As fall begins, the Law & Health Care Program at Maryland Carey Law prepares for another academic year and a schedule of exciting programming that will include a roundtable to discuss the role of law in the opioid crisis, a panel presentation on the problem of drug pricing and the growing number of state laws attempting to address it, the annual Health Law Regulatory and Compliance Competition, and a planned Health Law Roundtable that will look at issues at the intersection of health law and bioethics. Most importantly, we welcome a new cohort of students including not only our JD candidates but also those admitted to the health law-focused LLM and Master of Science in Law programs.

As the profiles below make clear, it has been a busy summer for the health law faculty, as they have developed and strengthened academic collaborations, both domestically and internationally, published important scholarly contributions, and continued to work at the forefront of health law scholarship and advocacy.
Faculty Profiles

Richard Boldt

Richard Boldt, the T. Carroll Brown Professor of Law, has been a member of the Maryland Carey Law faculty since 1989. In addition to constitutional law and criminal law courses, he teaches the mental disability law course in the health law program. He has written extensively on drug courts and other problem-solving courts; his recent scholarship has focused on the legal system's role in mental health treatment.

Professor Boldt has several articles in progress including an article to be published in an upcoming issue of the Drexel Law Review. In the article, entitled “Emergency Detention and Involuntary Hospitalization: Assessing the Front End of the Civil Commitment Process,” he discusses the dramatic shifts in the allocation of mental health treatment resources, notably the shift away from extended inpatient stays to a system that relies largely on outpatient care with brief inpatient stays during acute episodes. Several factors have contributed to this shift: the civil rights movement of the 1970s that ushered in an era of deinstitutionalization, advances in psychotropic medications facilitating faster stabilization of symptoms, and changes in health finance rules that saw states shifting the costs of care for those with severe mental illness to federal government insurance programs.

Although the care landscape has changed, the laws in many states that govern involuntary hospitalization have not been updated to reflect this current model of care. In these jurisdictions, an individual may be subject to involuntary commitment without timely judicial review. While the law may require judicial review within a set time period, the legal protections that such review is meant to provide are rendered moot if the statutory timeline exceeds the length of hospitalization.

In Maryland, petitions for emergency commitment filed by a family member or friend must undergo judicial review. In contrast, mental health professionals and law enforcement may execute a petition without judicial review for up to 10 days with the possibility of extension for an additional seven days. This time period far exceeds the typical length of stay for most patients having an acute psychiatric episode.

While other states have updated their commitment laws to reflect the realities of current treatment and allow for judicial review at an earlier date, there still exist procedural hurdles such as the requirement that a patient request a hearing in order to trigger judicial review that may prove too burdensome for some individuals.

Boldt argues that state laws regarding the involuntary commitment process should be updated to reflect current clinical realities and incorporate requirements for prompt mandatory judicial review. While acknowledging the key role that medical professionals play in that process, Boldt asserts that the legal system plays an equally important role in ensuring that constitutionally mandated protections of individual rights are observed.

Boldt's second article focuses on the
increasing use of non-professional peer support workers in mental health and substance abuse treatment settings. In the article, he explores the history of using community health workers (CHWs) to address health concerns such as HIV in developing countries. He then examines the barriers to implementing a similar model in the U.S. such as concerns related to reimbursement for such services, licensure issues as well as the interprofessional conflict that may result among professionals such as nurses and social workers who have traditionally provided case management services in health care settings.

Boldt then reviews the implementation of this care model in several states via demonstration grants, highlighting those states that have overcome the obstacles by employing a team-based approach to care and reimbursement. He concludes that current evidence provides strong support for the community health worker model, particularly in low resource settings. CHWs, also called peer support specialists or navigators in the literature, play an important role in a more holistic, culturally competent model of care that achieves improved outcomes at the patient and population level.

Leslie Meltzer Henry

Professor Leslie Meltzer Henry has been a member of the faculty since 2008. An attorney and bioethicist by training, her current research focuses on legal and ethical issues that arise in the context of research with pregnant women. With coauthors from across the country, Henry recently published an article in the Hastings Center Report, entitled “Research with Pregnant Women: New Insights on Legal Decision-Making,” that examines the role of lawyers in decision-making about the inclusion of pregnant women in research. The paper is based on work that Henry and several of her coauthors completed as part of their participation in the NIH-funded PHASES Study (Pregnancy & HIV/AIDS: Seeking Equitable Study), which sought to address the systematic exclusion of pregnant women from HIV-related biomedical research.

The authors draw attention to the exclusion of pregnant women from most clinical trials, the frequent decision by pharmaceutical companies not to seek FDA approval of drugs for use in pregnancy, and drug labels that acknowledge the lack of drug testing in pregnant women. The resulting dearth of evidence about how most drugs work in pregnant bodies not only leaves physicians treating pregnant women with insufficient data on which to base treatment decisions, it also means that most drugs taken during pregnancy are prescribed off-label, an outcome that the authors note shifts liability from the pharmaceutical company to health care providers.

Based on input from legal professionals engaged in the research process at different levels and contexts (e.g. general counsels representing academic institutions, attorneys for pharmaceutical companies, and former regulators), the authors discuss various factors that influence legal decision-making with regard to the inclusion of pregnant women in clinical research. They expand upon the frequently cited obstacles of liability and DHHS regulations about research with pregnant women, and they provide a more comprehensive analysis of the factors contributing to pregnant women’s underrepresentation in research. The authors highlight that regardless of context (i.e. an academic institution or a pharmaceutical company), attorneys play an important role at each stage of the research process from conceptualization to FDA approval to post-approval marketing.

Henry and her coauthors identify several factors that influence legal decision-making with regard to the inclusion of pregnant women in research, including financial factors, ambiguity and inconsistency in the regulatory language governing the inclusion of pregnant women in research, concerns regarding liability and risk management, and venue-specific laws. In terms of financial factors, for example, the authors explain that pharmaceutical companies may have a financial disincentive to include pregnant women in research for drugs already approved for use in the general population because those drugs can be—and frequently are—prescribed to pregnant women off-label. Companies are able to avoid the potential delay in FDA approval and the additional cost that inclusion of pregnant women may entail.

