

LAW & HEALTH CARE

PROGRAM



FROM THE DIRECTOR

This has been a busy year for the Law & Health Care Program. We celebrated the 20th Anniversary of the Journal of Health Care Law & Policy, hosted the 7th Annual Health Law Regulatory and Compliance Competition, welcomed 2018 Rome Lecturer, Dr. Aaron Kesselheim of the Harvard School of Medicine, and collaborated with the Johns Hopkins Berman Institute of Bioethics on a joint faculty retreat. In this issue, we also highlight the work on the opioid epidemic of L&HCP faculty, as well as faculty and staff from our affiliate programs, the Center for Health and Homeland Security and the Legal Resource Center for Public Health Policy. We hope you enjoy our Summer Issue.

MARYLAND CAREY LAW FACULTY ADDRESS THE OPIOID EPIDEMIC

The opioid epidemic in the United States remains a serious public health concern with severe negative consequences for the individuals struggling with addiction, their families, and surrounding communities. In 2016, the most recent year for which data are available, more than 11 million people misused prescription opioid medication and more than 42,000 individuals died as a result of an opioid overdose (i.e. overdose from prescription opioids, heroin, and fentanyl).^{1,2} In recognition of the devastating impact of opioid abuse, in October 2017, the Acting Secretary of Health and Human Services declared the opioid crisis a public health emergency.³

Faculty and staff within the Law & Health Care Program at the University of Maryland Francis King Carey School of Law have been actively engaged in research, clinical work, and advocacy related to the epidemic. Professor Amanda Pustilnik recently completed an analysis of the origins of the epidemic and conditions, particularly the legal and policy factors, which contributed to its spread. Her research on the epidemic was included as a chapter in the Aspen Institute's report "Confronting Our Nation's Opioid Crisis," published in late 2017.⁴ *(Continued on next page)*



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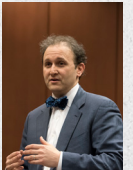
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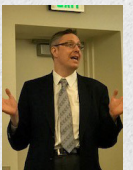
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The *Law & Health Care Newsletter* is published by the Law & Health Care Program at the University of Maryland Francis King Carey School of Law
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In “The Law’s Responses to the Opioid Epidemic,” Pustilnik provides a comprehensive overview of the events (namely approval of OxyContin in 1996), agencies (FDA, DEA, CMS, among others) and laws (such as the Controlled Substances Act) that have played a part in the increased use of opioids and subsequent spike in rates of addiction and overdose. As Pustilnik notes, the “large set of actors, with quite disparate mandates, powers and policies can create inconsistencies and coordination problems in responding to the national drug epidemic.”²⁴ At the same time, however, this complex framework provides opportunity for innovative legal approaches.

At the federal level, there was a push during the Obama Administration to integrate efforts in the health and criminal law contexts with an emphasis on treatment and improved care, an acknowledgement that previous efforts focused on punitive measures and incarceration had been ineffective in addressing the crisis. Under the current administration, the future direction of federal policy is unclear. As a result, much of the push for innovative approaches to the opioid epidemic is occurring at the state level. There is, for example, increasing reliance on data to allow states to identify troubling prescription patterns and high-risk areas and individuals. Prescription drug monitoring programs (PDMPs) are one example of this type of data-driven initiative. States are able to identify providers engaged in questionable prescribing practices as well as patients who may be doctor shopping.

Other efforts at the state level include increased funding and expanded access to medication-assisted treatment, such as methadone, which has demonstrated higher effectiveness than more conventional addiction recovery programs. Harm reduction is another increasingly popular approach

among legislators. Safe injection facilities that allow individuals to use drugs under medical supervision have been opened in West Virginia and Washington State with similar legislation pending in several other states. Other legislative harm reduction strategies include so-called Good Samaritan and safe harbor laws that are designed to encourage individuals to seek assistance in the case of drug overdose without fear of criminal prosecution or other legal repercussions.



Prof. Amanda Pustilnik

There remain, however, significant legal obstacles to local, state and federal efforts to curb opioid abuse. These include conflicts between these new legislative efforts and existing federal laws grounded in an outdated perspective on drug addiction as a moral failure and a voluntary behavior that governments should not incentivize through provision of treatment services.

Evidence of substance abuse can prevent access to social services programs such as Medicaid, the Supplemental Nutritional Assistance Program and Temporary Assistance for Needy Families. According to Prof. Pustilnik’s analysis, as of March 2017, fifteen states mandated drug testing for recipients of state-administered federal benefit programs. Such rules have an inherent conflict with evidence-based approaches to the epidemic that emphasize access to treatment.

