

LAW & HEALTH CARE



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NEWSLETTER

L&HCP FACULTY AWARDED NIH GRANT TO STUDY REGULATION OF MICROBIOTA TRANSPLANTATION

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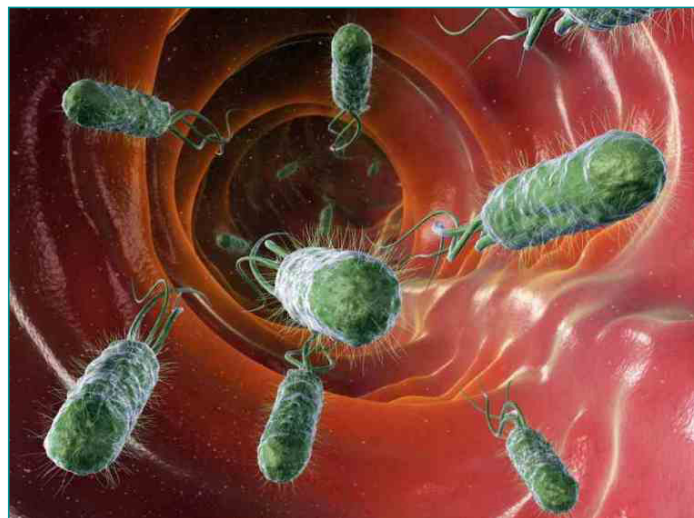
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In June, Director of the L&HCP Diane Hoffmann, along with colleagues at the University of Maryland Schools of Law, Medicine, and Pharmacy, were awarded an NIH grant to study the legal and regulatory aspects of a cutting edge medical treatment called microbiota transplantation. Hoffmann will serve as Principal Investigator for the two-year grant, *Microbiota Transplantation: Recommendations for a Regulatory Framework*, that will look at options for regulating current and emerging uses of microbiota transplantation including fecal, vaginal, skin, anterior nares, oral, and whole body transplants. Collaborating with Hoffmann as Co-Investigators 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 Roghmann, Department of Epidemiology and Public Health, University of Maryland School of Medicine
- Dr. Erik Von Rosenvinge, University of Maryland School of Medicine and Department of Gastroenterology, Veterans Affairs Maryland Health Care System
- Virginia Rowthorn, Law & Health Care Program, University of Maryland Carey School of Law

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The project builds on Hoffmann's prior NIH grant that assessed the regulatory framework for probiotics (or live microorganisms which when administered in adequate amounts confer a health benefit on the host) in the United States by convening a multidisciplinary Working Group to provide a critical review of current probiotic regulation. From 2009 to 2014, Hoffmann and her co-investigators studied how the Food and Drug Administration (FDA) should regulate probiotics under a grant funded by NIH's Human Microbiome Project (HMP), a \$150 million NIH initiative to characterize the microbial communities found at several different sites on the human body and to analyze the role of these microbes in human health and disease. Until recently, the abundant community of human-associated microbes (which outnumber human cells by about ten to one) was largely unstudied, leaving their influence upon human development, physiology, immunity, and nutrition almost entirely unknown. The HMP was established to support the comprehensive characterization of the human microbiota and analysis of their role in human health and disease. Advances in DNA sequencing technologies have created the field of metagenomics that allows analysis of genetic material harvested directly from microbial communities. HMP scientists are using metagenomics and genetic analyses of available reference microbial strains to understand the complexity of human-associated microbial communities and how the microbiome and human host interact to support health or to trigger disease. One of the most significant outgrowths of the HMP is advanced research into probiotics.

A portion of HMP funds was set aside to study the Ethical, Legal, and Social Implications (often referred to as the ELSI issues) of the HMP's scientific goals and these early HMP grants were administered by the National Human Genome Research Institute (NHGRI). Both Hoffmann's 2009 and 2015 awards were ELSI grants. The first was awarded by NHGRI and the most recent by the National Institute of Allergy and Infectious Diseases. Hoffmann's collaborators on the probiotic grant were Drs. Palumbo and Ravel (along with Dr. Claire Fraser, Professor and Director, Institute of Genome Sciences, University of Maryland School of Medicine, and Jack Schwartz, Adjunct Professor at University of Maryland Carey School of Law) which led to numerous publications and follow-on work (see box, page 6).

In addition to the development of probiotic therapies, advances in our understanding of the human microbiome are also likely to make microbiota transplants – or transplantation of bacteria from a healthy individual to a patient recipient to cure or manage a health condition - increasingly common. At present, there is much interest and evidence-based support for one type of microbiota transplant: fecal microbiota transplantation (FMT). FMT involves the transplantation of fecal material into a patient recipient to treat various severe intestinal disorders. Interest in FMT is growing as strong evidence is emerging that FMT is effective in treating *Clostridium difficile* infection and may also be effective in treating other gastrointestinal conditions. FMT has been discussed widely in Atlantic Magazine ("When Feces Is the Best Medicine"), the New Yorker ("The Excrement Experiment"), and the New York Times ("When Pills Fail, This, er, Option Provides a Cure").

FMT is most commonly performed via colonoscopy using fecal material that is typically donated by a relative or partner and tested in advance for bloodborne infectious agents. There is growing interest in administering the treatment in pill form for patients who may not be able to tolerate another delivery system and to make the treatment more palatable from an aesthetic and procedural perspective. At least one stool bank has been created to collect stool samples from healthy, pre-screened individuals, process the donations, and sell the product to clinics and there appears to be growing interest in this type of venture. Other researchers are working on a cocktail of gastrointestinal bacteria collected from healthy volunteers and grown in the lab (to mimic the microbiome) that can be delivered in pill form. This has been referred to as “synthetic feces”.

FMT is raising new legal and regulatory questions for FDA. At present, via draft guidance released in July 2013, FDA stated that it would exercise enforcement discretion allowing physicians to use FMT to treat *Clostridium difficile* infection in patients who have not responded to standard therapies without filing an investigational new drug (IND) application with the agency. The enforcement discretion policy does not extend to other uses of FMT so that a physician wanting to use FMT for any other condition must file an IND. The guidance notes that “FDA intends to exercise this discretion on an interim basis while the Agency further considers the matter.”

Although FMT is the focus of much attention, emerging microbiota transplantation options include vaginal, skin, oral, and anterior nares transplantations. A further cutting edge use of microbiota transplantation is “whole microbiome” transplantation pioneered by Dr. Maria Dominguez-Bello in which babies born via Cesarean section are swabbed in material that is placed in the mother’s birth canal during birth, allowing for babies to be exposed to important bacteria present in the vaginal canal. Dr. Dominguez-Bello has speculated that lack of exposure to these microbiota might explain why C-section babies are at greater risk of developing Type 1 diabetes, celiac disease, asthma or obesity.¹ Use of these other microbiota transplantation options is still in its infancy and there has been little, if any, discussion in the literature as to their appropriate regulation.

Hoffmann’s project will provide a timely examination of the appropriate regulatory path for fecal and other types of microbiota transplantation.

