

LAW & HEALTH CARE



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NEWSLETTER

LAW & HEALTH CARE PROGRAM WELCOMES PROFESSOR FRANK PASQUALE

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Health information technology can save lives, cut costs, and expand access to care. But its full promise will only be realized if policymakers broker a “grand bargain” between providers, patients, and administrative agencies. In exchange for subsidizing systems designed to protect intellectual property and secure personally identifiable information, key stakeholders should have full access to key data those systems collect. (Frank Pasquale 2012)



Professor Frank Pasquale

The timing of Professor Frank Pasquale’s arrival at the University of Maryland Carey School of Law is auspicious. Just as the United States is poised to launch major data-sharing initiatives to implement the Affordable Care Act, we are welcoming to our faculty someone who has given great thought to both the peril and promise of health information technology. Pasquale, who just started his first semester at the law school, is well known in legal academia and beyond for asking big questions about a big field: information and the challenges posed to information law by rapidly changing technology, particularly in the health care, internet, and finance industries. As an overarching theme in the new Health Information Privacy and Innovation Seminar he is teaching next semester, Pasquale is asking his students to consider the massive amount of health information we generate as a nation and how it is (and isn’t) used. He wants them to think about why an email user’s preferences in, for example, the purchase of a car can be determined by a search engine in less than a second, but a dying patient cannot use similar technology to determine what end-of-life decisions have been successful for those suffering a similar range of conditions.

While Pasquale was a law student at Yale Law School he was more interested in the fields of technology and intellectual property than health law. But his slow and steady migration to law and medicine can be seen from a paper he wrote as a student that was ultimately published in the *YALE JOURNAL OF LAW & THE HUMANITIES*. His paper, “Two Concepts of Immortality: Reframing Public Debate on Stem-Cell Research,” focused on stem cell and regenerative technologies

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Frank Pasquale

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but took a deep philosophical, rather than regulatory, approach to these issues. He discussed the potential for replacing or regenerating human cells, tissues or organs and how doing so (or fears about doing so) implicated different visions of what it meant to be human. “Those reflections still inform my teaching of end of life issues in my Health Law Survey course,” Pasquale says.

After Yale, Pasquale spent two years at the law firm of Arnold & Porter where he received a “baptism by fire” education in health law. Pasquale helped prepare administrative filings for pharmaceutical companies who were seeking Medicare reimbursement for new products. This practice immersed Pasquale in the complex world of health care financing, intellectual property, and innovative health technologies – a triad that still forms the core of his scholarly agenda. While at Arnold and Porter, he wrote an article entitled, “Toward an Ecology of Intellectual Property: Lessons from Environmental Economics for Valuing Copyright’s Commons,” that led to his first teaching position at Seton Hall Law School.

Although he was hired as an IP scholar, in his enthusiasm to teach, he agreed to take on several health law courses to cover for faculty who were on leave. Fascinated by the material and the diverse range of students and community members he encountered, he wrote several articles on aspects of health care regulation and finance. His work has covered specialty hospitals, concierge medicine, and access to care. The rest, as they say, is history. Professor Pasquale became a valued and respected teacher at Seton Hall and we are honored to have him here at UM Carey Law.

Pasquale has published over 25 articles on health and information law and he has a number of projects in the pipeline. An overall theme of Pasquale’s work is protecting the health care system from business logic appropriate in other sectors, but ill-suited for vulnerable patients. Many thought leaders believe that the health sector must adopt the metrics of Wall Street and Silicon Valley to adapt to the 21st century. Pasquale’s forthcoming book, *The Black Box Society: Technologies of Reputation, Search, and Finance* (under contract to Harvard University Press), reverses that logic, reasoning that reforms to promote access, accountability, and quality in health care should be adopted in America’s internet and finance sectors.

Pasquale’s recent scholarship promotes the expanded use of information technology in health care for the benefit of individuals and communities. His most recent work, “Grand Bargains for Big Data: the Emerging Law of Health Information,” argues that the full promise of health information technology to save lives, cut costs, and expand access to care will only be realized if policymakers broker a “grand bargain” between providers, patients, and administrative agencies. The grand bargain, as Pasquale sees it, is that in exchange for subsidizing systems designed to protect intellectual property and secure personally identifiable information, key stakeholders should have full access to key data those systems collect. He argues that CMS’s data-mining program to ferret out fraud could be a stepping stone toward collecting information to promote personalized comparisons of treatment effectiveness. He further argues that better collection and dissemination of health information is an important policy goal.

For an upcoming symposium at University of North Carolina Law School this fall, Pasquale will present a talk entitled “Best Practices in the Outsourcing of Health Care Decisionmaking.” In this talk, he addresses CMS’s practice

of outsourcing decisions regarding the purchase of drugs, devices, information technology, insurance, and medical care to private entities. He looks at two models of outsourcing such decisions – private licensure and deputization. In private licensure, firms offer a stamp of approval to certify that a given technology or service is up to statutory or regulatory standards. Via deputization, firms can pursue a regulatory or law enforcement role to correct (and even punish) providers who have failed to meet standards or acted fraudulently. He notes that while both models have merits, they can also be abused if private licensors or deputies are not adequately supervised, or if they are faced with too crude an incentive framework. His article suggests a set of best practices for the outsourcing of responsibility to these health care decisionmakers.

Professor Pasquale will present another paper called, “The Health Information Games: An Impossibility Theorem of Health Data Flow Optimization” at the University of Houston Law School this semester. The paper takes on three broad assumptions about health information policy. First, many perceive a tension between regulation and innovation, especially with regard to privacy regulations that many believe are keeping researchers, companies, and providers from aggregating the data they need to promote innovation. Second, aggregation of fragmented data is seen as a threat to its proper regulation, creating the risk of breaches and other misuse. Third, a prime directive for technicians and policymakers is to “give patients control over their data,” to introduce ever more granular methods of monitoring, sharing, and securing information. Pasquale’s paper questions those assumptions, which he calls (respectively) the Privacy Threat, the Aggregation Threat, and the Control Solution. In his view, in some contexts, strong rules regarding data acquisition, transfer, analysis, and use are key components of an innovation ecosystem. Also, some types of important privacy harms can only be remedied when there is some central authority with access to all relevant databases. Fragmentation of information, far from always helping privacy, may create Kafkaesque scenarios where individuals feel helpless to

correct damaging misconceptions about them. But the Control Solution should not be the only, or even primary, response to the Aggregation Threat. Indeed, giving patients “control” over “their” data may sometimes only worsen threat scenarios, particularly in an era of big data.