As Pustilnik notes, opioid manufacturers have been able to reap tremendous profits through product sales but do not bear any of the costs associated with improper use and abuse of that product. That cost is borne largely by state and federal government and ultimately taxpayers. Pustilnik argues that lawmakers should adopt approaches that have been successful for other public health issues such as tobacco, drunk driving, and environmental pollution. These models, she argues, have been successful in their ability to align commercial interest with the public interest by establishing penalties and other sanctions that will provide incentives for responsible corporate behavior. She likens pharmaceutical companies to bar operators – once civil and criminal penalties were imposed and enforced on operators for selling excess amounts of alcohol to patrons. Approaches that rely on individual court cases, however, are unlikely to have a large-scale deterrent effect.

The Tobacco Master Settlement Agreement serves as another potential model. There are clear parallels between the tobacco and opioid industries – misrepresentations of product risks and aggressive marketing, among others. The Settlement provides significant compensation to states and places strict restrictions on tobacco marketing. Such a model could be employed in the opioid context as well. The model's strengths lie in its ability to begin to shift the costs of the epidemic back to manufacturers and may serve as a more effective national strategy versus a case-by-case litigation approach.

The epidemic of opioid abuse must be addressed at all levels, i.e., local, state and federal, with a multifaceted approach that includes public health and medical professionals as well as policy, judicial, and law enforcement

entities. In order to adequately address the root causes of the epidemic, however, Pustilnik makes a convincing argument that legal approaches must focus on the actions of drug manufacturers.

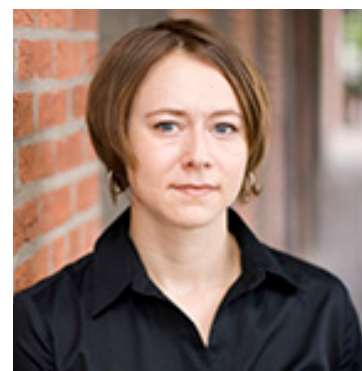
University of Maryland Center for Health & Homeland Security Aids in Maryland's Response

In Maryland, opioid-related deaths nearly quadrupled between 2010 and 2016 (final numbers for 2017 are still pending but suggest that rates continue to rise). In response, in March 2017, Maryland Governor Larry Hogan declared the opioid addiction crisis a state of emergency. Since the declaration, the staff at the University of Maryland Center for Health and Homeland Security (CHHS) has been actively engaged in a statewide, multiagency effort to combat and prevent opioid addiction, overdose and death.

CHHS staff member Birch Barron is currently serving as Deputy Director and Chief of Staff to Clay Lance, the Senior Emergency Management Advisor to the Governor, at the Opioid Operational Command Center (OCCC), the body responsible for coordinating the state's opioid response. Prior to the establishment of the OCCC, many agencies at the state and local level were working to address the opioid epidemic but there was little communication or coordination between agencies or dissemination of best practices and lessons learned.

The OCCC provides statewide coordination of the many stakeholders involved in addressing the crisis, including the Maryland Emergency Management Agency (MEMA), the Maryland Department of Health (MDH) as well as ten other state agencies and representatives from all twenty-four counties in the state.

Other members of the CHHS team are also contributing to the effort. Trudy Henson '08, CHHS Public Health Program Director, and Michael Tension '15, Senior Law & Policy Analyst, have been collaborating with MEMA and the OCCC to write the OCCC review and transition report. The report examines activities undertaken since the declaration, identifies the legal issues that may arise during a transition out of the state of emergency and provides a framework for that transition. The report was completed in late February but has not yet been released to the public.



Trudy Henson

Maryland's approach to the opioid crisis, as a state of emergency rather than a public health emergency, raises many legal and policy issues. Trudy Henson examines these with students in her course Law and Policy of Emergency Public Health Response. Prof. Henson notes, "One reason that Maryland chose to address the opioid crisis under a general state of emergency is that such a declaration gives the Maryland Emergency Management Agency jurisdiction and one of MEMA's strengths is its ability to coordinate resources as well as its incident command structure that provides a ready-made framework for the response. This approach recognizes that the opioid crisis is not only a public health issue but a problem that has wide repercussions for education, housing, and law enforcement among

(Continued on page 5)

WHAT ABOUT TREATMENT FOR CHRONIC PAIN?

In all of the debate surrounding the opioid epidemic, an important segment of the population is often forgotten – patients suffering from chronic pain for which opioid medication remains the only effective treatment. Diane Hoffmann, Professor and Director of the Law & Health Care Program, has a longstanding research interest in the treatment of chronic pain. In 1997, Hoffmann was named a Mayday Scholar by the Mayday Foundation, an organization dedicated to alleviating the incidence and consequence of chronic pain. As a result of that award, she has been able to examine the issue in depth and make important contributions to the literature regarding the legal obstacles to the treatment of pain.