Using the same research method that Hoffmann and her collaborators used with their probiotics project, Hoffmann will convene approximately 25 expert stakeholders to form a Working Group that will collaborate over the course of three meetings to craft recommendations. The invited stakeholders who will meet for the first time in Baltimore on December 3 and 4 include scientists, clinicians, patient and professional association advocates, bioethicists, government regulators, academics, lawyers, and individuals from the biotechnology industries who have an interest in microbiota transplantation or expertise relevant to the proposed project. The Working Group will evaluate alternative regulatory options for microbiota transplantation and consider which regulatory approach or approaches would work for these procedures in a way that meets specific criteria for regulatory effectiveness. Regulatory frameworks that may be appropriate in whole or in part for microbiota transplantation include the frameworks for regulating biological products, blood and blood products, vascularized organs, human cells, tissues and cellular products. The Working Group will also consider whether a hybrid or new regulatory scheme is best to ensure the safety, effectiveness, and accessibility of the procedures. The investigators will include a description of the Working Group process and the recommendations in a paper or series of papers.

¹See interview with Dr. Dominguez-Bello regarding the preliminary results of her research that were presented at the 2014 conference of the American Society for Microbiology in Boston. WBUR radio interview, June 25, 2014. <http://commonhealth.wbur.org/2014/06/birth-canal-bacteria-c-section>



THE MICROBIOTA RESEARCH TEAM

Dr. Frank Palumbo

Frank Palumbo, Ph.D., JD, is a professor at the University of Maryland School of Pharmacy and Executive Director of the school's Center on Drugs and Public Policy. He is also an adjunct professor at the University of Maryland Carey School of Law where he teaches food and drug law.



What is your connection to the project from a professional perspective and why did you become involved in it?

I had the pleasure of working with Diane Hoffmann, Jacques Ravel, and Virginia Rowthorn, among others, on an NIH probiotics project where we assessed the current regulatory structure surrounding probiotics and made recommendations for regulatory changes.

What will you bring that is unique to the project?

I am a pharmacist-attorney with a particular interest in food and drug law and have been practicing and conducting research in that area for many years.

Why do you think it's important to study and make recommendations about microbiota transplantation at this point in history?

We are learning so much about the human microbiome and are just scratching the surface of possibilities in research and treatment. Along with this comes federal and state law and regulation to protect those who are subjects of the treatment. Laws and regulations provide an approach that may indeed lead to proof of safety and effectiveness.

From your perspective, why is an interprofessional approach important to studying how microbiota transplantation should be regulated?

The answers to the questions we raise require an interdisciplinary approach, including assessments of treatment and procedures, basic scientific knowledge, and regulatory pathways to facilitate microbiota transplantation use.

What excites you about participating in the project?

It is a new area that is suddenly garnering a great deal of attention and I am honored to be part of the early phase of research. And---I really enjoy working with my colleagues.

Dr. Mary-Claire Roghmann

Dr. Mary-Claire Roghmann is a Professor of Epidemiology & Public Health at the University of Maryland School of Medicine. She is an infectious disease physician and clinical investigator whose research is focused on understanding bacterial and host determinants of S. aureus colonization, transmission and infection with the goal of developing better ways of preventing S. aureus infections, including those caused by antibiotic resistant strains such as MRSA.



What is your connection to the project from a professional perspective and why did you become involved in it?

I'm an infectious disease physician, epidemiologist and researcher interested in preventing infections. Manipulation of our microbiomes is a novel approach to this goal and microbiota transplantation is the first step in this pathway.

What will you bring that is unique to the project?

My perspective as an infectious disease physician focuses on prevention. In addition as an epidemiologist, I bring a population-based

perspective.

Why do you think it's important to study and make recommendations about microbiota transplantation now (at this point in history)?

Now is the most important time to do this as we enter a new era when people think about how we could manipulate our microbiome to improve health.

Dr. Erik Von Rosenvinge



Erik Von Rosenvinge, MD, is an Associate Professor of Medicine in the Division of Gastroenterology & Hepatology at the University of Maryland School of Medicine and Chief of the GI Section at the Veterans Administration Maryland Health Care System. Dr. Von Rosenvinge has performed fecal

microbiota transplants on a number of his patients.

What is your connection to the project from a professional perspective and why did you become involved in it?

As a clinical gastroenterologist, I see patients with diseases associated with alterations in the gastrointestinal microbiome, such as intestinal infections, Crohn's disease, and irritable bowel syndrome. One disease strongly linked to an abnormal microbiome is Clostridium difficile infection, a bacterial infection of the colon that typically begins after taking antibiotics and can cause severe diarrhea, toxic megacolon, and even death. This infection has a tendency to relapse after treatment and at times can be extremely difficult to cure.

After observing patients miserable from this disease, reading about 'miracle cures' from fecal transplantation, and reviewing the emerging scientific literature supporting the procedure, I began offering this procedure to my patients and have had great success. For a brief period the FDA prevented me from providing this procedure to my patients as they began requiring an IND

application that I, and most people performing the procedure, did not have. After an outcry from the medical community and patients, the FDA stopped enforcing this policy for patients with C. difficile infection not responding to conventional medical therapy.

While I appreciate that I can again offer my patients this procedure, I also appreciate the FDA's desire to regulate microbiota transplantations. While altering a patient's microbiome through fecal transplantation has been shown effective for Clostridium difficile infection, so far it has not proven effective for other conditions, has risks, and has been attempted for a myriad of conditions. I'm optimistic that the Working Group convened under this grant will help guide the FDA in a way that helps them strike a balance that allows for these procedures for conditions where they are proven to work, fosters rigorous scientific research, and maximizes patient safety.

What will you bring that is unique to the project?

As the only study team member that has performed microbiota transplantations on patients, I have a unique perspective on how they are performed and what regulatory issues have arisen at our local institution. I also have access to patients who can share their experiences.

From your perspective, why is an interprofessional approach important to studying how microbiota transplantation should be regulated?

While seemingly simple, microbiota transplantation is a complex process, especially as currently performed. Is the donor microbiome a drug? A biologic product? A tissue? And how do you regulate a product for which the exact contents are unknown and change with every sample? By bringing together a broad team with expertise in the scientific, clinical, legal, and regulatory arenas, we hope to answer some of these important questions.

Did you ever think you would be part of a project initiated at the law school and how has been working with lawyers been so far?

Having several lawyers in the family, who believe they are correct ALL the time, I didn't think I would be part of a project initiated at the law school, but so far it has been a lot of fun.

Dr. Jacques Ravel



Dr. Jacques Ravel is Professor of Microbiology and Immunology at the University of Maryland School of Medicine and Associate Director for Genomics, Institute for Genome Sciences. He is a national leader in microbial genomics and grantee of several HMP grants from NIH.

What is your connection to the project from a professional perspective and why did you become involved in it?

As a researcher working on understanding the role of the human microbiome in health and diseases, I worked with the team on a previous project evaluating the regulatory framework for probiotics in the US. My own work on the vaginal microbiome is connected to both the use of probiotics and microbiota transplants in order to restore vaginal health.