Finally, for a special issue on neoliberalism for the journal *Law & Contemporary Problems*, Pasquale is writing an article called, “Health Care Cost Cutting: Is the Cure Worse than the Disease?” in which he questions the current rage for cost-cutting in health care. In his article, he notes that many of the architects of health care reform were also deeply concerned about rising health care costs as seen in the legislation’s very name (the Patient Protection & Affordable Care Act, not Quality Care Act or Accessible Care Act). He believes that funds could be better allocated within the health care sector, but there’s little evidence they need to be reallocated outside the sector any more than funds need to be allocated out of the energy, finance, or telecommunications industries to more productive enterprises.

In addition to his prodigious scholarly work, Professor Pasquale has testified before the Judiciary Committee of the House of Representatives, appearing with the General Counsels of Google, Microsoft, and Yahoo. He has also presented before a Department of Health & Human Services/Federal Trade Commission Roundtable and panels of the National Academy of Sciences. He is an Affiliate Fellow of Yale Law School’s Information Society Project and a member of the Advisory Board of the Electronic Privacy Information Center. Pasquale has served on the executive board of the Health Law Section of the American Association of Law Schools (AALS), and has served as chair of the AALS section on Privacy and Defamation.

As he gets used to living in Baltimore and having to depend on a car for the first time (having just moved here from Brooklyn), Professor Pasquale is getting to know his new students and charming the faculty and staff with his open door and warm personality. He’s also actively tweeting about the subjects he is working on and many beyond that. Follow him on Twitter at @HealthPI.

LAW & HEALTH CARE PROGRAM DIRECTOR DIANE HOFFMANN AND UM CAREY PROFESSOR PETER DANCHIN LEAD INTERDISCIPLINARY HIV/AIDS WORKSHOP IN MALAWI

Diane Hoffmann, UM Carey Law Professor and Director of the Law & Health Care Program, and Peter Danchin, UM Carey Law Professor and Director of the International Law Program, spent two weeks in Malawi this summer working with a team of interprofessional students from the University of Maryland Baltimore (UMB) Schools of Law, Dentistry, Medicine, Nursing, Pharmacy, and Social Work. The student team (and rotating faculty members) spent six weeks in Malawi working on two separate projects – one relating to HIV/AIDS that Hoffmann and Danchin led at Malawi’s Chancellor College of Law and another that focused on “mapping” a rural community with a standardized social science tool. Hoffmann and Danchin’s work is part of an ongoing collaboration with Chancellor College of Law that they hope to carry into the future starting with a visit by Malawian law faculty to the law school in Spring 2014.

The interprofessional summer project in Malawi is an initiative of the Global Health Interprofessional Council (GHIC) at UMB. GHIC, which was originally established with funds from an NIH Fogarty Center “Framework Program for Global Health” grant in 2006, has sent interprofessional teams to Malawi since 2010. The project is designed to bring UMB students and faculty together with their Malawian counterparts to study pressing global health issues. The project is relatively unique in professional education for its commitment to teaching students from diverse professions how to work together to conduct a meaningful project that is relevant to the needs of the local community. Students described their interdisciplinary experiences through reflective memos.

"In a foreign setting and culture, my personal adaptation was contingent on the interdisciplinary setting. Through the immersion into an interdisciplinary/intercultural setting, I had to adapt both physically and mentally. Finding commonalities between the professions and the cultures was my key to successfully adapting. By finding that professional connection and human connection, I was able to see my role as a dentist in a new light."

Peter Krumbaar
School of Dentistry, Malawi 2013



*Professor Chikosa Banda, Chancellor College Malawi,
L&HCP Director Diane Hoffmann and UM Carey
Professor Peter Danchin*

In 2010 the UMB team worked with Duke researchers to study and make recommendations regarding the legal and medical needs of orphans and vulnerable children in a rural Malawian district; in 2011 the team studied health care utilization for the first signs of malaria in children as part of UMB School of Medicine Professor Miriam Laufer’s existing NIAID-funded clinical trials in Blantyre, Malawi; and in 2012 the team conducted WHO’s Safe Motherhood survey in the Chikwawa District of Malawi under the direction of the district’s health officer and UMB faculty. During these first three summers, law students and faculty ensured that the legal components of each summer’s project were informed and assisted by legal experts on the ground in Malawi. This effort led to several meetings with the Dean and faculty of Chancellor College, particularly Professor Chikosa Banda, an expert in human rights law. For the 2013 summer project, Professors Banda, Hoffmann, and Danchin organized a workshop for students and faculty from both universities on the subject of HIV/AIDS.

Although UM Carey and Chancellor College of Law function in very different national legal frameworks - most notably in the importance of extrajudicial tribal law in Malawi – both schools are committed to providing clinical legal assistance to individuals with HIV/AIDS in their communities. UM Carey’s HIV/AIDS clinic is over 20 years old and Chancellor College’s is just a few years old, but given Malawi’s long-time struggle with the epidemic, both schools have much to learn from each other.



Shamarla McCoy (UM Carey 3E) and students from Chancellor College of Law, Malawi

As background, UM Carey Law has offered an HIV/AIDS legal clinic since 1998, which is now taught by L&HCP Professors Deborah Weimer and Sara Gold. The clinic was started in the darkest period of the AIDS epidemic in Baltimore prior to the advent of antiretroviral treatment (ART) that transformed the disease to a relatively chronic, long term condition. ART changed the nature of the clinic's caseload over time from primarily discrimination and standby guardianship cases to cases dealing with medication adherence and helping HIV/AIDS patients re-enter the workforce with appropriate accommodations and support. UM Carey's HIV/AIDS clinic has had a successful long-term partnership with the outpatient pediatric AIDS clinic at the University of Maryland Medical System.