Hoffmann continues to examine the impact of the latest policy developments resulting from the opioid epidemic. In fall 2017, she spoke to clinicians and researchers during Pain Grand Rounds in the Department of Neurology and Neurosurgery at the Johns Hopkins School of Medicine. In her talk “Legal and Ethical Challenges to the Treatment of Chronic Pain Patients,” Prof. Hoffmann reviewed the collateral damage of prior attempts to address the issue of opioid overprescribing, namely disciplinary and prosecutorial actions against physicians treating chronic pain patients within the standard of care. This was due in part to a lack of understanding of chronic pain treatment on the part of federal agencies and state licensing boards responsible for oversight of physicians. Indeed, these entities have struggled to establish and enforce a consistent standard for opioid prescriptions.

At the same time, there has been considerable pressure for state and federal agencies to respond to the rapid increase in rates of opioid misuse and abuse. After many years without a consistent policy, in 2016, the CDC issued guidelines for prescribing opioids to treat chronic pain. The guidelines emphasize the importance of prescribing only when necessary, at the lowest dose and for the shortest duration possible and only in the context of close patient monitoring. The guidelines have spurred legislative action in many states and include efforts to limit dosage and quantity of opioid prescribing. Many state Medicaid Programs have also adopted the CDC guidelines and DEA has stepped up its enforcement, with a significant increase in the number of administrative actions against physicians to remove their registration to prescribe controlled substances as well as criminal prosecutions.

“I think it’s clear now in hindsight that the policy pendulum swung too far in the direction of liberalization of opioid prescribing. Now I fear the pendulum is swinging too far in the direction of restrictiveness,” said Hoffmann. “In the effort to combat the opioid epidemic, state and federal authorities are depriving patients of an appropriate and effective treatment for chronic pain.” Recently, Hoffmann co-wrote a letter to the editor of the Washington Post, making these points in response to an op-ed criticizing an effort by Human Rights Watch to look at the effects of opioid limits on the treatment of chronic pain (see Hoffmann and Nicholson, Reasonable Questions on Opioids, Washington Post, May 16, 2018).

many others.”

Local Level Approaches: The Legal Resource Center for Public Health Policy

The Legal Resource Center for Public Health Policy (LRC), led by Professor Kathleen Hoke, has been working in the area of addictions since its founding in 2001. Originally created with funds from Maryland’s settlement with tobacco companies, the Center provides legal guidance to state and local governments, lawmakers, non-governmental organizations and health advocacy groups. In the nearly twenty years that the Center has been working with local health officers, its attorneys and staff have developed a strong reputation as a reliable resource for legal and technical assistance. As local agencies started to confront the opioid epidemic, they began contacting the LRC for assistance.

Much of LRC’s work in the context of opioids focuses on the tracking of legislation in Maryland and nationally. The LRC, along with students from the law school’s Public Health Law Clinic, provides concise summaries of all opioid legislation introduced during the Maryland legislative session as well as weekly updates of each bill’s status, hearing dates, etc. The LRC also holds biweekly conference calls during the legislative session that provide stakeholders the opportunity to ask questions about specific bills and share information.

In the 2017 legislative session, more than sixty opioid bills were introduced in the Maryland General Assembly. With such a high volume of legislation, this tracking provides critical support to local agencies and organizations working to

improve public health. It also helps to inform LRC’s work with the Opioid Workgroup of the Health and Government Operations Committee of the Maryland General Assembly.

In addition to the legislative tracking, LRC staff and student attorneys are frequently called upon by lawmakers to provide background research on opioid-related initiatives in other states. A state delegate, for example, recently contacted the LRC to find out what other states are doing to encourage pregnant women to seek treatment for opioid addiction. This is a difficult population to reach given the stigma associated with addiction and fears that child protective services



will become involved.

Outside of the legislative session, the LRC team spends time working with local health departments, giving presentations on the latest developments in public health policy at the state and national level. They also work closely with the judiciary, conducting educational sessions and developing materials to inform judges of policy changes (e.g. changes in insurance coverage requirements) that might influence decisions in the sentencing phase of trials.

LRC Staff Attorneys Mellissa Sager and Brooke Torton work

with the Baltimore Area Health Education Center to offer semiannual Interprofessional Education Training to students from the University of Maryland Baltimore professional schools (Law, Medicine, Pharmacy, Dentistry, Social Work, and Nursing). Students analyze case studies, discuss recent policy changes (e.g. Maryland’s Good Samaritan Law which provides legal protection to individuals to encourage emergency service contact in case of overdose) and receive training in the administration of Naloxone to prevent opioid overdose deaths.

Professor Hoke is also engaged in activities at the campus level through the University’s Center for Addiction Research, Education and Services (CARES), an interprofessional effort to address the adverse impact of addiction. Hoke serves on the Steering Committee where she contributes her expertise in policy advocacy to inform the Center’s efforts to provide addiction-related policy consultation and analysis to local and state government policy makers.