Despite obstacles, the authors conclude by emphasizing the critical need for guidance regarding the inclusion of pregnant women in clinical research, particularly in light of the recent outbreak of Zika virus and the continuing challenges presented by the HIV epidemic, and they recommend, as a starting point, careful review of legal decision-making processes that have resulted in the inclusion of pregnant women in research.

Diane Hoffmann

Diane Hoffmann, the Jacob A. France Professor of Health Care Law and Director of the Law & Health Care Program, recently returned from Aberdeen, Scotland, where she spent the month of July and early August teaching a course in Comparative Health Law, at the University of Aberdeen School of Law (see article about her experience on p. 13). In
Hoffmann and the study team recently completed a second article stemming from their work on the microbiome entitled “Regulation of Microbiota Transplantation: Balancing the Need for Information on Safety and Efficacy with Patient Access.” In the article, the authors take the position that the advent of microbiota transplants (e.g., fecal microbiota transplants to treat C. difficile) creates some challenges for regulators. There is no consensus on how these transplants should be regulated and the FDA has issued three draft industry guidance documents on the subject over the last four years, each one different than the one before. The challenge comes because the material that is transplanted – a community of living organisms – is unlike the small molecule chemical products that FDA typically regulates as drugs. Yet, the practice of microbiota transplantation is still relatively new and many argue we do not know all the potential adverse effects, especially long term, that the practice may have for patients. Others argue that there is enough evidence to show that the transplants, at least for C. diff, are both safe and effective and that they do not need to be regulated as drugs. The authors call for a regulatory framework for FMT that balances the need for additional research on safety and efficacy with appropriate patient access and recommends such a framework as a model for FMT as well as other types of microbiota transplants (e.g., vaginal, skin, nares and oral) that may be available in the future.

Professor Hoffmann gave a presentation on the topic of microbiota transplantation at the 4th ELSI (Ethical, Legal and Social Implications) World Congress. The meeting, held on the campus of UConn Health and the Jackson Laboratory for Genomic Medicine in Farmington, Connecticut in June 2017, was co-sponsored by the National Human Genome Research Institute, the Columbia University Medical Center, UConn Health, and the Jackson Laboratory.

Hoffmann also continues to explore the changing legal and regulatory landscape for medical marijuana. In early June, she gave a presentation on the topic at the American Society of Law, Medicine and Ethics annual Health Law Professors conference at Georgia State University School of Law. She is currently preparing a manuscript analyzing the barriers to medical marijuana rescheduling at the federal level. In the article, she reviews recent decisions by the DEA and FDA declining to move cannabis from its current status as a Schedule I substance and examines the rationales presented in those decisions to assess the potential for rescheduling in the future. Hoffmann argues that the federal government’s current stance on rescheduling medical marijuana (i.e., requiring that cannabis go through the FDA drug approval process) is an insurmountable obstacle and thus it is raising false hopes for those requesting that the plant be rescheduled. She discusses the challenges posed by putting a plant through the drug approval process, in particular addressing consistency from batch to batch, safe administration and dosing. Another challenge includes the willingness of a sponsor to take the financial risk of putting a plant through the process. Exclusivity would be a significant problem given the ability of patients to obtain medical marijuana for a number of conditions in over 28 states.

Kathleen Hoke

Kathleen Hoke is Professor of Law and Director of the Network for Public Health Law, Eastern Region at Maryland Carey Law. Professor Hoke teaches a Public Health Law course at the school in addition to directing the Public Health Law Clinic. She also directs the law school’s Legal Resource Center for Public Health Policy (LRC). The LRC provides legal guidance to state and local
governments, legislators and non-governmental organizations on public health issues ranging from tobacco regulation to obesity prevention and assists with the development of policies that promote public health.

In her role as Director of the Network for Public Health Law, Eastern Region, she has been writing about scope of practice laws. Professor Hoke recently co-authored an article in the Journal of Law, Medicine & Ethics, entitled “Expanding Access to Care: Scope of Practice Laws.” Hoke and coauthor Sarah Hexem, Policy Director of the National Nurse-Led Care Consortium, examine the impact of scope of practice laws that govern allied healthcare professionals on health care provision and outcomes. Focusing on nurse practitioners and allied dental providers, they evaluate current scope of practice laws using the “Triple Aim” framework developed by the Institute for Health Improvement: better care, reduced healthcare costs and improved health. In the case of nurse practitioners, the authors argue that there is little evidence that legislative restrictions on their scope of practice (e.g. requiring physician collaboration) results in better care. In fact, there is no evidence of reduced quality of care in states that do not employ such restrictions. In terms of cost, studies have shown that nurse practitioners provide high quality care at costs equal to or lower than physician care. These studies, however, fail to account for the impact of restrictive scope of practice laws on cost.

In the case of allied dental providers (i.e. dental hygienists, therapists and assistants), the authors assert that expansion of scope of practice laws for these professionals may help to address persistent issues of access to proper dental care among historically underserved populations. Several promising approaches are currently being implemented in various states including the use of telemedicine to facilitate supervision by a dentist, removal of practice restrictions in specific designated settings, and expansion of dental provider categories to include dental therapists, i.e., mid-level professionals who can provide basic preventive and restorative oral healthcare. Each of these approaches may increase access to care, reduce health care costs, and result in improved health outcomes. The authors conclude by encouraging researchers to conduct formal evaluations of expanded scope of practice initiatives to assess their effectiveness and impact on population health.

**Frank Pasquale**

Professor Frank Pasquale joined the faculty of the School of Law in 2013. His research focuses on various areas including health information law, health finance law and bioethics. Pasquale recently published, with coauthor Dr. Gordon Hull of the University of North Carolina Charlotte, an article in the peer-reviewed journal Biosocieties entitled “Toward a critical theory of corporate wellness.” In the article, Pasquale and Hull examine the proliferation of corporate wellness programs under the rationale of improved employee health and decreased health care costs for employers. They argue that there is limited evidence to support that rationale. To date, the programs have not demonstrated their effectiveness in improving individual health outcomes and have not resulted in reduced health care expenditures for employers. In fact, the wellness programs themselves often cost more to implement than any savings enjoyed as a result of their implementation.