Through the UM Carey HIV/AIDS legal clinic, student attorneys provide legal services to individuals with HIV who usually have nowhere else to turn for advice, advocacy and legal representation. The clinic also focuses on "impact work" with the legislature and through litigation and has an excellent track record with the Maryland General Assembly. As an example, students were instrumental in the passage of a child welfare bill that allowed caregivers of children to sign affidavits to enroll children in school if they move into a new county. Prior to the passage of this bill, when a parent died of AIDS, and the children moved to live with their grandparent or another relative, the child(ren) would often be forced to sit out of school for months while the grandparent sought an order of legal custody from the Circuit Court.

Chancellor College's HIV/AIDS legal clinic was created in 2011 to serve indigent clients in the vicinity of the law school campus in Zomba, Malawi. The clinic plays an especially important role in providing free legal services because the government-run legal aid bureau does not maintain a branch office in the Zomba region. The HIV/

"We each perceive the world through the lens of our own culture, which includes our profession. Therefore, by working together in an integrated team, the group was able to approach the issue in a holistic manner, looking not only at the medical, but the psychological, and legal aspects that are involved in patient care."

Samantha DuFlo
School of Medicine, Physical Therapy
Malawi 2013

AIDS Clinic handles a catalogue of issues relating to people living with or affected by HIV/AIDS such as spousal desertion; employment discrimination; and limited or no access to health care and related nutrition services. The clinic provides legal advice and, when appropriate, initiates legal action on behalf of their clients.

The Chancellor College law clinic has a partnership with healthcare providers in the District Health Office which provides training to students on the sensitivities of working with people living with HIV/AIDS. UM Carey applies a similar model and invites medical providers and social workers to address the class to educate students about HIV illness and the challenges faced by children and families. The success of this interdisciplinary approach to teaching students informed the development of this summer's HIV/AIDS workshop in Malawi.

During the first two days of the two-week project, Professors Hoffmann, Danchin, and Banda led the participating US and Malawian students through diverse activities to learn about HIV/AIDS in Malawi from several professional perspectives. Students met with representatives of the WHO-sponsored "mother2mother" program in which HIV-positive mothers are trained to provide support and counsel to newly-diagnosed mothers. The group also met with a prominent Malawian pharmacist who provided an overview of pharmaceutical treatment of HIV/AIDS in Malawi, and toured two HIV/AIDS clinics, one is an urban area and one is a less-developed region. Finally, to give students an idea of the legal framework in which the law school and legal clinic work, the students toured the High Court of Malawi.

The second part of the HIV/AIDS workshop took place at Chancellor College in Zomba. The faculty and students from both schools made presentations about HIV/AIDS in Malawi and the United States from multiple professional perspectives. Professor Hoffmann's talk focused on the U.S. legal response to the AIDS epidemic, particularly in the areas of discrimination and public health measures. Professor Danchin's talk focused on the international response to the epidemic, particularly the use of the international health and human rights framework to address access to treatment. The various presentations led to the

most vibrant and eye-opening component of the workshop – facilitated case studies. These case studies – in which both groups actively participated - gave students free rein to share their views and expertise with each other. The case studies focused on a number of legally and ethically complicated situations that arise in the context of HIV/AIDS:

1. “Testing Positive” – in this case study, a Malawian woman tests positive for HIV when she visits a health clinic for an unrelated problem, but is scared to tell her partner about her test result because of the partner’s history of abusive treatment. The students were asked to think about if, and how, the patient or provider should inform the partner and how to ensure that the patient and her children can receive the treatment they need.
2. “Another Positive Test” – the woman who tested positive for HIV in the prior case study is pregnant and comes back to the clinic as planned – but without her two children as she previously agreed. She has not told her partner about her positive test result and has had unprotected sexual relations with him. The students were asked to think about potential criminal and civil liability of the patient and the provider for not revealing the positive test result to the partner and whether the patient is legally obligated to seek treatment for her children and/or unborn child.

To initiate conversation, the faculty asked the students to discuss which laws in Malawi and the United States apply to the distinct issues in the case studies and how the respective country’s health care systems and the financial constraints of the patient impact how each issue might be addressed by authorities. Both case studies stimulated lively discussions about what the response would be in each country and what, ideally, it should be if the appropriate medical and legal resources were in place. Hoffmann and Danchin later commented that the UMB students were surprised to learn that the responses of the Malawian students to the case studies were often very different from



UMB Students and Faculty with Chancellor College Students and Faculty

what they expected and, at times, quite divergent from the views expressed by the UMB students.

In addition to the substantive learning on HIV/AIDS and community mapping that took place this summer, the students spent a great deal of time reflecting on the interprofessional and intercultural aspects of their summer experience. For many students, this was their first experience interacting and working with students from other professional schools and students from other cultures.

Before concluding the HIV/AIDS workshop at the law school in Zomba, the faculty and students discussed how the two clinics might collaborate in the future. To this end, Professor Banda and a member of Chancellor College’s clinical law program plan to visit UM Carey Law in Spring 2014 to speak to students and faculty about their work and to sit in on our clinical law courses to gain an overview of the work of our clinical faculty and their teaching methods. GHIC also plans to continue our collaboration with Chancellor College by sending a smaller team of one faculty member and two or three students (likely from law, social work and nursing) to spend some time next summer in Zomba working with Chancellor College’s HIV/AIDS legal clinic. Finally, preliminary conversations are underway to host a Fall 2014 conference in Baltimore, co-sponsored by Chancellor College, on international law and global health in the context of southern Africa. More information about these activities will be forthcoming shortly.

"[Working with Malawian law students] I noticed that because the students didn't have many resources, they worked harder and were able to develop arguments straight from their minds without reference to notes, textbooks or laptop computers. They also helped each other and worked more collaboratively. I learned so much from them. They taught me about what kind of law student I want to be moving forward and ultimately, what kind of lawyer I will become."

Shamarla McCoy
Carey School of Law, Malawi 2013

VIRGINIA ROWTHORN LEADING GLOBAL HEALTH GROUP ON CAMPUS

Virginia Rowthorn, the Managing Director of the Law & Health Care Program, was recently appointed to serve as the Co-Director of UMB's Global Health Interprofessional Council (GHIC) after having served on the Council for 6 years. GHIC was originally created with an NIH Fogarty International Center Framework Program for Global Health grant to develop interprofessional research and education opportunities for students and faculty on the UMB campus, which is home to six professional schools – law, medicine, nursing, pharmacy, dentistry, and social work.

