

# LAW & HEALTH CARE



UNIVERSITY of MARYLAND  
FRANCIS KING CAREY  
SCHOOL OF LAW

Spring 2015  
Vol. 22, no. 2

NEWSLETTER

## CONNECTING THE CLASSROOM TO THE WORKPLACE



*Joella Roland 3L and Professor Kathleen Hoke*

### IN THIS ISSUE:

Connecting the Classroom to the Workplace.....	1
History of the Law & Health Care Program's Externship Program .....	3
Defensive Medicine and Maryland's New Global Budget Model.....	7
Professor Frank Pasquale's Latest Project: <i>The Week in Health Law</i> Podcast.....	11
Law & Health Care Program Collaborates with UM School of Dentistry.....	12
Professor Martha Ertman Partners with Hospital Lawyer to Teach Contract Drafting.....	13
Fourth Annual Health Law Competition Attracts Record Number of Participants.....	14

Succeeding in an externship placement – which typically involves working in a legal setting under the supervision of a practicing attorney – requires a combination of legal skills and confidence. Possessing the former is critical to developing the latter. The Law & Health Care Program (L&HCP) at University of Maryland Carey School of Law has a robust didactic and clinical curriculum that gives students the tools they need to approach the challenges of a broad variety of externship placements. The L&HCP externship program offers 34 placements in government agencies, advocacy and trade organizations, hospitals, and legislatures. This article focuses on the critical link between classroom training and practical experience. We asked several of our current externship students to reflect on the classes that have helped them secure and thrive in their placements. A strong connection between theory and practice at the externship level is a critical first step to ensuring that our health law students are ready to enter the job market when they graduate.

The substantive aspects of health law are covered in our extensive health law courses and clinic offerings. These courses and clinics offer a combination of theory and practical concepts, and, in the case of clinics, opportunities for client representation. Through our full-time faculty and adjunct professors, the curriculum

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Baltimore, MD 21201

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includes courses on the business aspects of the health care system; health policy and advocacy issues; regulation of the delivery of health care and development of new therapies; and bioethics. We asked some of our current externship students what courses or clinics were helpful to them for their current externship placements. A sampling of their answers appear below.

**The Student:** Joella Roland

**The Health Law Clinic:** The Public Health Law Clinic (Professor Kathleen Hoke)

**The Externship Placement:** US Department of Health and Human Services, Office of General Counsel, General Law Division

Joella Roland, a third year law student, is externing in the General Law Division of the US Department of Health and Human Services (HHS) Office of General Counsel's General Law Division. HHS's Office of General Counsel provides legal support and representation to all of HHS's divisions and the General Law Division, in particular, provides legal advice and litigation support for matters such as appropriations, copyright law, and disputes involving the Federal Tort Claims Act (including medical malpractice), the Freedom of Information Act and Privacy Act, Federal contract law, personnel law, and labor relations law. Joella began her externship in January under the supervision of HHS attorney Douglas Kornreich, Senior Procurement Attorney. In her externship position, Joella has undertaken a number of complex administrative legal tasks including:

- Reviewing a request for proposals (RFP) to determine if it complied with applicable appropriations law.
- Performing legal research regarding the discretion of contracting officers in procurement.
- Reviewing a software licensing agreement and considering whether the agreement's language conflicted with Federal Acquisition Regulations (FAR) requirements.

To succeed in this placement, Joella has depended on many aspects of her legal education to date, including courses in Administrative Law, Health Care Law and Policy, and Government Contracts. However, she particularly noted the training she received in Professor Kathleen Hoke's Public Health Law Clinic as critical to her ability to tackle her externship assignments. She noted:

*The skills I learned in the Public Health Law Clinic have been a great asset in my time externing at the Office of General Counsel within the Department of Health & Human Services. In particular, the practice I received writing concisely has enabled me to draft memos and briefs with little guidance. The experience examining public health initiatives has allowed me to quickly analyze Department initiatives through a critical lens.*

## HISTORY OF THE LAW AND HEALTH CARE PROGRAM'S EXTERNSHIP PROGRAM

When Professor Karen Rothenberg created the L&HCP in 1984, one of her first initiatives was to establish an externship program. The first two she created were at the National Health Law Program (NHeLP) in Washington, DC, and University of Maryland Medical System. When current Director of the L&HCP Professor Diane Hoffmann joined Rothenberg in 1987, the externship program grew to include additional placements in the Baltimore/Washington, DC area and in Geneva at the World Health Organization and UNAIDS. In order to meet the ABA requirement for a tutorial component to all externships, Rothenberg and Hoffmann designed a workshop for all health law externship students. The goal of the two-credit class is to help students make the transition from law school to a work environment. The course does not focus on the substantive aspects of health law but rather the aspects of health law practice that often are not covered in didactic courses, specifically the role of health lawyers in different settings and how that affects the legal work they do. Hoffmann has written about this course in an article titled "Health Law Practice Workshop: Bridging Externship Placements and the Classroom." [http://digitalcommons.law.umaryland.edu/fac\\_pubs/1016/](http://digitalcommons.law.umaryland.edu/fac_pubs/1016/). This course is currently taught by Virginia Rowthorn, Managing Director of the L&HCP.

The Public Health Law Clinic is headed by Kathleen Hoke, Associate Professor of Law and Director of both the Legal Resource Center for Public Health Policy and the Network for Public Health Law, Eastern Region. These centers provide state and local public health law officials with legal assistance on a variety of public health law issues. Clinic students draft legislation, conduct research on the public health powers of towns and counties, and identify effective public health practices throughout the country. In the process, students gain an acute understanding of the interplay between federal, state, and local government and develop creative problem-solving skills. Recent Clinic alumni have taken positions at the Maryland Department of Health and Mental Hygiene and the federal government, particularly in health-related agencies.

