accessed Jan. 6, 2010, pg. 1-2.
4. Community Catalyst, Free Care Compendium, Overview, accessed Jan. 6, 2010, http://www.communitycatalyst.org/projects/hap/free_care/pages?id=0002.
5. This conclusion is based on research of Mississippi law and was confirmed by the Mississippi Hospital Association and the Mississippi Primary Care Association.
6. See, e.g., MISS. CODE ANN. §13-115-31 (2009).
7. Maryland Health Services Cost Review Commission, Report to the Governor: Review of Financial Assistance and Credit Collection Activities of Maryland Hospitals 10 (Feb. 2009).
8. Hospital Billing and Collection Practices <http://www.aha.org/aha/content/2004/pdf/guidelinesfinalweb.pdf>

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LAW & HEALTH CARE PROGRAM

FACULTY UPDATES

KAREN ROTHENBERG VISITS CHINA TO DISCUSS HEALTH CARE REFORM

In 2009, China unveiled a blueprint for health care reform, kicking off a decade of much-anticipated reform to fix its ailing medical system and to ensure fair and affordable health services for its 1.3 billion citizens. The Central Committee of the Communist Party of China and the State Council, or China's Cabinet, jointly endorsed and issued the "Guidelines on Deepening the Reform of Health Care System" after about three years of intense debate and repeated revision. By 2020, according to the blueprint, the world's most populous country will have a basic health care system that can provide safe, effective, convenient and affordable health services to urban and rural residents.

China is abuzz with the issue of health care reform and health policy officials have reached out to scholars in the United States to help them plan for the future. One of those scholars is Professor Karen Rothenberg who took part in a two-day meeting on health care and social security reform at Peking University. Professor Rothenberg was invited to the December meeting to brief Chinese scholars and gov-



Professor Karen Rothenberg

ernment officials on the U.S. health care system and reform proposals, and their implications for workers. She used a fictional character named "John" who was injured in a fall to explain the U.S. health care system. This graphic depiction of how our health care system works ignited a lively and fruitful debate.

While in China, Professor Rothenberg was invited to make a similar presentation at Tsinghua University. She delivered her presentation, "Access to Health Care in the U.S.—Current Challenges and Proposals for Reform" at Tsinghua's new Health Care Law Research Center.

Center Chief Director Professor Wang Chenguang, formerly served as Dean of Tsinghua University and is currently Vice Chairperson of the Chinese Health Law Society. Professors Rothenberg and Chenguang are exploring the possibility of future collaborations between Tsinghua and the Law School. In late January, Professor Chenguang visited the School of Law and met with L&HCP faculty to discuss future collaboration.

AMANDA PUSTILNIK STUDIES PAIN IMAGING TECHNOLOGIES AND THE ROLE OF PAIN IN THE LAW

The explosion in new sciences—particularly neuroscience—not only may, but will foreseeably change the law's idea of the physical person. Much of the excitement about the potential changes to the law's conception of the person goes to areas of decision-making, rationality, or issues of age-related development. These areas of inquiry may produce insights that profoundly transform legal doctrine and scholarship, but Professor Amanda Pustilnik is studying what she argues is the area of more immediate legal and scholarly potential that will develop from advances in neuroscience—physical pain. In her forthcoming article, Professor Pustilnik asserts that pain is ubiquitous across legal domains, and important within them. For instance, whether one qualifies for certain legal entitlements, like disability payments, often flow from determinations related to pain. Within tort, the most significant and often



Professor Amanda Pustilnik

most troubling category of damages is that of pain and suffering. Within criminal law, certain offenses are defined and distinguished by the degree of pain or "excess pain" the perpetrator inflicted on the victim. The lawfulness of certain sanctions and procedures, ranging from the death penalty to interrogation techniques and detention conditions, also often are determined by reference to painfulness. She therefore argues that the practical implications of pain, and issues surrounding its detection and measurement, are substantial. Further, Professor Pustilnik believes that the role played by pain within the law, and how new pain imaging technologies may change ideas about the body in pain, provide a fascinating site for scholarly understanding of the concept of the embodied person within the law and how embodiment takes on normative dimensions.

LAW & HEALTH CARE PROGRAM

FACULTY UPDATES

LESLIE MELTZER HENRY STUDIES PRIVACY AND DIGNITY

Professor Henry's recent scholarship has been devoted to privacy and dignity. In "Visionary Pragmatism and the Value of Privacy in the Twenty-First Century," she and co-author Professor Danielle Citron argue that despite extensive scholarly, legislative, and judicial attention to privacy, our understanding of privacy and the interests it protects remains inadequate. At the crux of this problem, is privacy's protean nature—it means "so many different things to so many different people" that attempts to articulate just what it is, or its importance, have failed or become unwieldy. As a result, important privacy problems remain unaddressed, often to society's detriment.

