This semester, the Law & Health Care Program (L&HCP) welcomed its newest faculty member, Natalie Ram. Professor Ram’s work is at the intersection of innovative biotechnology and the law. A Greenwall Faculty Scholar in Bioethics, Ram is a leading expert on genetic privacy and the law, publishing groundbreaking research in *Harvard Law Review*, *Stanford Law Review*, *Columbia Law Review*, *Northwestern Law Review* and *Iowa Law Review*, among others.

“We are very excited to have Natalie join our faculty,” said the program’s director Diane Hoffmann. “Her scholarship on the use of consumer genetic databases for law enforcement purposes raises profound privacy issues for individuals and families. Her work is at the cutting edge of health law and criminal law and has significant policy implications.”

Most recently, she has gained national recognition for her work on issues related to law enforcement access to consumer genetic databases like 23andMe, GEDmatch, and other DNA repositories. Continued on next page.
“It’s really important to make clear the stakes that are involved when law enforcement can exploit genetic data in new ways,” says Ram. “We should carefully consider those stakes before we rubber stamp these new kinds of forensic methods and then find that we’ve sacrificed a whole lot of privacy that we did not intend to sacrifice.”

Professor Ram has written about recent site policy changes at the online genealogy website that law enforcement has recently begun to use to conduct a “forensic technique known as genetic genealogy: a method in which investigators try to link crime scene DNA to DNA from biological relatives in the hopes of generating leads for identifying suspects or remains.” Most famously, law enforcement pursued genetic genealogy to apprehend the man alleged to be the Golden State Killer, a moniker for a criminal supposedly responsible for more than 150 violent crimes in California between 1974 and 1986. Reflecting on this new means of solving crimes, Professor Ram raises important legal and ethical concerns about the constitutionality of such techniques and “the risks of putting so much decision-making power in the hands of a private entity.”

Since investigators cracked the decades-old Golden State Killer case in 2018 using familial identification DNA evidence obtained from GEDmatch, Ram has been consulted regularly by national media outlets. She has appeared on CNN, national radio broadcasts “Science Friday” and “Here & Now,” and been quoted in the Wall Street Journal, Washington Post, and BuzzFeed News. She also has written several op-eds for Slate and published articles in the scientific journals Science and Nature Biotechnology. In her most recent article for Slate, Professor Ram continues her important contributions to the evolving dialogue surrounding issues of innovative DNA technology and resulting privacy concerns.

Ram also is a leading voice in Maryland’s conversation around state regulations on law enforcement access to genetic databases. Last year, she published an article in the Maryland Bar Journal and was invited by a member of the Maryland House of Delegates to testify in Annapolis in support of a bill prohibiting familial searching in DNA databases.

As a former law clerk for Judge Guido Calabresi of the U.S. Court of
Appeals for the Second Circuit and then for Justice Stephen G. Breyer of the U.S. Supreme Court, Professor Ram also has a particularly well-informed perspective on the criminal law implications of the use of such technology by law enforcement.

In an interview with PBS, she discussed the 2018 Supreme Court decision in *Carpenter v. United States*, which held that warrantless searches of cellphone location data are unconstitutional invasions of reasonable expectations of privacy. She noted that “this ruling is likely to apply more broadly to deeply sensitive information shared with a third party, such as genetic data.”

Ram has expanded upon this topic in numerous scholarly works and presentations, including her most recent article on the subject, “Genetic Privacy After Carpenter,” and her presentation on “(In)voluntariness in Forensic Genealogy” at the Harvard Law School’s Consuming Genetics conference in the spring of 2019.

In addition to her significant scholarly contributions to the field of bioethics and privacy, Professor Ram also brings her thorough and energetic teaching style to Maryland law students. Her teaching interests include bioethics, property, intellectual property, civil procedure, and criminal procedure.

Professor Ram studied public and international affairs at the Woodrow Wilson School at Princeton University before receiving a JD from Yale Law School. After completing her clerkships on the U.S. Court of Appeals and the U.S. Supreme Court, Professor Ram practiced law at a firm in Washington, D.C. prior to her work as an assistant professor of law at the University of Baltimore School of Law.

Professor Ram is excited and delighted to join the University of Maryland Francis King Carey School of Law, and in particular about joining the excellent faculty in the Law & Health Care Program. “The Law & Health Care Program is well-established and widely-respected, and I am thrilled to count myself among its faculty. I am excited about the possibilities that joining this program, the law school, and the University of Maryland— with its excellent medical school as well—will bring for my research and teaching.”

Professor Natalie Ram
Professor Diane Hoffmann and Co-Investigators Awarded $1.1M NIH Grant

In August, Professor Diane Hoffmann and an interdisciplinary team of co-investigators from the University of Maryland Baltimore (UMB) were awarded a $1.1 million grant from the National Institutes of Health’s (NIH) National Human Genome Research Institute for their project “Microbiome-Based Diagnostics: Stakeholder Perceptions and Implications for the Regulatory Framework.” The team will study the appropriateness and adequacy of current regulatory frameworks for microbiome-based diagnostic tests and develop comprehensive recommendations for improvement.

This is the third NIH grant Professor Hoffmann, who is the principal investigator (PI), and a number of her current coinvestigators, have received to address regulatory issues associated with new microbiome-based therapies and diagnostics. The first award was to explore regulatory issues for probiotics sold as food and dietary supplements, while their second grant focused on the regulation of microbiota transplants.

Microbiome research has led to promises of using the bacteria in an individual’s gut to diagnose or predict everything from that individual’s propensity for obesity to their mental health, sometimes through at-home testing kits. While much of the research in this area has focused on infectious disease diagnostics, more recent development has focused on tests to identify microbial characteristics or risk factors associated with non-communicable chronic diseases. There are now several commercially available microbiome-based personalized tests. Companies like Viome, DayTwo, uBiome, and Thryve have sold or are selling direct-to-consumer tests claiming to tell you what your microbiome looks like, how it compares to that of others, and what foods you should eat or dietary supplements you should take. These are not “diagnostic” tests, but more like informational or recreational tests, although some companies also try to sell you probiotics that “match up” with your microbiome profile. There are, however, numerous companies with diagnostics in various stages of development that will be able to identify biomarkers for cancer. Some of these tests must be ordered by a physician while others are direct-to-consumer or are contained within “citizen science” projects that provide individuals with information on the composition of their microbiome if they consent to the use of their biological samples in research studies.

