

PROFESSOR FRANK PASQUALE – CHALLENGING CONVENTIONAL WISDOM AND CHANGING THE NARRATIVE ON THE FUTURE OF THE U.S. HEALTH CARE SYSTEM



Professor Frank Pasquale

When Professor Frank Pasquale joined the Maryland Carey Law faculty in 2013, the U.S. was on the verge of launching major data-sharing initiatives to implement the Affordable Care Act. At that time, in a previous edition of this newsletter, Pasquale warned that new and rapidly changing technologies held both promise and peril for the health care industry. Now, three years later, the Affordable Care Act has transformed all sectors of the health care industry and Pasquale’s message is still the same, if slightly more urgent, and decision makers are listening. In July 2016, at the White House-

sponsored Artificial Intelligence Now conference which convened leading thinkers on robotics law and policy, Pasquale gave a talk on automation in health care. In the talk, he warned about problems likely to be caused if robots prematurely replace the work of humans. A recording of Pasquale’s talk is available at <http://ainow.staging.mysociety.org/schedule/conference/presentation/complementary-vs-substitutive-automation-healthcar>. This high profile talk capped a year of speaking and writing on cutting edge topics in health information law and policy, including talks at the Food and Drug Administration, the European Medicines Agency, and the London School of Economics (with the head of NHS Digital, Britain’s leading health data authority).

On April 6-7, 2017, Pasquale will be hosting a roundtable at Maryland Carey Law that focuses on automation in health care called “The Future of Automation, Clinical Decision Support, and Robotics in Health Law & Policy.” The by-invitation roundtable will bring together thought leaders

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Symposium

THE FUTURE OF AUTOMATION, CLINICAL DECISION SUPPORT, AND ROBOTICS IN HEALTH LAW & POLICY

April 7, 2017, Maryland Carey

Symposium Topics

- How do stakeholders assure data quality given increasing demands on the time of providers?
- What are best practices for assuring privacy when innovations like cloud robotics could lead to constant real-time monitoring of patients?
- How should learning health care systems and predictive analytics programs be audited for quality and reliability?
- Are “care robots” a practical solution to the aging of the baby boomers, or an oxymoron?
- Will certain forms of sophisticated data analysis become the “standard of care?” Should they?
- Do current or future payment models bias the development of technology in certain directions?
- What is the potential for data-driven health care to curb or exacerbate health disparities?
- Can black box medicine, such as machine learning that cannot be reverse engineered or otherwise understood by humans, offer valid clinical decision support? Should versions of it be made available to consumers as apps?

in health technology and law to consider regulatory issues raised by the rise of population health management, predictive analytics, and robotics. Each field raises fundamentally new issues with respect to data management and privacy, liability, and reimbursement.

The roundtable will include participant experts in the fields of electronic health records, clinical decision support, and robotics. To kick off the roundtable, renowned expert in health information technology, Nicolas P. Terry, will serve as the law school’s Rome Lecturer on Thursday, April 6 at 5pm in the Ceremonial Moot Court Room. Professor Terry is the Hall Render Professor of Law and Executive Director of the William S. and Christine S. Hall Center for Law and Health at Indiana University’s Robert H. McKinney School of Law. The lecture is open to the public.

The roundtable will be an opportunity for Pasquale to engage stakeholders in robust discussions on the topics that he has been writing and lecturing about in the last few years—and to sound the warning bell regarding premature automation of critical tasks. Machines are edging out the human worker with many potential consequences, including mass unemployment. But there are bright spots as machines evolve. Pasquale suggests that robotics or software are not just beneficial, but potentially lifesaving, replacing humans “for dangerous or degrading work.” Technological innovations can help collect trash or remediate sites contaminated by nuclear radiation, for example. But automating health industry jobs such as providing care and counseling patients and their families raises different questions entirely. For example, one company has already developed a baby seal robot to comfort patients in hospitals and nursing homes.



Paro the Robo-Seal, a therapeutic robot baby seal to calm patients in hospitals and nursing homes

The current push for automation is a call-to-action for regulators, according to Pasquale: “Retarding automation that controls, stigmatizes and cheats innocent people is a vital role for 21st century regulators.” Using automation to slash prices should not be the primary goal of this new era of technology, Pasquale cautions, because it is too easy for automation’s proponents to change and radically simplify tasks and then declare their work done. Maintaining and improving quality are just as important as cost cutting. Pasquale is under contract with Harvard University Press to publish a book on this topic called “Humane Automation: The Future Logic of Professionalism” in 2018.

Pasquale’s book will discuss the impact of automation on a number of professions, including

medicine. Pasquale believes that medicine is moving forward with automation on the assumption that much of what doctors do is algorithmic and that much of the work of health care is matching a set of symptoms to an optimal cure or treatment—a pattern recognition problem ideally suited to machine learning. Although recognizing the promise of automation to improve health outcomes, particularly in the developing world, Pasquale is urgently asking policy makers to understand that medicine’s new wave of big data and predictive analytics could mislead patients, erode physicians’ skills, and subject the most vulnerable patients to “cookbook medicine” that fails to respect their values or interests, to the extent it replaces (rather than complements) the work of qualified professionals.

Pasquale believes that, at present, software doesn’t have the “spontaneity, creativity, flexibility, and perceptiveness that are the hallmarks of skilled doctors and nurses.” While some areas of medicine, such as monitoring drug interactions are appropriate for automation, some areas clearly are not. And even automated clinical decision support for drug-drug interactions has created a problem of “alert fatigue,” which technologists and policymakers have yet to solve. When it comes to end of life care, Pasquale notes, easing the anxiety and suffering of others requires a human touch. The idea of mapping out every possibility in advance, and mechanizing the termination of treatment, should alarm anyone with personal or professional experience in an intensive care unit, nursing home, or hospice. The stakes are so high, the concept of quality of life so personal and ineffable, the decision-making so properly shared among family and providers, that algorithms should only aid around the edges. Pasquale will be presenting his work at a conference at Princeton this December organized by Paul Starr (author of *The Transformation of American Health Care*).

Cautiously developing technology to improve the field of medicine while preserving the humanity of providing care will certainly cost money and time, according to Pasquale. “As professionals grapple with new forms of advice and support based on software and robots, they deserve laws and policies designed to democratize opportunities for productivity and autonomy,” he says. As implementation of the Affordable Care Act moves forward, Pasquale is clear that the cost-savings anticipated under the Act and future legislation must not create such an

administrative and technological burden for physicians that current and future providers leave the field.