What will you bring that is unique to the project?

My expertise is in understanding the functional role of microbes in health and characterization of the human microbiome. These are important aspects to characterizing material to be transplanted and also evaluating the success of a transplant.

From your perspective, why is an interprofessional approach important to studying how microbiota transplantation should be regulated?

Regulation involves many components from legal aspects, to information for consumers, to technical feasibilities, and, of course, regulation of product safety. To capture nuances associated with all these aspects, a multidisciplinary approach is essential.

Did you ever think you would be part of a project initiated at the law school and how has been working with lawyers been so far?

I never imagined myself working with faculty at the law school. When they approached me about the probiotics project, right away I saw the potential for a true collaboration, and my expectations were met. It has been a great experience. When they contacted me to contribute to this project, I never hesitated!

DIANE HOFFMANN CONTINUES WORK ON PROBIOTICS

At the end of Professor Hoffmann's NIH grant to study the regulation of probiotics, Hoffmann and her colleagues completed an extensive white paper and published articles in *SCIENCE* and the *JOURNAL OF FOOD AND DRUG LAW* based on the paper. Both written works described the recommendations that came from Working Group meetings. Since the publication of the articles, Hoffmann has continued to speak and write about probiotics and other legal/ethical issues that came out of her study of the HMP and regulation of probiotics.



Articles

- Diane E. Hoffmann (with Jack Schwartz) "Stopping Deceptive Health Claims: The Need for a Private Right of Action under Federal Law" (forthcoming in *AMERICAN J. OF LAW & MED.*)
- Diane E. Hoffmann (with C.M. Fraser, F.B. Palumbo, J. Ravel, V. Rowthorn, & J. Schwartz) "Probiotics: Achieving a Better Regulatory Fit," 69 *J. FOOD & DRUG L.* 237 (2014)
- Diane E. Hoffmann (with C.M. Fraser, F.B. Palumbo, J. Ravel, K. Rothenberg, V. Rowthorn, & J. Schwartz) "Probiotics: Finding the Right Regulatory Balance," 342 *SCIENCE* 314-315 (October 18, 2013)
- Diane E. Hoffmann (with Dennis Fortenberry & Jacques Ravel), "Do potential changes to the Common Rule adequately address new areas of research: A case study focusing on the Human Microbiome Project" 41 *JOURNAL OF LAW, MEDICINE & ETHICS* 454 (Summer, 2013)

Lectures, Workshops & Speaking Engagements

- "Does Research on the Human Microbiome raise unique ethical or legal issues?" Institute of Medicine Annual Meeting, National Academy of Sciences Washington, D.C. (Oct. 19, 2014)
- Federal Regulation of Probiotics, Microbiota & Health Workshop, International Life Sciences Institute, Washington, D.C. (April 27, 2015)
- "Federal Regulation of Probiotics: An Analysis of the Existing Regulatory Framework" at FDA Symposium "Linking the Microbiome to Health, Safety, and Regulation," College Park, MD (September 29-30, 2015)

IT'S ALL BUSINESS TO SOME HEALTH LAW GRADUATES: INNOVATIVE VENTURES CREATED BY MARYLAND CAREY HEALTH LAW ALUMS

Although most of our health law students graduate and begin work in law firms or government positions, some entrepreneurial former students have started their own health-related businesses and all of them credit their law degree as critical to their success. In this article, we feature three former students who went on to start their own businesses in three different, highly regulated areas of health and health care.

M. Jason Brooke '10, CEO & General Counsel, Vasoptic Medical Inc.

Jason, a 2010 graduate of the law school, was a scientist before he was a lawyer. Before studying law, Jason obtained a BS in Biological Resources Engineering at University of Maryland College Park and an MS from Johns Hopkins in Biomedical Engineering. He then worked as a senior scientist developing implantable pacemakers and defibrillators for Boston Scientific Corporation.



As a law student, Jason externed at the Center for Devices & Radiological Health at FDA and served as Editor-in-Chief of the law school's *Journal of Health Care Law & Policy*. Upon graduation, he became an Associate at the law firm of Epstein Becker & Green (EBG) and, after several years of successful practice focused on the medical device and mobile health industries, Jason took the leap into the world of entrepreneurship, leveraging his experience in medical device development as a lawyer, biomedical engineer, and scientist. His organization, Vasoptic Medical Inc., is commercializing technology that allows a doctor or scientist to non-invasively evaluate blood flow in the

small blood vessels of any tissue that can be exposed to light. Vasoptic is currently working on a product line of retinal imagers that will allow scientists to use their technology for research purposes and doctors to diagnose and manage ophthalmic diseases that include diabetic retinopathy (the leading cause of blindness in American adults) and retinopathy of prematurity (one of the leading causes of blindness in children around the world).

Since starting the business a little over three years ago, Brooke and his colleagues have made progress on both business and technology development fronts. Through close collaboration with the University of Maryland Medical Center and the Johns Hopkins University, the Vasoptic Team has been lucky enough to win over \$1M in grants from the National Institutes of Health's Small Business Innovative Research (SBIR) Program to develop the retinal imaging technology and to evaluate the use of their technology in surgical settings. They also recently received a \$250,000 investment from the Abell Foundation, a non-profit dedicated to the enhancement of the quality of life in Maryland, with a particular focus on Baltimore.

The company is now moving beyond the research stage toward clinical testing and deployment. After consultation, FDA recently determined that their device is a "non-significant risk," which means that Vasoptic can evaluate the retinal imager in a clinical setting without significant regulatory hurdles that often accompany the evaluation of investigational medical devices. Brooke has big dreams for Vasoptic and hopes to see the company's technology impact the optical health of people in the US and beyond. In addition to moving ahead on the business front, Brooke and his colleagues are committed to being involved in the community - Team Vasoptic participates annually in the American Diabetes Association's Walk to Stop Diabetes to help fundraise for the organization.

How did his legal training help get him where he is today? According to Brooke, his legal training "has been critical to Vasoptic's success thus far. The medical device industry, and healthcare more generally, is heavily regulated. Understanding FDA

regulations and CMS reimbursement requirements (not to mention corporate governance rules), gives us a leg up as an early stage company to ensure that we are developing our technology to be safe and effective to, ultimately, improve access to quality care at lower costs for the millions of people who need it most.” With such vision and passion for medical device development, it is not surprising that Jason was recently named one of Baltimore’s 40 Under 40 by the *Baltimore Business Journal*.

Kylyn (Deary) Mead ’11, President and CEO, Go Docs Go

When Kylyn was just two years out of law school, she started her own “house call medicine” business called Go Docs Go. She credits growing up in a family that owned a home health care business and a year as an attorney in the compliance department at the University of Michigan Health System as the foundation for her jump into business but, by any judge, she is a risk taker and it looks like her risk has paid off. Kylyn now runs a business that employs 40-45 employees and makes over 1500 house calls each month to patients in Michigan and Indiana. Even more impressively, she entered a relatively niche area of health care delivery that is now starting to turn heads in Washington as a way to save costs for Medicare. Congress endorsed a house call medicine demonstration project in the Affordable Care Act.