Through scholarship, advocacy and technical assistance, Law & Health Care Program faculty, staff and students are making important contributions to local, state and national level efforts to address the epidemic of opioid abuse and remain committed to finding solutions. Multi-level, multidisciplinary approaches that include a health law perspective will be essential to these efforts. *(Continued on page 12)*

JOURNAL OF HEALTH CARE LAW & POLICY CELEBRATES 20TH ANNIVERSARY

The Journal of Health Care Law & Policy recently celebrated its 20th Anniversary with a dinner attended by faculty, current student editors and alumni. The night was highlighted by recollections from faculty on the Journal's history and accomplishments and from alumni on their experiences working on the student-led publication.

After welcoming attendees, current Editor-in-Chief Hassan Sheikh and Managing Editor Eleanor Chung introduced Professor Karen Rothenberg who reflected on the Journal's founding. She talked about the initial vision behind the creation of the Journal, a publication designed to disseminate the latest research of leading scholars working in the area of health law and policy. It also served the important purpose of providing students with exposure to the latest scholarship on leading issues in health law such as the Supreme Court's decision in the *Cruzan* case and implications of the AIDS epidemic for health care workers. Initially used solely to publish articles generated from symposia hosted by the Law & Health Care Program, after a few years the Journal was able to dedicate one issue per year to unsolicited articles, cementing its status among legal academics in the field as well as interdisciplinary scholars and policy makers.



Faculty, alumni, and student-editors gather at the Journal's anniversary dinner.

Law & Health Care Program Director and Professor Diane Hoffmann then offered remarks on the Journal's many accomplishments over the past two decades including its role as a resource for policy makers on cutting-edge issues. The first issue published by the Journal, for example, focused on conducting medical research with individuals lacking decision-making capacity and included articles by leading bioethicists and clinicians. Articles from the issue were later cited by the National Bioethics Advisory Commission in its report on Research Involving Persons with Mental Disorders that May Affect Decision-making Capacity.



Deepti Kulkarni '08

Hoffmann noted that the Journal has also successfully established itself as a forum for the publication of multidisciplinary perspectives on pressing topics in health law and policy, attracting not only health lawyers but also medical researchers, physicians, legislators, practicing lawyers, policy makers, bioethicists, industry representatives, and patient advocates.

This multidisciplinary approach became the model for the Journal's symposium issues. The Journal has published 27 symposium issues based on Health Law Conferences and Roundtables as well as 13 articles from the endowed Stuart Rome lecture. These have included manuscripts by Prof. Lawrence Gostin from Georgetown University, Prof. William Sage from University of Texas, Prof. Robert Burt and more recently, Prof. Abbe Gluck, from Yale Law School, Nancy-Ann DeParle, the former director of the Centers for Medicare and Medicaid Services, and Daniel Levinson, Inspector General for the U.S. Dept. of Health and Human Services, among others. Hoffmann concluded by praising the Journal for providing students with an invaluable opportunity to learn from leading scholars about many different areas of health law and policy.

Former Editors-in-Chief Adrian Wilairat '06, now Writer-Editor for the U.S. Department of Justice at the Office for Victims of Crimes, and Deepti Kulkarni '08, an associate attorney at Sidley Austin, echoed Professor Hoffmann's sentiments, sharing their reflections on their experience working on the Journal and expressing gratitude for the skills

developed during their respective tenures. Current faculty advisor to the Journal, Professor Frank Pasquale, then shared his thoughts on the bright future ahead for the Journal. The speakers were followed by the presentation of awards to authors and student contributors who published the most cited publications in the Journal. The Editors-In-Chief who marshalled these important manuscripts to publication were also recognized. A complete list of awardees is included below.

AWARD OF SCHOLARLY EXCELLENCE

(Awarded to individuals who published the most cited publications)

- Paul Steven Miller, *Is there a Pink Slip in My Genes? Genetic Discrimination in the Workplace*
- Sara Rosenbaum, *Medicaid at Forty: Revisiting Structure and Meaning in a Post-Deficit Reduction Act Era*
- Robert A. Mikos, *Preemption Under the Controlled Substances Act*
- Theresa Glennon, *The Stuart Rome Lecture: Knocking Against the Rocks: Evaluating Institutional Practice and the African-American Boy*
- Paul Arshagouni, *“But I’m an Adult Now ... Sort of” Adolescent Consent in Health Care Decision-Making and the Adolescent Brain*
- Elizabeth Tobin Tyler, *Allies Not Adversaries: Teaching Collaboration to the Next Generation of Doctors and Lawyers to Address Social Inequality*
- Jennifer L. Pomeranz, *Compelled Speech Under the Commercial Speech Doctrine: The Case of Menu Label Laws*
- Deborah Kaplan, *The Definition of Disability: Perspective of the Disability Community*
- Adrian Wilairat, *Faster, Higher, Stronger? Federal Efforts to Criminalize Anabolic Steroids and Steroid Precursors*
- Ellen A. Callegary, *The IDEA’s Promise Unfulfilled: A Second Look at Special Education & Related Services for Children with Mental Health Needs After Garret F*