The risks of cost-cutting in health care was addressed in Pasquale's 2015 article, "The Hidden Costs of Health Care Cost-Cutting: Toward a Postneoliberal Health-Reform Agenda" in Duke Law School's *Law and Contemporary Problems* (77 *Law & Contemporary Problems* 171-193 (2015)). In the article he states that beneath the superficial consensus that "health care is too expensive," there are raging debates on strategies of cost containment with some favoring supply-side limits by reducing the quantity or price of providers and others focusing on the demand side and reducing expenditures on health care. Others support the "quality movement" and believe costs can be reduced by shifting spending to effective interventions. But Pasquale thinks policymakers need to take an urgent step back and ask the basic question—how much should our society spend on health care? The article provides a rationale for why this question must be answered before policymakers point to high health care spending in itself as a rationale for reducing the purchasing power of patients, reducing compensation of physicians, nurses, and other providers, or deterring investment in hospitals, drugs, and devices. While there is a clear case for redistributing funds within the health sector from less to more effective forms of care, we should not be quick to assume that shrinking the sector would lead to more productive spending in other areas.

In a recent post on *Technology, Academics, Policy* (TAP) Blog, Pasquale refined the themes he discussed at the White House AI Now Conference and in his Duke article. In the blog he discusses the pushback he got after the conference. Even if complementary automation is better now, his critics asked "Shouldn't our policy reward firms that try to eliminate ever more labor costs? Doesn't *everyone* agree that the U.S. spends too much on health care—and isn't technology the best way of reducing that spending?" His blog post summarized his view that health economists need to offer a "positive industrial policy on where health spending should be going" rather than simply support austerity in health care spending without a foundational understanding of how spending should look.

Pasquale's work goes beyond health care professions and focuses on automation in other professions as

well, including the law. Last year he published a short article in the *UCLA Law Review Discourse* titled "Four Futures of Legal Automation," (63 *UCLA L. Rev. Disc.* 28 (2015), co-authored with computer programmer Glyn Cashwell) that discusses how automation will affect the future of the legal profession. In addition, Pasquale recently published two reviews of books that discuss the advance of automation: *The Future of the Professions* by Richard and Daniel Susskind in the *L.A. Review of Books* (March 15, 2016) and *The Second Machine Age: Work, Progress, and Prosperity in a Time of Brilliant Technologies* by Erik Brynjolfsson and Andrew McAfee's in *Boundary 2's* online edition (*January 20, 2015*).

In addition to his scholarship on automation and the professions, Pasquale devotes time each week to examine broader developments in the field in his podcast, *The Week in Health Law*. Pasquale has produced nearly 70 episodes of the podcast with his co-host Professor Nicolas Terry. Recent topics of the podcast have included the Affordable Care Act and its impact on insurers, the ways health care is failing the obese, ransomware and its effect on the health care industry, drug pricing, and bioethics in reproductive technology development. Recently, for Episode 67, Pasquale and Terry had former L&HCP student Ameet Sarpatwari '13 on the podcast. Sarpatwari is now an instructor in medicine at Harvard Medical School and an associate epidemiologist with Brigham and Women's Hospital. (See p. 5 for more about Sarpatwari.) The podcast focused on the effects of laws and regulations on therapeutic drug development, approval, use, and related public health outcomes. The podcast is available on iTunes and Google Play Music. Pasquale has also published several pieces addressing other issues in health law and policy over the past year. They include *Reforming the Law of Reputation* which addresses cutting edge challenges to health privacy caused by hacking and republication of breached medical records and *Health Information Law*, a chapter in *The Oxford Handbook of American Health Law*—which convened thought leaders in health law and policy to write about topics for which they are recognized experts. He is presently working on a piece exploring the privacy implications of corporate wellness programs.

LAW & HEALTH CARE PROGRAM ALUMS IN ACADEMIA

The Law & Health Care Program at the University of Maryland Francis King Carey School of Law aims to prepare its students for any number of careers, and several recent graduates have gone on to distinguish themselves in the field of academia.

Ameet Sarpatwari, PhD, JD, graduated from the School of Law with the Certificate in Health Law in 2013. Upon graduation, he was awarded the Joseph Bernstein Award for the most significant student piece of scholarly writing in health law. He now works as an instructor in medicine at Harvard Medical School and an associate epidemiologist with Brigham and Women's Hospital. He also serves as assistant director for the Program On Regulation, Therapeutics, And Law (PORTAL) at the hospital and teaches public

health law at the Harvard T.H. Chan School of Public Health.

Sarpatwari studies pharmaceutical policy issues such as the rising cost of prescription drugs and the U.S. Food and Drug Administration's post-approval safety and effectiveness monitoring systems. A list of his recent publications are provided in the box below. Sarpatwari says he is currently working on developing ethical norms for the effective and equitable use of a particular safety program—risk evaluation and mitigation strategies (REMS) with elements to assure safe use—based on epidemiological investigations and focused interviews with patients, physicians, and regulators.

Cont. on page 6

Ameet Sarpatwari: Selected Publications

- Kesselheim AS, Avorn J, Sarpatwari A. "The high cost of prescription drugs in the United States: origins and prospects for reform." *JAMA*. 2016;316(8):858-71.
- Sarpatwari A, Avorn J, Kesselheim AS. "State initiatives to control medication costs—can transparency legislation help?" *N Engl J Med*. 2016;374(24):2301-4.
- Sarpatwari A, Avorn J, Kesselheim AS. "Progress and hurdles for follow-on biologics." *N Engl J Med*. 2015;372(25):2380-82.
- Sarpatwari A, Kesselheim AS. "The case for reforming drug naming: should brand name trademark protections expire upon generic entry." *PLoS Med*. 2016;13(2):e1001955.
- Kesselheim AS, Avorn J, Sarpatwari A. "The high cost of prescription drugs in the United States: origins and prospects for reform." *JAMA*. 2016;316(8):858-71.
- Sarpatwari A, Choudhry NK, Avorn J, Kesselheim AS. "Paying physicians to prescribe generic drug and follow-on biologics in the United States." *PLoS Med*. 2015;12(3):e1001802.
- Darrow JJ, Sarpatwari A, Avorn J, Kesselheim AS. "Practical, legal, and ethical issues in expanded access to investigational drugs." *N Engl J Med*. 2015;372(3):279-86.
- Sarpatwari A, Franklin JM, Avorn J, Seeger JD, Landon JE, Kesselheim AS. "Are risk evaluation and mitigation strategies associated with less off-label use of medications? The case of ITP." *Clin Pharmacol Ther*. 2015;97(2):186-93.
- Sarpatwari A, Kesselheim AS, Malin B, Gagne JJ, Schneeweiss S. "Ensuring patient privacy in data sharing for postapproval research." *N Engl J Med*. 2014;371(17):1644-49.
- Sarpatwari A, Avorn J, Kesselheim AS. "Using a drug-safety tool to prevent competition." *N Engl J Med*. 2014;370(16):1476-78.
- Sarpatwari A, Robertson CT, Yokum DV, Joiner K. "Crowdsourcing public health experiments: a response to Jonathan Darrow's 'Crowdsourcing Clinical Trials'." *Minn. Law Rev*. 2014;98:101-20.