Pasquale and Hull question the validity of corporate wellness programs on several grounds, apart from their failure to meet their stated goals. First, the programs are often premised on the notion that an individual’s health is almost entirely attributable to individual choices and behavior. Such a premise fails to account for important factors that are outside of individual control, namely genetic susceptibility, environmental exposure and disease etiology that may have little or nothing to do with individual health behaviors.

Second, in contrast to early wellness programs implemented in the 1980s, participation in current programs is increasingly compulsory with associated incentives (e.g. discounted copays) and penalties (e.g. higher premiums, removal from coverage) to ensure employee participation and compliance. As the authors note, however, individuals confronting complex health conditions are often also those least able to meet the requirements of the programs and are therefore rendered even more vulnerable to poor health outcomes when program penalties are assessed. Programs that are structured in this manner effectively shift risk and cost on to the employee who is least able to absorb it.

Third, the authors question the increasing use of surveillance and express concern about the encroachment of the workplace into employees’ personal lives through program reporting requirements and proliferation of wearable
technology that monitors health indicators and behaviors. Given the non-negligible expense of corporate wellness programs and the lack of evidence to support them in terms of improved health outcomes for employees or savings in healthcare costs to employers, the authors argue that investment in public health programs, which already undergo rigorous evaluation, typically employ evidence-based approaches and have demonstrated effectiveness, is a more promising approach to achieve wellness programs’ stated goals. To the extent that the wellness program model is employed, the authors advocate for changes to the federal regulatory framework to require employee input in wellness program development.

In addition to his research, Pasquale hosts the popular podcast “The Week in Health Law” with Indiana University law professor Nicolas Terry. Since 2015, Profs. Pasquale and Terry have been engaged in weekly conversations on the latest issues in the field. A recent broadcast, for example, looked at the issue of prescription drug pricing and featured Law & Health Care Program alumnus Ameet Sarpatwari, who currently serves as Assistant Director of the Program on Regulation, Therapeutics and Law at Harvard Medical School. For access to past podcasts, search for The Week in Health Law on your favorite podcast app. Show notes appear at http://twihl.com/.

Amanda Pustilnik

Amanda Pustilnik has been on the faculty at the Law School since 2010. In addition, she is a permanent faculty member at the Massachusetts General Hospital Center for Law, Brain & Behavior. Her research focuses on the intersection of neuroscience and the law, with a particular focus on the treatment and measurement of physical and emotional pain in legal contexts. Professor Pustilnik recently chaired the law and ethics section of a task force convened by the International Association for the Study of Pain (IASP) that issued the first guidance of any professional body on the uses of neuroimaging as legal evidence. This consensus statement, “Brain Imaging Tests for Chronic Pain: medical, legal and ethical issues and recommendations,” appeared in Nature Reviews Neurology - https://www.nature.com/nrneurol/journal/vaop/ncurrent/pdf/nrneurol.2017.122.pdf.

The consensus statement is broadly applicable to the neuroimaging of many subjective states, but focuses on chronic pain, a set of misunderstood conditions affecting up to 1/3 of people in their lifetime and costing legal and medical systems billions of dollars. The paper proposes criteria and standards for pain neuroimaging in clinical and legal settings, while emphasizing the need to protect parties and the legal system itself from unreliable data.

The consensus statement is the result of work begun in 2014, when Professor Pustilnik and David Seminowicz, a professor in the Department of Neural and Pain Sciences at the University of Maryland School of Dentistry, convened a meeting of neuroimaging researchers, legal academics and judges to determine whether brain imaging techniques could be used in legal claims about pain.

Professor Pustilnik also recently served as an advisor to the Aspen Institute's Health Strategy Group on the topic of the opiate epidemic.

Co-chaired by Kathleen Sibelius and Tommy Thompson, the former secretaries of Health and Human Services under Presidents Barack Obama and George W. Bush, the group brought together expertise from government, private industry, and philanthropy, as well as scholars in law, economics, and addiction studies. The Health Strategy Group's recommendations will be published in late 2017, and will be focused on practical targets for reducing harm from the epidemic.

Karen Rothenberg

Karen Rothenberg, Marjorie Cook Professor of Law and founding director of the Law & Health Care program, continues to pursue her work exploring the pedagogy of theater to engage audiences regarding the complex ethical issues associated with genome sequencing.

She was recently invited to present a theatrical work as part of the 2017 Annual Meeting of the AIDS Clinical Trial Group (ACTG) Network, held in Washington D.C. in June. Sponsored by NIH's National Institute of Allergy and Infectious Diseases, the ACTG is a network of domestic and international researchers, organizations, and advocates working to address HIV/AIDS and associated infectious diseases in low resource settings.

The presentation, entitled “Bioethics in Play: The Drama of DNA,” examines the complexities that arise when incidental findings are discovered through genome sequencing. Rothenberg notes, “The
Housing as a Social Determinant of Health: Professor Deborah Weimer Works to Address Access to Justice in Landlord-Tenant Disputes

Deborah Weimer, Professor of Law and Law & Health Care Program faculty member, established and directs the Health Care Delivery and HIV/AIDS clinic at the School of Law. The clinic, now co-directed by Visiting Assistant Professor Sara Gold, has been representing clients living with HIV since 1988.

It was through her experience working in the clinic that Professor Weimer came to fully appreciate the critical role housing plays as a social determinant of health. The ability of individuals to engage in healthy behaviors and follow care regimens is largely predicated on access to safe and affordable housing. Weimer and coauthors explored this issue in depth in the chapter “Patients and Families Living with HIV/AIDS” in Poverty, Health and Law: Readings and Cases for Medical-Legal Partnership (eds. E. Tobin Tyler, E. Lawton, et al.). In the chapter, they highlight the importance of stable housing to successful HIV/AIDS care and the increased vulnerability of individuals living with HIV/AIDS to “losing their housing due to rising medical and housing costs, reduced ability to work and discriminatory housing practices, among other factors.”