AWARD OF SCHOLARLY EXCELLENCE - STUDENT PUBLICATIONS

(Awarded to individuals who published the most cited student publications)

- Adrian Wilairat, *Faster, Higher, Stronger? Federal Efforts to Criminalize Anabolic Steroids and Steroid Precursors*
- Erin Myers, *The Manipulation of Public Opinion by the Tobacco Industry: Past, Present, and Future*
- Carrie A. Roll, *The Human Papillomavirus Vaccine: Should It Be Mandatory or Voluntary?*
- Jake Schaller, *Not for Bathing: Bath Salts and the New Menace of Synthetic Drugs*
- Lucy W. Shum, *Educationally Related Mental Health Services for Children with Serious Emotional Disturbance: Addressing Barriers to Access Through the IDEA*
- Amanda S. Pitcher, *Contrary to First Impression, Genes are Patentable: Should There be Limitations?*
- Samantha Schad, *Adolescent Decision Making: Reduced Culpability in the Criminal Justice System and Recognition of Capability in Other Legal Contexts*
- Sara Klemm, *Keeping Prevention in the Crosshairs: A Better HIV Exposure Law for Maryland*
- Michael J. McKeefery, *A Call to Move Forward: Pushing Past the Unworkable Standard That Governs Undocumented Immigrants’ Access to Health Care Under Medicaid*
- Anne Erikson Haffner, *The Increasing Necessity of the Tort System in Effective Drug Regulation in a Changing Regulatory Landscape*

CITATION FOR OUTSTANDING SERVICE

(Awarded to Editors-in Chief who published the ten most cited publications)

M. Jason Brooke
Rebecca Wizeman Hall
Deepti A. Kulkarni
Melissa M. McDonnell
Marc A. Nardone
Scott D. Nelson

Michael J. Pappas
Melanie Santiago
Amy F. Siegel
Sally Terese Vecchio
Nisha Wagle
Adrian Wilairat

DR. AARON KESSELHEIM DELIVERS 2018 ROME LECTURE ON DRUG PRICING

On March 8, 2018, the Law & Health Care Program and the Center on Drugs and Public Policy at the University of Maryland School of Pharmacy co-sponsored the 2018 Stuart Rome Lecture and follow on panel, "Drug Pricing and Prospects." The Stuart Rome Lecture was established in 1984 to honor the memory of Stuart Rome, a prominent health law attorney, community activist, art patron, and humanitarian in the Baltimore Area. This year's lecture was delivered by Aaron Kesselheim, MD, JD, MPH.

Dr. Kesselheim is the Director of the Program on Regulation, Therapeutics and Law (PORTAL) in the Division of Pharmacoepidemiology & Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital as well as an Associate Professor of Medicine at Harvard Medical School. His research focuses on the effects of intellectual property laws and regulatory policies on pharmaceutical drug development and the cost and availability of prescription drugs.

Drug prices have increased dramatically in recent years. In 2015, prescription drug spending in the United States increased by 12% and again by 6% in 2016 to a total of \$450 billion, accounting for one-fifth of all health care spending. The bulk of this money is directed to brand name drugs, which account for 72% of all drug spending although they comprise only 10% of prescriptions. Generic



Dr. Aaron Kesselheim delivers Rome Lecture.

drug prices have also increased dramatically. Dr. Kesselheim provided a detailed overview of the current state of prescription drug pricing in the U.S. and the clinical consequences of increases, including lower patient adherence when more expensive brand name drugs are prescribed instead of a more affordable generic.

He then dispelled several myths about price increases such as industry arguments that such increases are necessary to support innovation. Kesselheim noted that there is no association between research and development costs and drug prices. Most research and development for new drug products is conducted in academic institutions receiving public funding from entities such as the National Institutes of Health. In addition, according to an analysis conducted by Dr. Kesselheim and Dr. Ameet Sarpatwari '13, drug manufacturers spend only 10-20% of revenue on research and development in contrast to 20-30% on marketing and administration costs and the 20-30% paid to shareholders.

Kesselheim also disputed the assertion that onerous regulatory hurdles at the FDA are driving price increases, noting widespread use of expedited approval pathways by the majority of new drugs as well as faster FDA approval times than counterparts in Europe and Canada.

Kesselheim asserted that drug prices are rising because pharmaceutical companies are allowed to charge whatever the market will bear while employing strategies that undercut competition and hinder the ability of payers to provide counterweights that might reduce high prices. He then discussed various policy solutions that might be employed based on where the drug product is in the drug development "life cycle."