As a member of GHIC, Rowthorn helped create the GHIC Malawi project, a novel global health experiential learning project which takes a group of students from all of the UMB professional schools to Malawi for six weeks in the summer to work on a global health project with Malawian counterparts. The project, which just sent its fourth team in Summer 2013, is designed to teach students how to work together as an interprofessional team to study and write about a global health issue such as maternal mortality or health care access for orphans and vulnerable children. Rowthorn served as one of the rotating faculty members in Malawi in the project's inaugural year (2010) and in 2012.



Virginia Rowthorn

Designing the Malawi project with her GHIC colleagues was an important learning experience in how to structure an interprofessional global health experience. It turns out that creating such a project is challenging for a number of reasons both logistical and substantive. Planning an appropriate project with Malawian counterparts that includes a component that is relevant to all the professions is difficult but actually less time consuming than some of the administrative barriers, such as working with differing school calendars and credit requirements. Another area that is challenging is preparing the students to work together as a coherent team. This process is more involved than ensuring that qualified students are selected by participating faculty members and teaching students the substantive skills they need to participate in the project in a meaningful way. As GHIC faculty members have come to learn, working successfully as a team is more than a function of proximity and familiarity – it is a skill that must be taught. This led Rowthorn and others to ask how the skills, attitudes and values of the growing field of interprofessional education (IPE) can be adapted to global health education?

To answer this question, Rowthorn, and her Co-Director Jody Olsen (School of Social Work) are hosting a by-invitation roundtable on October 25 called Building Global Health Team Excellence: Developing an Interprofessional Skills Competency Domain. The focus of the roundtable is to look at the intersection of global health education and IPE to determine what IPE concepts should be part of a well-designed global health education program to ensure that global health lives up to its definition – and promise – as a truly interprofessional field. The 35 invited guests represent over 10 professional schools, experts in both IPE and global health, and representatives of NIH, the Institute of Medicine, Consortium of Universities for Global Health, and Association of Schools of Public Health. Rowthorn and her co-organizers plan to develop the results of the meeting into a white paper that they hope will initiate the process of developing a model curriculum to prepare students to collaborate successfully in the area of global health.

Rowthorn, who graduated from UM Carey School in 1997, served as a Peace Corps Volunteer in the Marshall Islands and worked for U.S. Senator Alan Cranston (D-CA) on the Senate Veterans Affairs Committee prior to law school. After graduation, she was an Associate at DLA Piper and a Legislative Attorney in the Office of the General Counsel at the Department of Health and Human Services. Since joining the law school in 2006, Rowthorn has directed the L&HCP's health law externship program and taught the Health Law Practice Workshop. In her position as Managing Director of the L&HCP, she has also been instrumental in creating several new learning opportunities for health law students including the annual health law service trip in which a group of students spend their last week of winter break working with attorneys at the Mississippi Center for Justice on projects mainly centered in the Delta region of Mississippi. Rowthorn is in the process of completing an LLM in Global Health Law at Georgetown Law.

NEW FUNDING AND NEW SUPPORT IN LAW SCHOOL'S DRUG POLICY AND PUBLIC HEALTH STRATEGIES CLINIC

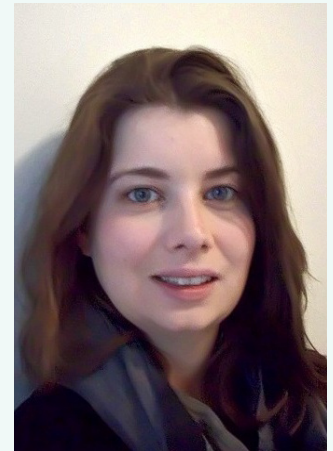
Professor Ellen Weber's Drug Policy and Public Health Strategies Clinic has received a two-year \$275,000 grant from the Open Society Foundation to ensure that individuals with substance use disorders have access to comprehensive treatment in Maryland's private and public insurance markets under the Affordable Care Act. Building on its policy work that helped shape Maryland's framework for the delivery of addiction and mental health services, the Drug Policy Clinic will now focus on the real-time implementation of the State's Health Exchange and Medicaid programs. Clinic students, under the supervision of Professor Ellen Weber and Clinic Staff Attorney, Geraldine Doetzer, will provide legal assistance to individuals who experience problems accessing addiction treatment services. They will also serve as a "watch-dog" over the enforcement of key federal and state standards designed to protect consumers who need addiction treatment. According to Professor Weber, "providing legal services to individuals who are enrolled in the new insurance programs will also help us identify and evaluate access problems and then develop policy 'fixes' to address gaps in service delivery." This is Professor Weber's second grant from the Open Society Foundation to support the Drug Policy Clinic's advocacy work in the implementation of federal health reform in Maryland.



Professor Ellen Weber

GERALDINE DOETZER JOINS AS STAFF ATTORNEY

The Drug Policy Clinic is very excited to have Geraldine Doetzer join the implementation phase of its Advancing Access to Addiction Treatment Initiative. Ms. Doetzer brings extensive legal services and policy advocacy experience in public benefits and health insurance to the project. Before joining the Drug Policy Clinic, Ms. Doetzer was the staff attorney at the Health Insurance Counseling Project at the George Washington University Law School, Jacob Burns Community Legal Clinics in Washington, D.C. She provided representation and advice to residents with health law problems, advocated on behalf of low-income consumers and persons with disabilities during the District's implementation of health care reform, and supervised advanced law students enrolled in George Washington's Health Rights Law Clinic. Prior to her work at the Health Insurance Counseling Project, Ms. Doetzer was the housing attorney at the National Law Center on Homelessness & Poverty. She started her legal career as the first Equal Justice America Fellow at the Legal Aid Justice Center in Virginia, where she established a public benefits practice and a medical-legal partnership with a federally-funded health clinic. The Clinic team looks forward to the opportunity to work with its community partners to translate health care policy into meaningful access to addiction treatment.