Professors Henry and Citron discuss whether the privacy framework proposed by Daniel J. Solove in his new book *UNDERSTANDING PRIVACY*, can reverse this state of affairs by providing a pluralistic conception of privacy that recognizes the societal value of privacy protections. They conclude that Solove's pragmatic approach succeeds because it is dynamic as well as functional. It is poised to respond to existing privacy issues, yet nimble enough to tackle emerging problems. Nevertheless, Professors Henry and Citron warn that without further guidance to policymakers about how to apply his framework, Solove's proposal is susceptible to the kind of non-pragmatic decision-making he eschews. It of-



Professor Leslie Meltzer Henry

fers no safeguards, for example, to prevent decision makers from rendering judgments based on their philosophies, preferences, or emotions, and it provides little advice to policymakers weighing competing privacy risks. In these respects, Professors Henry and Citron suggest that Solove's approach would benefit from a more transparent decision-making process as well as rules of thumb intended to guide policymakers through some of privacy's more complicated terrain.

In another forthcoming article, "Deciphering Dignity," Professor Henry draws on her interest in dignity's usage in law, ethics, and public policy to think through a narrow question about dignity's role in the bioethics of human enhancement technologies. She considers the arguments made by Fabrice Jotterand and other bioethicists who aim to repudiate the claim made by transhumanists that individuals can enhance their dignity through technological modification. The trouble on both sides of the debate, Henry argues, is it is extremely difficult to make normative comparisons about human and post-human dignity without first infusing dignity with particular metaphysical assumptions. She offers a brief taxonomy of dignity to illustrate the various meanings that animate the debate, and she demonstrates how the taxonomy can clarify and lend moral salience to the issues at hand.

DONALD GIFFORD PUBLISHES BOOK ON THE USE OF LITIGATION TO SOLVE PUBLIC HEALTH PROBLEMS

Professor Donald Gifford's new book *SUING THE TOBACCO AND LEAD PIGMENT INDUSTRIES: GOVERNMENT LITIGATION AS PUBLIC HEALTH PRESCRIPTION* (University of Michigan Press, 2010) explores *parens patriae* litigation by state governments against manufacturers of cigarettes, lead pigment, handguns, and other products. Professor Gifford explains that widespread public health problems caused by product exposure bedeviled courts for decades. Traditional tort doctrines, with their origins in nineteenth-century cases involving traumatic collision injuries, blocked the recovery of victims of tobacco-related illnesses and childhood lead poisoning. During the same period, regulatory authorities, influenced by business lobbyists, failed to protect the public. Public health advocates and state officials, therefore, greeted the arrival of *parens patriae* litigation against product manu-



Professor Don Gifford

facturers in the 1990s as an almost magical means of overcoming the legal obstacles that had prevented individuals from recovering for product-caused harms.

Fifteen years later, however, Professor Gifford paints a more realistic picture—one where courts, through their refusal to expand traditional tort claims, have effectively foreclosed the use of litigation as a means to solve product-caused public health problems. According to Professor Gifford, even if the government were to prevail, the remedy in such litigation, whether achieved through judicial decree or settlement, is unlikely to be effective. Finally, he contends that by shifting the powers to regulate products and to remediate public health problems from the legislature to the state attorney general, raises important concerns about the appropriate allocation of powers among the branches of government.

SPRING CONFERENCES

The Law & Health Care Program and its affiliated centers and programs have hosted a number of conferences and roundtables this semester on health-related topics.

April 1, 2010

2nd Annual Veterans' Legal Assistance Conference

(Leadership in Public Service Program and the Law & Health Care Program)

This conference provided a forum for discussing critical issues facing veterans, including access to health care for women veterans, homelessness, veterans in the justice system and new legislative initiatives. The conference also included training for lawyers interested in representing veterans in their claims for service-related disability benefits.

April 2, 2010

The Future of Genetic Disease Diagnosis and Treatment: Do Patents Matter?