The new tests raise new ethical concerns that are similar to those raised in the early days of genetic testing – appropriate communication of test results, concerns about clinical validity and utility (particularly with regard to direct-to-consumer tests), informed consent, privacy and the potential for discrimination and stigma. The Genetic Information Nondiscrimination Act (GINA) of 2008 was passed amid growing concern that information gleaned from genetic testing could result in the stigmatization or discrimination by employers and health insurers against individuals with particular health conditions. Could microbiome-based
diagnostics present a similar risk of stigma and discrimination? If so, will GINA apply to microbiome-based tests?

Other concerns include the potential use of the tests to predict predisposition for disease based on microbial composition without offering any clinical utility. Or, the possibility that the test could uncover disease status or risk as an incidental or secondary finding. For direct-to-consumer products, there is a risk that consumers will be misled by claims that are not supported by the research in addition to the risks associated with providing results to individuals who lack the expertise to understand them. Others have argued that providers ordering these tests may have insufficient expertise to interpret results and rely too heavily on the expertise of the commercial laboratories that sell the tests. In the context of “citizen science” initiatives, there are research ethics concerns particularly with regard to informed consent and the extent to which participants understand the downstream implications of providing biological samples particularly when many risks are as yet unknown.

The UMB team will utilize the expertise and resources of the Schools of Law, Nursing, Pharmacy, and Medicine and their proximity to the University of Maryland Medical Center to take a close look at the implications of this new field of diagnostics. The microbiome project will evaluate the existing legal and regulatory frameworks that apply to these new products and their use and assess patient and provider perspectives on their value, utility, and potential for misuse in order to inform future regulatory approaches for these tools and ensure their appropriate use in patients. The overall goal of the project is to inform and support policy and regulatory approaches that stimulate scientific discovery, identify and address problems or gaps in the current regulatory and legal framework, and encourage innovation while ensuring new microbiome-based products are safe and effective.

“Microbiome-Based Diagnostics: Stakeholder Perceptions and Implications for the Regulatory Framework.”
University of Maryland, Baltimore Co-Investigators

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Director, Law & Health Care Program
Jacob A. France Professor of Health Care Law
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Dr. Anita Tarzian
Associate Professor
School of Nursing

Professor Frank Palumbo
Executive Director, Center on Drugs and Public Policy
School of Pharmacy
Karen Rothenberg, the Marjorie Cook Professor Emeritus of Law, retired this summer after 36 years of teaching at the law school. Professor Rothenberg’s decades long career as a health law scholar, teacher, and mentor includes, among her many other impressive achievements, being the founding director of the Law & Health Care Program (L&HCP) and a former dean of the University of Maryland School of Law.

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I write this article for the newsletter as someone who was mentored by Karen, who has benefited from her wisdom and advocacy, who has collaborated with her on policy initiatives, co-authored articles with her, worked for her as associate dean, co-taught courses with her, and who has been her colleague and friend for over 30 years.

A Career in Three Parts
Part 1
Karen started at the law school in 1983, just a few years before me, and her plan was to develop and grow a law and health care program. She was prescient about the field of health law. After graduating from law school at the University of Virginia, she worked for the law firm of Covington & Burling, in Washington, D.C. where Charles Miller was her mentor. On reflecting on her time at the firm, Miller said:
“I always knew that Karen was destined to be a leader in health law when she joined our firm in 1979 and told me she wanted to develop a health law practice before we knew there was such a field as health law. Karen had the vision to see that we were then on the brink of a great development in this field, and the energy to convert that vision into reality. Her decision to join the University of Maryland faculty and head up the Law & Health Care Program when no one could have told you what such a program really would or should entail further illustrates that she was a true pioneer and destined for great accomplishments.”

In large part, I was hired to help Karen build the L&HCP. For the next dozen years, we worked closely together as colleagues developing the program, teaching and working on our scholarship. As an assistant professor,
Karen was incredibly prolific and, it seemed to me when I arrived, had already made a name for herself in the health law and policy academy. In the first four years of her professorship she had been a legal consultant for the American College of Nurse-Midwives, served on a National Institutes of Health (NIH) consensus panel on the use of diagnostic ultrasound imaging in pregnancy, and led a task force to plan a forum held by the NIH and the International Childbirth Education Association on Medical Malpractice Issues in Obstetrics.

During the next eight years she served on numerous boards, advisory and planning committees, and as an officer or leader in a number of health law organizations. These positions included the Board of Directors of the National Health Law Program, chair of the Association of American Law Schools’ section on Law, Medicine & Health Care, and member of the Institute of Medicine’s Committee on Legal and Ethical Issues Relating to the Inclusion of Women in Clinical Studies.

Early on in her career, Karen developed a relationship with a number of researchers and policy makers at the NIH and spent several sabbaticals and leaves (under the Intergovernmental Personnel Act) at different institutes there. The first was in the spring of 1991 when she worked at the National Institute for Child Health and Human Development. In the course of her work there, she met Elizabeth Thompson and became very interested in newly available prenatal genetic tests and the profound issues they raised for pregnant women. This experience was to be the foundation for much of her early and long-term scholarship. During this time, Karen was focused primarily on women’s health and reproductive issues and women in clinical trials. With the coming of the genetic revolution, Karen became embroiled in the world of prenatal genetic testing, co-editing her first book with Elizabeth Thomson on that topic. It was this work that led to what has become the scholarship for which she is most well-known: legal issues in research and clinical practice involving genetic testing and treatment.

From September of 1995 until May of 1996 Karen spent the academic year at the NIH’s Office of Research on Women’s Heath as a special assistant to the director, Vivian Pinn. There she continued her work on the inclusion of women in clinical trials and expanded her scholarship on genetic issues. From 1995 to 1999, she published numerous articles on such topics as genetic discrimination and health insurance, the challenge of too much genetic information, genetic information and the workplace, cancer genetic susceptibility testing, privacy in genetics research, and cloning.