Ameet Sarpatwari '13

When asked about how his law school experience is relevant to what he is doing now, Sarpatwari responded that “[t]he stellar faculty” at Maryland Carey Law helped to prepare him for his career. “Having the chance to learn from some dynamic scholars, particularly Richard Boldt, JD, and Rena Steinzor, JD, was invaluable. The one-on-one interaction, outside of class—you don’t get that elsewhere.”

Sarpatwari also valued his “field experience,” including an internship working with Marjorie Cook Professor of Law Karen Rothenberg, JD, MPA, on her bioethics research at the National Institutes of Health (NIH). He also worked with Ellen Weber, JD, in the Drug Policy Clinic that she founded at Maryland Carey Law, helping to draft and advocate for a Maryland law that increased access to naloxone, an opioid overdose antidote.

Maryland Carey Law’s L&HCP also helped launch another recent graduate into a career in academia. Since earning his law degree and the Certificate in Health Law in 2011, **Michael Ulrich, JD, MPH**, has worked at the University of Maryland Center for Health & Homeland Security, earned his master’s at the Harvard School of Public Health, worked at the National Institute of Allergy and Infectious Diseases’ Division of AIDS and just completed a two-year fellowship at Yale Law School working with Abbe Gluck, professor of law and faculty director of the Solomon Center for Health Law and Policy. In each of these positions, Ulrich managed to publish several articles. Writing, he says, is a passion. Evidence of this is the list of articles he has published since graduating. This fall Ulrich begins a new position as an assistant professor of health law, policy and management at the Boston University School of Public Health.



Michael Ulrich '11

Michael Ulrich: Selected Publications

- Ulrich M. “Law and Politics, an Emerging Epidemic: A Call for Evidence-Based Public Health Law.” *American Journal of Law & Medicine*. 42 (2016): 256-283.
- Ulrich M (with others). “Lincoln’s Promise: Congress, Veterans, and Traumatic Brain Injury.” *Hastings Center Bioethics Forum* (2016).
- Ulrich M. “Challenges for People With Disabilities Within the Health Care Safety Net.” *15 Yale Journal of Health Policy, Law, and Ethics* 247 (2015).
- Ulrich M. “The Impact of Law on the Right to Water and Adding Normative Change to the Global Agenda.” *48 George Washington International Law Review* 43 (2015).
- Ulrich M. “Guidance From Vaccination Jurisprudence.” *13 American Journal of Bioethics* 40 (2013).
- Ulrich M. “The Duty to Rescue in Genomic Research.” *13 American Journal of Bioethics* 50 (2013).
- Ulrich M. “With Child, Without Rights?: Restoring a Pregnant Woman’s Right to Refuse Medical Treatment Through the HIV Lens.” *24 Yale Journal of Law and Feminism* 303 (2012).
- Ulrich M. “Resource Restraints: Rethinking Disclosure of Individual Genomic Findings.” *128 Michigan State University Journal of Medicine and Law* 127 (2012).
- Ulrich M. “Researchers Without Borders?: Limiting Obligations of Ancillary Care Through the Rescue Model.” *Vanderbilt Law School Health Law and Public Policy Forum* (2011).

Ulrich said there is no question what inspired him to join academia—the faculty in the Law & Health Care Program at Maryland Carey Law. “What helped me the most was the open door policy that every professor had,” Ulrich said. “I loved the professors’ willingness to go above and beyond. With my papers, they would go through the issues with me, and suggest what to read, and go over my research. That’s really what drew me to the teaching part of academia. It was such a huge benefit and added so much to my learning experience. I wanted to provide that for

students by teaching.”

Ulrich began his academic career speaking at the 39th Annual Health Law Professors Conference held this year at Boston University (BU) School of Law. Ulrich’s talk was titled, “The Right to Bear Arms: A Public Health Law Approach.” Ulrich will begin at BU by teaching a health law policy course this fall. He will also continue writing about gun rights and applying public health law doctrine to second amendment rights.

HEALTH LAW STUDENT ATTENDS SETON HALL LAW HEALTHCARE COMPLIANCE CERTIFICATION PROGRAM

Hillary Cleckler (3L) was awarded a scholarship to attend Seton Hall Law’s Healthcare Compliance Certification Program in June—the fourth Maryland Carey Law student to win the scholarship in the last several years. Cleckler, who graduated from University of Michigan with an undergraduate degree in English, applied for the scholarship to learn more about a field into which she has already made significant inroads. Last Spring, Cleckler externed at the Office of Chief Counsel to the Inspector General of HHS doing health care fraud and abuse work. After the compliance program in June, Cleckler spent the rest of the summer clerking at the inhouse counsel’s office at the University of Maryland Health Care System.

Cleckler was grateful for the opportunity to attend the compliance program saying “I learned so much while I was there, especially about laws I hadn’t encountered thus far such as the FCPA and the Sunshine Act and got to meet people who have extensive experience in healthcare compliance.” In this final year of law school, Cleckler is busy as the President of the Student Health Law Organization and an editor on the *Maryland Law Review*.