Although the Public Health Law Clinic does not teach students about procurement law, it provided Joella with the skills – and perhaps more importantly – the confidence to tackle an intimidating body of laws and regulations that govern the nation's health care system.

**The Student:** Michael Vinluan

**The Health Law Course:** Advanced Bioethics and the Law (Professor Leslie Meltzer Henry)

**The Externship Placement:** Food and Drug Administration's Office of Policy in the Office of the Commissioner



*Prof. Leslie Meltzer Henry and Michael Vinluan 2L*

Michael Vinluan is a rather unique law student: he's a US-certified physician with a medical degree from the Philippines and a member of the American College of Legal Medicine. Prior to coming to law school, he saw the intersection of medicine and the law in his position as Senior Medical Communication Specialist for the CDC. Since coming to law school, Michael has taken advantage of multiple externship

and internship experiences to gain experience in health law, particularly in food and drug law. In addition to his current externship placement, Michael has externed in the FDA's Center for Drug Evaluation and Research in both the Office of Medical Policy and the Office of Regulatory Policy, and at Johns Hopkins Health System Corporation. Michael was recently chosen as one of the "Leaders of Tomorrow" by the Maryland Regional Biotech Forum.

The FDA's Office of Policy develops and coordinates agency policy to advance FDA's mission and to encourage consistency in the development and content of policy across FDA's centers. Michael's current placement is with Jarilyn Dupont, Director of Regulatory Policy. Michael brought considerable experience to the externship and was able to jump in immediately. His first project involved the Food Safety Modernization Act. He was asked to help in developing proposed rules concerning the importation of food in the U.S. via the Foreign Supplier Verification Program for Importers of Food for Humans and Animals, and the standards for produce safety called the *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*. These are landmark regulations because it will be the first time that FDA will have a substantial role in regulating the importation of food and the agricultural industry in the United States. On another project about prescription drug promotion, Michael was asked to analyze and comment on policy issues concerning the First Amendment and communication of certain medical information. His latest assignment involves a proposed regulation to enhance transparency in reporting clinical trial results to ClinicalTrials.gov.

Michael credits the Advanced Bioethics Seminar taught by Leslie Henry as providing an ethical framework for his multiple experiences at FDA. Professor Henry, who is also a core faculty member at the Johns Hopkins Berman Institute of Bioethics, is a national expert on bioethics and the law. Prior to joining the law school faculty, Professor Henry completed a post-doctoral fellowship in bioethics and health policy at Johns Hopkins School of Public Health and Georgetown Law Center. The Advanced Bioethics Seminar focuses on the legal regulation of medical decision-making. Topics include the doctrine of informed consent, decision-making for

*Cont. on page 9*

## LAW & HEALTH CARE PROGRAM CURRENT EXTERNSHIP PLACEMENTS 2014-15

- AARP Foundation Litigation
- AIDS Action
- Care First Blue Cross Blue Shield
- Center for Health and Homeland Security (UMB)
- Center for Medicare Advocacy, Inc.
- CMS, Center for Consumer Information and Insurance Oversight (CCIIO)
- CMS, Center for Medicare
- CMS Office of Hearings
- Dimensions Healthcare System
- FDA, CDER, Office of Medical Policy
- FDA Office of Legislation
- FDA, CDER, Office of Drug Security, Integrity, and Recalls
- FDA, Office of the Commissioner, Office of Policy
- Hilltop Institute
- Johns Hopkins Legal Department
- Keswick Health Community Health Services
- Maryland Board of Physicians
- Maryland Department of Health and Mental Hygiene, Office of Governmental Affairs
- Maryland Disability Law Center
- Maryland Office of the Attorney General, Office of Health Decisions Policy
- Maryland Office of the Attorney General, Department of Health and Mental Hygiene, Health Occupation Boards
- Maryland Office of the Attorney General, Health Education and Advocacy Unit
- Maryland Medicaid Fraud Control Unit
- Medstar Health, Office of the General Counsel
- Network for Public Health Law – Eastern Region
- PhRMA (Pharmaceutical Manufacturers Association) Office of Policy
- U.S. Attorney's Office for the District of Maryland
- U.S. Department of Health & Human Services, Public Health Division
- U.S. Department of Health & Human Services, Office of the Inspector General
- University of Maryland Medical System, Office of the General Counsel
- University of Maryland Medical System, Maryland Medicine Comprehensive Insurance Program
- University of Maryland Medical System, Office of Government and Regulatory Affairs

**The Student:** Darci Smith

**The Health Law Course:** Drug Policy and Public Health Strategies Clinic (Professor Ellen Weber)

**The Externship Placement:** U.S. Department of Health and Human Services, Office of General Counsel, Public Health Division

Darci Smith is a third year health law student who externed last semester in the Public Health Division of HHS's Office of General Counsel. The Public Health Division provides legal advice and representation to the National Institutes of Health, the Indian Health Service, and the Centers for Disease Control and Prevention on a myriad of issues including medical and biological research, women's health, and Native American health. Darci's placement supervisor was Sandra Pressman, an alumna of Maryland Carey Law and Senior Attorney in the Division. In her placement, Darci has undertaken a wide variety of projects including:

- Researching administrative issues such as the scope of appropriated funds; whether a particular program listed in the federal register is required to obtain state approval before changing an aspect of the program; and drafting a technical rule for a name change of an Indian Health Service program.
- Researching and summarizing all cases and administrative actions since 1999 brought against the IHS, Bureau of Indian Affairs, and the Department of the Interior under the Indian Self Determination Education Assistance Act and the Patient Safety and Quality Improvement Act.