During this time, she also developed and honed certain positions on significant ethical issues created by genetic testing and genetic research. These included the idea that not all medical/genetic information is a good thing. This idea ran counter to the general medical view at the time that more information is better. However, Karen persuasively argued in a number of forums that sometimes people might not want to know that they are likely to develop a certain disease or disabling condition such as Huntington’s or Alzheimer’s, particularly when there is no cure for the disease. Karen also had strong concerns about discrimination based on the results of genetic testing and published several articles in the prestigious journal, Science, about the potential use of genetic test results by health insurers to deny individuals insurance and by employers who might choose not to hire someone with a predisposition to a serious genetic disease.

Part 2
Karen’s concerns about the use of genetic test results to discriminate led her to help to lay the groundwork for legislation at the federal and state levels that would prohibit the use of such test results by insurers and employers. But her work on this important legislation was put on hold momentarily as she took over as interim dean (1999–2000) and then dean (2000–2009) of the law school. During this time Karen kept up her work on legal and policy issues arising out of the developments in genetics. In particular, she continued her advocacy for the Genetic Information Nondiscrimination Act (GINA), which was ultimately passed by Congress in

**Karen Rothenberg: A Legacy of Innovation and Passion, cont.**

Continued on next page.
Karen Rothenberg: A Legacy of Innovation and Passion, Cont.

2008, and worked with members of the Maryland General Assembly to pass similar legislation in Maryland.

While serving as dean, Karen somehow also managed not only to sit on the newly established Maryland Stem Cell Commission, but also to chair it – a time consuming and demanding job. It was a significant role which required establishing all the procedures, protocols, and policies by which the commission would allocate a several million-dollar budget to Maryland scientists performing stem cell research. Jack Schwartz, who sat on the Stem Cell Commission at the time Karen served as chair, wrote in a tribute to Karen about the controversy that enshrouded the effort to establish a stem cell commission in California but reported that “Karen had the discernment to know that the best path forward for the Maryland effort would be . . . quiet and steadfast professionalism – a scientifically sound grant review process, free of conflicts of interest and political agendas.”

Part 3
In the last phase of her career, after stepping down as dean, Karen married her love of theater with her passion for the ethical, legal, and social issues arising out of research and clinical practice related to genetics and devoted much of her scholarship to the use of plays to explore and mine those issues. She has written articles about plays that many of us have read or seen performed examining the scientific and ethical questions they raise, often foreshadowing some of the current dilemmas we face as a society in whether and how to regulate science. But she also sees plays as vehicles for examining relationships in ways that the study of science alone may not allow. Professor Frank Pasquale commented about how “Karen’s turn to literature recognizes that our plays and poems, stories and films, reveal patterns of power and meaning in the world by exploring the ramifications of critical relationships. They illuminate fundamental aspects of human experience.” While Karen explored the depths of existing literature to illustrate aspects of the human condition affected by science, she was not content to simply analyze the writings of others. In addition, she co-authored several original plays designed specifically to examine some of the intractable dilemmas that current genetics research and clinical practice raise. Often enlisting colleagues to play the actors in her theatrical productions, Karen used these plays as a way to generate conversations between scientists, bioethicists and health law academics and to help researchers understand the difficult decisions patients must make as a result of new genetic information and technologies.

Also, in this phase of her career, Karen spent several years at the NIH as senior advisor to Eric Green, director of the National Human Genome Research Institute (NHGRI) and at the Clinical Center working with Ben Berkman and others. While there Karen developed “the idea for an intensive workshop where students would research and analyze a range of ethical, legal and policy questions raised by the increasing prevalence of human genome sequencing in research.” Karen called on several colleagues at the NIH to serve as supervisors for law students in a non-traditional law school course that was part externship, part seminar and part clinic. In another tribute to Karen, Professor Michael Ulrich, a former student in this innovative class, says he felt empowered as a student to have the opportunity to work with these genetic experts on cutting edge genetic policy issues. He is just one of the many students Karen empowered and inspired in her years of teaching health law.

Conclusion
As Karen’s colleague for the last 32 years I have truly been fortunate. I have been touched by her generosity, creativity, encouragement and friendship. The latter is something I treasure and hope will continue for many years to come.

References
1. Personal email correspondence to Diane E. Hoffmann from Charles Miller (1999).
6. For a description of the course, see Karen H. Rothenberg and Benjamin E. Berkman, Teaching Law Students to be Policymakers: The Health and Science Workshop on Genomic Research, 40 J. L. MED. & ETHICS 147 (2012).
Professor Deborah Weimer started teaching at the University of Maryland School of Law in 1988. She grew up on Long Island and put herself through college at State University of New York, as the first member of her immediate family to attend college, with a combination of jobs, scholarships, and loans. She attended law school at New York University during an exciting time. NYU law faculty and students were deeply involved in the civil rights movement, as well as the antiwar movement, and she worked with other students to create the New York University Public Interest Law Foundation, which funded public interest placements for lawyers, before graduating in 1978.

Although Professor Weimer began her legal career with New York City’s largest municipal public employee union, she soon was awarded a grant by the NYU Foundation to provide legal assistance to disabled textile workers through the Brown Lung Legal Center in Columbia, South Carolina. There she trained lawyers handling workers’ compensation cases and worked hard to increase occupational safety protections and to make the workers’ compensation system more responsive.

In 1982, Professor Weimer joined the Palmetto Legal Services Program in Columbia, South Carolina, adding an employment law specialty to her practice. She litigated in federal and state courts, including wrongful discharge and Fair Labor Standard Act cases, and also handled a “general practice” legal services caseload, all while also chairing a statewide Employment Law Task Force. Early in her career, she was developing the multi-tasking skills that she has used all her professional life.

In 1985, Professor Weimer began a two-year Fellowship at Temple University School of Law, where she collaborated in teaching Civil Trial Advocacy, Bankruptcy, Property, and the Lawyering Process, which included brief writing and oral advocacy. There, she earned her LLM in Legal Education.

In 1987, she moved to Maryland and worked for seven months in a civil rights firm with LGBT clients before being hired at Maryland on a Department of Education grant to establish a medical-legal partnership at the Pediatrics clinic at what is now the University of Maryland Medical Center (UMMC). This was one of the earliest legal-medical clinical partnerships in the country. Professor Weimer quickly expanded it to create one of the first, if not the first, law school clinics in the country serving patients with acquired immune deficiency syndrome (AIDS). When the three-year Department of Education grant ended, the Maryland Legal Services Corporation stepped in and has continued to fund it in significant part for almost 30 years.