(Intellectual Property Law Program)

This year's *Journal of Business and Technology Law* Spring Symposium explored the implications of intellectual property, particularly patent exclusivity, on the medical diagnosis and treatment of gene-based diseases. The symposium gathered experts from academia and professional and regulatory institutions to discuss the implications of two landmark cases poised to change the future of biotechnology patents—*Bilski v. Kappos*, which challenged the patentability of certain business methods, and *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, the suit filed against Myriad Genetics (among others) by the ACLU which challenged the company's patents on two genes linked to breast and ovarian cancers. To learn more about the Symposium, visit

www.law.umaryland.edu/faculty/conferences/detail.html?conf=97

April 16, 2010

Roundtable on Legal Impediments to Telemedicine

(Law & Health Care Program)

This roundtable looked at legal obstacles that stand in the way of robust implementation of telemedicine. Providing health care services where distance separates the participants, or telemedicine, has boomed in recent years, not just because of technological advances but as a multifaceted response to address inadequate access to care and rising health care costs. As technology has improved and enthusiasm to use telemedicine has grown, however the legal framework in which medicine is practiced has not evolved to meet the unique legal issues raised by telemedicine. The Roundtable focused on three legal impediments to the uptake of telemedicine: practitioner licensure, credentialing and privileging, and medical malpractice. The Roundtable brought together 20-25 telemedicine stakeholders, including telemedicine industry representatives, government regulators, health care providers, and policy makers along with several legal academics. Using case studies in each area, the stakeholders and academics discussed areas of concern and consensus that will lead to policy recommendations and a white paper. To learn more about the Roundtable, visit www.law.umaryland.edu/telemedicine

April 28, 2010

Disability, Health Care & Ethics – What Really Matters

(Maryland Healthcare Ethics Committee Network and Law & Health Care Program)

This conference was designed to broaden participants' understanding of the concerns and rights of people with disabilities in the context of health care encounters. Persons with cognitive and physical disabilities comprise a growing sector of our society, yet health care providers and ethics committee members may lack knowledge, skills, and insight related to disability rights and its impact on health care delivery and ethical decision-making. Conference panelists spoke about the history of discrimination against people with disabilities and the rise of the "social model" of disability, current biases among some health care providers that disadvantage persons with disabilities, and knowledge, strategies, and resources health care professionals and ethics committee members should have or be able to access to appropriately respect disability rights at their institutions and in health care encounters. To learn more about the Conference, visit

www.law.umaryland.edu/faculty/conferences/detail.html?conf=92

L&HCP FACULTY NOTES

From May 2009 to April 2010

KATHLEEN DACHILLE

Presentations

“Flavored Tobacco Products: Legislative Activity and Options and Fire-Safe Cigarettes: How This Legislation Swept the Country Like Wildfire,” National Conference on Tobacco or Health, Phoenix, Arizona (June 10, 2009)

“Maryland Legislative Process and the Role of Young Advocates,” TRASH Youth Advocacy Training, Baltimore, Maryland (November 7, 2009)

“Nutrition Labeling in Chain Restaurants: Increasing Knowledge and Decreasing Waistlines,” American Public Health Association Annual Meeting, Philadelphia, Pennsylvania (November 10, 2009)

“The Family Smoking Prevention and Tobacco Control Act of 2009: Relevant Provisions and Potential State and Local Government Action,” MD QUIT Annual Conference, Ellicott City, Maryland (January 21, 2010)

MICHAEL GREENBERGER

Presentations

“Adapting to New Threats: H1N1 Flu and You,” Moderator, University of Maryland School of Law Annual 9/11 Commemoration, University of Maryland School of Law, Baltimore, Maryland (September 16, 2009)

“Strengthening Security and Oversight at Biological Research Laboratories,” Hearing Witness, United States Senate Committee on the Judiciary Subcommittee on Terrorism and Homeland Security, Washington, DC (September 22, 2009)

Panelist, “Civil Liberties Implications of the Government’s Response to H1N1,” Constitution Project and University of Maryland Center for Health and Homeland Security Event, National Press Club, Washington, DC (October 28, 2009)

“Training in Law and Policy Issues Related to the Public Health Response

to Biological Emergencies: Public Health Catastrophes—Past, Present, and Future,” Keynote Speaker and Panel Facilitator, University of Maryland Center for Health and Homeland Security H1N1 Symposium at the Mid Atlantic Regional Center for Excellence Conference, George Mason University, Manassas, Virginia (November 10-11, 2009)

“Disease or Disaster: Are We Ready to Respond,” Panelist, United States Naval Institute Homeland Security Webinar, United States Naval Academy, Annapolis, Maryland (November 12, 2009)

Participant, “Governors Emergency Management Advisory Council,” Annapolis, Maryland (December 14, 2009)

Publications

“State and Federal Emergency Powers,” in *Homeland Security: Legal and Policy Issues* 21 (with Arianne Spaccarelli) (Joe D. Whitley & Lynne K. Zusman, eds., 2009)