Darci credits the training she got in Professor Ellen Weber's Drug Policy and Public Health Strategies Clinic with her ability to succeed in her externship. Weber's clinic examines a range of public health and civil rights strategies to assist persons with histories of drug and alcohol dependence gain access to health care and fight discrimination based on their disability. Students work on projects designed to ensure access to health care through Medicaid and private health insurance under the Affordable Care Act (ACA). For example, students educate consumers and treatment providers about the key provisions of the ACA; represent clients who have problems enrolling in

public or private insurance or accessing drug treatment services; and evaluate and recommend policy changes to improve Maryland's implementation of the ACA and the Mental Health Parity and Addiction Equity Act on behalf of consumers with alcohol and drug problems. Through this process, students gain substantial experience in interpreting and applying statutory and regulatory standards under Medicaid, the ACA and disability discrimination standards.

According to Darci,

*My experience with the Drug Policy and Public Health Strategies Clinic prepared me in a variety of ways for my externship placement with the Public Health Division. First, the Drug Policy Clinic exposed me to large portions of statutory and regulatory law, which taught me how to research and properly read and analyze statutes and regulations. Second, the Clinic focused on a number of sections of the ACA, enabling me to understand the changes occurring in health law and to effectively comprehend and research issues posed to me during my externship. Additionally, the Clinic developed my legal writing skills in a way that had not been addressed in my other classes. These writing skills were invaluable when I was drafting rules for HHS, OGC, or writing memorandums for staff attorneys.*

**The Student:** Sherri Weinstein

**The Health Law Course:** Health Information Privacy and Innovation (Professor Frank Pasquale)

**The Externship Placement:** Legal and Compliance Division, University of Maryland Faculty Physicians, Inc.

Sherri Weinstein is a third-year evening student who knows the meaning of hard work. During the day, she works as a program specialist in the Office of Evaluation and Inspections at the HHS Office of the Inspector General in Washington DC, and in the evening pursues her legal degree at the law school. Finding externships for evening students is always a challenge, but a flexible schedule and the proximity of University of Maryland Faculty Physicians, Inc. (FPI) to the law school and Sherri's apartment made



*Prof. Frank Pasquale and Sherri Weinstein 3L*

this semester's placement possible. FPI coordinates and supports the clinical activities of the University of Maryland School of Medicine. The organization provides services for approximately 1,000 full-time faculty members involved in teaching, research, and clinical practice with 22 professional associations. FPI also employs over 1,000 non-physician staff who support the clinical practices of the school's faculty. FPI staff – which includes a number of attorneys – provides administrative support functions such as business development, finance, human resources, information technology, compliance, legal affairs, practice operations support, and reimbursement management to physician practice groups. The legal and compliance division helps with the core FPI functions of developing common practice standards, collecting and reporting statistical and financial data, and contracting with providers and payers.

This semester, Sherri was been tasked with researching and helping draft a social media policy and a cloud computing policy. Sherri credits the Health Information Privacy and Innovation course taught by Professor Frank Pasquale with helping her carry out these assignments. The Health Information Privacy and Innovation course focuses on the uses (and misuses) of health information compiled about patients, insureds, research subjects, physicians, hospitals, and populations. Students in the course study medical privacy law and issues of privacy,

security, and accuracy of medical data as well as post-ACA concerns about balancing privacy, innovation, access, and cost-control. One specific issue Pasquale touches on in the course is the new ability of patients to personalize their medical records with the help of cloud computing firms and what law should govern this digital migration.

Pasquale brought this cutting edge course to the L&HCP when he came to the law school last year. The course provides an opportunity to share his vast knowledge and scholarship in the area of information policy and big data with students. Pasquale is a national expert on information law and how it is affected by rapidly changing technology, particularly in the health care, internet, and finance industries. His book *The Black Box Society: The Secret Algorithms that Control Money and Information* (Harvard University Press, 2015) uses health information technology law as a model for governing the fast-growing, big data economy.

According to Sherri,

*Through my internship at the University of Maryland Faculty Physicians Group, Inc. I am using concepts I learned in my Health Information Privacy seminar and Health Care Law and Policy course. I am regularly researching different HIPAA compliance situations, such as the use of social media, and the Health Information Privacy seminar has provided me with a strong background on the topic. Additionally, the Health Care Law and Policy course gave me a broad overview of health law issues, so I am now comfortable researching a public health question one day and reviewing a policy on termination of care another day.*

**The Student:** Jaclyn Machometa

**The Health Law Course:** Health Care Law & Policy (Professor Frank Pasquale)

**The Externship Placements:** University of Maryland Medical System's Office of Government and Regulatory Affairs and Johns Hopkins Health System Corporation's Legal Department

Since before she entered law school, Jaclyn Machometa knew she wanted to use her law degree

*Cont. on page 10*

# WILL DEFENSIVE MEDICINE AFFECT THE ABILITY OF MARYLAND HOSPITALS TO CONTROL COSTS UNDER THE STATE'S NEW GLOBAL BUDGET PAYMENT MODEL

Last November, Professor and L&HCP Director Diane Hoffmann was asked by Maryland's Health Services Cost Review Commission (HSCRC) to assess and prepare a report on the implications of the practice of defensive medicine for the implementation of



*Prof. Diane Hoffmann*

Maryland's new all-payer model and global budget hospital payment strategy. The Commission's request was a response to legislation passed by the Maryland General Assembly in its 2014 session requiring that the HSCRC consider "the impact and implications that defensive medicine has on hospital costs and the goals underlying the all-payer model contract." Hoffmann worked with Professor Brad Herring, PhD, Associate Professor of Health Economics at Johns Hopkins Bloomberg School of Public Health, on the project.