What is a house call medicine? Go Docs Go provides health care in the home for people who cannot travel to a health care facility because of age, illness or disability. Go Docs Go uses physicians and nurse practitioners to perform the same services that a patient would receive in a traditional primary care physician office setting, including diagnosis, evaluation and treatment. The company also helps coordinate medical care with other providers including physical therapy and hospice care. For the most part, Go Docs Go is paid by patients’ Medicare Part B coverage. While it is primarily a geriatric practice, Go Docs Go also has a number of younger veterans on their rolls.

Kylyn’s biggest satisfaction from starting Go Docs Go has been her ability to provide for her patients beyond medical care. Patients who cannot get to the hospital often have difficulty accessing social services as well and often seek care in emergency rooms for

problems that could have been dealt with more easily – and more cheaply – in the home. It’s for this reason that CMS is studying house call businesses via their Independence at Home program and considering how to reward businesses that save money for Medicare. At this point, the program is in the demonstration stage, but Kylyn hopes her company will be able to reap the benefits of the program in the future.

Kylyn’s legal training has been critical to her success as a business leader. She notes that her industry is highly regulated and that her legal skills are critical during negotiations with the state, insurance carriers and Medicare. Further, with all her employees, she has to understand contracts, human resources, and business law. Even when she does use outside counsel, her legal training allows her to speak comfortably with other lawyers. Overall, she credits her legal training with her ability to approach any problem with common sense.

Marcus Wang ’08, Co-Founder and General Manager, ZytoGen Global Genetics Institute



Although he did not receive the Health Law Certificate as a student, with the launch of ZytoGen Global Genetics Institute in 2013, Marcus Wang ’08 has joined the Law & Health Care Program family at Maryland.

Wang partnered with two globally-renowned pioneers in the field of

infertility medicine to found ZytoGen, a molecular genetics laboratory providing Preimplantation Genetic Screening (PGS) to patients and clinics in the United States, Latin America, and Asia, through its CLIA-certified laboratory in Baltimore County. ZytoGen uses PGS to screen embryos for chromosomal abnormalities prior to implantation in the mother during the IVF process. The screening empowers

families to identify healthy embryos, lower the risk of miscarriage, and increase the likelihood of a successful pregnancy.

By optimizing conditions for single embryo transfer, ZytoGen also allows women the choice of avoiding the risks associated with multiple pregnancies, including selective reduction. Known for its cutting edge technology and rapid turnaround time, ZytoGen continues to innovate, most recently by conducting the world's first randomized clinical study on the efficiency of Next Generation Sequencing for PGS.

Despite his lifelong passion for business, Marcus grew up with a great deal of interest in, and respect for, the medical profession, which he sees as truly helping people. Both his parents are physicians, and his own interest in medicine spurred him to premed coursework at Harvard University as an undergraduate. Along with his interest in medicine, Marcus brings his international business experience to the operation of ZytoGen. Self-taught and fluent in both Mandarin and Cantonese Chinese, Marcus worked for the State of Maryland as an International Investment and Trade Specialist for China before coming to the law school and focusing on business law. Upon graduation, he practiced corporate law at the Manhattan office of DLA Piper before leveraging his business and legal skills to manage Under

Armour's expansion into the China market.

While he still consults for U.S. businesses concerning China market entry, ZytoGen "completes a dream" for Marcus. As a boy, his parents would inspire him at the dinner table with stories of helping their patients. Today, he is humbled to help families fulfill their dreams. Recently, he spoke to a mother who brought a healthy baby to term after getting the green light from ZytoGen on a genetic screening. Hearing the baby's happy babbling in the background of the call convinced Marcus that he is in the right field.

How does he use the law in his position as head of a health care company? He credits law school with giving him a broad range of skills that have been critical to handling the legal and regulatory issues that are part of any start-up business, especially in the health arena. In 2011, Mr. Wang was honored by the Maryland Daily Record, Maryland's premier business journal, as one of the "20 In Their 20s", based on "professional accomplishment, civic involvement and impact of achievement." In October, Marcus will be speaking at the 30th anniversary of the L&HCP about the future of health law, specifically the intersection of law and biotechnology. What does the future hold for Marcus? It's likely something that will continue to make us incredibly proud to call him an alum.

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LAW SCHOOL'S NEW BUSINESS FELLOWSHIP PROGRAM FEATURES PLACEMENTS AT LOCAL HEALTH CARE CORPORATIONS

The University of Maryland Francis King Carey School of Law recently launched a Business Fellowship Program to place law students and recent graduates in Baltimore-area businesses. The new initiative is designed 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. Three prominent health care institutions are inaugural partners in the program. The University of Maryland Medical System (UMMS) is sponsoring a year-long postgraduate fellowship which was awarded to 2015 health law graduate Jaclyn Machometa. FutureCare, which operates nursing and rehabilitation centers across the Baltimore/Washington area, and LifeBridge Health, which owns a number of local hospitals, are participating in the 10-week summer fellowship.

Modeled after the judicial clerkship and internship experience, the Maryland Carey Law Business Fellowship Program offers fellows professional employment, mentoring, and a stipend with Baltimore-area businesses or organizations. Fellows will work in a corporate counsel's office or in business operations. Given the number of health law students interested in these opportunities, other fellowships with health-related organizations in Baltimore are currently under negotiation.

PROFESSOR KATHLEEN HOKE'S PUBLIC HEALTH EFFORTS DRAW \$1 MILLION IN GRANT FUNDING



In addition to teaching the popular Public Health Law Clinic, Professor Kathleen Hoke is also the Director of the Network for Public Health Law, Eastern Region and the Director of the Legal Resource Center for Public Health Policy at the University of Maryland Carey School of Law. The Network provides technical legal assistance to public health professionals and their attorneys at all levels of government, while the Legal Resource Center provides technical legal assistance to Maryland state and local health officials and organizations working on tobacco control and other public health issues. For FY 2016, the organizations have been awarded grants in excess of \$1 million to support their work. Below is a brief summary of the activities and grants Professor Hoke and her staff are undertaking:

Legal Resource Center for Public Health

The Center will continue working under their 2001 grant from the Maryland Department of Health and Mental Hygiene (DHMH) to provide legal support to communities, community groups, employers, local governments, and State legislators and agencies interested in reducing the negative health consequences of tobacco use. In addition, the Center will continue its injury prevention work that started in 2011 under a DHMH grant that is part of the Centers for Disease Control (CDC)'s Core Violence and Injury Prevention Program.

Network for Public Health Law, Eastern Region

The Network was funded through a 2010 grant from the Robert Wood Johnson Foundation which has continued to fund the Network with a current grant through 2017. The Network also has two grants from the CDC. The first is in partnership with Change Lab Solutions and the National Alliance of State Pharmacy Associations to examine effective approaches to the development of collaborative practice agreements between physicians and pharmacists and to develop a case study on a state law expanding scope of practice laws for allied health professionals. CDC also provided funds to the Network to study state efforts to address student athletes' return to the classroom after sustaining a concussion, as well as to update an existing database of state youth sports-related traumatic brain injury laws. Finally, the Network is working with funds provided by the Maryland Center of Excellence on Problem Gambling to support the Center's policy and legislative work.