Geraldine Doetzer

PROFESSOR LESLIE MELTZER HENRY ADVANCES DIALOGUE ON HOW TO COMPENSATE INJURED RESEARCH SUBJECTS

L&HCP Professor Leslie Meltzer Henry recently published an article in the *JOURNAL OF LAW, MEDICINE, & ETHICS* (JLME) that queries why the United States has consistently failed to create a no-fault compensation program for injured human research subjects. The article, “Moral Gridlock: Conceptual Barriers to No-Fault Compensation for Injured Research Subjects,” is available at the following link: http://digitalcommons.law.umaryland.edu/fac_pubs/1336/ (41 *JOURNAL OF LAW, MEDICINE & ETHICS* 411 (2013)). Henry, who is also an associate faculty member at the Johns Hopkins Berman Institute of Bioethics, published the article in a symposium issue of JLME that she guest edited. The publication, “Revising the Common Rule: Prospects and Challenges,” was based on presentations made at a 2012 roundtable that was jointly sponsored by the L&HCP and the Berman Institute.

In her thought-provoking article, Henry outlines the federal regulations that govern biomedical research, most notably those enshrined in the Common Rule. She argues that these regulations express a protectionist ethos aimed at safeguarding subjects of human experimentation from the potential harms of research participation but, in at least one critical way, they have always fallen short of this promise: if a subject suffers a research-related injury, then neither the investigator nor the sponsor has any legal obligation under the regulations to care for or compensate the subject. Because very few subjects with research-related injuries can meet the financial or evidentiary requirements associated with a successful legal claim to recover the costs associated with their injuries, most injured subjects must shoulder the burden of those expenses alone.

Henry outlines 40 years of history in which national advisory panels have concluded that this result is out of step with the Common Rule's otherwise protectionist promise. Nonetheless, when the Department of Health and Human Services released an Advance Notice of Proposed Rulemaking in 2011 suggesting potential changes to the Common Rule, it made no mention of compensation for research-related injuries. Henry's article asks why, despite decades of federal-level panels recommending no-fault compensation for research-related injuries, the United States has so strongly resisted change. She suggests that a central reason for the current impasse is that, despite consensus among federal advisory committees that there is an obligation to



Professor Leslie Meltzer Henry

compensate injured subjects, the committees have not coalesced around a moral justification for that duty. Although multiple justifications can support and even strengthen a single ethical obligation, Henry argues that the reverse has occurred in this context. Her article demonstrates that the committees' articulation of multiple ethical principles – including humanitarianism, professional beneficence, and compensatory justice – results in incongruent obligations that favor different kinds of compensation systems. This is the “moral gridlock” that makes it extremely difficult to determine what kind of compensation scheme to implement. In conclusion, Henry suggests that recognizing and grappling with moral gridlock is a critical first step on the path to a more systematic approach to compensating injured research subjects.

EXTERNSHIP AT FDA LEADS TO ORISE FELLOWSHIP

Theresa Mahfood (2L) came to University of Maryland Carey Law to pursue her interest in health care policy and biomedical science and was able to find a summer externship that married these interests perfectly. Mahfood split her time as a summer extern at the U.S. Food and Drug Administration between two offices - the Office of Legislation and the Office of Minority Health. While there, she became very involved with the Language Access Plan, a federally mandated plan aimed at improving the FDA's communication with non-English speaking patients in the U.S., mainly by enhancing the agency's website and use of social media, television advertising, and drug labeling. The Language Access Plan will play an important role in improving health literacy among minority populations by providing user friendly information in multiple languages on a wide range of health topics related to food, drugs, devices, and biologics. At the end of her externship, she was honored to accept a part-time paid position with the Office of Minority Health as an Oak Ridge Institute for Science and Education (ORISE) Research Fellow, working under the Director of the Office of Minority Health, Dr. Jonca Bull. As a fellow, Mahfood will continue her work on the Language Access Plan while also getting to work on other important projects related to genetics, culture, and health issues affecting minority populations.



Theresa Mahfood 2L

L&HCP OFFERS INNOVATIVE NEW COURSE: LICENSING AND DISCIPLINING OF HEALTH CARE PROFESSIONALS SEMINAR

The Law & Health Care Program is now offering an innovative course that explores an important, but little discussed, component of health care regulation: the law governing discipline of health care professionals. This new seminar focuses on the substantive and procedural issues that arise out of the disciplinary process, including unauthorized practice, standard of care and professional incompetence, reciprocal discipline, overutilization of health care services, illegal prescribing, moral turpitude, and the meaning of the term “in the practice of.” The seminar also covers procedural issues that arise during the investigative and adjudicatory stages of a disciplinary proceeding, such as board investigative authority, the right to counsel, discovery, confidentiality, and sanctioning, including an examination of disproportionate sanctioning of health care providers based on criteria such as race, national origin, and level of training. The course is taught by John Nugent (Principal Counsel) and Janet Brown (Assistant Attorney General) of the Maryland Attorney General’s Health Occupations and Litigation Division. Nugent and Brown also serve as externship supervisors for students who want to spend a semester gaining practical experience in their Division. The highlight of the seminar is a mock case resolution conference exercise in which students are given a fact pattern and have the opportunity to represent opposing sides and preside over a case resolution conference.

L&HCP GRADUATES RECORD NUMBER OF HEALTH LAW CERTIFICATE STUDENTS

At this year's graduation, the 16th year that the Law & Health Care Program (L&HCP) has been granting a certificate to those students who concentrate in health care law, a record 44 students qualified for the Health Law Certificate. The students in this group completed at least 17 of their 85 law school credits in health law, participated in a health law clinic or externship, and wrote a scholarly paper on a health law topic. The growth in the program likely reflects the important national dialog the country is undertaking as a result of health care reform. The Affordable Care Act and the subsequent Supreme Court case highlighted the essential role that the law and lawyers play in shaping and ensuring access to health care. Many health law students have told faculty members that national discussions of health care reform sparked a desire in them to get involved in this critical debate. A number of certificate students had the chance to be part of health care reform as students in different ways. For example, several students externed at the CMS Center for Consumer Information and Insurance Oversight (CCIIO) helping in the effort to develop health insurance exchange regulations; others participated in the Loyola Beazley Law School's Health Law Transactional Competition; and many took part in the law school's annual health law service trip to Mississippi in which students created pamphlets for the community to explain the impact of the Affordable Care Act.