## Background

Maryland is now the only state where hospitals are not reimbursed for Medicare covered patients using the inpatient and outpatient prospective payment systems (IPPS and OPSS). In 1977, the federal government granted Maryland a waiver exempting it from using the prescribed Medicare payment models for hospitals. Waivers to Maryland and a few other states were granted to allow them to experiment with setting hospital rates. In order to secure a waiver, rates at each hospital had to be approximately the same for all payors: Medicare, Medicaid, commercial insurers, private payors and the uninsured AND in order to maintain the waiver, states were required to keep the growth in Medicare payments per inpatient case below the growth of inpatient Medicare costs nationally.

Under the waiver, Maryland's HSCRC set rates for hospital inpatient services, as well as outpatient

services located at the hospital. Medicare payments to Maryland's hospitals have generally been greater than they have been to hospitals in other states. Medicare allowed such higher payments in order to ensure that Maryland's uninsured received adequate hospital care and as long as the growth rate for Medicare inpatient services was lower in Maryland than the national average.<sup>1</sup>

For over 30 years, using this all payer model, Maryland was able to successfully control the growth in its per admission hospital costs relative to the nation. While the system worked well for three decades, incentives established by the waiver, as well as recent hospital efforts toward better population health (consistent with the Affordable Care Act), drove hospitals to provide more care on the outpatient side. This shift in care increased the acuity and costs of services left on the inpatient side making the state unable to keep its cost growth rate down and at risk of losing its waiver. As a result, in January 2014, Maryland entered into a new agreement with CMS to control costs on a per capita basis under the all payer system with a global budget payment model.

Under the old model, the focus was on controlling increases in Medicare inpatient payments per case. However, according to the HSCRC, the new model "focuses on controlling increases in total hospital revenue per capita." Under the new methodology, the Commission prospectively establishes a fixed annual revenue cap for each hospital, which encourages hospitals to focus on "population-based health management." The revenue cap is determined "from an historical base period that is adjusted to account for inflation updates, infrastructure requirements, population driven volume increases, performance in quality-based or efficiency-based programs, changes in payer mix and changes in levels of [uncompensated care]."<sup>2</sup>

Under the new all-payer model, the HSCRC will continue to set rates for all payers but overall per capita hospital spending may not grow more than 3.58 percent per year. This is the average growth rate of the state's economy over the last decade.

The Commission is refining its methodologies to incorporate this per-capita population health approach into hospital rate setting. If Maryland fails during the five year performance period of the model and does not implement a corrective action plan that is acceptable to CMS, Maryland hospitals must transition to the national Medicare payment system.

Professor Uwe Reinhardt, a health economist at Princeton University, commented in an article about the new reimbursement system: “This is without any question the boldest proposal in the United States in the last half century to grab the problem of cost growth by the horns.”<sup>3</sup> Others have touted the plan as a potential model for other states.

The Commission has made it a priority to look at ways that the new hospital payment system can align with the interests and incentives of physicians, other providers, and consumers. If, in fact, there is a misalignment of incentives and interests of hospitals and physicians, it will be very difficult to meet the quality and cost requirements of the new all-payer model. Physicians have argued that one area of concern in addressing these quality and cost goals is the threat of malpractice suits. This led the General Assembly to require the Commission to seek a better understanding of the ways in which defensive medicine might affect its ability to implement the new all payer contract.

### The Problem of Defensive Medicine

In preparing their report to the HSCRC, Hoffmann and Herring reviewed over 70 articles and studies on the existence and extent of defensive medicine, i.e. how much it impacts overall health care costs. They found that the extent of defensive medicine is very difficult to get a handle on, in large part because of the ways in which defensive medicine is measured. The basic methodologies described in their report include:

- Qualitative surveys of physicians, i.e., direct survey questions or clinical scenarios with follow up questions for decision-making rationale, for overall amount of defensive medicine.
- Econometric analyses looking at the impact of malpractice risk on health care outcomes (e.g., utilization, spending, mortality) for

changes in defensive medicine. Some studies use direct measures of risk such as malpractice premiums, claims frequency, and award size, while others examine changes in state laws such as damage caps and changes to joint and several liability.

Both of these methods have significant shortcomings. The former are based on what physicians say they do but not necessarily on what they actually do. As noted in their report, the latter “can provide evidence of the impact of differences in malpractice liability risk on physicians’ use of tests or procedures” (and thus document a change in defensive medicine) but they do not enable one to produce a direct estimate of the overall magnitude of defensive medicine. Rather, they are a rough lower-bound estimate of the costs of defensive medicine. Based on a 2006 CBO report assessing the impact of various tort reforms on health care costs, Hoffmann and Herring cited estimates of the amount of hospital expenditures attributable to defensive medicine (across all states) ranging from 1.6 percent - 4.7 percent. The percentages differed based on the specific tort reform that was the subject of the study. The tort reforms included a cap on non-economic damages, modification of the joint and several liability rule (to a proportionate share liability rule), a cap on attorneys’ fees, implementation of a collateral source rule, and a cap on punitive damages. (While four of the five tort reforms were found to reduce hospital spending, modification of the joint and several liability rule was found to increase hospital spending.)