UPCOMING CONFERENCE: ROUNDTABLE ON CLINICAL TRIALS AND ACCESS TO ESSENTIAL MEDICINES IN AFRICAN COUNTRIES

On October 29-30, Law & Health Care Program faculty members Diane Hoffmann and Leslie Meltzer Henry along with Professor Peter Danchin, Director of Maryland Carey Law's International and Comparative Law Program, are hosting a *Roundtable on Clinical Trials and Access to Essential Medicines in African Countries*. The meeting is being co-sponsored by the Faculty of Law at Chancellor College in Malawi and will bring together an international group of legal scholars and medical researchers to examine ethical and legal challenges to developing and distributing essential medicines in African countries. The by-invitation-only meeting will focus on four topics:

- Access to essential medicines as a human right
- The law and ethics of clinical trials: what rules should govern clinical research in Africa?
- What do clinical researchers and sponsors owe to host communities?
- Legal regimes and obstacles: free trade, intellectual property, and access to medicine

In addition to Maryland Carey Law faculty, panelists include:

- **Danwood Chirwa**, professor, University of Cape Town Law Faculty
- **Hilda Kaluwa Soko**, law lecturer, University of Malawi Chancellor College of Law
- **Lucie White**, professor, Harvard Law School
- **Victor Mwapasa**, associate professor, University of Malawi College of Medicine
- **Miriam Laufer**, associate professor, University of Maryland School of Medicine
- **Mark Barnes**, partner, Ropes & Gray, LLP
- **Joseph Mfutso-Bengo**, professor of Bioethics and director of the Centre for Bioethics, University of Malawi College of Medicine
- **David Wendler**, senior investigator and head of the Section on Research Ethics, NIH
- **Seema Shah**, faculty bioethicist, NIH
- **Chikosa Banda**, faculty of Law, University of Malawi Chancellor College of Law
- **Lisa Forman**, assistant professor, University of Toronto Law School
- **Heinz Klug**, professor and director, Global Legal Studies Center, University of Wisconsin

The roundtable is partially funded by the University of Maryland Baltimore Center for Global Education Initiatives which has supported collaboration between the Faculty of Law at Chancellor College in Malawi and Maryland Carey Law since 2010. In 2013, L&HCP Director Diane Hoffmann and Maryland Carey Professor Peter Danchin traveled to Malawi to host a joint workshop on HIV/AIDS legal issues with Chancellor College faculty and students. Following that visit, law faculty and students from both schools have made several trips across the Atlantic to learn from each other and share experiences in legal education. This roundtable is the latest initiative of this unique collaborative relationship.

The roundtable is also supported by the generous support of Alan & Nancy Eason; the Stuart Rome Lecture Fund; the Reuben Shiling Mental Health Law Fund; the Leonard C. Homer/Ober|Kaler Law and Health Care Fund; and the Dr. Richard H. Heller Fund

PROFESSOR AMANDA PUSTILNIK AND OTHER L&HCP FACULTY BLOG ON PAIN IMAGING AND THE LAW



L&HCP Professor Amanda Pustilnik, a nationally recognized scholar on law and neuroscience, recently hosted a series of blog posts on the topic of pain imaging and the law for Harvard Law School's *Bill of Health* blog. The series was partly derived from three symposia Pustilnik has been involved with over the last 18 months. The first was in April 2014 at the University of Maryland called "Imaging the Brain, Changing Minds: Chronic Pain Neuroimaging and the Law." This meeting brought together pain neuroimaging researchers, legal decision-makers, and legal scholars for a cross-disciplinary dialog regarding the potential impact of neuroimaging on legal and cultural norms and led to a number of publications authored by Pustilnik (listed in the Faculty Highlights section, page 19).

In April 2015, while Pustilnik was the inaugural Senior Fellow in Law & Applied Neuroscience at Harvard Law School and a faculty member at the Center for Law, Brain & Behavior (CLBB) at Massachusetts General Hospital, she participated in a conversation among experts called "Models of the Mind:

How Neuroscience, Psychology, and the Law Collide." This meeting, which took place at Harvard Law School, convened experts in neuroscience, psychology, and the law to discuss three distinct models on the causes of human behavior and how these three models understand cause and effect, attribute blame, and think about rehabilitation. Finally, in June 2015, Professor Pustilnik spoke at a public symposium sponsored by CLBB and Harvard's Petrie-Flom Center called "Visible Solutions: How Neuroimaging Helps Law Re-envision Pain" that brought together the leading experts in neuroscience and law to wrestle with the critical question: what can, and should, the law do with what we know about pain and the brain?

To develop the series of blog posts, Pustilnik recruited L&HCP Professors Frank Pasquale and Diane Hoffmann to contribute along with other law faculty and pain researchers. Hoffmann, who has written extensively about legal issues surrounding pain treatment, used the blog post to call for a federally-funded ELSI (ethical, legal, and social implications) program, similar to the ELSI program that accompanied the Human Genome Project, to study potential consequences of brain-based pain imaging. L&HCP Professor Frank Pasquale discussed some of the political and sociological underpinnings of the impulse to measure and quantify pain and the potential risk of doing so to individuals with disabilities. Pustilnik provided introductory and concluding posts. The blogposts are available at the links below:

What Should the Future Look Like for Brain-Based Pain Detection? Three Eminent Scholars Weigh In,

by Amanda C. Pustilnik

<http://blogs.law.harvard.edu/billofhealth/2015/07/31/what-should-the-future-look-like-for-brain-based-pain-measurement-in-the-law-three-eminant-scholars-offer-their-views/>

An ELSI Research Program for Pain Research: A Call to Action,

by Diane Hoffmann

<http://blogs.law.harvard.edu/billofhealth/2015/07/31/an-elsi-program-for-pain-research-a-call-to-action>

Of Algorithms, Algometry, and Others: Pain Measurement and the Quantification of Distrust,

by Frank Pasquale

<http://blogs.law.harvard.edu/billofhealth/2015/07/31/of-algorithms-algometry-and-others-pain-measurement-the-quantification-of-distrust/>

Neuroimaging as Evidence of Pain: It's Time to Prepare,

by Hank Greely

<http://blogs.law.harvard.edu/billofhealth/2015/07/31/neuroimaging-as-evidence-of-pain-its-time-to-prepare/>

Other contributors to the series of blogposts include Karen Davis, Martha Farah, David Seminowicz, and Francis X. Shen.