Because, especially in the 1980s and 1990s, AIDS was such a fatal disease, the focus of Professor Weimer’s clinics and Legal Theory & Practice courses included not only clients who had tested positive for human immunodeficiency virus (HIV), but also the children of those clients, including some children who were also HIV-positive, and grandparents of those children who had to assume parental responsibilities. These clinics have always had interdisciplinary components, and in one, a research component. One that focused on grandparent families included a formal study to test the effectiveness of the interdisciplinary approach, which Professor Weimer describes, because of this holistic approach, as one of her “most rewarding clinics.” This was a partnership with the Schools of Social Work and Nursing.

Professor Weimer’s scholarship has grown out of her practice. She has been one of the leading scholarly Continued on next page.
voices, in Maryland and nationally, on Standby Guardianship and Foster Care issues for HIV-infected children or the surviving children of parents who died of AIDS, among other topics.

She has received a number of awards for her extraordinary work, including the Maryland Legal Services Corporation’s Benjamin L. Cardin Distinguished Service Award, the University of Maryland Community Service Award, and the Maryland Bar Foundation’s Award for Professional Legal Excellence in the Advancement of Unpopular Causes. The National Jurist Magazine also recognized her AIDS Clinic in a national survey titled “Law Clinics that Make a Difference.” Her work also includes a voluminous amount of presentations, many on interdisciplinary panels, to a wide variety of audiences.

It is daunting, if not impossible, to summarize her legacy, but several central themes emerge.

1. Combining Legal Leadership in the Field and an Extraordinary Education for her Students
Professor Weimer and her students became the legal leaders in Maryland, and early-on nationally, in the legal battle against AIDS and its tragic consequences. Today, our clinic retains that important role. With the advances of medicine, it is focusing on the legal obstacles people living with HIV face in getting life-saving medical care, like health insurance, stable and safe housing (i.e., no mold or lead paint), protection from employment discrimination, and SSDI benefits. Many of her former students, now lawyers practicing throughout Maryland and beyond, have said that their participation in her clinic was the critically important experience in persuading them to embark on legal services and public interest careers or to do substantial amounts of pro bono work in their private practices.

2. Being a Reformer
From 1988 to 1995, Professor Weimer was a member of an interdisciplinary legislative advocacy committee that proposed and supported reforms in Annapolis. From 1993 to 1994 alone, she and her students played key roles in drafting and supporting Maryland’s Standby Guardianship Act, which allows a person facing death to provide for loved ones (for example, by avoiding the unnecessary placement of children in foster care), and Maryland’s Needle Exchange Pilot Program in Baltimore City, for which they drafted the legislation as a way to prevent the spread of HIV. They also won important court decisions, including those proscribing discrimination based on one’s medical condition and requiring informed consent for medical testing and treatment.

3. Exemplifying Leadership and Partnership in the UMB Community
The list of Professor Weimer’s UMB partnerships is long. It includes not only the initial pediatrics project with UMMC, but also the Social Work and Nursing Schools’ grandparents’ project and the formation of many informal relationships among doctors and medical students, nurses and nursing students, social workers and social work students, and Professor Weimer and her law students. These have brought to life one of the purposes of a multi-graduate school campus to engage the disciplines in working with each other, which, in turn, helped make Maryland Carey Law’s Health Law and Clinical Law programs among the best in the country.

4. Introducing Students to the General Practice of Law
Professor Weimer’s clinics have also introduced students to the types of general law practices that sustain solo and small firms, where many Maryland students may end up. This has been an important, often overlooked benefit, that AIDS clinic alumni have emphasized. There is no specialized body of “AIDS law.” Rather, the practice includes many subject matter practices: access to health care, housing, family law, benefits, guardianships, wills, anti-discrimination laws, and more, all of which are integral parts of the AIDS clinic practice.

5. Demonstrating Willingness to Take on New Challenges
The willingness to take on new challenges has been a hallmark of Professor Weimer’s career, demonstrated most recently by her creation of a new Legal Theory & Practice course. Creatively, it combines property and health law issues, including the remediation of mold and lead paint, while also focusing on professional responsibility issues, specifically the misbehaviors of lawyers who oppose unrepresented parties. Students provide legal representation to tenants and write a semester paper about their experiences. She describes this course in a 2017 article in the Hastings and Poverty Law Journal, “Deepening Lawyer Role Education to Serve Students and Society.”
6. Modeling the Qualities of a Good Lawyer
Above and beyond all of her other remarkable achievements, Professor Weimer remains a model of an extraordinary lawyer. She is committed to her clients, often working seven days a week, 52 weeks a year, and sometimes in 24-hour work days, to meet her commitments.

She always pays careful attention to ethical issues and demonstrates that ethical behavior is an essential part of law practice. She displays a creativity and willingness to expand and diversify her practices and courses to meet unmet legal and educational needs. Through it all, she maintains an extremely high standard of professionalism while being a powerful advocate, and remains a superb example not only for her students, but also for her colleagues and every member of the legal profession.

Though she will be greatly missed by the law school community, Professor Weimer’s legacy will undoubtedly continue on through the Medical Partnership Clinic she created, as well as the impact she has had on so many former students, clients, and colleagues. Her impact on the Law & Health Care Program, law school, and state of Maryland will be felt for years to come.

Adapted from a tribute by Professor Michael Millemann.