It was this need that led Weimer to develop a new clinical course at the law school, Landlord Tenant Clinic: Legal Theory and Practice, in 2013. Students represent tenants in housing court proceedings, individuals who are rarely able to secure legal counsel to represent them. Many of the clinic’s clients are referred from the law school’s Health Care Delivery Clinic. A recent case involved exposure to lead paint; a family was referred by an HIV clinic after their fifteen-month-old child, during routine blood work, was found to have elevated lead levels. The city health department got involved and the clinic filed a petition for breach of the warranty of habitability. As a result of the clinic’s representation, the landlord was ordered to complete lead paint remediation. Student attorneys also obtained rent abatement for the family during remediation. Weimer notes, “There is a regulatory system in place to deal with lead paint but enforcement remains an issue. In collaboration with community organization partners, we are advocating on behalf of our clients with the city council to expand rental licensing requirements to include single family homes. Licensing requires thorough home inspections including testing for lead paint prior to rental and will help to protect city residents from the negative health effects of substandard housing.”

This summer, Professor Weimer published an article in the Hastings Race and Poverty Law Journal entitled “Deepening Lawyer Role Education to Serve Students and Society” where she advocates for wider recognition of access to justice issues in the law school curriculum. Weimer argues that failure to address the large numbers of individuals engaged in legal proceedings without

(continued on page 18)
The Law & Health Care Program conferred Health Law certificates on 35 graduating students at a breakfast reception on May 17, 2017. The reception marked the 20th year that certificates have been awarded to Maryland Carey Law students who have completed the rigorous academic and professional requirements that include health law coursework, practice-based learning, as well as a scholarly paper on a health law topic. Students in the health law program come from diverse backgrounds – some are seeking their legal education after significant experience in clinical settings as physicians, nurses and pharmacists. Others have engaged in advocacy and legislative work. They all share an interest in the legal and regulatory frameworks that support the health care system.

In her remarks, Professor Diane Hoffmann, Director of the Law and Health Care Program, lauded the group for their active participation in the opportunities available to health law students, such as the *Journal of Health Care Law & Policy*, the Student Health Law Organization, and health law competitions such as the National Health Law Moot Court Competition. She noted the evolving health policy and legal climate and expressed her confidence in the graduates’ ability to tackle the challenges and opportunities that lie ahead.

Below we highlight several of our 2017 graduates and their achievements:

**Alexandra Jabs**
Alexandra was exceptionally productive and highly motivated as a law student, completing her MPH at the Johns Hopkins Bloomberg School of Public Health, serving on the Health Law Moot Court Team, as well as completing externship placements at the Johns Hopkins Health System and the U.S. Food and Drug Administration. She also served as a faculty research assistant to Professor Diane Hoffmann, conducting research on actions by the FDA and FTC against food and supplement manufacturers for false health claims. In addition, Jabs was a student in the Public Health Law Clinic. Clinic Director Kathi Hoke told the audience at the reception that Alexandra and her clinic partner Douglas Elliott “were like workhorses, completing a review of domestic violence legislation for all 50 states as well as the District of Columbia, developing individual fact sheets for each state and an issue brief that were subsequently published by the Network for Public Health Law.” Alexandra is now working in the Office of the General Counsel for the U.S. Food and Drug Administration.

**Alison Best**
Alison was a remarkably active student during her time at MD Carey Law serving as co-President of the
Maryland Public Interest Law Project (MPILP), an officer of Maryland Carey Service Corps, and a member of the editorial board of the Maryland Law Review. In addition to these activities, Alison took full advantage of the many opportunities to engage in research and experiential learning, serving as a faculty research assistant and a law clerk with the Maryland Office of the Attorney General. She also performed admirably as a student attorney with the HIV/AIDS clinic at the law school. Clinic Co-Director Sara Gold praised Alison’s many strengths and skills as a legal researcher, excellent writer and sharp thinker and commended her for her willingness to move beyond her comfort zone in working with clients and increasing access to justice for those in need. During her year in the clinic, Alison and fellow student Matthew Ulander worked diligently on a case that resulted in their client being awarded approximately $40,000 in past disability benefits as well as monthly benefits going forward. Alison is currently serving as a judicial law clerk at the Maryland Court of Special Appeals.

Nadia Cheevers

Nadia Cheevers completed her law degree and health law certificate as an evening student while working full time and raising a family. Trained as a nurse, Nadia works as a Senior Risk Manager for the Maryland Medicine Comprehensive Insurance Program. In that position, she provides risk management support and education to the Departments of Surgery, Anesthesiology, Pathology and Ophthalmology at the University of Maryland Medical Center. In addition to these impressive responsibilities, Nadia also found time to work with Diane Hoffmann and Anita Tarzian, Program Coordinator for the Maryland Healthcare Ethics Committee Network, on a survey of health care facilities across the state to better understand how they are implementing the Medical Orders for Life Sustaining Treatment (MOLST) Law in the state. She was a major contributor to a manuscript about the survey that was accepted for publication in the Journal of Palliative Medicine. At the L&HCP certificate ceremony, Professor Hoffmann praised Nadia for her dedication and work ethic. Addressing her, Hoffmann said “I know it must have been difficult but you did it, you always had a smile on your face, and most importantly, you left a wonderful impression on everyone you interacted with.”

James Cook

As a student, James helped to launch one of the Drug Policy Clinic’s medical-legal partnerships at a local drug treatment program with the goal of ensuring that patients were enrolled in health insurance and could access drug treatment and other health services under Medicaid or private insurance. While James had planned to work on policy development when he entered the clinic, he agreed to work on this new initiative that provided invaluable legal assistance to many clients. Clinic Director and Professor Ellen Weber noted, “We watched James grow personally and professionally, as he gained confidence in his ability to help clients resolve their legal problems and work as part of a legal team. James demonstrated a level of empathy that we all strive for in our client representation and, as a result, he gained the trust of the program’s patients and became an indispensable resource to them.”