Hillary Cleckler (3L)

MICROBIOME TRANSPLANTATION PROJECT UPDATES

In June 2015, Director of the L&HCP Diane Hoffmann was awarded an NIH grant to study the legal and regulatory aspects of a cutting edge medical treatment called microbiota transplantation. The most commonly known form of microbiota transplantation is the fecal microbiota transplantation (FMT) to treat *C. Difficile* infection, but the project is also looking at how to regulate other uses of FMT as well as other emerging microbiota transplantation options including vaginal, skin, anterior nares, oral, and whole body transplants. See prior story about the grant in the Fall 2015 L&HCP newsletter. The Working Group of stakeholders convened under the grant met for the first time on December 3-4, 2015 and for the second time on May 2-3, 2016. The working group will meet for the last time on December 12-13, 2016, at the Maryland Carey Law to discuss final recommendations to include in a project white paper.

Project Updates

- On September 8, Hoffmann attended a one-day meeting of leading thinkers in microbiome-based research and in compassionate use hosted by Professor Arthur Caplan, founding Director of the Division of Medical Ethics at the New York University Langone Medical Center (NYULMC) and the founder of the NYULMC Working Group on Compassionate Use and Pre-Approval Access. The Compassionate Use Working Group studies issues relating to patients seeking access to therapies that have not received FDA approval but are in clinical trials. Professor Caplan organized the FMT meeting because of the parallels between patient requests for compassionate use exceptions for unapproved drugs and patients seeking access to fecal-based treatments for indications for which there is no supporting efficacy and safety data. The goal of the meeting was to bring together experts whose experience would be helpful to those in the field who are thinking through how to respond to such requests from patients.
- On May 31, Hoffmann and her co-investigators submitted formal comments to FDA on FDA's "Draft Guidance for Industry (FDA-2013-D-0811-0022): Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium*

difficile Infection Not Responsive to Standard Therapies." The comments informed FDA of the work of Hoffmann's grant-funded working group to date, noting that the comments to FDA were premised on the concept that "regulating FMT requires a framework that balances patient safety with the need to provide appropriate access to the procedure and one that does not unduly discourage research on the effectiveness of microbiota transplantations." The co-investigators also commented on FDA's regulation of FMT to date, specific aspects of the draft guidance including whether the traditional Investigational New Drug (IND) process is wholly appropriate for FMT, and whether certain IND requirements should be modified or waived for microbiota transplantation.

- Hoffmann and her co-investigators have submitted an article for publication in a forthcoming issue of the journal of *Gut Microbes* titled "Commentary: A Proposed Definition of Microbiota Transplantation for regulatory purposes." The commentary fills a vacuum in the regulatory discussion of microbiota transplantation which has proceeded to date without an accepted definition of microbiota transplantation from FDA or any other source. The commentary sets forth a definition based on working group discussion and co-investigator research. The article also highlights the critical need for a definition to guide how microbiota transplantation should be regulated because the definition of a product or process is often pivotal in determining which FDA regulatory pathway the product or process will traverse.

The other co-investigators on this project are Dr. Frank Palumbo, Center on Drugs and Public Policy, University of Maryland School of Pharmacy, Dr. Jacques Ravel, Institute for Genome Sciences, University of Maryland School of Medicine, Dr. Mary-Claire Rогhmann, Department of Epidemiology and Public Health, University of Maryland School of Medicine, Dr. Erik von Rosenvinge, Division of Gastroenterology, University of Maryland School of Medicine and Veterans Affairs Maryland Health Care System and Virginia Rowthorn, Law & Health Care Program, University of Maryland Carey School of Law.

LOCAL HEALTH CARE ORGANIZATIONS CREATE NEW BUSINESS FELLOWSHIPS



Evergreen Health Co-op

When the call went out to identify businesses to engage in Maryland Carey Law's new Business Fellowship Program, local health care organizations and alumni of the Law & Health Care Program were among the first to respond. The program places law students and recent graduates in Baltimore-area businesses to help Maryland companies and institutions meet their business and legal needs while providing growth opportunities for the next generation of law and business leaders. The program supports 10-week Summer Fellowships and year-long Postgraduate Fellowships. The University of Maryland Medical System (UMMS), FutureCare, LifeBridge Health, Evergreen Health, and Vasoptic Medical Inc. were among the inaugural fellowship partners offering paid placements to students. The program's postgraduate business fellowships are open to new Maryland Carey Law alumni who work for 12 months working in the legal and business departments of the organizations. According to Maryland Carey Law's Office of Career Development, after the first year of the program, employer organizations reported that they were extremely impressed with the work of

their fellows and the law school received extremely positive feedback from the selected students.

Jaclyn Machometa '15 spent her first year out of law school as a fellow in the Office of General Counsel at UMMS where she gained invaluable legal drafting experience in various health law matters including physician contracting, corporate transactions, corporate creation/structuring, guardianships, and affiliation and vendor agreements. She said of the Fellowship Program, "It was the perfect opportunity for me to gain hands on experience in the fields of both health and business law, two areas in which I hope to establish a successful law career." Vince Andrews, a 2016 graduate of the Law & Health Care Program, is the organization's current fellow.

Reena Palanival (3L) spent her summer as a fellow at Vasoptic Medical Inc., a company that is developing a low-cost, easy-to-use, portable retinal imager designed to non-invasively capture physiological information from the retina. This approach eliminates the need for pupil dilation or contrast dyes and allows for important eye exams to be performed in primary care and community care

environments to increase access to eye exams for at-risk and underserved populations. Vasoptic was started by L&HCP alum M. Jason Brooke (see Fall 2015 L&HCP newsletter) who rose to the challenge of creating a Fellowship opportunity to provide hands-on legal and business expertise to students. At her placement, Palanivel analyzed agreements for consistency and critical provisions relevant to the business operations, reviewed and summarized patent related prior art, researched and analyzed reimbursement policies related to retinal imaging, and drafted standard operating procedures for compliance with FDA regulations. She said of her time in the Fellowship that it was not only invaluable in providing her with experience in the interplay between health and business, but also professionally enriching, providing her with lifelong mentors.

L&HCP graduate Maryann Hong '16 is currently a postgraduate fellow at Evergreen Health, Maryland's only Health Care Cooperative, a member-driven company created under the Affordable Care Act as an innovative way to provide health insurance. One of Evergreen Health's attorneys is L&HCP alum, Elliott Hooper '13, who was instrumental in bringing Evergreen to the Business Fellowship Program. Of the Program, Hooper says the opportunity to partner with Maryland Carey Law and the L&HCP was particularly enticing to Evergreen Health. Evergreen Health was drawn to the Fellowship Program by the academic strength of Maryland Carey Law students and the well-versed background in health law students receive from the L&HCP. Evergreen Health felt the academic strength of the L&HCP would prepare fellows to actively contribute in a meaningful way from the outset of their fellowship.