Visiting Professor Matiangai Sirleaf Brings a Global Perspective to Maryland Carey Law

The Law & Health Care Program welcomes Professor Matiangai Sirleaf, who is a visiting associate professor of law for the 2019 fall semester. Professor Sirleaf brings her extensive scholarly expertise and practical experience in Global Public Health Law, International Human Rights and Criminal Law, and Post-Conflict and Transitional Justice, to the law school. She is currently an assistant professor of law at the University of Pittsburgh Law School, where she received the Chancellor’s Distinguished Research Award in 2019. Her work focuses on remedying the accountability and responsibility gaps that exist in international law. Her current research focuses on the disproportionate distribution of highly-infectious diseases and the role of law in facilitating this result. Professor Sirleaf was also recently awarded a Social Science Research Initiative grant for her proposal, “Understanding the Development and Impact of Neglected Tropical Diseases (NTDs) – 1950 to Present.” In addition, she was selected to present her paper “Disposable Bodies and Experimental Trials” at the 2019 Health Law Scholars Workshop jointly sponsored by St. Louis University School of Law and the American Society of Law, Medicine & Ethics.
The Law & Health Care Program is pleased to announce the appointment of Rebecca Hall as its new managing director. Hall is a 2013 graduate of Maryland Carey Law and the health law certificate program, and has practiced health law in the Baltimore and DC area since graduation, first representing the University of Maryland Faculty Physicians in downtown Baltimore and, most recently, splitting her time between Rockville and Hunt Valley as senior associate counsel for the nation’s leading network of pain management practices. She also draws on her experience prior to and during law school, which includes work for UnitedHealth Group, the Medicaid Fraud Control Unit of the Maryland Office of the Attorney General, the Court of Special Appeals of Maryland, and the Maryland General Assembly.

During her time as a health law student, Hall participated in numerous health law competitions, including the inaugural Health Law Regulatory & Compliance Competition, and led the *Journal of Health Care Law & Policy* as its editor in chief. Since graduating, Hall has remained involved in the program as a repeat judge of the Regulatory & Compliance Competition, student mentor, competition team advisor, and internship supervisor. Hall is thrilled to return to the Health Law Program at this exciting time. On starting the job she remarked: “Having been involved in almost every aspect of the program as a student, alumnus, and mentor, I am extremely excited to return to the law school in this capacity to encourage the next generation of health lawyers while continuing to build on the program’s excellent reputation for producing outstanding scholarship and exemplary practitioners. I look forward to getting to know each and every health law student and to engaging with our extensive alumni network to continue the program’s leadership in health law education and scholarship in my hometown of Baltimore and nationwide.”

In May, Lauren Levy, former managing director of the Law & Health Care Program, was appointed health officer for the Cecil County Health Department. Levy worked closely with Program Director Diane Hoffmann from July 2017 until May 2019, overseeing the program’s externships and nurturing the Law & Health Care Program. The health officer position marks a return of sorts for Levy, who worked in public health research and program management for many years before returning to school to complete her law degree as an evening student. In her new role, Levy serves as the executive officer for the agency, which employs 140 staff across six divisions.

“It has been a steep learning curve,” Levy said. “The health department is involved in a diverse range of activities – from treatment for substance use disorder to STD testing to diabetes prevention and environmental health, among many others. I have learned a lot in just a few short months.”

Levy credits her training through the Law & Health Care Program with helping her to navigate the new role. “Having the grounding in health law and policy has been invaluable. I am relying on the research and analytical skills I developed as a student in the health law program on a daily basis.”

Levy is excited to stay involved with the health law program as a member of the policy committee of the Maryland Association of County Health Officers, a group that works closely with the Legal Resource Center for Public Health Policy, led by Professor Kathi Hoke. “It was a difficult decision to leave the Law & Health Care Program. I am so glad to have the opportunity to continue working with the program’s stellar faculty, staff and students to develop policy approaches to address our most pressing public health challenges.”
Pain & the Law: Professor Diane Hoffmann Shares Expertise with Audiences from Coast to Coast

Professor Diane Hoffmann, director of the Law & Health Care Program and Jacob A. France Professor of Health Care Law at the University of Maryland Francis King Carey School of Law, has written and spoken extensively about legal obstacles to, and gender disparity in, the treatment of pain. Over the summer, she shared her expertise on these topics in several fora.

On June 19, 2019, the University of Maryland, Baltimore (UMB) held a forum to share the work being conducted across disciplines on campus to better understand, treat, and modify the impact of chronic pain. Held in Baltimore, the event was moderated by Joel Greenberg, co-director of the University of Maryland Center to Advance Chronic Pain Research (CACPR). Professor Hoffmann was one of four expert panelists. Also presenting were Luana Colloca, associate professor at the University of Maryland School of Nursing and associate professor at the University of Maryland School of Medicine (UMSOM); Marcela Romero-Reyes, clinical associate professor at University of Maryland School of Dentistry (UMSOD) and clinical director of its Brotman Facial Pain Clinic; and Asaf Keller, professor at UMSOM. All are members of CACPR, and Hoffmann and Keller are on its executive committee. The multidisciplinary center is composed of nationally and internationally renowned clinical and preclinical translational scientists. The principal research focus of CACPR members is on the physiological, genetic, and psychosocial underpinnings of the development and persistence of debilitating chronic pain conditions.

Greenspan, professor and chair of the UMSOD Department of Neural and Pain Sciences, characterized chronic pain as a high-impact, complex problem affecting the quality of life of millions of U.S. residents who are kept from doing the things they need or want to do. “We’ve got a wide swath of talent,” he said, referring to UMB’s top-tier scientists and clinicians, adding that such breadth is needed to continue making progress.

Hoffmann spoke about the current state of chronic pain in the aftermath of the opioid epidemic and the crackdown by law enforcement on physicians prescribing large volumes of opioids. This in turn has frightened physicians, causing many to “stop seeing chronic pain patients or tapering them off of opioids involuntarily, literally abandoning them,” she said. “In some cases, such abrupt removal of opioid treatment has led to suicides,” she added. This kind of abandonment can be grounds for malpractice or action by state medical boards. Hoffmann attributed the situation in part to the actions of over half of state legislatures to codify specific dosage and duration limits for opioid prescribers based on a prescribing guideline issued in 2016 by the Centers for Disease Control and Prevention (CDC). The guideline, however, was intended as a discretionary suggestion for primary care providers not as a mandatory rule. In response, last December, Hoffmann and colleagues published an article in STAT, “Overzealous use of the
CDC’s opioid prescribing guideline is harming pain patients,” about the situation and she and other pain-treatment advocates urged adoption of more compassionate tapering, among other things. However, in April, she noted, authors of the CDC guideline, alarmed by reports of its misuse, published a commentary in a prominent medical journal advising against its misapplication, which, they acknowledged, can risk patient health and safety. “I’m hopeful this is a first step in efforts to rectify overzealous application of the CDC guideline,” she told the group.