To celebrate the students' accomplishments and give the group a proper sendoff, L&HCP faculty and administrators hosted a graduation breakfast on May 15 for the students and their family members. At this breakfast, faculty members spoke about the individual accomplishments of this record-breaking group and their contributions to the Program. The group of 44 was impressive in so many ways that it is hard to characterize all the ways they learned from, and contributed to, the L&HCP. To give a flavor of some of their accomplishments, we highlight five students who represent the breadth and variety of students who earned the Health Law Certificate in 2013.

Chad Brooker

During his first law school summer, Chad split his time working at the U.S. Dept. of Health and Human Services for both the Assistant Secretary for Planning and Evaluation—working on enhancing innovation and development of pharmaceuticals and RF-ID tagging of medical device products—and the HHS Office of the Inspector General. In the Spring of 2012, Chad externed with the in-house counsel's office at the Johns Hopkins Health System where he researched the legality and ethics



2013 Health Law Certificate Graduates with L&HCP Director Diane Hoffmann

of medical treatment decisions and advised on physician-patient interactions and the adoption of an electronic medical record system. During his second summer, Chad served as a summer associate in-house at America's Health Insurance Plans, focusing on federal and state pharmaceutical policy and ERISA. After realizing his passion for insurance law during that summer, Chad began working at CCIIO where he was a member of the policy team and helped to draft the rules on Essential Health Benefits, Actuarial Value calculations, and the Exchange Benefit and Payment Parameters. It was due to this position that Chad was recruited by Access Health Connecticut (Connecticut's ACA Insurance Exchange) as a Legal and Policy Analyst in order to help them implement the ACA in that State and to guide the compliance efforts for the Exchange. As a student, Chad wrote three articles on health law and policy topics that have been or will be published: on the female contraception mandate (UMD Journal of Race, Religion, Gender and Class), fraud and abuse implications of electronic medical records (forthcoming Yale Law Journal of Health Policy, Law and Ethics), and state efforts to combat specialty pharmaceutical tiering (forthcoming American University Law School Health Law and Policy Brief).

Rebecca Hall

After graduating from University of Maryland in 2007, Rebecca worked for UnitedHealth Group as a proposal writer before applying to law school. This experience

working closely with health lawyers led to her interest in health care law, and that focus motivated Rebecca to choose Maryland Law because of the strength and reputation of the L&HCP. She competed in Maryland's first two Health Law Regulatory and Compliance Competitions and represented the L&HCP at the L. Edward Bryant, Jr. National Health Law Transactional Moot Court Competition at Loyola Chicago. During law school, Rebecca also worked on a variety of health law issues while interning for the Maryland Court of Appeals and later for the Medicaid Fraud Control Unit of the Office of the Attorney General. Additionally, Rebecca served as the Editor-in-Chief of the *Journal of Health Care Law & Policy*, in which her own article on the Affordable Care Act was published. Rebecca started her career as a staff attorney for the University of Maryland Faculty Physicians (FPI). At FPI, Rebecca is working directly on a variety of legal issues that affect the academic medical center, including regulatory and compliance work, fraud and abuse issues, implementation of HIPAA, HITECH, and Affordable Care Act policies, physician contracting, and medical research issues, among others.

Christine Hein

Christine is a 2005 graduate of The Johns Hopkins University. At UM Carey Law she pursued the Health Law Certificate and the Business Law Concentration. She wrote her Advanced Certification Paper on the Food Safety Modernization Act's International Capacity Building provisions, which combined her interests of food safety and its effect on health and business. Christine externed in the Maryland Office of the Attorney General Health Occupations Prosecution and Litigation Division, and later externed in the Office of General Counsel at the U.S. Dept. of Health and Human Services, Public Health Division. In addition to these externships, Christine worked as a Research Assistant for Professors Hoffmann and Rowthorn on their NIH-funded project on the regulation of probiotics. In the summer of 2012, she worked at the USDA Office of the Inspector General. As the Student Health Law Organization's (SHLO) Event Coordinator, Christine focused on health-related charity events, like the Lawyers Have Heart fundraiser and race for the American Heart Association. Christine has started her legal career as a judicial law clerk at the Maryland Court of Special Appeals in Annapolis with Judge Robert A. Zarnoch.

Abe Gitterman

As an evening student, Abe worked full-time for a medical education company during the day, focusing on the pharmaceutical and medical device industry and healthcare compliance. This particular focus gave him a passion for FDA law, which led him to receive a scholarship to Seton Hall School of Law's Healthcare



2013 Graduate Blair Inniss and her mother at L&HCP Breakfast Celebration

Compliance Certificate Program as a 1L. He also competed in the School of Pharmacy's Interprofessional Patient Management Competition in his 1L year. He was the brainchild behind UM Carey Law's new and innovative Health Law Regulatory & Compliance Competition, which will be held for the third time on February 8, 2014. Abe participated heavily in the SHLO during his three years at Maryland, serving as Co-President and Competition Chair, and attending and organizing various programs and events. Abe won or placed in a number of health law writing competitions including the 2012 ABA Health Law Section Writing Competition and the Food and Drug Law Institute's H. Thomas Austern Memorial Writing Competition. Several other articles he wrote on drug regulation have been published in law journals. In addition, he held various health-related externships at FDA, HHS-OIG and DOJ's Consumer Protection Branch. In November, he will be starting as an associate in the FDA-Healthcare group of Arnold & Porter, LLP, in Washington, DC.