Media/Interviews

Interview, “Annapolis Company Surges Ahead with Anthrax Vaccine,” *The Capital* (February 27, 2010)

Other Activities/Appointments/Awards

Appointment, Advisory Committee, American Bar Association Standing Committee on Law and National Security (August 2009)

Appointment, Vice Chair, Governor’s Emergency Management Advisory Council (August 2009)

Appointment, Chair, Governor’s Emergency Management Advisory Council (December 2009)

DEBORAH HELLMAN

Publications

“Prosecuting Doctors for Trusting Patients,” 16 *George Mason Law Review* 701 (2009)

“Willfully Blind for Good Reason,” 3 *Criminal Law and Philosophy* 301 (2009)

LESLIE MELTZER HENRY

Presentations

“Allocating Limited Health Care Resources: The Ethical Issues,” University of Maryland School of Medicine, Baltimore, Maryland (September 9, 2009)

“Legal and Ethical Issues in End-of-Life Care,” University of Maryland School of Medicine, Baltimore, Maryland (September 9, 2009)

Organizer and Moderator, “Pediatric Care: Legal and Ethical Issues in Treatment Refusals,” Roundtable Event at the University of Maryland School of Law, Baltimore, Maryland (September 10, 2009)

“The Ethics and Regulation of Human Stem Cell Research,” Maryland Stem Cell Research Fund, Greater Baltimore Committee, Baltimore, Maryland (September 15, 2009)

“Ethical Criteria for Allocating Scarce Resources during Pandemics,” Department of Pediatrics, Sinai Hospital, Baltimore, Maryland (December 2, 2009)

“Spheres of Dignity: Conceptions and Functions in American Constitutional Law,” Case Western University School of Law, Cleveland, OH (April 15, 2010)

Other Activities/Appointments/Awards

Appointment, Associate Faculty, Johns Hopkins Berman Institute of Bioethics (2009)

DIANE HOFFMANN

Publications

“Medical Marijuana and the Law,” Perspective, 362 *NEJM* 1453 (April 22, 2010) (with Ellen Weber)

“Teaching Health Law—A Health Law Practice Workshop: Bridging Externship Placements and the Classroom,” 37 *Journal of Law, Medicine & Ethics* 513 (2009)

“Physicians Who Break the Law” 53 *St. Louis University Law Journal* 1049 (2009)

“Comparative Health Law and Policy: What, if Anything, Can We Learn From Other Countries?” 37:4 *Journal of Law, Medicine & Ethics* 790 (Winter 2009)

Presentations

“Physicians Who Break the Law,” Presentation at the 32nd Annual Health Law Professors Conference, Cleveland, OH (June 2009)

“Rationing Scarce Medical Resources During a Pandemic Flu,” The University of Maryland School of Law Annual 9-11 Commemoration Event: Adapting to New Threats: H1N1 Flu and You,” University of Maryland School of Law, Baltimore, Maryland (September 16, 2009)

“The Disparity Toward Women in Pain,” Second Annual Women in Pain Conference: Gender Matters – Building Bridges to Optimum Health, Los Angeles, California (September 18, 2009)

“The Challenges of Crafting an Educational Curriculum in Interdisciplinary Settings,” Conference on Interdisciplinary Collaborative Education: Partnerships Between Law Schools and the Health Professions, Georgia State Law School, Atlanta, Georgia (September 25, 2009)

“Gender Disparities in the Treatment of Pain,” Maryland Women’s Law Center forum on “Is Women’s Health Taken Seriously?,” University of Maryland School of Law (October 20, 2009)

“Ethical Issues of Rationing During a Pandemic Flu,” Maryland Healthcare Ethics Committee Network, University of Maryland School of Law (October 27, 2009)

Other Activities/Appointments/Awards

Awarded Grant from National Human Genome Research Institute for 3-year Project on the Regulation of Probiotics (2009)

Guest Editor, *Journal of Law, Medicine & Ethics* symposium on Comparative Health Law and Policy.