Panelist Asaf Keller, from the School of Medicine, described an initiative of the University of Maryland Strategic Partnership: MPowering the State that supports both professionals in the field and university students across disciplines. “Clearly what is needed is a much more rational approach to pain management in general and to opioid prescription in particular. We are addressing this issue at all the schools on campus,” he said, describing ways of imparting knowledge necessary to apply this rational approach. Keller also outlined other efforts such as a “cuddling” initiative to help babies who are in misery after being born with neonatal opioid abstinence syndrome. These infants, born to mothers who used opioids during pregnancy, fare better if provided skin-to-skin contact. “It’s very low cost, very low-tech,” he said.

Romero-Reyes, a researcher and clinician at the Dental School, said her focus is to provide evidence-based pain management for facial pain. Such pain can have multiple causes. “As a clinician, I have the opportunity to see firsthand the needs of this patient population,” she said. “As a scientist, I’m able to translate those needs to research questions,” such as current studies on overcoming neuropathic pain.

Colloca, a faculty member at the School of Nursing, asked the group, “How can we better manage pain?” Demand is great for solutions beyond opioids, and a patient’s own mindset could be part of the solution. Colloca suggested that patients be asked to describe their pain levels not as a number, ascending from mild to severe, but rather as a ranking of everyday activities they can do. She also proposed thinking about approaches to help people increase their tolerance of pain, perhaps by stimulating the brain to produce natural substances that combat pain messages or by distractions such as a virtual reality.

At the outset of the forum, guests at the event had a chance to try a virtual reality simulation used by Colloca in her research, as a potential distraction to pain. Several took part in a demonstration in which a headset took each individual to an undersea setting where a whale loomed overhead. Members of Colloca’s lab were eager to show off its research, which is also supported by MPowering the State.

During a question-and-answer session to conclude the event, guests shared observations and problems of their own or of family members who struggle with chronic pain. Patient Dante Wheatley was accompanied by his mother, dental assistant Kim Jones, and by her employer, Willie Richardson, DDS, who all spoke of how chronic, high-impact pain has affected Wheatley’s daily life.

Hoffmann also spoke at several other events related to chronic pain over the summer. In July, she spoke at the Healthy Women Science, Innovation & Technology Summit on Chronic Pain in Women, focusing her remarks on disparities in the treatment of women for chronic pain. On August 14th, Hoffmann traveled to Sacramento, California where she participated in a legislative briefing on chronic pain. Hoffmann, along with other pain experts including Sean Mackey, chief of the Division of Pain Management at Stanford University, Christin Veasley, director of the Chronic Pain Research Alliance, and Steven Richeimer, chief of Pain Medicine, University of Southern California, urged the California legislature to adopt several recommendations to improve chronic pain treatment.

Hoffmann and these experts developed the recommendations as part of a California Pain Summit, held last November in Los Angeles by For Grace, a non-profit organization that advocates for better care and treatment of women with chronic pain. Hoffmann is on the Board of For Grace.
The Public Health Law Clinic and Network for Public Health Law Continue to Influence State Policy on Cannabis Regulation

In 2014, the Maryland General Assembly passed legislation permitting the use of cannabis for certain medical conditions and the creation of a medical cannabis industry, from growers to distributors. The state’s medical cannabis system, which allows patients with qualifying conditions certified by an authorized health care provider to acquire cannabis from licensed dispensaries, opened for business in December 2017. Medical cannabis in Maryland has generated a whirlwind of legal, public health, and social justice issues, not the least of which is the fact that cannabis (marijuana) is still defined by the federal government as a “Schedule I drug,” “with no currently accepted medical use and a high potential for abuse” under the Controlled Substances Act, making it illegal under federal law to use, even for medicinal purposes. The University of Maryland Francis King Carey School of Law and the Network for Public Health Law have been at the forefront of addressing these complicated challenges to ensure a safe, efficient, and equitable medical cannabis system.

The Public Health Law Clinic, directed by Professor Kathleen Hoke, has been involved in Maryland’s medical cannabis program since its inception. The clinic has played a key role in educating Maryland’s public health community by tracking and reporting on cannabis legislation every session. In addition, under Professor Hoke’s guidance, clinic students have advocated for key cannabis legislation in Annapolis. This past session, clinic student John Travers ’19 testified in support of legislation that would have authorized institutions of higher education and related medical facilities, like the University of Maryland, Baltimore (UMB), to conduct research related to medical cannabis. Clinic student Kevin Redden ’20 testified in support of a Senate bill that would have prohibited the revocation of parole based on use or possession of cannabis for qualified patients and licensed individuals in the cannabis industry. Redden testified that punishing parolees who are certified patients or licensees within the state-created medical cannabis industry subverts the goals of the medical cannabis program and is detrimental to public health. The provisions in these bills were absorbed into a larger medical cannabis bill, Maryland House Bill 17/Senate Bill 857, which passed in the State Senate and the House of Representatives. Governor Larry Hogan signed the legislation in April and it went into effect on July 1.

In addition to her work with the Public Health Law Clinic, Professor Hoke is the executive director of the Network for Public Health Law’s Eastern Region. The Network for Public Health Law is a national organization funded by the Robert Wood Johnson Foundation. The network’s Eastern Region is housed in the law school. The network provides legal assistance on a broad spectrum of public health issues, including the regulation of cannabis. Eastern Region Associate Director Mathew Swinburne ’08 is the network’s expert on the legal and public health issues associated with cannabis. He regularly meets with health departments, health care providers, hospitals, business and professional associations, law enforcement, and government officials to provide guidance on a myriad of legal challenges. The broad spectrum of concerns he hears about include illegal youth access, employment drug testing, medical cannabis use in public housing, product safety, and over-the-counter sales of CBD products.

Given the outpouring of interest in legal issues raised by the state’s
School of Pharmacy Offers MS in Medical Cannabis

The University of Maryland, Baltimore (UMB) continues to lead the field of medical marijuana through initiatives in its other professional schools. The School of Pharmacy recently launched a new and unique Master of Science (MS) in Medical Cannabis Science and Therapeutics to provide students with the knowledge and skills needed to support patients and the medical cannabis industry, add to existing research in the field, and develop well-informed medical cannabis policy. The MS in Medical Cannabis Science and Therapeutics is the first graduate program in the country dedicated to the study of medical cannabis. It aims to meet the needs of all individuals interested in advancing their knowledge about medical cannabis, including health care professionals such as physicians, nurses, and pharmacists; scientists and regulators; growers and dispensary owners; and policy and industry professionals.