Hannah Levinson

Hannah came to Maryland Carey Law specifically to study health law. During her second year, she served as Vice President of the SHLO and in this role, she created the SHLO peer mentor program and organized an exclusive UM Carey Law mentor program with the Maryland State Bar Association Health Law section. She was a student attorney in the HIV/AIDS Healthcare Delivery and Child Welfare Clinic as well as the Manuscripts Editor of the *Journal of Health Care Law & Policy*. While at UM Carey Law, she held numerous internships. She served as a law clerk at the NYC Health and Hospitals Corporation; a law



L&HCP Managing Director Virginia Rowthorn, Dr. Thelma Wright (UM Carey Law '13), L&HCP Director Diane Hoffmann

clerk at Sinai Hospital of Baltimore; a summer graduate associate at the NYC Medicaid Fraud Unit; and a law clerk in the CMS Office of Hearings. She won first place in Maryland's Interprofessional Patient Management Competition, which challenges students to create an interdisciplinary patient case plan. She also competed with two other students at Loyola Beazley Law School's Health Law Transactional Competition in Spring 2013. Hannah was invited to speak at the 2013 Health Care Compliance Association's annual Compliance Institute, where she gave a presentation on the value of law clerks and junior attorneys in compliance positions. Hannah was awarded the William P. Cunningham Award for exceptional achievement and service to the law school. She has started her career as an Associate in the Health Law Practice Group of the firm Broad and Cassel in Fort Lauderdale, FL.

2013 HEALTH LAW CERTIFICATE RECIPIENTS

Elsa Anna Abraham
 Rachel Elizabeth Almaraz
 Brett A. Baulsir
 Chad Ivan Brooker
 Tina Rechelle Buford
 Lisette Burton
 Victoria Chihos
 Michael Anthony Damiano
 Margaret D. Davis
 Alan J. Dunklow
 Sydney Ann Dunning
 Caroline Anne Fields
 Marissa Friedman
 Abraham Gitterman
 John Francis Glass
 Richard Goodell
 Jhanelle A. Graham
 Joshua Seth Greenfield
 Rebecca Wizeman Hall
 John Hopewell Hebb III
 Christine Frazier Hein
 Paul Heinmuller
 Melissa Sidman Heitt
 Matthew Elliott Hooper
 Blair Marie Inniss
 Marshall E. Jackson Jr.
 Anna Elizabeth Sidney Johnston
 Melissa Kim
 Aileen Susanna Labi
 Heain Lee
 Hannah Louise Levinson
 Jennifer Rachel Lipshultz
 Diana Michelle Lockshin
 Kristina Laura Miller
 Matthew Scott Mora
 Elizabeth Louise Peterson
 Rachel Rosen
 Ameet Vilas Sarpatwari
 Jameson Eliseo Sauseda
 Melissa Schefkind
 Gabriel Scott
 Dawn Ware
 Thelma Bernice Wright
 Crystal M. Zorbaugh

LAW & HEALTH CARE PROGRAM PUBLICATIONS, PRESENTATIONS, AND OTHER HONORS

August 2012 – August 2013

SARA GOLD

Presentations

“A Multidisciplinary Approach to Reducing HIV/AIDS,” World AIDS Day Lunch & Learn, sponsored by the Office of Interprofessional Service Learning and Student Initiatives, University of Maryland Baltimore, Baltimore, Maryland (November 30, 2012)

“Broadening the Scope: Adapting Litigation Clinics to the Changing Legal Market and Practice,” Poster Presentation for 2013 AALS Conference on Clinical Legal Education, San Juan, Puerto Rico (April 28-May 1, 2013)

MICHAEL GREENBERGER

Presentations/Interviews

“Public Health Preparedness for Emerging and Re-Emerging Infectious Diseases,” Middle Atlantic Regional Center for Excellence for Biodefense and Emerging Infectious Diseases – Public Health Emergency Response Conference, Ellicott City, Maryland (January 28, 2013)

“Legal Aspects of Mass Immunization and Routine Vaccination,” Lecture, Center for Vaccine Development Vaccinology Course, University of Maryland School of Medicine, Baltimore, Maryland (March 4, 2013)

“Due Process and the Next Influenza Pandemic: Reconciling the Need to Protect Our Citizens from the Deadly Flu with Imperfect Countermeasures,” 36th Annual Health Law Professors' Conference, Seton Hall University School of Law, Newark, New Jersey (June 8, 2013)

LESLIE MELTZER HENRY

Publications

“Moral Gridlock: Conceptual Barriers to No-Fault Compensation for Injured Research Subjects,” 41 J.L. MED & ETHICS 411(2013).

“Introduction, Revising the Common Rule: Prospects and Challenges,” 41 J.L. MED & ETHICS 386 (2013).

Guest Editor, Symposium Issue: “Revising the Common Rule: Prospects and Challenges,” 41(2) J.L. MED & ETHICS (2013).

Guest Editor, Special Issue: “Strategies for Health Care Cost Containment,” 15(3) J. HEALTH ECON. & POL'Y (2012).

Presentations/Interviews

“Respect and Dignity for Patients and Families in the ICU: A Conceptual Model,” EMERGE/Moore Foundation Grant Group, Johns Hopkins Hospital SICU (March 26, 2013)

Interview, “Health Care Reform,” C-SPAN (April 23, 2013)

“Just Compensation: Toward a No-Fault Scheme for Research-Related Injuries,” 36th Annual Health Law Professors' Conference, Seton Hall University School of Law, Newark, New Jersey (June 8, 2013)

Honors/Grants

Spotlight Member, American Society of Law, Medicine & Ethics (June 2013)

Team Lead, Dignity Conceptual Model, Gordon and Betty Moore Foundation, “Acute Care/ICU Multi-Center Feasibility Study” (continuing)

DIANE E. HOFFMANN

Publications

“Do potential changes to the Common Rule adequately address new areas of research: A case study focusing on the Human Microbiome Project?” (with Dennis Fortenberry & Jacques Ravel), 41 JOURNAL OF LAW, MEDICINE & ETHICS 454 (Summer, 2013)

“Health Claim Regulation in the EU and the US: Which is the Better Approach?” 4 BENEFICIAL MICROBES 109 (March 2013)

Presentations/Interviews

“Medically Ineffective Treatment,” Department of Medicine Grand Rounds, University of Maryland Medical Center, Baltimore, MD (Oct. 3, 2012)

“Legal Issues In Probiotic Regulation,” at Issues in Medical Ethics 2012, 23rd New York Regional Conference, Mount Sinai School of Medicine, New York, NY (Oct. 12, 2012)

“Legal and Ethical Challenges in Large-Scale Genome Sequencing, at Genomics and Clinical Medicine,” sponsored by Leadership Maryland and University of Maryland School of Medicine, Institute for Genome Sciences, Baltimore, MD (April 11, 2013)