In addition to looking at studies of the impact of tort reform on defensive medicine, the two researchers looked at studies of the impact of financial incentives on defensive medicine. They were unable to find any studies examining the direct association between defensive medicine and the implementation of global budgets but found two studies that examined the effect of the interaction between tort reforms and managed care on health care spending. These studies looked at whether the adoption of managed care might exacerbate or mitigate the amount of defensive medicine practiced by physicians. The studies found that “managed care and liability reform are substitutes,”<sup>4</sup> and that HMOs can “reduce ‘defensive’ healthcare costs . . . absent tort reform.”<sup>5</sup> These two

studies, however, did not indicate whether the cost reductions attributable to defensive medicine were driven more by capitated payments to providers or other managed care cost control techniques such as utilization review.

### Defensive Medicine in Maryland

In order to determine the impact of the practice of defensive medicine in Maryland hospitals on the ability of the HSCRC to manage cost growth under the new all-payer model, Hoffmann and Herring looked for data from Maryland that might be relevant. The two found no Maryland data indicating that its physicians are unique in their practice of defensive medicine. Ultimately they concluded that “despite a relatively large body of literature examining the practice of defensive medicine, there are simply no reliable estimates of the baseline costs of defensive medicine to the health care system.” However, they did say that one could make two inferences from the literature, one about the extent of defensive medicine in Maryland compared to the rest of the country; the other about the ability of the HSCRC to control costs. First, based on tort reforms implemented in Maryland as compared to other states,<sup>6</sup> one could conclude, with several caveats, that defensive medicine may be lower in Maryland than in other states. Second, one could conclude that if “the effect of managed care on defensive medicine is due to financial incentives of a plan’s payment model (instead of utilization review or some other aspect of managed care), then the new all-payer global budget model could mitigate the practice of defensive medicine in Maryland.” This conclusion assumes alignment of physician and hospital incentives. This may not be the case however given that physicians will still be paid under a fee-for-service model while hospitals will be paid under the new global budget model. In order to align incentives the Commission is considering approaches such as gain sharing, pay for performance, shared savings, and integrated care networks.

Hoffmann and Herring presented their preliminary findings to several working groups appointed by the HSCRC on January 9, 2015 and Hoffmann presented their final report to the HSCRC on March 11, 2015. A copy of their final report is available at <http://www.hscrc.state.md.us/documents/commission-meeting/2015/03-11/Defensive-Medicine-Final-Report-3-16-15.pdf>

- 1 B. Rosen, “An HSCRC Primer,” Topics (Spring 2013) available at <http://www.gflaw.com/pubs/GordonPubDetail.aspx?xpST=PubDetail&pub=1052>
- 2 Completed Global Budgets under the All-Payer Model, available at <http://www.hscrc.state.md.us/global-budgets.cfm>.
- 3 Jay Hancock, Maryland’s bold Hospital Spending Plan Gets Federal Blessing, Kaiser Health News (Jan. 10, 2014) available at <http://kaiserhealthnews.org/news/maryland-hospitals-radical-plan-limit-spending-change-payment/>.
- 4 Daniel P. Kessler & Mark B. McClellan, Malpractice Law and Health Care Reform: Optimal Liability Policy in an Era of Managed Care, 84 J. PUB. ECON. 175 (2002).
- 5 Ronen Avraham et al., The Impact of Tort Reform on Employer-Sponsored Health Insurance Premiums, 28 J.L. ECON. & ORG. 657 (2012).
- 6 Maryland implemented a cap on non-economic damages in 1986 but has not changed its joint and several liability rule.

### Michael Vinluan

Cont. from p. 4

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incompetent patients, withholding and withdrawing of life-sustaining care, physician-assisted suicide and euthanasia, assisted reproduction, avoidance of reproduction, and the sale/donation of body parts and services. Relevant to Michael’s work at the FDA, Professor Henry asks students to consider the content and consistency of current law, the policy goals motivating regulation, the impact of technological innovation, and directions for legal reform.

According to Michael,

*Ethical principles are – or should be – at the root of all health-related laws and regulations. By recognizing the interplay of bioethics and law, agencies create policies that promote scientific integrity while protecting the well-being of patients. My coursework in bioethics with Professor Henry gave me the guiding principles I need to analyze the work of the FDA through an ethical lens.*

## Jaclyn Machometa

Cont. from p. 6



*Jaclyn Machometa 3L and Prof. Frank Pasquale*

in a public service capacity. Last year, she externed with Project HEAL, a community-based medical-legal partnership sponsored by the Maryland Center for Developmental Disabilities. In that position, she worked with her supervisors to provide comprehensive advocacy and legal services for children with intellectual and developmental disabilities and their families. Jaclyn is convinced that the medical-legal partnership model is a useful model to approach other complex legal situations faced by vulnerable populations and recently applied for a grant to expand Project HEAL's services after she graduates from law school. To thrive in the world of public service law and advocacy, Jaclyn decided to extern this semester in both a hospital's governmental affairs office and a hospital's legal department.