Marc Falvo

Marc Falvo was an active member of the Law & Health Care Program, serving as Secretary of the Student Health Law Organization as well as student attorney with the law school’s Health Care Delivery Clinic where he represented low-income clients living with HIV/AIDS. Falvo recently began his appointment as an Attorney Fellow with the Office of the General Counsel at the University of Maryland Medical System. Marc was selected for the fellowship opportunity from a competitive pool of applicants from Maryland Carey Law.

Marc credited the coursework he completed as part of the Health Law Certificate Program, particularly the Business Aspects of Health Law course and Professor Pasquale’s Health Care Law & Policy course, in helping him to navigate this new role. “The Office of the General Counsel addresses legal issues for 12 hospitals across the state. My health law coursework has helped to inform my work on assignments ranging from physician service agreements to Stark law to questions involving HIPAA, among others.” At the L&HCP certificate breakfast, Professor Frank Pasquale told the audience that “Marc Falvo has an outstanding career ahead of him.”
David Clark, an emergency department physician with the Maryland Emergency Medicine Network in Prince George’s County, followed a similar path to that of Cozanne Brent. After practicing medicine for 30 years, Dr. Clark began to consider the next phase of his career and decided to explore graduate education. While researching programs in healthcare management, Dr. Clark learned about the health law MSL at the University of Maryland and decided to apply. He was motivated, he said, by the many changes that were happening in the field of medicine and the impact of laws like the Affordable Care Act on the practice of medicine. Dr. Clark said of his post-degree plans, “I am excited about the possibilities – to be able to shape policy and the future of medicine in a legal capacity.”
After ten years working with L&HCP Director Diane Hoffmann, Virginia Rowthorn is leaving the Program to become the Executive Director of the University of Maryland Baltimore’s Center for Global Education Initiatives. In her new role, she will lead the interprofessional global health activities for the campus-wide center with an emphasis on community-based research and service projects in international and domestic settings. She will also facilitate the Interprofessional Global Health Grant Program, an initiative that she conceived and implemented. Ms. Rowthorn has been serving as Co-Director of the Center for the past three years.

Ms. Rowthorn joined the School of Law in 2006 as the Coordinator of the Law & Health Care Program. In 2009, she was promoted to Managing Director, taking on additional responsibility for program administration. She has been actively involved in all aspects of the program including teaching the Health Law Practice Workshop, advising students in activities ranging from externships to regulatory competitions, as well as contributing to grant writing and administration of several federal grants and scholarship on telemedicine, microbiota transplantation and interprofessional global health education.

Diane Hoffmann noted, “Rowthorn’s contributions to the Law & Health Care Program are innumerable. She has helped to shepherd this program to its current position as one of the leading health law programs in the country in addition to expanding opportunities for students, particularly in the area of global health. I know that she will enjoy great success in her new role.”

The Law & Health Care Program is pleased to announce the appointment of Lauren Levy as its new Managing Director. Ms. Levy is a 2011 graduate of the School of Law and the health law certificate program. She comes to the law school from the University of Maryland School of Medicine where she served as a faculty Research Associate in the Department of Epidemiology & Public Health and Assistant Director of Research for the Maryland Center of Excellence on Problem Gambling. Ms. Levy has worked in the field of public health for more than 20 years in domestic and international settings including the development of reproductive health programs in Latin America and the Caribbean, evaluation of maternal and child health interventions in West Baltimore and management of an NIH-funded career development program in women’s health, among other roles.

Her health law experience includes positions in the Medicaid Division of the then-Maryland Department of Health and Mental Hygiene (now the Maryland Department of Health) office of the Maryland Office of the Attorney General, where she drafted appellate briefs for cases involving Medicaid eligibility determinations; a private employee benefits consulting practice, working with clients to interpret various provisions of the Affordable Care Act; and an elder law firm.

In addition to her JD, Ms. Levy holds a Master of Public Health degree from the Columbia University Mailman School of Public Health.
Frank Pasquale, Professor of Law at Maryland Carey Law, was recognized as one of the top ten most cited authors in health law scholarship, according to an analysis conducted by two prominent health law experts. Professors Mark Hall of Wake Forest University School of Law and I. Glenn Cohen of Harvard Law School presented the results of their analysis in a post published on Harvard’s Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics blog. The authors found that Professor Pasquale’s work was cited approximately 300 times between 2010 and 2014.

Pasquale has written across several subfields in health law, including health care finance and regulation, bioethics, and data protection.

For example, he has researched health data policy in work that recognizes both the rapidity of technological advances and the unintended consequences of the interaction of legal rules (such as privacy, intellectual property, and antitrust laws). In the co-authored piece, “Protecting Health Privacy in an Era of Big Data Processing and Cloud Computing,” Pasquale and Tara Ragone combined careful analysis of the implications of the HIPAA Omnibus Rule with interviews with leading attorneys about optimal methods of implementing security and other safeguards. Pasquale’s work is among the leading U.S. legal research cited relating to regulation of algorithmic ranking, scoring, and sorting systems.

In health care finance, Pasquale has completed a trilogy of articles explaining the law and policy of tiering in national and international health systems, and proposing reforms. These articles covered the complex legal regulation of concierge medicine, single-specialty hospitals, and access to patented drugs. Each article unraveled the complex interactions among providers, insurers, and regulators, to expose the ways in which seemingly neutral regulatory decisions could either exacerbate or alleviate health disparities.

In bioethics, Pasquale’s early work explored the ethics of human enhancement from the perspective of political economy (including analyses of genetic engineering and cognition-enhancing drugs). He has recently critiqued the rise of corporate wellness programs in an article in Biosocieties (discussed on page 5 of this newsletter). Pasquale’s approach attempts to set the study of corporate wellness on a new path, away from technocratic experimentalism, and toward more democratic participation in the definition and pursuit of “wellness.”