“Legal Issues in Integrative Medicine,” Health Wellness Conference, sponsored by the Center for

Integrative Medicine, University of Maryland Baltimore, Baltimore, MD (May 4, 2013)

“A Modified Private Right of Action for false or misleading health claims under the Food Drug and Cosmetic Act of the Federal Trade Commission Act: Would it Help?” Annual Health Law Professors Conference, Seton Hall Law School, Newark, NJ (June 7, 2013)

“An Interdisciplinary Global Health Learning Project in Malawi,” Annual Health Law Professors Conference, Seton Hall Law School, Newark, NJ (June 7, 2013)

“The U.S. Legal Response to HIV: Public Health and Discrimination,” University of Malawi, Chancellor College of Law, Zomba, Malawi (June 19, 2013)

KATHLEEN HOKE

Presentations/Interviews

“Going Beyond the FDA Ban on Flavored Cigarettes,” National Conference on Tobacco or Health, Kansas City, Missouri (August 15, 2012)

Oral and written testimony, Public Hearing on the Regulation of Smoking Cessation/Nicotine Replacement Therapy Products, submitted on behalf of the Tobacco Control Legal Consortium, Food and Drug Administration, Silver Spring, Maryland (December 17, 2012)

“Powers of County Legislatures and Board of Health in Charter Counties,” Community Transformation Grant Regional Meeting, Aberdeen, Maryland (January 10, 2013)

“Multidisciplinary Approach to Tobacco Policy without Seeking Legislative Change,” Maryland Cancer Collaborative Annual Meeting, Baltimore, Maryland (January 14, 2013)

Testimony, In Support of Senate Bill 69 (Increasing Penalties for Cigarette Smuggling) Before the Senate Budget and Taxation Committee of the Maryland General Assembly Annapolis, Maryland (January 30, 2013)

AMANDA PUSTILNIK

Presentations/Interviews

“Alternative Courts & Guilty Pleas: A Complicated Compromise,” American Bar Association, Criminal Justice Section, Washington, DC (October 26, 2012)

“Neurotechnologies at the Intersection of Criminal Procedure and Constitutional Law,” NYU Criminal Theory Workshop, New York, New York (October 29, 2012)

“Law & Neuroscience for Scientists: Pain Science as a Model of How Law and Science Interrelate,” Stanford University Pain Neuroimaging Center, Palo Alto, California (January 11, 2013)

“Models of the Mind: How Neuroscience, Psychology, and the Law Collide,” The Center for Law, Brain, and Behavior, Harvard Medical School – Massachusetts General Hospital, Boston, Massachusetts (April 25, 2013)

KAREN ROTHENBERG

Publications

“Mixed Messages: The Intersection of Prenatal Genetic Testing and Abortion,” (with R. Rebouche), 55 HOWARD LAW JOURNAL 983 (2012) (Wiley A. Branton Symposium) http://digitalcommons.law.umaryland.edu/fac_pubs/1234/

“Teaching Law Students To Be Policymakers: The Health and Science Workshop on Genomic Research,” (with B. Berkman), 40 JOURNAL OF LAW, MEDICINE & ETHICS 147 (Spring 2012) http://digitalcommons.law.umaryland.edu/fac_pubs/1198/

“Manipulating Fate: Medical Innovations, Ethical Implications, Theatrical Illuminations,” with L. Bush, 13 HOUSTON JOURNAL OF HEALTH LAW & POLICY 1 (2012) http://digitalcommons.law.umaryland.edu/fac_pubs/1279/

Presentations/Interviews

“An Interactive Play: Drama, Discourse and Genomics: From IRBs to IFs,” with L. Bush, the American Society of Human Genetics 62nd Annual Meeting, San Francisco, California, (November 9, 2012)

“It’s Not That Simple,” Café Scientifique, Canadian Institutes of Health Research, Montreal, Canada (April 18, 2013)

Participant, International Workshop on “Exploring the Unique Social/Ethical and Health Systems Challenges of Low Cost Whole Genome Sequencing” and Chair, Health System session, Institute of Genetics - Canadian Institutes of Health Research and Genome Canada, Montreal, Canada (April 19-20, 2013)

VIRGINIA ROWTHORN

Publications

La tutela (guardianship) y sus alternativas: un manual sobre la ley de Maryland (Spanish translation of the Guardianship Handbook with co-editor Ellen Callegary and translator Eleana Gomez) (2012)

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*Comments and letters should be
forwarded to the above address.*

Presentations/Interviews

“A model for interprofessional global health education for graduate professional students,” poster presentation at Consortium of Universities for Global Health conference (March 14-16, 2013)

“Global Challenges in Women’s and Children’s Health: An Ethical and Legal Perspective,” lecture for online University of Maryland University College course “Global Challenges in Women’s and Children’s Health” (2013)

ELLEN WEBER

Publications

“Failure of Physicians to Prescribe Pharmacotherapies for Addiction” excerpt reprinted in Alex Kreit, *Controlled Substances: Crime, Regulation, And Policy* (Carolina Academic Press, 2012) http://digitalcommons.law.umaryland.edu/fac_pubs/962/

Presentations/Interviews

Guest, Enforcement of the Mental Health Parity and Addiction Equity Act, Marc Steiner Show (August 8, 2012)

“ACA 101: What the Law Does and the Supreme Court Said,” State Legislative Leaders Foundation and Johns Hopkins Medicine, 2012 Health Care Summit: The Affordable Care Act: Fact, Fiction and Implementation, Baltimore, Maryland (September 14, 2012)

“Mental Health Parity and Addiction Equity Act,” Testimony, House Health and Government Operations Committee and Senate Finance Committee, Annapolis, Maryland (February 27-28, 2013)

“Coverage of Mental Health and Substance Use Disorder Services: Essential Health Benefits Implementation,” State of the States: Health Care Reform Roundtable, University of Maryland Carey Law School, Baltimore, Maryland (March 1, 2013)

“Incorporating Naloxone into Overdose Prevention Strategies: Legal and Regulatory Issues,” Maryland Opioid Overdose Prevention Planning Conference, Catonsville, Maryland (March 27, 2013)