In her placement at the University of Maryland Medical System's (UMMS) Office of Government and Regulatory Affairs, Jaclyn is working on matters relating to the health care system's legislative and advocacy efforts at the local, state, and federal level. The office monitors legislation and regulatory activity with an eye to protecting and enhancing UMMS missions. The externship has proven to be a valuable experience for Jaclyn. Her first assignment was to study the "social determinants of health" model and brainstorm ways to incorporate concepts from the model into the UMMS medical system. This research aligned well with Jaclyn's background as an undergraduate Psychology/Human Services major and with her future goals. A subsequent project

involved familiarizing herself with health-related bills currently proposed in the Maryland General Assembly, specifically the MRI Self-Referral Bill and the federal Advancing Care for Exceptional Kids Act of 2014 in the event that the office needs to draft testimony from these bills later in the legislative session.

When asked which health law course was most helpful in preparing her for this placement, Jaclyn named the health law program's survey course: Health Care Law and Policy, taught this past Fall by Professor Frank Pasquale. Health Care Law and Policy is the only course required of all students pursuing the L&HCP's concentration in health law. The introductory course surveys current federal and state regulatory schemes governing the provision of healthcare. The class focuses on three major themes: quality of care, access to care, and cost containment. Students learn about professional licensure, malpractice, the provider-patient relationship, informed consent, the regulation of healthcare facilities, public and private insurance regulation, the Affordable Care Act, and bioethics of organ transplantation and end of life care. Jaclyn said of this course:

*While working as a Law and Policy extern for the University of Maryland Medical System's Office of Government and Regulatory Affairs, I frequently use my comprehension of the concepts I learned in Health Care Law and Policy. Those concepts have come in especially handy when reviewing and summarizing the newest federal regulations to arise out of the Affordable Care Act's statutory mandates that affect charitable hospitals across the nation, including UMMS.*

Jaclyn is also externing this semester in the Legal Department at the Johns Hopkins Health System Corporation and Johns Hopkins Medicine with UM Carey Law alumna Margaret (Meg) Garrett, a risk management attorney. In this position, Jaclyn conducts legal research on patient care and risk management issues to ensure that the hospital system conducts its activities in accordance with applicable law, accreditation standards, and its core mission. Jaclyn cited a number of courses and clinics that have helped her succeed in this externship. Specifically, she said:

*I have found that my knowledge of the legal and bioethical issues surrounding patients' rights taught in the End-of-Life Care Seminar (Adjunct Professor Jack Schwartz), Critical Issues in Health Care (Professor Diane Hoffmann), and the Civil Rights of Persons with Disabilities Clinic (Adjunct Professor Marc Charmatz) is immensely beneficial to my work with the Johns Hopkins Legal Department's Risk Management, Patient Care and Ethics team, where I am frequently asked to research and present on related topics during weekly update meetings.*

## PROFESSOR FRANK PASQUALE'S LATEST PROJECT: *THE WEEK IN HEALTH LAW PODCAST*

On the heels of his new book *The Black Box Society*, tireless Law & Health Care Program (L&HCP) Professor Frank Pasquale has taken to the "airwaves" with a new weekly podcast called *The Week in Health Law*. Pasquale, along with Professor Nicolas Terry, Executive Director of the Hall Center for Law and Health at Indiana University McKinney School of Law, are hosting weekly "commuting-length" conversations with guests on the most pressing issues in health law and policy. The podcast website is <http://twihl.com/>.

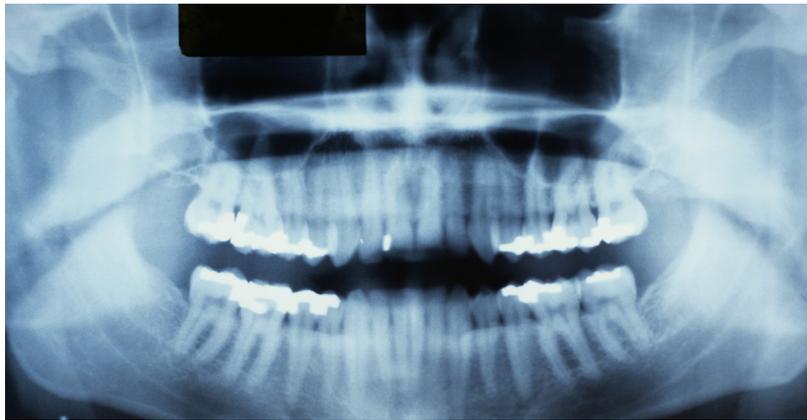
Pasquale and Terry have hosted episodes on a wide range of cutting edge topics and engaged several health law professors to participate in the webcast including:

- University of Kentucky School of Law Professor Nicole Huberfeld. Huberfeld discussed the new Google/Mayo Clinic initiative on health searches that is being undertaken to improve the quality of health-related search content. Google recently announced that it has tapped doctors, medical illustrators and the Mayo Clinic to develop in-depth information for more than 400 health and medical conditions. (Episode 2)
- Professor Abigail Moncrieff of the Boston University School of Law, a leading expert on the law and policy of federalism and constitutional law. Pasquale, Terry and Moncrieff discussed oral argument in *King v. Burwell*, the latest legal challenge to PPACA to reach the Supreme Court. (Episode 3)
- Professor Erin C. Fuse Brown of Georgia State University's College of Law, an expert on the law and policy of health care pricing. This podcast focused on Elisabeth Rosenthal's *New York Times* series on excessive, surprising, and worrisome health pricing practices. (Episode 5)

To access *The Week in Health Law*, subscribe at iTunes, listen at Stitcher Radio and Podbean (<http://twihl.podbean.com/>) or search for *The Week in Health Law* on your favorite podcast app. Show notes appear at <http://twihl.com/>.