At present, Pasquale is working on several health law-focused research projects, including an article on reimbursement for medical robotics, an analysis of the interaction of privacy and human subject research regulations, and a study of health care expenditures based on the emerging methodology of law and macroeconomics.

The full ranking can be found here: http://blogs.harvard.edu/billofhealth/2017/04/18/most-cited-health-law-scholars/
It has been more than thirty years since a nursing colleague encouraged Randi Kopf to pursue her legal education. At the time, Ms. Kopf was teaching in the graduate program of the University of Maryland School of Nursing as well as working as a family oncology nurse practitioner. She would often delve into the ethical and legal issues that arise in the healthcare setting with her students and she thought that training in the law would help to inform her teaching.

Given her connection to the University of Maryland, the School of Law seemed like a natural fit. She entered the law school just as the Law & Health Care Program was being developed by Professors Karen Rothenberg and Diane Hoffmann. She notes, “In addition to a number of nurses, there were many other clinicians attending – physicians, dentists. It was a very exciting time to be a part of the program.”

As an oncology nurse practitioner, Kopf was no stranger to the role of law in health care matters. She frequently found herself involved in legal issues with patients such as wills, patient rights, visitation, etc. “Now cancer can be considered a chronic illness. Back then, cancer patients had a much shorter life expectancy. There was an urgency to the issues that came up, these end-of-life legal issues required timely action.”

Kopf recalls of her days at the law school, “I took every health law course that I could. These courses as well as contracts, torts and administrative law inform my legal practice to this day.”

Kopf was also fortunate to complete an internship at the National Institutes of Health Office of the General Counsel. “The general counsel at NIH is truly working at the nexus of law and medicine. That experience really solidified it for me. I knew that I was going in the right direction,” Kopf says of her internship experience.

After graduation, Kopf jumped into the field with both feet. She accepted a position in the Health Law practice group of Nixon, Hargrave, Devans & Doyle (now Nixon Peabody) and she was invited to serve on the Maryland legislative committee that was responsible for writing the first Health Care Decisions Act for the state. That was the first of many invitations Kopf has received over the years to contribute her unique expertise as a nurse attorney. After several years at the law firm, Kopf decided to establish a solo practice, Kopf Health Law, LLC. In her practice, Kopf works with physicians and other health care providers on issues ranging from medical practice establishment and acquisition, employment agreements, contract negotiation, administrative regulatory issues and health information technology matters.

Apart from her dedication to clients, Kopf is also deeply committed to service, in the profession and beyond. She has been active in professional organizations serving as Chair of the Health Law Section of the Montgomery County Bar Association and as a member of the health law section of the Maryland State Bar Association. She supports her fellow nurse attorneys through, among other activities, leadership roles with The American Association of Nurse Attorneys (TAANA) and Chesapeake Nurse Attorneys, Inc.

She has been called upon by Congressional Committees, patients’ rights groups and others to educate and advocate. She recalled a recent example where the National Labor Relations Board released guidelines regarding the use of social media for employers that directly conflicted with HIPAA regulations. Kopf was able to...
advocate for her clients and the board then issued exceptions and additional guidance for health care employers.

That recent case drew on Kopf’s significant expertise at the intersection of healthcare and technology. She lectures and writes frequently for both lawyers, clinicians, and patients, helping each group to successfully navigate the electronic age in healthcare. She has recently given talks, for example, regarding the use of social media in health care settings as well as legal practices.

A recent career highlight for Kopf was the opportunity to present Anita Hill, Professor at Brandeis University Heller School for Social Policy and Management, with the Mary Eleanor McGarvah Award at TAANA Foundation’s 35th Annual Meeting and Educational Conference in Boston, MA. Professor Hill was recognized for her contributions to equal justice, social justice and support of women’s rights.

Kopf says, “People sometimes ask me why I became an attorney if I loved being a nurse practitioner. The way I see it, each of my degrees and professional experiences have built on each other. It has been a natural progression from providing care to patients as a nurse, beginning to address end-of-life legal issues as an oncology nurse practitioner, to serving as an attorney-advocate for health care professionals and patients. It has been a continuum. I love being a nurse attorney and the health law program at the University of Maryland prepared me well.”

L&HCP Professor Kathleen Hoke Receives National Award for Contributions to Public Health Law

L&HCP Professor Kathi Hoke was awarded the Jennifer Robbins Award for the Practice of Public Health Law by the Law Section of the American Public Health Association at the organization’s 2016 Annual Conference. The award is given to mid-career professionals in recognition of “outstanding dedication and leadership in the field of public health law” and is named in honor of Jennifer Robbins, a public health lawyer who practiced in the Office for Civil Rights at the U.S. Department of Health, Education and Welfare. She subsequently served as an Assistant Attorney General in Maryland and principal counsel for the state’s Department of Health and Mental Hygiene.

Like Robbins, Professor Hoke spent a number of years working as an Assistant Attorney General in Maryland and has devoted her career to the integration of law into public health. Professor Hoke remarked, “It is an honor to be recognized by my peers in the APHA Law Section and I am particularly honored to receive this award in memory of Jennifer Robbins.”
In July, a Maryland Carey Law team spent two weeks in Malawi alongside Chancellor College of Law faculty and students to study how law school clinics can be used to address environmental and public health injustices. The project was sponsored by the Law & Health Care Program (L&HCP) and the Environmental Law Program at the School of Law, the University of Maryland Baltimore Center for Global Education Initiatives (CGEI) and the University of Malawi Chancellor College Faculty of Law (Chanco). The Maryland Carey Law team was comprised of Professor Bob Percival, Robert F. Stanton Professor of Law and Director, Environmental Law Program; Virginia Rowthorn, (then Managing Director of the L&HCP and now Director of CEGI), health law student Julia Kenny (2L), environmental law student Taylor Lilley (3L), and Atiji Pheri (LLM, Environmental Law ’17) who is from Malawi. On the Malawi side, Professor Chikosa Banda, Dean Garton Kamchedzera, and Patrick Chinguwo, the Director of the Clinical Program led the project.