MARYLAND CAREY LAW FACULTY SPEAK AT ANNUAL HEALTH LAW PROFESSORS MEETING

Several Law & Health Care Program faculty members spoke at the 39th Annual Health Law Professors Conference in June. The conference was co-sponsored by the American Society of Law, Medicine & Ethics, Boston University School of Law, and Boston University School of Public Health.

Preeti Emrick, University of Maryland Center for Health and Homeland Security and University of Maryland Law School, *U.S. Public Health Law: Archaic or Relevant in the Context of Ebola?*

Diane Hoffmann, University of Maryland Law School, *Microbiota-Related Therapies and the Challenges They Create for FDA*

Leslie Meltzer Henry, University of Maryland Law School, *Conducting Research with Pregnant Women: Ethical and Legal Challenges in the Zika Pandemic*

Frank Pasquale, University of Maryland Law School, *Data Acquisition and Consent in Learning Health Care Systems*

PROFESSOR KATHLEEN HOKE BRINGS TOGETHER PUBLIC HEALTH STAKEHOLDERS AROUND COMPLEX HEALTH ISSUES



Professor Kathleen Hoke

As part of its mission to provide *pro bono* technical legal assistance on a wide range of public health issues, the Legal Resource Center for Public Health Policy (LRC) at the University of Maryland Francis King Carey School of Law is continually searching for ways to reach a broader variety of stakeholders.

In June, the LRC co-hosted the Maryland Healthy Housing Symposium at Turf Valley Resort and Conference Center in suburban Baltimore. LRC Director and Law School Professor Kathleen Hoke, JD '92, greeted approximately 100 federal, state, and local health and housing officials at the symposium, which focused on challenges faced by vulnerable populations who live in substandard housing, increasing their susceptibility to related illness and injury.

The symposium topics included: the link between housing and health; the environmental exposures that affect individuals in the home (e.g. lead, radon, mold, etc.); the impact smoking has on individuals living in multi-unit housing; and the U.S. Department of Housing and Urban Development's (HUD) proposed rule to prohibit smoking in public housing—specifically, what it would mean for public housing authorities and residents in Maryland.

Hoke noted that “since its inception in 2001, the LRC has worked to assist state and local public health officials to address the devastating impact of exposure to secondhand smoke, with a particular focus on vulnerable populations, such as youth, senior citizens, and those with chronic illnesses.”

The LRC assisted with gaining passage of the 2007 Maryland Clean Indoor Air Act and related regulations, securing protections for hospitality workers who had been carved out of protections when other workplaces were rendered smoke-free in 1992. “Seeking these same protections for those exposed in public housing was a natural extension of these earlier efforts,” Hoke said.

In addition to attracting public housing authorities, property managers and owners, local health departments and coalitions, and faith- and community-based organizations from across Maryland and the District of Columbia, the symposium also featured a wide range of health and housing experts as speakers.

Peter Ashley, DrPH, HUD's director of Healthy Homes and Lead Hazard Control, discussed the agency's role in overseeing public housing authorities and federally subsidized properties, and promoting healthier homes programs nationwide. He highlighted economic, health, and safety reasons for HUD proposing a rule that would require all public housing authorities to prohibit smoking in individual units, common areas, and within 25 feet of buildings.

“Secondhand smoke has a lot of toxic and carcinogenic chemicals, and it doesn't stay only in the unit of the smoker in a multi-family property,” Ashley said. “Also, tobacco smoking is an important safety issue in that it is the major cause of fatal residential fires.”

Cliff Mitchell, MS, MD, MPH, director of the Environmental Health Bureau for the Maryland Department of Health and Mental Hygiene (DHMH), which co-sponsored the symposium with Maryland Carey Law, spoke about the link between housing and emotional, mental, and physical health; the importance of providing healthy and safe living spaces, particularly for vulnerable populations, such as children; and the prominent role that communities play in ensuring access to healthy and safe housing.

Meet Will Tilburg, the Legal Resource Center's Deputy Director



William Tilburg

Will Tilburg is the Deputy Director of the Legal Resource Center for Public Health Policy and Senior Staff Attorney with the Network for Public Health Law, Eastern Region, both of which are located at Maryland Carey Law. Tilburg graduated with honors from the law school in 2011 and started working in both his current roles shortly after graduation. He assists the Director of both programs, Professor Kathleen Hoke, in their work with state and local legislators, government attorneys, and health officials on legal and policy issues related to public health. Tilburg is also an adjunct professor at Maryland Carey Law and University of Maryland School of Public Health, where he teaches courses on health law and ethics, environmental law, and oral advocacy. His focus areas include housing, environmental health, medical marijuana, nutrition and physical activity, and tobacco control. In June 2016, Tilburg organized the Maryland Healthy Housing Symposium mentioned in the prior article that brought together 100 stakeholders to focus on challenges faced by individuals living in substandard housing. In September, he organized and moderated a panel at the National Public Health Law Conference in Washington, DC called “Efficient, Health and Safe Housing.” The session examined innovative state and local policy interventions to improve the housing situation of vulnerable populations.

Other speakers included LRC deputy director and symposium organizer William Tilburg, JD '11; Dana Moncrief, MHS, CHES, chief, Statewide Public Health Initiatives, DHMH; Tiffany Smith, MHSA, from Howard County Housing; Tiffany Nicolette from Shelter Properties, LLC; Laura Hale from the American Lung Association; and Bob Vollinger, MSPH, program director, Tobacco Control Research Branch, National Institutes of Health.

“The speakers brought many different perspectives to the discussion of ethical and effective methods of assuring healthy housing for the least among us,” said Hoke, who opened and closed the five-hour symposium. “Simply gathering an eclectic group of health and housing officials, offering various voices and perspectives during the symposium, and allowing for vigorous discussion created an environment rich for further collaboration and cooperation. This cross-

cutting effort should result in comprehensive policy options to reduce not only exposure to secondhand smoke but also to other environmental hazards, such as radon and mold.”

In addition to tobacco regulation and environmental health, the LRC has been examining the public health consequences of electronics; the medical use of marijuana; and regulation of gambling hotline ads. Hoke sees the Center playing an even greater innovative role in the future.