“Medical cannabis has been legalized in 33 states, including Maryland, as well as in Washington, D.C., Guam, and Puerto Rico,” says Natalie D. Eddington, dean and professor of the School of Pharmacy. “This number is only expected to increase in the future, fueling a demand for an educated workforce that is well-trained in both the science and therapeutic effects associated with this medicinal plant.

Graduates of the program will be able to help identify patients appropriate for medical cannabis therapy and determine appropriate dosing and administration for those patients; ensure the safe and effective design, development, and manufacture of medical cannabis products; identify potential research opportunities related to the science and health effects of the cannabinoids found in medical cannabis; and participate in health policy decision-making processes related to medical cannabis. Coursework will include a class on federal and state cannabis laws and policies.

The Public Health Law Clinic and Network for Public Health Law Continue to Influence State Policy on Cannabis Regulation, cont.

medical cannabis program, the law school, the Network, and the Maryland Commission on Civil Rights co-sponsored a conference at Maryland Carey Law this past May. The conference focused on the evolving legal landscape for medical cannabis at the federal and state level, the science of medical cannabis, and issues of employment and housing law that impact employees and tenants who use medical marijuana. As a result of this conference and the network’s recognized expertise, Hoke and Swinburne were invited to be part of the Maryland Medical Cannabis Commission’s workgroup that is developing regulations for Maryland’s newly legalized edible cannabis products (e.g. cannabis infused cookies and candies). Edible cannabis products create unique public health challenges including their attractiveness to children, food safety concerns, and potential dosing problems. The Maryland Medical Cannabis Commission also posted draft regulations on edibles, which are available at http://bit.ly/2kp05Se.

Regulation of cannabis continues to advance in Maryland at a blistering pace. Several bills were introduced this past session to legalize recreational cannabis in Maryland, all of which died in committee. However, the General Assembly created a bipartisan workgroup of senators and delegates to study the implications of a recreational cannabis system and to make recommendations for potential legislation in 2020. Again, the legislature reached out for the network’s expertise. Swinburne conducted multiple presentations for the work group on federal regulation of cannabis and the variety of state approaches to regulating recreational cannabis use.

As the cannabis industry continues to grow and the laws regulating it evolve, the University of Maryland Francis King Carey School of Law and the Network for Public Health Law will continue to be a critical resource at the vanguard of this field.
Kathleen Hoke
was quoted in *Mother Jones*’ “Juuls Campaign to Raise the Tobacco Age is More Complicated than it Seems” on August 22.

“Though legislation to raise the legal age for tobacco consumption to 21 may sound like a move to protect youth from harmful health effects, experts say it’s more complicated than that. ‘We see that they want to put this out there to make it look like they’re the good guy,’ Hoke says. ‘But they’re not really trying. They don’t expect it to really hurt their business.’ The legislation would have a ‘negligible’ impact on smoking, she says. Without dedicated enforcement—which fluctuates with state budgets and is complicated by the internet marketplace—raising the age limit may not do much. Raising the age to 21... could prohibit local governments from passing measures that could also alter teen use, like banning flavored tobacco.”

Rena Steinzor
was quoted in *Propublica*’s “The Car Seat Industry Helped Delay a Child Safety Regulation — Again” on August 20.

“Consumer advocates have raised concerns about the delays. ‘I don’t understand why anyone hasn’t sued,’ said Rena Steinzor, a professor of administrative law at the University of Maryland School of Law. An agency can be sued for unreasonable delays in implementing regulations or for failing to meet a deadline specified by Congress. ‘Unless they are worried that the Trump [National Highway Traffic Safety Administration] would come up with a very weak rule,’ she added.”

Frank Pasquale
was quoted in “Health Data Outside HIPAA: The Wild West of Unprotected Personal Data” in *The Health Care Blog* on August 12.

“Quoted in the NCVHS report, Law Professor Frank Pasquale concluded that for health data outside the healthcare sector, ‘in many respects, it is anything goes.’”

Natalie Ram
was quoted in “Customers Handed Over Their DNA. The Company Let the FBI Take a Look” in *The Wall Street Journal* on August 22.

“Taking a DNA test does not just tell a story about me. DNA tests inevitably reveal information about many other people too, without their consent,” says Natalie Ram, an associate professor of law at the University of Maryland Francis King Carey School of Law, who studies genetic privacy. “Should genetic databases be allowed to make up the rules as they go along?” ... Ms. Ram, of the University of Maryland, thinks consumers should be required to take affirmative steps to opt in to law-enforcement matching, rather than having to decide to take steps to opt out.”
At the 2019 Reception for Health Law Certificate Graduates, held at Westminster Hall on May 17, the Law & Health Care Program, along with many members of its more than 20 full time faculty and adjunct instructors, celebrated the successes of each of the 25 exemplary health law certificate students. This was the 22nd year that the Law & Health Care Program awarded Health Law Certificates to students who completed the concentration in health law, which 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. Most of the students went well beyond the minimum health law credits and engaged in numerous and varied externships and activities, which made the L&HCP class of 2019 a wonderfully rich and active group of students.

Many certificate recipients showed outstanding leadership throughout their law school careers, including at the helm of the Journal of Health Care Law and Policy, which serves as a forum for the interdisciplinary discussion of leading issues in health law, medicine, and health policy, and the Student Health Law Organization, which does a wonderful job of developing events and opportunities for students. Other health law students represented the law school proudly in the national health law competitions, including fielding a strong team in Maryland Carey Law’s Health Law Regulatory and Compliance Competition. These are just a few of the impressive endeavors undertaken by this special group of students.

Health law students often come to the program with impressive academic credentials from other prestigious institutions. Many of this year’s graduates have advanced degrees, including master’s or doctoral degrees in Pharmacy, Public Health, and Business Administration. Certificate recipients will go on to work in a variety of impressive jobs, including in large law firms, federal agencies, and judicial clerkships, but every recipient graduates well prepared for a successful, rewarding career in health law and policy. Below, we highlight just a few of our exceptional 2019 graduates and their achievements.