This year’s project was the latest in a long collaboration between the University of Maryland Baltimore (UMB), Maryland Carey Law and Chanco. It began in 2010 when CGEI sent an interprofessional team of faculty and students to Malawi to study the health and legal needs of orphans and vulnerable children. The project was designed to teach students the value of an interprofessional approach to global health. The project was sited in Malawi because UMB, through School of Medicine faculty member Miriam Laufer, had an ongoing NIAID grant in Blantyre, Malawi. That study provided an infrastructure to support the interprofessional project and a vehicle to engage with community members, health professionals, and health and human rights lawyers.

In the summer of 2013, L&HCP Director Diane Hoffmann and Maryland Carey Law Professor Peter Danchin traveled to Malawi and worked with Professor Chikosa Banda to organize a workshop for students and faculty from both universities on the subject of HIV/AIDS. In subsequent years, Professor Banda and others from Chanco have visited Maryland Carey Law for joint meetings and conferences. A specific focus of one of these meetings was clinical legal education and the University of Malawi’s progress in this area. In the last eight years, Chanco has developed a number of legal clinics on various topical areas including disability and HIV issues. In 2016, Professor Banda proposed a visit by Professor Percival to Malawi to support Chancellor College’s fledgling Environmental Justice and Sustainability Clinic. Percival created the law school’s Environmental Law Clinic.

Clinical legal education is a relatively recent development in Malawi but is developing at a rapid pace. To date, Chanco’s clinics have been initiated based on student interest in a particular topic. Participation in the clinics is voluntary and not credit bearing. Recently, however, Malawi’s Council on Legal Education approved a revised curriculum that requires more opportunities for students to engage in practice-based education during their four years of law school.

Chanco’s Environmental Law and Sustainability Clinic was started in 2014 and was designed to support advocacy and litigation around environmental and public health issues. The group has engaged in community outreach activities, including clean-ups in the Chanco and Zomba area, tree planting, and street law activities targeting primary schools and community members (mainly communicating environmental messages).

The project commenced with a day of presentations and discussion on the
topic of environmental justice, public health, and the role of clinical legal education in promoting both. The workshop took place at a time when these themes are in a transformative moment in Malawi. The Malawian Parliament recently approved a new Malawi Environment Management Act (EMA) that created a new Environmental Protection Authority. The agency will have greater enforcement authority than did the Environmental Affairs Department of the Ministry of Natural Resources which depended on the Department of Justice to perform enforcement. Environmental law is an area with robust opportunities for a legal clinic to provide technical assistance to the government and NGOs and to represent communities in legal challenges.

The workshop was a fruitful source of discussion focused on approaches to clinical legal education in various jurisdictions and the pros and cons of emulating such approaches in the Chanco curriculum. When some Chanco students noted that not all Malawian law students want to litigate and, further, may be hesitant or unenthused about taking on politically-charged legal issues, Professor Percival described how the Maryland Carey Clinical Law Program takes an expansive view of the law’s role in environmental justice and public health by engaging students in negotiation, advocacy, advising clients, as well as litigation. These classroom discussions were followed by several site visits across Malawi. The faculty and students from both schools traveled in convoy which proved to be a rich and fun source of bidirectional learning. The trip included an encounter with a group of 20 elephants that (peacefully) surrounded their car on a quiet road in a game reserve. The site visits included the office of the Leadership for Environment and Development (LEAD) Initiative, a group that undertakes capacity building and action projects that support climate change adaptation, public health and environmental development. It helps other local institutions by providing objective information and practical policy and program proposals that foster environmentally sound and socially equitable development.

LEAD values an interprofessional approach to public health and environmental justice as evidenced by its intensive program for law students. One issue that requires an interdisciplinary approach is the use of treated mosquito nets for fishing, a common practice. Addressing this practice requires public health, environmental, and social work professionals.

In addition, the group visited attorneys working for the Malawan Environmental Affairs Department; a fishing site and cholera hotspot in Lake Chilwa; the Mulanje Mountain Conservation Trust; the Centre for Environmental Policy and Advocacy (CEPA); and the Mudi River which runs through Blantyre City. The Mudi river is heavily polluted by industrial waste and sewage. CEPA is making efforts to have the sewer pipes rehabilitated and also lobbying to have the government release funds allocated for the rehabilitation of the city’s entire sewage system.

To close out the project, the Maryland and Chanco teams met to discuss extending this valuable teaching and learning collaboration through joint scholarship, teaching, and experiential learning opportunities on both sides. The July trip was generously supported by the David and Leslie Glickman Interprofessional Health Law Fund.
I had the good fortune to spend most of the month of July and the first week of August teaching at the summer program in comparative law at the University of Aberdeen – a collaboration between the University of Baltimore and University of Maryland Schools of Law, in Baltimore, MD and the University of Aberdeen School of Law in Aberdeen, Scotland.

This trip was the realization of a long held aspiration for me. During my dozen years as Associate Dean at Maryland, it was often my job to select the faculty member who would have the opportunity to teach and live in Aberdeen for the summer program. Sadly, I was unable to choose myself so had to wait until I stepped out of the Dean’s office and back to the faculty before I was able to put my hat into the ring of potential faculty members who might be selected for this unique opportunity. I was especially excited to be chosen this past year as Maryland faculty who have been to Aberdeen and taught in the program have had wonderful things to say about it.

I was also excited by the prospect of teaching a comparative health law course. At Maryland, I have taught numerous health law courses ranging from our survey course, Health Care Law & Policy, to specialized courses on End of Life Care and Health Care for the Poor, among others. Although I had taught a Comparative Health Law course several years ago, I had not had the opportunity to focus on one other country and to have experts from that country come and lecture in the course. That was a big attraction of the Aberdeen course for me. Prior to the summer, I worked with then head of school Anne-Michele Slater and Professor Greg Gordon (the current head of school) to prepare for the course. I shared my vision for the course with them and Anne-Michele and Greg identified a stellar group of guest speakers.