“In collaboration with the Department of Health and Mental Hygiene and Maryland’s 24 local health departments, we are working to develop sound, evidence-based policy options appropriate for state and local governments and for public and private housing. The Maryland Healthy Housing Symposium took us another step along that path.”

LAW & HEALTH CARE PROGRAM GRADUATES 38 STUDENTS



2016 Health Law Certificate Graduates and L&HCP Faculty

At a gala celebration in May, Dean Donald Tobin, L&HCP Director Diane Hoffmann, and L&HCP faculty celebrated the success of health law certificate students with their friends and family. The celebration marked the 19th year of the certificate program. The students were individually recognized by the faculty who delivered personal comments about each of the graduates before they got their certificate.

All of the program's certificate students followed different pathways determined by their particular interest within health law. Some focused on mental health issues, others on business aspects of the health care industry and still others on public health law. Below we share the pathways of several of our 2016 grads.

Vincent Andrews

Vincent graduated from Cornell University with an undergraduate degree in Industrial and Labor Relations in 2011 before coming to Maryland. While in law school, Vincent externed at Care First Blue Cross Blue Shield in their Office of General Counsel

where he worked on a wide range of issues including a subscriber appeal before an Administrative Law Judge and matters before the Maryland Insurance Administration. His supervisor, Meredith Borden, found him to be incredibly enthusiastic and eager to learn about the business side of the health care industry. Vincent wrote his Advanced Writing Requirement Paper on the relationship between state spending on mental health services for minors and rates of juvenile incarceration. The paper looked at how states interpreted and implemented SCHIP and IDEA, which in turn affected state spending on mental health services. Professor Diane Hoffmann, who was his faculty advisor, said of the paper, "[i]t went far beyond what I expected. While his legal research and analysis were excellent and thorough, Vincent also taught himself how to do multiple regression analysis—no easy task!" His enthusiasm and this experience led to his selection as this year's Business Fellow at the University of Maryland Medical System's in house counsel's office. In this position, he assists on a wide range of activities, from drafting physician

employment contracts and lease arrangements to analyzing patient care and Stark/anti-kickback issues. An article about the Business Fellowship appears on page 9 of this newsletter.



L&HCP Director Diane Hoffmann, 2016 Graduate Allison Kronback and Prof. Ellen Weber (from l to r)

Monica Basche

Like many health law students who come to Maryland Carey Law, Monica had health-related experience in her background. As a Legal Marketing Manager for Agora, a publishing and information services company, she worked primarily with clients in the dietary supplement industry, editing their marketing materials and newsletters. At the law school, Monica served as an executive articles editor for the *Maryland Law Review* and research assistant for Professor Donald Gifford in addition to participating in a number of organizations, externing at the Maryland Office of the Attorney General and Food and Drug Administration, and engaging in community service. Monica has chosen to pursue the judicial clerkship route to prepare her for her career. This year she will be clerking with Judge Adkins at the Maryland Court of Appeals and in August 2017, will start a two-year clerkship with Judge George Russell at the U.S. District Court for the District of Maryland. Describing her experience at the law school, Monica said, “Maryland’s Law and Health Care Program was one of the most important parts of my law school experience because it showed me how health law intersects with so many different practice areas and gave me access to externship opportunities that I wouldn’t have had anywhere else.”

Samantha Michelle Loh Collado

According to her mentor, L&HCP Professor Richard Boldt, Samantha stood out as a law student for multiple reasons—“she is serious, smart, and

incredibly well trained, but she is also optimistic, kind and empathic in a way that is impossible not to notice.” As Boldt’s research assistant, Samantha helped with a project examining the outpatient commitment of individuals with serious mental illness, which resulted in the development of an article that was published in the *New England Law Review*. According to Boldt, “her investigation of state statutes, funding mechanisms, and judicial opinions in the area was detailed, thorough, and absolutely essential to the overall project.” In addition, Samantha served on the Executive Board of the Student Health Law Organization, as managing editor of the *Journal of Health Care Law and Policy*, and also competed in both the Loyola Chicago National Health Law Transactional Competition and the Maryland Health Law Regulatory & Compliance Competition. Samantha came to the law school with a public health degree which helped her shine in Professor Weber’s Drug Policy Clinic. Professor Weber reported that her work on developing and drafting the Clinic’s comments to proposed State regulations on the certification of substance use treatment services and their integration with mental health services demonstrated the sort of methodical and thorough research and analysis that few students could have performed. Samantha is putting her health law and policy degree to use as regulatory counsel at the Center for Tobacco Control at FDA.



2016 Graduates Kelsey Harrer, Alexandria Montanio and Samantha Collado (from l to r)

Alexandria Montanio

Alex graduated from University of Virginia in 2011 with High Distinction in Psychology and Distinction in English. At the law school, she was equally as distinguished. Alex was 11th in her class, a Leadership Scholar, co-president of the winning Alternative

Dispute Resolution Team and staff editor of the *Journal of Health Care Law and Policy*. She also externed at the Maryland Disability Law Center (now Disability Rights Maryland) where she performed site visits to programs to check for abuse and neglect of vulnerable clients. Perhaps her most prominent achievement in law school was being part of the team that won the 5th Annual Health Law Regulatory and Compliance Competition held at the law school. This is the L&HCP's own competition but, during the first four years of the event, the Maryland team never placed. In 2016 with Alex and two fellow students, Maryland Carey Law brought home the big plaque. Professor Frank Pasquale, faculty mentor to the competition, said of Alex, "she is a brilliant writer and thinker, also blessed with a great sense of humor and perspective. She brought extraordinary real-world experience to both my health law and administrative law classes, and capped her career here with a contribution to the emerging field of algorithmic accountability. She uncovered problems in organ allocation I was unaware of, and has developed a clear regulatory proposal to address discrimination against the disabled in that context." Alex clerked at Evergreen Health (Maryland's only Health Care Co-op created under the ACA and described on p. 9). She is putting all this experience to work at Gordon Feinblatt in their litigation and health care practices as a first year associate.