KAREN ROTHENBERG

Presentations

Panelist, “Maryland’s Investment in Stem Cell Science,” The World Stem Cell Summit, Baltimore, Maryland (September 21, 2009)

“Pros and Cons of the Current Health Reform by Congress,” Faculty Lunch Colloquium, University of Hawaii, William S. Richardson School of Law, Honolulu, Hawaii (November 3, 2009)

“‘Distracted’ in Focus: Legal and Ethical Implications of ADHD for the Child, Parents, and Society,” Galiher Ono Distinguished Public Lecturer, University of Hawaii, William S. Richardson School of Law, Honolulu, Hawaii (November 4, 2009)

“Judging Genes: Implications of the Second Generation of Genetic Tests in the Courtroom,” Hawaii Judiciary Program, Honolulu, Hawaii (November 5, 2009)

JACK SCHWARTZ

Presentations

“The Impact of Health Care Reform on Legal Practice,” Health Care Reform Forum, University of Maryland Baltimore (September 3, 2009)

“Decisionally Incapacitated Patients,” Grand Rounds, Bon Secours Hospital, Baltimore, Maryland (November 13, 2009)

“Legal Framework for Advance Care Planning,” Geriatric Imperative Minimester, University of Maryland Baltimore (January 5, 2010)

“State Law Issues Affecting Data Pooling and Biospecimen Banks,” NIH Rare Disease Research Conference, Bethesda, Maryland (January 9, 2010)

“The Role of Medical Review Boards in Protecting Public Health,” Transportation Safety Board Conference, Washington, D.C. (January 13, 2010)

“Surrogate Decision-Making for Someone with a Disability,” Maryland State Bar Association Continuing Legal Education Program, Columbia, Maryland (April 23, 2010)

Publication

“Patient Rights: Ethics and the Clinical Care of Patients with Schizophrenia,” (with Evan DeRenzo et al.), in *SCHIZOPHRENIA: BIOPSYCHOSOCIAL APPROACHES AND CURRENT CHALLENGES* (S. Kasper and G.N. Papadimitriou, eds.) (New York: Informa Healthcare 2009)

LAWRENCE SUNG

Presentations

“Enforcing Stem Cell Patent Rights as Part of Your Business Plan While Avoiding Infringing Those of Your Competitors,” World Stem Cell Summit 2009, Baltimore, Maryland (September 22, 2009)

Moderator, Emerging Issues in Food and Drug Law: A National Conference for Lawyers, Policy-Makers, and Corporate Leaders, The Future of Generic Drugs: Patents, Exclusivity, and Litigation, Baltimore, Maryland (November 16, 2009)

Other Activities/Appointments/Awards

Reviewer, National Institutes of Health Research Grant Application Study Section—Centers for Excellence in Ethical, Legal and Social Implications of Human Genetics and Genomic Research, Bethesda, Maryland (November 19-20, 2009)

ELLEN WEBER

Publications

“Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance,” 13 *Journal of Health Care Law & Policy* 101 (forthcoming 2010)

“Medical Marijuana and the Law,” Perspective, 362 *NEJM* 1453 (April 22, 2010) (with Diane Hoffmann)

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9. "P&P Board Sample Hospital Charity Care Policy and Procedures," available at <http://www.hfma.org/library/accounting/reporting/400647.htm>
10. Available at <http://www.familiesusa.org/assets/pdfs/medical-debt-guide.pdf>.
11. Baltimore Sun Special Investigation, accessed on Jan. 6, 2010, <http://www.baltimoresun.com/news/nation-world/bal-hospitaldebt,0,2121674.storygallery>.
12. Maryland is the only state to retain an all-payer hospital rate setting system that is made possible by a federal Medicare waiver. Hospital billing rates are set by the Maryland Health Services Cost Review Commission.
13. Families USA Report, "Medical Debt: What States Are Doing to Protect Consumers," November 2009. Available at <http://www.familiesusa.org/assets/pdfs/medical-debt-state-protections.pdf>.
14. *Id.*
15. *Id.*
16. See, e.g., *Gardner v. N. Miss. Health Servs.*, 2005 U.S. Dist. LEXIS 45007 (D. Miss. 2005): Class action settlement (where NMHS agreed to provide free or discounted care to uninsured patients and apply these discounts retroactively to plaintiffs, and agreed to pursue less aggressive collection tactics) was submitted to the court in August 2004. In April 2005, NMHS had a change of heart and filed to dismiss the suit in its entirety. The court ruled that plaintiffs had failed to state a claim; plaintiffs' claim was based on the hospital's 501(c)(3) status as implying a contractual duty to provide charity care, and many federal district courts have rejected this premise. See also articles on these cases: Mississippi Nonprofit Hospital System Agrees to Settle Uninsured Patients' Claims (<http://healthcenter.bna.com/pic2/hc.nsf/id/BNAP-63WNGR?OpenDocument>) and Tax-Exempt Hospitals' Practices Challenged: 46 Lawsuits Allege That Uninsured Pay the Most (<http://www.washingtonpost.com/ac2/wp-dyn/A45531-2005Jan28?language=printer>).