The course focused on a comparison of four areas of health law and policy between the U.S. and the United Kingdom/Scotland: health care systems, medical malpractice systems, allocation of scarce health care resources, and regulation of the beginning and end of life. Our guest speakers were able to speak to each of these areas of law. They included Peter Feldschreiber, a dually qualified physician and barrister from London who specializes in the regulation of pharmaceuticals and medical devices and who advises both E.U. and U.S. health product companies on all aspects of European regulatory law; Neil MacLeod, a solicitor with the NHS litigation department in Scotland; Annie Sorbie and Edward Dove, both of whom specialize in health and medical law and have recently received faculty appointments at the University of Edinburgh; and Prof. Scott Styles, a member of the faculty at University of Aberdeen, who, among other things, is an expert in medical ethics.

Each of these guest speakers added a great deal of excitement to our class discussions as they helped us to compare the “system” in the U.S. with that of the U.K./Scotland. Several current events also made the course come alive for me and the students. The first was the advent of Brexit which is provoking much uncertainty in the medical profession regarding movement among the E.U. countries. One article in the news indicated that over half of E.U. health professional workers in the U.K. would leave. Brexit has also raised anxiety in the pharmaceutical and medical device industries about what will be required in the U.K. in terms of new product approval and marketing authorizations and whether the U.K. will remain a part of the European Medicines Agency (EMA).

A second relevant event for the course was the case of Charlie Gard, the infant in the U.K. who had a rare terminal genetic disorder (mitochondrial DNA depletion syndrome) that left him blind, deaf...
and unable to breathe on his own. His doctors and the hospital where he was receiving care felt that his case was hopeless and they should not be required to continue to treat him. His parents, however, took the case to court, fighting for the hospital to be required to keep Charlie on life support so that he could receive experimental treatment. Each day there were new developments in the case including the Pope and President Trump offering to do whatever they could to help the parents in their quest to keep the child alive. The case offered the class a chance to consider: What constitutes “futile” medical treatment? Who should make the decision to withdraw life sustaining treatment for a child in this condition— the parents, the doctors, or the courts? And what is in the child’s best interest?

The students enthusiastically met the challenge of debating the different aspects of health law and how they played out in the two different jurisdictions. Their keen interest in the issues under discussion made the class sessions lively and fun for me. The model of co-teaching a comparative health law class with experts from the jurisdictions being compared is a wonderful format for the faculty and the students.

Housing as a Social Determinant of Health: Professor Deborah Weimer... continued from pg 7

the ability to afford legal counsel comes at a significant cost, both economic and otherwise, to the individual and society. It also calls into question the court system’s ability to meet its constitutionally mandated commitment to due process.

Although she advocates for the inclusion of more in-depth discussion of access to justice concerns as part of civil procedure coursework, she argues that clinical legal education can be especially instructive in this regard. She writes: “...the most powerful way to engage students in understanding the failure of our current system is to involve them in representing clients whose rights would go unprotected but for their assistance.” It is this firsthand exposure, she posits, that provides the most vivid illustration of the problem of lack of access to counsel.

She concludes by advocating for additional instruction to law students regarding their responsibility, both professional and moral, in cases where the opposing party is unrepresented, questioning the appropriateness of zealous advocacy in such contexts and warning against actions that exploit the power imbalance in such cases.

Weimer touts innovative legal service provision models, such as medical-legal partnerships, encouraging interdisciplinary efforts to evaluate such models as potential remedies to the access to justice crisis facing the legal system.
Ellen Weber named Vice President for Health Initiatives of the Legal Action Center

Long-time Law & Health Care Program faculty member Ellen Weber has been appointed Vice President for Health Initiatives at the Legal Action Center, a non-profit law and policy organization in Washington, D.C., dedicated to advocacy on behalf of individuals with HIV/AIDS, criminal records and histories of addiction. Her new role at the LAC is a homecoming of sorts as Professor Weber worked for the organization from 1985 to 2002.

In 2002, Professor Weber joined the faculty at Maryland Carey Law. She established and directed the Drug Policy and Public Health Strategies Clinic, where she and clinic students focused on policy development to expand access to substance use treatment services. In recent years, Professor Weber and her students had focused on the implementation of the Affordable Care Act and the Mental Health Parity and Addiction Equity Act, supported by grant funding form the Open Society Foundation.

The Parity Act is a federal law that requires insurers to provide coverage to those with mental health or substance use problems that is comparable to the coverage provided to those with other medical problems.

“At the clinic, we have used the Parity Act to try to get the most expansive, nondiscriminatory health benefit for patients with mental health and substance use disorders,” Weber said. “We feel we’ve accomplished a lot by advocating for strict enforcement of that law in our state.”

Her new role at the Legal Action Center will also examine “how the parity law is being implemented both on the national level and in states,” Weber added. “We also will be developing litigation to enforce the parity act where we think litigation is necessary. I’ll be working to adapt and transfer to other states some of the enforcement strategies we’ve used through our work in Maryland.”

Weber’s new role is the next phase in her always diverse approach to this dynamic issue. “We’ve used the Parity Act and other Affordable Care Act protections in every way that we can to try to identify insurance coverage problems and fix those problems, from legislative activities to regulation development with agencies to individual client representation,” Weber said. “We use a variety of different strategies to take on these barriers that limit access to health care.”

L&HCP Director Diane Hoffmann said of Professor Weber’s departure, “Ellen’s contributions to the laws and policies regarding substance use disorder at the state and federal level are countless. We know that she will continue to serve as a staunch advocate for those struggling with addiction as well as those in recovery. We look forward to Ellen’s continued collaboration with the Law & Health Care Program as she moves into her new role. We are fortunate that our students will continue to have the opportunity to work with Ellen on these important legal and policy issues as externs with the Legal Action Center.”
Tune in to The Week in Health Law, a weekly podcast hosted by our own Professor Frank Pasquale and Professor Nicolas Terry, Executive Director of the Hall Center for Law and Health at Indiana University McKinney School of Law, that engages various guests in conversations about a wide range of issues in health law and policy.

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