Theresa Thompson

It's hard to exaggerate Theresa's commitment to the Law & Health Care Program during her three years at Maryland. She was the President of the Student Health Law Organization (SHLO) for two years, during which time the organization supported a number of new and highly successful educational and networking events. In particular, Theresa spearheaded the Health Law Networking and Resume Review Reception during which health law practitioners review student resumes in advance and go over them with students at a reception which also includes an element of "speed networking." In addition to her activities with SHLO, Theresa was on the team with Alex Montanio that won the Maryland Carey Law Health Law Regulatory and Compliance Competition. She also participated in the Loyola Chicago National Health Law Transactional Competition. Finally, she was manuscripts editor of the *Journal of Health*

Care Law & Policy, treasurer of the Women's Bar Association, and a UMB President's Entrepreneurial Fellow. She is now a first-year associate at Epstein Becker Green in Washington and has promised to stay involved as an alum for years to come.



L&HCP Director Diane Hoffmann, 2016 Graduate Michael Vinluan and Prof. Richard Boldt (from l to r)

Michael Vinluan

Michael came to the law school with a medical degree under his belt and prior to law school had worked with the CDC, consulting with clinicians and health departments across the United States on issues including critical health threats, disease outbreaks, and bioterrorism. His experience as a physician gave Michael a unique and valuable perspective on the topics raised in his health law courses—something appreciated by his professors and fellow students. Another way in which his medical background privileged Michael was in the realm of externships. He was able to secure multiple placements at FDA. These externships led to a one-year Fellowship in the FDA's Office of the Commissioner. He also served as a law clerk at Johns Hopkins Hospital in their in-house counsel's office. When each placement ended, his supervisors asked him to stay on but Michael was committed to finishing law school. During law school, Michael worked as a consulting medical expert for litigation law firms. He currently works as a medical-legal consultant for law firms in Washington, D.C. and Baltimore. According to his mentor, Professor Richard Boldt, "Michael is just the sort of person who makes our Law and Health Care Program so fabulous. I expect to hear great things about his work in the years to come, and I feel lucky to have had the opportunity to be a part of his legal education."

2016 HEALTH LAW CERTIFICATE RECIPIENTS

Samantha Altneu	Héctor Hernández	Julianna Kim	Siyang Song
Vince Andrews	Thomas Hoblitzell Jr.	Caroline Lee	Jenna Snyder
Loretta Bacon	Maryann Hong	Allison Kronback	Amethyst Spivak
Monica Basche	Diana-Lynne Hsu	Alexandria Montanio	Eric Suarez
Emilie Cobert	Minerva Hughes	Adetoro Olugbemi	Theresa Thompson
Samantha Collado	Megan Hurley	Maraya Pratt	Melissa View
Elizabeth De Santis	Sophia Jafrul	Heather Printz	Michael Vinluan
Apurva Dharia	Yevgeniya Kalinina	Amy Rappole	Sherri Weinstein
Alisha Duggal	Thomas Kandler	Ilan Roth	
Kelsey Harrer	Alex Kelly	Gabriel Rubinstein	

Third Annual Interprofessional Forum on Ethics and Religion in Health Care

CHALLENGES IN ORGAN DONATION & TRANSPLANTATION

TUESDAY, NOVEMBER 1, 2016

UMB'S SOUTHERN MANAGEMENT CORPORATION
CAMPUS CENTER

621 W. LOMBARD ST., BALTIMORE, MD

Presented by the University of Maryland Schools of Medicine, Nursing, Pharmacy, and Social Work; the UMB Graduate School; the Maryland Healthcare Ethics Committee Network at Maryland Carey Law; and the Institute for Jewish Continuity

HOFFMANN SELECTED TO SERVE ON COMPOSITE COMMITTEE FOR USMLE



Last spring, Professor Diane Hoffmann, director of the Law & Health Care Program at Maryland Carey Law, was asked by the president of the Federation of State Medical Boards if she would serve on the Composite Committee for the

United States Medical Licensing Exam (USMLE). The USMLE is the single pathway for licensure for all medical school graduates (from schools in the U.S. as well as other nations) who wish to practice allopathic medicine in the U.S. The exam provides state medical boards with information they need about the competency of applicants for licensure in their state. The Composite Committee is the governing board for the USMLE program. It is “responsible for the overall direction of the program identifying and approving procedures for scoring and determining the pass/fail standard, and all significant policies and procedures.”¹ The committee is composed of representatives from the Federation of State Medical Boards (FSMB), the National Board of Medical Examiners (NBME), the Educational Commission for Foreign Medical Graduates (ECFMG) and the public. The FSMB, a non-profit organization, represents the 70 medical and osteopathic boards of the United States and its Territories. The NBME, also a non-profit organization, prepares exams and assessments for a number of health professional groups and the ECFMG certifies international medical graduates desiring to enter U.S. graduate medical education.

All physicians who successfully completed medical school and residency and became licensed to practice medicine in the U.S. since the early 1990s have taken the USMLE. The exam replaced the NBME Part Examination Program and the Federation Licensing Exam (FLEX). The exam includes three standardized assessments called step exams. The first step is typically taken by medical students after

their second year of medical school. It focuses on the basic sciences and tests whether students understand and are able to apply scientific principles that form the foundation for the safe and competent practice of medicine. Step 1 scores are often used by residency programs in selecting graduating medical students. Failure on Step 1 may prevent a student from moving forward in the medical school curriculum from the basic sciences to the clinical sciences curriculum.

Step 2 is divided into two parts, Clinical Knowledge and Clinical Skills. Students must pass both parts in order to receive their medical degree and to be granted a temporary state license to practice during their first year of residency training. Step 2 evaluates whether a medical student or graduate can apply medical knowledge, skills and understanding of clinical science essential for providing medical care under supervision. The first part of the exam is given as a traditional exam; the second part, Clinical Skills, uses standardized patients and focuses on a candidate’s communication and problem-solving skills.

Step 3 is typically taken after the first year of medical residency and in all states passage of step 3 is required for permanent licensure. It assesses whether applicants “can apply medical knowledge and their understanding of biomedical and clinical science essential for the unsupervised practice of medicine, with emphasis on patient management in ambulatory settings.”²

Hoffmann attended her first meeting of the Composite Committee in June in Philadelphia and was impressed by the dedication and commitment of its members to ensure that the exam process is one that well prepares individuals to practice medicine and assures the public that their doctors have achieved a minimum level of competency.

¹ Who is USMLE? At www.usmle.org/about/

² Federation of State Medical Boards and National Board of Medical Examiners. United States Medical Licensing Examination: Step 3 at www.usmle.org/step-3/



THE AFFORDABLE CARE ACT: TOO BIG TO FAIL?