### 2019 Health Law Certificate Recipients

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<tr>
<th>Ashley Creech</th>
<th>Yuezhu Liu</th>
<th>Alec Prechtel</th>
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<td>Wenjia Ma</td>
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<td>Sarah Wicks</td>
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<td>Laura Daube</td>
<td>Laura Macherelli</td>
<td>Timothy P. Scott, Jr.</td>
<td>Ellis Zapas</td>
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<td>Lysette Alicia Deshields</td>
<td>Harriyah Narnor</td>
<td>Kiamesha Diamond Stewart</td>
<td>Vanessa Zehnder</td>
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<td>Tessa Devereaux</td>
<td>Ariel Neumann</td>
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<td>Jaclyn Fonteyne</td>
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<td>Moyosore Olayimika Koya</td>
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**Ashley Creech**

Ashley Creech was a keen student of health law and leader on campus and beyond. Ashley was an outstanding leader for the *Journal of Health Care Law and Policy* as its editor-in-chief. She inspired the entire board and group of editors to carefully and expertly prepare articles for publication, and together, they ensured that the journal remains an impressive venue for serious research. Ashley also mentored a very busy and high-achieving group of students, and her work leading the journal received the highest praise from faculty leaders. According to Professor Frank Pasquale, faculty advisor for the *Journal of Health Care Law and Policy*, who had Ashley in his class, Ashley is also an extraordinarily conscientious and thoughtful student. Ashley writes compellingly and her work is very carefully considered. In the classroom, Ashley dedicated herself to mastering the material, especially in the very comprehensive and challenging Health Care Law and Policy course. Professor Pasquale also described her as “terrific” and “involved in the law school community and beyond,” stating that Ashley “will be an excellent counselor to both business and government leaders.” Ashley will begin her legal career at Epstein, Becker & Green, P.C.
Lysette Deshields

Lysette Deshields came to the law school already having another professional degree, a Doctor of Pharmacy. And, already having a full-time job at the Food and Drug Administration (FDA) as a regulatory officer, Lysette came to Maryland as an evening student. She is also a lieutenant commander in the U.S. Public Health Service. Professor Diane Hoffmann met Lysette in the spring of 2017 when she was a student in Hoffmann’s Critical Issues in Health Care course, a multidisciplinary course that includes law, medicine, nursing, pharmacy, social work, graduate public health and sometimes dental students. Hoffmann remembers that “although she was quiet in the class, Lysette ended up with the highest grade of any law student.” Lysette’s law school work showed that in addition to the analytical skills she honed in pharmacy and law school, Lysette is a compassionate person who cares about others and is family oriented. Her outside experience includes having delivered patient counseling and drug utilization review for patients during a Haiti Medical Mission. Hoffmann remarked that Lysette’s “combination of analytical skills and compassion for others will serve her well as she pursues a career that takes advantage of her background as both a pharmacist and now a lawyer.” Lysette will put these skills to good use as she continues her career at the FDA’s Office of Compliance.

Jaclyn Fonteyne

Jaclyn Fonteyne has been described by her clinical supervisor, Professor Kathleen Hoke, as having a “larger than life presence in the Public Health Law Clinic.” Her success in the clinic and beyond can be attributed not only to her positive attitude, but also to her ability to receive advice and turn in a final work product that reflected her strong researching and writing skills as well as her ability to listen and incorporate feedback. Jaclyn has a special interest in food and drug law, which she put to good use as a Public Health Law Clinic student. One of the projects Jaclyn worked on during her time in the clinic was testimony before the Maryland House and Senate on a bill that will take effect this fall making 21 the new minimum age for purchasing tobacco products in the state. According to Hoke, “Jaclyn was poised and engaging during her testimony, but her substantive contributions to the bill behind the scenes were just as valuable.” In addition to her clinical work, Jaclyn was involved in many other student organizations and activities, including as an editor of the Maryland Law Review, peer advisor, teaching fellow, and member of the Alternative Dispute Resolution Team and the Student Health Law Organization. Among her other attributes, Jaclyn is also fluent in both French and German, having worked for a pharmaceutical company in Germany prior to law school. Jaclyn started in the Food, Drug, and Medical Device Regulatory Practice of Sidley Austin LLP’s Washington, D.C. office this fall.

Sarah Wicks

Sarah Wicks began her legal career at Hyman, Phelps & McNamara, P.C. this fall, where she is serving clients in the pharmaceutical and biotechnology industry using her strong knowledge of regulations and intellectual property transactions. Her law school record clearly shows her devotion to mastering those subject areas. During law school, Sarah served as a research assistant for faculty members and the Mississippi Center for Justice, a student attorney in the Intellectual Property Clinic, and a healthcare consulting firm intern at the United States Court of Federal Claims, the FDA, and a major pharmaceutical company, to name just a few of her many valuable experiences. During law school, she also earned her master’s degree in Public Health from the Johns Hopkins Bloomberg School of Public Health. She was a member of the Journal of Health Care Law and Policy, the Maryland Intellectual Property Student Association, and the Student Health Law Organization, and she co-authored a paper published in April in the International Journal of Pharmaceutics. There is no doubt that Sarah will excel in the legal profession, just as she did at Maryland.
9th Annual Health Law Regulatory and Compliance Competition

The Health Law Regulatory and Compliance Competition is a unique and innovative competition that challenges students to navigate through the complex regulatory landscape of health care law, including compliance with health care regulations and FDA law. The competition will be held on Saturday, February 22, 2019, from 8:00 a.m. until 3:00 p.m. at the University of Maryland Francis King Carey School of Law in Baltimore, Maryland.

About the Competition
The competition requires teams of 2-3 students to analyze a hypothetical fact pattern involving various interactions between health care stakeholders and entities participating in several health care activities that necessitate regulatory and compliance oversight. The fact pattern will be given to teams the day of the completion, and students will have approximately 1.5 hours to analyze the problem. Teams will then present their findings and recommendations to a panel of practicing regulatory and compliance attorneys. The 9th annual competition will focus on several interactions between various health care stakeholders, including hospitals, physicians, drug and device manufacturers and related third parties.

Call to Compete
If you would like to have a team from your law school participate in the competition, you can find additional details and information about how to register at https://www.law.umaryland.edu/Programs-and-Impact/Health-Law/HLRCC/.