LAW & HEALTH CARE PROGRAM CELEBRATES GRADUATION OF 30 STUDENTS



2015 Health Law Certificate Graduates and L&HCP Faculty

On May 14, Law & Health Care Program (L&HCP) faculty celebrated the graduation of 30 students who earned the health law certificate. The breakfast celebration was held in the law school's Westminster Hall with over 90 people in attendance, including family and friends of the graduates. This year marks the 30th anniversary of the Law & Health Care Program and the 18th year that the program has been awarding certificates to students who complete the concentration in health law. This concentration requires that the students take 17 of their 85 law school credits in health law, participate in a health law clinic or externship, and write a scholarly paper on a health law topic.

As part of the celebration, faculty members came to the microphone to share the accomplishments of each of the students. The comments they made, many of which included funny stories and fond memories, revealed an incredibly broad range of interests among the 2015 graduates. Their enthusiasm and energy enriched the program and inspired everyone in attendance. Below we highlight five of the students who received the health law certificate this year.

Nikita M. Floore

Nikita Floore came to the law school with a BA in English and MS in Rehabilitation Counseling

from Southern Illinois University. Prior to starting her law studies, she held a number of vocational rehabilitation positions at the U.S. Department of Veterans Affairs and the Tennessee Department of Human Services, including her final position as a Health System Specialist at the VA in Washington, DC where she managed a \$31 million operational budget for the Office of Primary Care. Her work in rehabilitation led Nikita to the L&HCP and ensured that she was a student leader while she was here. Nikita was a Leadership Scholar and served as an Admissions Ambassador for the Office of Admissions. She was also on the board of the Student Health Law Organization (SHLO) and participated in the Maryland Carey Service Corps trip to the Delta Region of Mississippi. She was able to travel back to Southern Illinois University as a participant in the Health Law Moot Court Competition sponsored by SIU's law school. Nikita spent her second summer at the American Health Lawyers Association as a Diversity Fellow and was very active while in law school with the Black Law Students Association. Professor Frank Pasquale who had Nikita for Health Care Law & Policy and Administrative Law told the audience at the graduation breakfast, "Nikita has been a leader in the health law program. She has brought extraordinary real-world experience to both my classes. I will

always remember Nikita as one of the most inspiring, dynamic, insightful, and professional students I've ever known." Nikita now works at FDA as Regulatory Counsel in the Center for Tobacco Products where she is responsible for assisting in the resolution of compliance issues concerning the application of the Tobacco Control Act.



Professor Leslie Meltzer Henry, 2015 Graduate Amy Dobrzynski and L&HCP Director Diane Hoffmann (from l to r)

Sean Gugerty

Sean Gugerty established himself as a leader in the health law program from the minute he stepped on campus. In his first semester, when L&HCP Director Diane Hoffmann asked for student volunteers, Sean took part in an initiative with the School of Medicine in which students from both schools were asked to work together on an end-of-life scenario and brainstorm about medical and legal solutions. His willingness to take this on in his first year is absolutely consistent with the type of student Sean was - dedicated, curious, bright, and helpful. There was rarely a time that L&HCP faculty reached out to students for help that the first response did not come from Sean. He was student chair for the law school's Health Law Regulatory and Compliance Competition, on the Executive Committee of the Moot Court Board, and Notes & Comments Editor for the Journal of Health Care Law & Policy. He also represented the law school at the Loyola University Chicago School of Law's Health Law Transactional Competition. At the celebration, Professor Kathleen Hoke said to the assembled group, "Sean was a student in my Public Health Law Clinic, so we spent quite a lot of time together over the course of the semester. And it was all to my benefit! Sean is not only bright, hard-working and impressively professional; he is also genuinely nice and engaging." Sean is now clerking for Judge

Sherrie R. Bailey in the Circuit Court for Baltimore County.

Ethan Han

Ethan came to Maryland Carey Law with a BA in Political Science from University of Michigan which clearly instilled in him the networking skills of a seasoned politician. Ethan may have set a record for the number of health law-related internships, externships and experiences he had as a student at the law school. He externed at a medical-legal partnership called Project HEAL at Baltimore's Kennedy Krieger Institute and at the Pacific Islander American Health Forum in Bethesda, Maryland. He interned (not for credit) at Dimensions Healthcare System and at the American Podiatric Medical Association. He was also a research assistant for L&HCP faculty member Deborah Weimer, a student attorney in the Public Health Law Clinic, and a member of the Executive Board of the Student Health Law Organization (SHLO). Finally, he found time to join Sean Gugerty as a teammate for the Loyola University Chicago School of Law's Health Law Transactional Competition where the team came in third place. Virginia Rowthorn, Managing Director of the L&HCP, said of Ethan, "There has not been a single SHLO event or initiative that Ethan didn't help organize (or at least it seemed that way). He will be missed tremendously." This year Ethan is clerking with Judge Alfred Nance of the Maryland Circuit Court.



2015 Graduate Kelsey-Anne Fung with her parents and Professor Frank Pasquale (from r to l)

Jaclyn A. Machometa

Jaclyn was recently selected to spend the year as a Postgraduate Business Fellow at the University of Maryland Medical System in the Office of the Legal Counsel (see box, page 10). Jaclyn's law school resume made this honor a natural fit. Jaclyn

was the Managing Editor of the *Maryland Law Journal of Race, Religion, Gender and Class*, Vice President of the Women’s Bar Association, awarded a Maryland Public Interest Law Project grant, and, upon graduation, winner of the Joseph Bernstein Award for written journal submissions for an article titled, “Round up the Usual Suspects: Advocating for Leniency on Consensual, Teenage Sext Offenders” (MD. J. RACE, RELIGION, GENDER & CLASS (Fall 2014)). She also externed at the Johns Hopkins Hospital System and at University of Maryland Medical System while she was a student. But these accomplishments and activities do not reflect the passion for social justice that Jaclyn was known for. Some of her most important experiences during law school were her time as a student Attorney in the Civil Rights of Persons with Disabilities Clinic and as a Fellow at Project HEAL (Health, Education, Advocacy, and Law) a medical-legal partnership supported by the Maryland Volunteer Lawyers Service (MVLS) and the Johns Hopkins Children’s Center. Jaclyn is committed to working for social justice and plans to find a job in this field when her Fellowship ends. As her clinic professor Marc Charmatz noted, “We’re very sad she’s graduating, but thrilled to see the health law field receive such a competent and committed advocate.”

Neha Patel

Neha Patel is a truly gifted student of both pharmacy and law. She graduated with a PharmD and JD in May and just started as an Associate at Arnold & Porter in their FDA and Healthcare practice. Neha excelled in both schools. At the School of Law, she was active in SHLO and represented the law school at our own Health Law Regulatory and Compliance Competition. At the School of Pharmacy, she won



2015 Graduates Ashley Woolard, Theresa Mahfood, Oyinladun Adeleye and Nikita Floore (from l to r)

3rd Place in the University of Maryland's Center of Excellence in Regulatory Science and Innovation Competition, was on the Dean’s List (top 3%), and won the Student Government Association Leadership Award among other accolades. Although she took classes simultaneously at both schools, she was able to fully immerse herself as a scholar in both communities. In addition to interning twice in the FDA Commissioner’s office (once in the Office of Policy and Planning and once in the office of Health and Constituent Affairs), she was a student research assistant in the School of Pharmacy’s Center on Drugs and Public Policy. Neha wrote a paper for Professor Frank Pasquale on drug-drug interaction alerts that was, according to him, “a truly thoughtful, important contribution to the field. It offered a smart, sensible way of tiering alerts so as to reduce physician and pharmacist ‘alarm fatigue’ while simultaneously anticipating liability concerns.” He also predicted that “Neha is going to be a leader in the field of health law and policy, bringing deep expertise in both law and science to the most pressing problems.”