OCTOBER 20, 2016, 5:30-7:00 PM

UNIVERSITY OF MARYLAND CAREY SCHOOL OF LAW
CEREMONIAL MOOT COURT ROOM, FIRST FLOOR

OPEN TO PUBLIC, RECEPTION TO FOLLOW

As the 2016 Presidential election nears, candidates on different sides of the aisle have very different views of the future of the Affordable Care Act (ACA). Hillary Clinton wants to “defend and expand” the ACA and make a “public” insurance option available to consumers. Donald Trump asserts that “on day one of the Trump Administration, we will ask Congress to immediately deliver a full repeal of Obamacare.” Members of Congress are equally split on the law’s future.

It has been over five years since the law was enacted. Who have been the winners and who have been the losers under the most ambitious overhaul of the nation’s health care system since Medicare was created in 1965? What is the future of the law if Clinton wins or if Trump wins? Is it too big to fail? Which components of the ACA are at most risk with either candidate? This election panel will look back at the history of the ACA but, more importantly, look forward to the program’s future with representatives from government agencies, insurance agencies and consumer representatives.

Panelists

Leonardo Cuello, JD, Director, Health Policy, NHeLP

Elizabeth Milito, JD, Senior Executive Counsel at National Federation of Independent Business

Kimberly Robinson, JD, Partner, Funk & Bolton and Executive Director of the League of Life and Health Insurers of Maryland

Beth Sammis, Adjunct Lecturer, Anne Arundel Community College and Board Member, Consumer Health First (former Acting Insurance Commission for the State of Maryland)

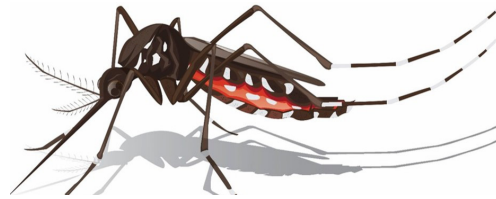
Moderator

Diane E. Hoffmann, JD, MS, Professor of Law, Director, Law & Health Care Program University of Maryland Carey School of Law

Sponsored by the Karen Rothenberg and Jeffrey Seltzer Law & Health Care Program Fund

SAVE THE DATE

ZIKA GLOBAL TO LOCAL: ADDRESSING THE EPIDEMIC FROM AN INTERNATIONAL AND INTERPROFESSIONAL LENS



As the Zika virus moves deeper into North America, different sectors of U.S. society are mobilizing to address the epidemic by preventing the spread of the virus, identifying patients, treating affected individuals, and working toward a vaccine. Faculty members at University of Maryland, Baltimore (UMB) are on the front line of the fight against Zika using their expertise to develop and refine the legal, medical and regulatory tools needed to face a new epidemic. How Zika is addressed in the U.S. and our own community in Baltimore will be greatly informed by the experience of countries in South and Central America where the virus first emerged.

The Law & Health Care Program and the Center for Global Education Initiatives is hosting a panel on February 15, 2017 to learn about the Zika virus from UMB faculty on the front lines of Zika research as well as from the Costa Rican Ambassador to the U.S. who brings his perspective as both a government official in an affected country and a biotechnologist. Join us at this informative public discussion.

Panelists

Dr. Roman Macaya, ambassador of Costa Rica to the U.S. Ambassador Macaya has a multidisciplinary background as a scientist, businessman, advocate, politician, and academic. As a chemist and biochemist by training, Ambassador Macaya has led R&D teams in the fields of biotechnology and biomedical research. The Ambassador has authored numerous articles in peer-reviewed journals in the life sciences and was lead inventor on a patent application for a drug candidate. As an Ambassador, Dr. Macaya has given Science Diplomacy a high priority, an effort that has yielded concrete results in science and technology collaborations between the United States and Costa Rica.

Professor Michael Greenberger, professor at Maryland Carey Law and director of the University of Maryland Center for Health and Homeland Security (CHHS). Professor Greenberger and CHHS are actively working with governmental clients to develop plans on how to respond to emerging infectious diseases, including Zika.

Professor Leslie Meltzer Henry, professor at Maryland Carey Law. Professor Henry and colleagues at other institutions were recently funded by the Wellcome Trust to develop ethical and legal guidance for conducting research with pregnant women during public health emergencies, like the Zika crisis, where there is an urgent need to attend to the health needs of pregnant women and their offspring. The project is called “Conducting Ethical Research with Pregnant Women in the Emerging Zika Pandemic and Beyond: Challenges Arising in Public Health Crises.”

Dr. Jon Mark Hirshon, professor in the Department of Emergency Medicine and in the Department of Epidemiology and Public Health at the University of Maryland School of Medicine. He is the former director of the Charles McC. Mathias, Jr. National Study Center for Trauma and EMS and is currently the senior vice-chairman of the University of Maryland, Baltimore's IRB. Dr. Hirshon recently published “Zika Virus: Critical Information for Emergency Providers” with colleagues and, as a board member of the American College of Emergency Physicians, is working on the organization's guidelines for the virus.

Dr. Kathleen Neuzil, director, Center for Vaccine Development at University of Maryland School of Medicine. The Center for Vaccine Development has been chosen as one of three study sites in a human safety trial of a new Zika vaccine. The early-stage study will evaluate the experimental vaccine's safety and ability to generate an immune system response in participants.



LAW & HEALTH CARE PROGRAM

500 West Baltimore Street

Baltimore, MD 21201

www.law.umaryland.edu/healthlaw

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

SUPPORT THE LAW & HEALTH CARE PROGRAM

The Law & Health Care Program has hosted a number of hallmark meetings and roundtables to bring together health care practitioners, legal academics, medical experts, scientists, and policymakers to examine cutting-edge issues in health policy, law, or ethics. Over the next 30 years, we hope to count you as a partner in this effort. We plan to build on the stellar foundation we have created as health law educators to keep asking questions and pushing the field of health law forward. In order to do this, we are asking for your support. Every contribution helps our program achieve its goals.

There are two ways to give to the Law & Health Care Program:

~ Online at <http://www.law.umaryland.edu/give/healthlaw>

~ Mail, by sending a check made payable to: UMBF, Inc./ Law & Health Care
to 620 West Lexington Street, 2nd Floor, Baltimore, MD 21201

Funds for the Law & Health Care Program are administered by the University of Maryland, Baltimore Foundation, Inc.