Market Exclusivity Period

In the initial post approval period, new brand-name drugs are guaranteed six to seven years of market exclusivity with longer periods granted for new antibiotics and biologics. Drugs also enjoy patent protections. In addition to the advantages of exclusivity,

manufacturers further benefit from limits on public payers. Medicare, for example, is unable to negotiate drug prices. Private payers are also limited in their ability to negotiate lower prices, primarily due to the lack of comparative effectiveness data available at the time of approval as well as state law coverage requirements.

Kesselheim offered several countermeasures to the problem such as authorization for public payers to use formularies and negotiate drug prices (currently prevented under the Medicare Part D statute) or use international reference pricing so that U.S. drug prices remain in line with what other countries are paying manufacturers.

There are additional policy opportunities at the provider level to address drug pricing as evidenced by California's recent effort to prohibit manufacturer coupons and discounts for brand name drugs when a generic is available. While the consumer is shielded from price increases via copay coupons, payers must pay for the increases associated with these drugs. Other efforts at the provider level include integration of value-based prescribing into professional education or through electronic medical record point-of-care reminders.

Transition From Brand Name to Generic

Kesselheim noted that the availability of generic versions of brand-name products is the most important factor in drug pricing. As brand name drugs reach the end of their market exclusivity period, however, manufacturers have become adept at taking steps to extend exclusivity through, for example, payments to generic producers in exchange for dropping lawsuits to gain market access or the development of "a thicket of secondary patents." Other strategies include manufacturer refusal to provide samples to generic manufacturers, which are required to conduct bioequivalence studies.



Drs. Frank Palumbo and Bill Padula (l.)

At this stage in the life cycle, Kesselheim sees several opportunities for reducing drug prices including a review of settlements between generic and brand name manufacturers.

Generic Competition Phase

Once the exclusivity period ends, generic manufacturers enter the market and, in theory, competition between them drives down prices. In practice, Kesselheim noted, there are fewer competitors in the U.S. market than in other countries. He proposed several solutions to address the lack of market competition including importation of generics from well-regulated markets in other countries and changes to the regulatory framework that can stimulate increased competition such as expedited review of generic applications when there are three or fewer drugs in the market.

There is a pressing need to address the cost of prescription drugs, Kesselheim concluded, as increasing prices will continue to result in negative consequences for patients and the entire health system. Dr. Kesselheim's lecture was followed by a panel of experts on pharmaceutical drug pricing.

Frank Palumbo, JD, PhD, Executive Director of the Center on Drugs and Public Policy at the University of Maryland School of Pharmacy, provided an overview of pharmacy

benefit managers and their role in drug costs.

Joshua Auerbach, Esq., Special Assistant & Senior Litigation Counsel, Maryland Office of the Attorney General, discussed the Maryland anti-price gouging statute and subsequent litigation brought by generic manufacturers. The Maryland statute was challenged shortly after it passed in 2017 by the professional association of generic drug manufacturers (*Association for Accessible Medicines v. Frosh*). In April 2018, a three-judge panel of the U.S. Court of Appeals for the Fourth Circuit held that the Maryland statute violates the dormant commerce clause by directly regulating the price of transactions outside of the state. Maryland Attorney General Brian Frosh has requested that the full court rehear the case.

William V. Padula, PhD, MS, MSc, Assistant Professor, Department of Health Policy & Management, Johns Hopkins Bloomberg School of Public Health, provided an overview of approaches other states have taken to stem increases in prescription drug costs. Finally, Ameet Sarpatwari, JD ('13), PhD, Assistant Director of PORTAL, discussed the market for biologics and biosimilars, noting that FDA has approved few biosimilars, making competition in the biologics space unlikely.

CLINIC SPOTLIGHT: CIVIL RIGHTS OF PERSONS WITH DISABILITIES CLINIC

Students with interest in health law have several options available to them in order to obtain professional experience during their studies including three health law clinics and more than two dozen externship placement opportunities. The Civil Rights of Persons with Disabilities Clinic, one of the oldest disability rights clinics in the country, has been providing legal services to clients with disabilities since 1975.

Clinic History

Professor Emeritus Susan Leviton founded the clinic, then called the Developmental Disabilities Clinic, the same year that Congress passed the Education for All Handicapped Children Act (later renamed the Individuals with Disabilities Education Act, or IDEA). The law required all public schools to provide children with disabilities equal access to education and mandated provision of special services to meet the specific needs of children with disabilities. That statute came two years after the passage of the Rehabilitation Act of 1973, the first federal civil rights law for individuals with disabilities. The EAHCA gave parents a role in the educational process and facilitated parental involvement with schools to identify and secure what their children needed to be successful.

Professor Leviton recalls, “These laws, the Rehabilitation Act and the EAHCA, marked the beginning of a new era. Prior to their passage, parents of children with disabilities were encouraged

to institutionalize them. This was a completely new area of the law and a tremendous learning opportunity for our students.”