2015 HEALTH LAW CERTIFICATE RECIPIENTS

Oyinladun O. Adeleye	Ethan Han	Nicholas Rodriguez
Lindsay Erin Bramble	Andrés Heiney-González	Jason Alan Ruben
Evelyn Castillo	Grant Herdrich	Mellissa Sager
Amy Dobrzynski	Lindsey E. Imus	Samantha Sherman
Benjamin L. Eastman	Suela John	Darci Marie Smith
Debra Zweier Ehudin	Connie Lee	Michael N. Tennison
Nikita M. Floore	Lindsay Lowe	Trevonne Victoria Walford
Kelsey-Anne C. Fung	Jaclyn A. Machometa	Andrew Weissenberg
Andrew Geltman	Theresa Mahfood	Ashley Woolard
Sean Gugerty	Neha Patel	



PAST, PRESENT & FUTURE
CELEBRATING THIRTY YEARS OF
THE LAW & HEALTH CARE PROGRAM

**30TH ANNIVERSARY CELEBRATION OF THE
LAW & HEALTH CARE PROGRAM**

**THURSDAY, OCTOBER 15, 2015
4:00 P.M.**

UNIVERSITY OF MARYLAND CAREY SCHOOL OF LAW

**JOIN PROGRAM ALUMNI, FACULTY, FRIENDS, AND STAFF FOR AN EVENING
OF LEARNING AND REMINISCING!**

Panels moderated by our renowned faculty will examine the past, present, and future of health law with experts including:

- Joanne Pollak '76, senior vice president, general counsel and chief of staff, Johns Hopkins Medicine
- Sanford Teplitzky, principal, Ober|Kaler
- Jack Schwartz, adjunct professor and former Maryland assistant attorney general and director of Health Policy Development
- Carolyn Quattrocki, executive director, Maryland Health Benefit Exchange
- Peter Parvis '77, principal, Miles & Stockbridge
- Marcus Wang '08, general manager and co-founder, ZytoGen, LLC
- David Cade '85, CEO, American Health Lawyers Association

The evening will also include a staged reading and facilitated discussion of "Bioethics in Play: The Drama of DNA," a play co-authored by Professor Karen Rothenberg that probes the ethical and legal dimensions of emerging medical technologies.

To register, please go to:

<http://maryland-carey-law.ticketleap.com/healthcare30/>

LAW & HEALTH CARE PROGRAM

FACULTY HIGHLIGHTS

RICHARD BOLDT

Publications

“Perspectives on Outpatient Commitment,” 49 *NEW ENGLAND LAW REVIEW* 39-80 (2014)

“The ‘Voluntary’ Inpatient Treatment of Adults Under Guardianship,” 60 *VILLANOVA LAW REVIEW* 1-52 (2015)

Presentations and Speaking Engagements

“Restorative Justice and Sentencing Alternatives, Advanced Topics in Sentencing,” Judicial Institute of Maryland (March 2015)

SARA GOLD

Presentations and Speaking Engagements

Presenter *HIV Criminalization: Preparing the Future Program*, JACQUES Initiative of the Institute of Human Virology at the University of Maryland School of Medicine (March 31, 2015)

Honors/Appointments

Member, Baltimore City HIV Planning Group and Commission, Baltimore, Maryland (Commission sworn in by Mayor Stephanie Rawlings-Blake on November 5, 2014)

MICHAEL GREENBERGER

Presentations/Panel Facilitations

“Legal Preparedness after Hurricane Sandy,” Public Health Law Conference, Atlanta, Georgia (October 16, 2014)

“Legal Aspects of Mass Immunizations and Routine Vaccination,” Center for Vaccine Development Vaccinology Course, University of Maryland School of Medicine (February 18, 2015)

“Legal Issues Arising from Ebola and other Global Pandemic Diseases,” New York Bar Association’s Council on International Affairs, New York N.Y. (February 24, 2015)

Honors/Appointments

Appointment to the National Academies of Science, Engineering, and Medicine’s Committee on Science, Technology, and the Law

LESLIE MELTZER HENRY

Publications

“Just Compensation: A No-Fault Proposal for Research-Related Injuries,” *J.L. & BIOSCIENCES* (with Megan E. Larkin and Elizabeth R. Pike) (2015)

“Respect and Dignity: A Conceptual Model for Patients in the Intensive Care Unit,” 5 *NARRATIVE INQUIRY BIOETHICS* (Special Issue) 5A (with Cynda Rushton, Mary Catherine Beach, and Ruth Faden) (2015)

“Linking Patient Registries and Biorepositories” in Agency for Healthcare Research and Quality, *Registries for Evaluating Patient Outcomes: A User’s Guide* (with Benjamin Greenberg and Helen Moore) (4th ed., forthcoming 2015)

Presentations/Panel Facilitations

“The Ethics of Digital Experimentation,” The Conference on Digital Experimentation, MIT, Boston, MA (October 10, 2014)

“The Law and Ethics of Digital Experimentation,” American Health Lawyers Association and Drexel School of Law, Philadelphia, PA (October 23, 2014)

“Just Compensation: A No-Fault Proposal for Research-Related Injuries,” Trans-NIH Bioethics Advisory Committee (T-NBC), National Institutes of Health, Bethesda, MD (January 20, 2015)

“Minor Consent: A Survey of State Laws,” at conference “Examining Mature Minor Consent for Participation in HIV Prevention Research,” co-sponsored by the National Institute of Allergy and Infectious Disease (NIAID), National Institute of Mental Health (NIMH), and National Institute of Child Health and Development (NICHD), Rockville, MD (June 24, 2015)

Honors/Appointments

Promoted to full Professor of Law with tenure (effective July 1, 2015)

DIANE HOFFMANN

Publications

“Laying the Foundation for an Interprofessional, Comparative Health Law Clinic,” (with C. Banda

and K. Amuli) 42 J. LAW, MED. & ETHICS 392 (Fall 2014)

Report to the Maryland Health Services Cost Review Commission on Defensive Medicine, (with B. Herring) (February 15, 2015)

“Increasing Access to Dental and Medical Care by Allowing Greater Flexibility in Scope of Practice,” (with R. Manski and V. Rowthorn) 105 AJPH 9 (September 2015)

“Stopping Deceptive Health Claims: The Need for a Private Right of Action under Federal Law” (with Jack Schwartz) (forthcoming in AMERICAN J. OF LAW & MED.)

Presentations/Panel Facilitations

“Does Research on the Human Microbiome raise unique ethical or legal issues?” Institute of Medicine Annual Meeting, National Academy of Sciences Washington, D.C. (Oct. 19, 2014).