Frank Pasquale has been a professor at University of Maryland Carey School of Law for two years. His research addresses the challenges posed to information law by rapidly changing technology, particularly in the health care, internet, and finance industries. He is a member of the Council for Big Data, Ethics, and Society, and an Affiliate Fellow of Yale Law School's Information Society Project. You can contact him on Twitter, for health law tweets only at @HealthPI (for Health Privacy and Innovation), and at @FrankPasquale for tweets related to his book, *The Black Box Society*.

# LAW & HEALTH CARE PROGRAM DRILLS INTO COMPLEX TOPICS WITH UM SCHOOL OF DENTISTRY COLLEAGUES



The University of Maryland Baltimore campus is home to six professional schools – the Schools of Law, Nursing, Social Work, Medicine, Pharmacy and Dentistry. These scholarly communities provide a rich opportunity for interprofessional collaboration on a number of cross-cutting health issues. While initially one might not think that a law school would find ways to work with a dental school, in the last two years, Law & Health Care Program faculty have enjoyed particularly close ties with the UM School of Dentistry.

In 2014, L&HCP faculty member Amanda Pustilnik, a national expert on legal and policy issues at the intersection of neuroscience and the law, co-hosted a roundtable called *Imaging the Brain, Changing Minds: Chronic Pain Neuroimaging and the Law* with David A. Seminowicz, PhD, a professor in the Department of Neural and Pain Sciences at the UM School of Dentistry. Pustilnik, who is away this semester as a fellow at Harvard Law School’s Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, and Seminowicz designed the roundtable as an interdisciplinary collaboration between pain neuroimaging researchers, legal decision-makers, and legal scholars. Its goal was to create dialogue between these fields and to make legal actors aware of recent breakthrough work in neuroimaging that has led to a paradigm shift in understanding chronic pain. Pustilnik and Seminowicz have written several papers based on the roundtable. The papers discuss the potential of this new science to change legal doctrines and shift legal and cultural norms about chronic pain diseases and their sufferers.

Faculty at the UM Dental School’s Department of Neural and Pain Sciences where Dr. Seminowicz is a faculty member study the brain mechanisms of pain and the relationship between brain activity and the various pain dimensions. The department uses brain imaging technology with humans and rodents to help identify brain regions and circuits that change with chronic pain.

This year, L&HCP Director Diane Hoffmann and Managing Director Virginia Rowthorn worked with Richard J. Manski, DDS, MBA, PhD, Director of the UM School of Dentistry’s Division of Public Health, on a paper about increasing the scopes of practice of dentists and physicians. Their paper “Increasing Access to Dental and Medical Care by Allowing Greater Flexibility in Scope of Practice,” is forthcoming in the *American Journal of Public Health*. The genesis of the paper was recognition of the work that advocates have done in recent years to increase access to health care by expanding the roles of both dentists and physicians. Already, dentists have a role in screening for certain medical conditions that manifest in the oral cavity and, in a related vein, pediatricians are becoming more involved in the oral health of children who often do not see a dentist in their first two years of life. The paper describes the significant legal and other barriers that stand in the way of allowing dentists to do more primary health care, physicians to do more oral health care, and both professions to collaborate.

Finally, L&HCP Professor Kathleen Hoke, Director of the Public Health Law Network – Eastern Region, and her colleague Kerri McGowan Lowrey, Deputy

*Cont. on page 16*

# PROFESSOR MARTHA ERTMAN PARTNERS WITH HOSPITAL LAWYER TO TEACH CONTRACT DRAFTING



*Prof. Martha Ertman*

Martha Ertman, Carole & Hanan Sibel Research Professor at Maryland Carey Law, has taught a seminar on Drafting Negotiated Contracts for several years. Each year, the seminar is planned around a hypothetical scenario such as a moving company purchasing two moving trucks or a restaurateur purchasing a restaurant. Much to the delight of health law students, Professor Ertman has worked with lawyers at the University of Maryland Medical System (UMMS) to create scenarios involving health care transactions. Two years ago, the class focused on the purchase of a medivac helicopter by a non-profit hospital. This Spring semester, Ertman and UMMS attorney Melissa Green crafted a hypothetical transaction about a hospital purchasing the practice of an orthopedic surgeon.

To create the documents that transfer the orthopedic practice to the hospital, seminar students negotiate and draft a letter of intent, asset purchase agreement, employment agreement, promissory note, financing statement, and security agreement. On each assignment, students receive detailed feedback on formatting a contract, conforming the contract to legal doctrine, the practicality of the contract terms, as well as feedback regarding clear, concise writing.

Ertman invited a number of experts to speak to the class including Dr. William Smulyan, an orthopedist who has experience in transactions similar to the one tackled by the class.

## **The Hypothetical Scenario**

*Dr. Hugo Bones, J.D., M.D. has been a practicing orthopedist for three decades and plans to practice for another decade. His solo medical practice is registered in Maryland under the name Orthopedics Associates, LLC which pays his salary, his six employee's salaries, and overhead for the practice, including rent on their leased premises, employees' health insurance and other benefits. Baltimore General Hospital, Inc., a Maryland corporation, has offered to purchase the practice.*

The student response to this class has been overwhelmingly positive. When Dr. Smulyan came to class, the students pressed him with questions about what issues a doctor would most want to consider when selling his practice. Along the same lines, Melissa Green provided vital information that helped students better understand the business deal and translate that deal into written documents. According to Professor Ertman, “classroom simulations of a transaction created to resemble real-life as much as possible can only work well with active participation by practicing attorneys and other professionals who know what the people in a deal want – and want to avoid.”