In 1983, Professor Stanley Herr, a longtime disability advocate, joined the law school faculty and assumed leadership of the clinic. Professor Herr’s contributions to disability rights are well documented. In the early 1970s, he served as lead counsel in *Mills vs. Board of Education* where the legal team successfully argued for access to public education for all children including those with disabilities. That landmark decision later provided the foundation for the EACHA. By all accounts, Herr was an indefatigable disability rights advocate, receiving honors from many organizations in his career including The ARC and the American Bar Association.

Through their work with the Maryland Disability Law Center (now Disability Rights Maryland), Prof. Herr befriended Marc Charmatz, an attorney with the National Association of the Deaf (NAD), a grassroots civil rights advocacy organization that represents deaf and hard of hearing individuals. In 1999, when Herr took a sabbatical from the law school, he asked Charmatz to lead the clinic in his absence. Sadly, Prof. Herr was unable to return to his role, dying from cancer in 2001.

Prof. Charmatz carried on Herr’s legacy and assumed leadership of the clinic for the next 18 years. During that time, he continued to serve as litigation counsel at NAD



Professor Emeritus Susan Leviton

and began to combine his work there with his work at the clinic. Charmatz recalls, “While I have tremendous respect for those engaged in work at the policy level, I am client-driven - I want to represent individuals, particularly those having difficulty finding counsel. I knew we had plenty of clients in need of representation at NAD. I realized that working in collaboration with NAD would be a great educational tool to teach students about real-world legal representation in the context of disability rights.”

In recognition of his contributions, Charmatz’s work as an advocate for individuals with disabilities was recently featured in an article in the *ABA Journal* magazine discussing



Professors Stanley Herr and Diane Hoffmann, circa 1995

the origins and achievements of the disability rights movement.

In 2014, Charmatz recruited Caroline Jackson, Staff Attorney with NAD, to serve as co-instructor. He stepped down from his role directing the clinic after the Spring 2017 semester; Anna Bitencourt joined as clinic co-director in fall 2017. Prof. Bitencourt currently serves as a staff attorney and Director of Intake at NAD.



Marc Charmatz

Prof. Jackson joined the NAD as a Skadden Fellow after law school. Long interested in disability rights, Jackson worked as a sign language interpreter in New York City before returning to school to pursue her law degree. Prof. Bitencourt, who is deaf, worked in private practice for several years after law school and occasionally received referrals or requests for assistance in cases involving deaf clients from the NAD. She began working at NAD part-time and was then invited to join the organization on a full-time basis to direct client intake and litigate cases.

Training Students to Advocate for Civil Rights

Jackson and Bitencourt work with student attorneys to represent clients with disabilities in a variety of settings and collaborate with other organizations involved in broad impact litigation.

The classroom component of the clinic provides students with a

foundation in disability law including the Americans with Disabilities Act, the Rehabilitation Act as well as related laws in the areas of education, employment and public benefits. Clinic students handle cases at all stages of legal proceedings, including initial client interviews, drafting pleadings, counseling, discovery, motions practice, trial and appeal. Through their participation in the clinic, they develop an understanding of the public policy issues that influence the ability of individuals with disabilities to participate in society as well as the various stakeholders involved in protecting and promoting disability rights.

Many of the cases students handle address issues of communication access for deaf and hard of hearing individuals. Deaf and hard of hearing individuals and their family members face obstacles in a variety of settings from schools to health care institutions to jails where deaf individuals lack access to the tools necessary to allow for effective communication and adequate engagement. Students participate fully in the intake process, receiving initial calls from potential clients, learning how to communicate with clients and obtain facts about their case. Students work closely with Ms. Bitencourt to review the facts of each case and determine if



Clinic Co-Directors Caroline Jackson and Anna Bitencourt

it is suitable for litigation. Caroline Jackson supervises the litigation component.

The clinic handles a wide variety of cases – education, employment, and access to health care. Last year, for example, students represented an individual who was denied admission to a radiology technician training program because she was deaf. That case went to jury trial and was ultimately resolved in the client's favor. Students also engage in advocacy outside the courtroom, drafting demand letters on behalf of clients to ensure that accommodations such as captioning and interpreters will be provided in various contexts. In addition to the nuts and bolts of litigation and advocacy, students learn about deaf culture and work closely with deaf professionals. They also learn about the protection and advocacy system established by federal law to protect disability rights.

Many of the clinic's student attorneys have continued to advocate for the rights of individuals with disabilities. Munib Lohrasbi '17, an alumnus of the law school and former student attorney with the clinic, was awarded an Open Society Institute-Baltimore Community fellowship to improve conditions for people with disabilities in prison in Maryland. He is working with Maryland's federally mandated Protection & Advocacy agency, Disability Rights Maryland, to inspect state prison facilities and evaluate current assessment and accommodation procedures for individuals with disabilities.