“Religious, Medical, and Legal Perspectives on End of Life Issues,” Panelist, University of Maryland Baltimore Interprofessional Conference, Baltimore, MD (Nov. 10, 2014)

“How will the practice of defensive medicine affect the ability of the Maryland Health Services Cost Review Commission to implement its new global budget reimbursement model?” Maryland Health Services Cost Review Commission, Baltimore, MD (Jan. 9, 2015 and March 11, 2015)

Federal Regulation of Probiotics, Microbiota & Health Workshop, International Life Sciences Institute, Washington, D.C. (April 27, 2015)

“Medically Ineffective Treatment in Maryland,” Prince George’s Hospital Center CME Lecture, Cheverly, MD (April 30, 2015)

“Federal Regulation of Probiotics: An Analysis of the Existing Regulatory Framework” at FDA Symposium, "Linking the Microbiome to Health, Safety, and Regulation," College Park, MD (September 29-30, 2015)

Honors/Appointments/Grants

Grant to study the practice of defensive medicine for the Maryland Health Services Cost Review Commission (Jan. 2015)

Awarded two-year NIH Grant (ELSI grant from NIAID), “Microbiota Transplantation: Recommendations for a Regulatory Framework” (June 2015)

KATHLEEN HOKE

Publications

“Guidelines for Avoiding Pitfalls when Drafting Juvenile Curfew Laws: A Legal Analysis,” 8 ST. LOUIS U. JOURNAL OF HEALTH LAW & POLICY 301 (with Elyse R. Grossman) (2015)

Presentations/Panel Facilitations

“Emerging Issues in Public Health Law” at National Public Health Law Conference, Atlanta, GA (October 17, 2014)

“The State’s Role in Tobacco Regulation” at the Food and Drug Law Institute’s Annual Conference, Washington, DC (April 21, 2015)

FRANK PASQUALE

Publications

“Privacy, Autonomy, and Internet Platforms,” in PRIVACY IN THE MODERN AGE (edited by Marc Rotenberg, Jeramie Scott, and Julie Hurwitz, 2015) (discussing the Facebook emotional manipulation experiment)

“Promoting Innovation While Preventing Discrimination: Policy Goals for the Scored Society,” 89 WASHINGTON LAW REVIEW 1413 (2015) (with Danielle Keats Citron)

“The Algorithmic Self,” 17(1) HEDGEHOG REVIEW 23 (2015)

Presentations/Panel Facilitations

Mitchell Lecture: “Who Rules Big Data?,” SUNY Buffalo Law School (March 27, 2015)

Commenter on two papers on law and synthetic biology and law and genetics at Yale Law School’s Innovation Beyond IP conference (March 28, 2015)

Multiple book talks re: THE BLACK BOX SOCIETY at Harvard Law School, the Rochester Institute of Technology, Georgetown University Center for Privacy and Technology, and the Columbia University Division of Social Science

Honors

Named Editor-in-Chief of LAWS, a peer-reviewed journal of legal theory

Named, Member of the Advisory Board, JOURNAL OF LEGAL EDUCATION

Named, Member of the Advisory Board, the Data Competition Institute.

AMANDA PUSTILNIK

Publications

“Imaging Brains, Changing Minds: How Neuroimaging Can Transform the Law’s Approach to Pain,” 66 ALA. L. REV. 1099 (2015)

19 J. HEALTH CARE L. & POL’Y 1 (2015) (symposium issue)

- “Legal and Neuroscientific Perspectives on Chronic Pain”
- “‘Excess Pain’ and the Reasonable Suffering Standard in Disability Law”
- “Chronic Pain, “Psychogenic” Pain, and Emotion in Tort and Disability”
- “Translational Expectations & Issues: Making it Work in Practice”

“Let’s Stamp Out Perversion: Against the Abuse of Civil Commitment for the Post-Carceral Detention of “Sexually Violent Predators” blog post on CATO UNBOUND (Cato Institute Blog) (June 9, 2015)

KAREN ROTHENBERG

Publications

“The Ethical, Legal, and Social Implications Program of the National Human Genome Research Institute: Reflections on an Ongoing Experiment” (with J. McEwen, J. Boyer, K. Sun, N. Lockhart and M. Guyer), 15 ANNUAL REV. GENOMICS HUM. GENET. 481 (September 2014)

THE DRAMA OF DNA: NARRATIVE GENOMICS, (with L.W. Bush) Oxford Univ. Press (2014)

“Finding Fault? Exploring Legal Duties to Return Incidental Findings in Genomics Research,” (with E.R. Pike and B.E. Berkman), 102 GEORGETOWN L.J. 795 (2014)

“Setting the Stage: Enhancing Understanding of Bioethical Challenges with Theatre,” 11 IND. HEALTH L. REV. 1 (2014)

Presentations/Panel Facilitations

Presenter and Facilitator (with L. Bush), “Bioethics in Play: The Drama of DNA”, Berman Institute of Bioethics Intensive, Johns Hopkins University, Baltimore, MD (June 4, 2015)

Presenter, “All the World’s a Stage: Exploring Bioethical Challenges with Theatre”, Cultural Programs of the National Academy of Sciences, *Performing Science*, DC Art Science Evening Rendezvous, Washington, DC (June 18, 2015)

Presenter and Facilitator (with L. Bush), “Clinical Genomics in Play: The Drama of DNA”, Festival of Genomics, Frontline Genomics, Boston, MA (June 23, 2015)

Invited participant, Workshops on Privacy and Trust, Precision Medicine Initiative, White House Office of Science and Technology Policy, (March and July 2015)

VIRGINIA ROWTHORN

Publications

“All Together Now: Developing a Team Skills Competency Domain for Global Health Education,” 42 JOURNAL OF LAW, MEDICINE & ETHICS 550 (2015) (with Jody Olsen).

“Identifying Interprofessional Global Health Competencies for 21st Century Health Professionals,” 81 ANNALS OF GLOBAL HEALTH 239 (2015) (with others).

“Putting the Pieces Together: Creating and Implementing an Interprofessional Global Health Grant Program,” HEALTH CARE: THE JOURNAL OF DELIVERY SCIENCE AND INNOVATION (Global Health Issue) (with Jody Olsen) (forthcoming Winter 2015)

ELLEN WEBER

Presentations

“Licensure Standards for Opioid Treatment Programs and Compliance with the Americans With Disabilities Act,” Testimony before the Maryland Senate Finance Committee and House Health and Government Operations Committee (Feb. 18 and March 31, 2015)

“Mental Health Parity and Addiction Equity Act,” Testimony before the Maryland Senate Finance Committee and House Health and Government Operations Committee (Feb. 25 and 26, 2015)

Honors/Appointments/Grants

Weber’s Drug Policy and Public Health Solutions Clinic was also awarded a third two-year grant from the Open Society Institute-Baltimore for \$280,000 to help establish a medical-legal partnership with two drug treatment programs to address insurance coverage issues and access to health services.



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

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