This teaching collaboration is the most recent opportunity that the law school has had to work with lawyers at UMMS to create learning opportunities for UM Carey Law students. For years, Law & Health Care Program students have worked and externed in UMMS offices and you can often find Green and her colleagues at the law school speaking in health law courses, coaching students for competitions, and attending networking events. About the seminar, Director of the L&HCP Diane Hoffmann commented, “We are very lucky that UMMS is close to the law school physically (it's across the street) and

*Cont. on page 16*

## FOURTH ANNUAL HEALTH LAW COMPETITION ATTRACTS RECORD NUMBER OF PARTICIPANTS



*University of Maryland Carey School of Law Team with L&HCP Faculty Members and Competition Organizers*

Despite a dramatic snowstorm that swept up the east coast on Saturday, February 21, nothing could dampen the spirits of participants in the Fourth Annual Health Law Regulatory and Compliance Competition at the University of Maryland Carey School of Law. Students from 14 different law schools across the country participated in this unique, day-long competition that allowed students to act as regulatory and compliance lawyers confronted by a complex series of potentially improper corporate practices. This was the fourth year that the Law & Health Care Program held the competition which was created in recognition of the need for lawyers with expertise in health care regulations and compliance and to give students a competitive venue to practice their developing legal skills in this area.

This year's competition was sponsored by Ober|Kaler, Arnold & Porter LLP, the American Health Lawyers Association (AHLA), the ABA Health Law Section, and the Food and Drug Law Institute (FDLI).

During the competition, teams of three get a fictional fact pattern that they see for the first time on the day of the competition. This year's fact pattern focused on several interactions between various health care stakeholders, including hospitals, physicians, drug and device manufacturers, and related third parties. Students had 90 minutes to sift through the problem which included FDA issues (pre-clinical research, clinical trials, marketing applications, post-marketing requirements), bioethical research, and fraud and abuse issues. Students are given a template answer sheet to note down the compliance and regulatory concerns they identify, the applicable laws or regulations, and any recommendation they have to solve or mitigate the problem. Students then present their findings to a panel of judges in a mock board room-style presentation. For the first round, the students present their findings as attorneys for the company in the fact pattern and, in the second round, as federal government lawyers investigating the misdoings. A public final round to determine the

first and second place winners in the law school's Ceremonial Moot Court Room was cancelled because of the bad weather.

Thirty-six regulatory and compliance attorneys from Baltimore and Washington, D.C. braved the wintry weather to judge the student presentations. These attorneys, who are faculty members, adjuncts, alums, and friends of the L&HCP, represented the full range of attorneys who focus on regulatory and compliance issues on a daily basis. Among the judges were lawyers from the nation's top health law firms – including Arnold & Porter, Hogan Lovells, Hyman Phelps McNamara, and Epstein Becker Green – as well as attorneys from CMS, HHS Office of the Attorney General, and FDA.



*2015 Health Law Regulatory and Compliance Competition Reception*

The winners of this year's competition were:

- 1st place – American University Washington College of Law
- 2nd Place – Loyola University Chicago School of Law
- 3rd Place – University of California Hastings College of Law
- 4th Place - University of Maryland Carey School of Law

The University of Maryland Carey School of Law Competition team was comprised of students Samantha Collado, Sherri Weinstein, and Amy Dobrzynski. Abe Gitterman, a 2013 graduate of the law school and Associate at Arnold & Porter, helped create the competition and headed up the planning committee this year. Apurva Dharia 2L was the student chair for the competition.

“We are delighted to see how this competition has taken off in just four years,” said Diane Hoffmann, Director of the L&HCP. “It is a sign of how quickly the field of health law is growing that so many current law students are seeking training in compliance and regulatory law and are enthusiastic to test their fledgling skills in a complex and difficult competition. We are thrilled to offer a venue to showcase these talented students.”



*The University of California Hastings College of Law Team make the most of a snowy day*



## LAW & HEALTH CARE PROGRAM

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

### Law & Health Care Program Drills into Complex Topics with UM School of Dentistry Colleagues

Cont. from p. 12

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Director for the Network's Eastern Region, have worked with the UM School of Dentistry to study policy options to increase access to oral health care by, among other things, allowing dental hygienists to provide more services with less direct supervision. Lowrey reached out to Marion C. Manski, RDH, MS, Director of the Dental Hygiene Program at UM School of Dentistry, to learn more about the work of dental hygienists and their role in oral health care. Hoke and Lowrey worked with other Network attorneys to create a series of state reports that describe the state of oral health care and the oral health workforce in each state as well as an accompanying issue brief. The ultimate goal of the project is to increase access to oral care particularly for vulnerable populations.

### Prof. Martha Ertman Partners with Hospital Lawyer to Teach Contract Drafting

Cont. from p. 13

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professionally. There is no better way to train students than to give them the opportunity to think through a realistic transaction with a lawyer who deals with these issues on a day to day basis. By working with Green, Professor Ertman has created a unique course that gives our health law students and other students a great practical learning opportunity that will facilitate and smooth their transition into legal practice."

In speaking about her experience with the course, Green said "Courses like Professor Ertman's are exactly what law schools need to be doing more of and it has been a pleasure collaborating with her on it."

The course has also been recognized as a model for legal education. U.S. Department of Education Deputy Undersecretary Jamieenne Studley singled the course out in her keynote address at the AALS meeting in January 2015 about what directions legal education should take.