Other graduates have gone on to hold positions at the Department of Justice and disability rights advocacy organizations in other states, a testament to the clinic's lasting impact on students.

MICROBIOTA TRANSPLANT PROJECT UPDATE

Professor Diane Hoffmann and co-investigators from the University of Maryland Schools of Law, Pharmacy and Medicine hosted the final meeting of the Microbiota Transplantation Working Group on February 23, 2018. The meeting was the fourth in a series of meetings supported by Professor Hoffmann's NIH-funded project, Microbiota-Transplantation: Recommendations for a Regulatory Framework.

The working group comprises experts and stakeholders including physicians, researchers, bioethicists, lawyers, as well as representatives from private industry engaged in microbiota transplantation. In addition to updates on fecal microbiota transplantation (FMT) and stool-based drugs, the final meeting also included presentations on newer areas of research such as vaginal microbiota transplants and vaginal

seeding, where newborns delivered via caesarean section are swabbed with the mother's vaginal fluids to mimic the transfer that happens during vaginal births. Several industry representatives gave presentations on new microbiome-based diagnostics. After the presentations, members broke into small groups to discuss the ethical and legal implications of microbiome-based diagnostics and therapeutics.

The meeting was the first since the publication of the article, "Improving regulation of microbiota transplants," in the journal *Science* in December 2017. That article, based in part on the prior working group meetings, proposes a framework for the regulation of fecal microbiota transplantation (FMT). Hoffmann and her co-authors propose a three-track framework that aims to balance patient

access with safety and effectiveness concerns. The framework requires increasing regulatory oversight based on source of stool (e.g. person known to patient vs. stool bank) and level of processing (stool vs. stool-based products).

The article is available to download via Prof. Hoffmann's faculty profile on the law school website.

Hoffmann also presented on the topic at an educational session held by the American Gastroenterological Association at the Crohns & Colitis Foundation's Annual Meeting in Las Vegas in January.

MARYLAND CAREY LAW FACULTY ADDRESS THE OPIOID EPIDEMIC

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MARYLAND CAREY LAW TEAMS PREVAIL IN 7TH ANNUAL HEALTH LAW REGULATORY AND COMPLIANCE COMPETITION



Maryland Carey Law students Eli Sherlock, Ashley Creech, and Kellie Taylor took first place; classmates Jessica Ramdat and Jennifer Ponce-Mejia placed third.

The Seventh Annual Health Law Regulatory and Compliance Competition was held on Saturday, February 23, 2018 at Maryland Carey Law. More than 30 students from nine law schools competed in the event this year.

Maryland Carey Law took first place in the competition. Team members (pictured above) Ashley Creech, Kellie Taylor, and Elias Sherlock were coached by Sean Gugerty '15 and Samantha Collado '16. The other winning teams were American University Washington School of Law (second place) and the second University of Maryland team (third place).

Students were given 90 minutes to analyze a hypothetical fact pattern involving various interactions between health care stakeholders and entities engaged in activities that necessitate regulatory and compliance oversight. Participants then present their findings

and recommendations to a panel of practicing health lawyers. Nearly 30 attorneys from a broad range of organizations served as judges, including CMS, FDA, law firms and private industry. This year's competition focused on healthcare fraud and abuse, rural hospitals, payers, credentialing and challenges associated with telehealth services implementation, payment and reimbursement.

Professor Diane Hoffmann commended the students for their participation, noting, "The competition provides students with a glimpse of real-life health law practice by tackling complex matters that require thoughtful and thorough analysis and a time-sensitive response. All of the participants should be proud of their performance today."

At the luncheon following the competition, David Cade '85, CEO of the American Health Lawyers

Association, provided the keynote address and congratulated the participants on both their participation in the competition and decision to pursue careers in health law. Mr. Cade then announced the winners and presented the awards. Students on the winning teams also received prizes generously donated by the American Health Lawyers Association and the Food and Drug Law Institute.

The competition received generous support from the following sponsors:

Premier Sponsor: Baker Donelson

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7TH ANNUAL HEALTH LAW REGULATORY AND COMPLIANCE COMPETITION



From top left: The American University team; American Health Lawyers Association CEO David Cade '85 delivers the keynote address; Prof. Diane Hoffmann welcomes participants and judges.

LAW & HEALTH CARE PROGRAM COLLABORATES WITH JOHNS HOPKINS BERMAN INSTITUTE OF BIOETHICS ON FACULTY RETREAT

On April 11, 2018, faculty from the Law & Health Care Program participated in a collaborative retreat with faculty from the Johns Hopkins Berman Institute of Bioethics. Although L&HCP faculty members Karen Rothenberg and Leslie Henry have held affiliate faculty appointments at the Berman Institute for many years, the retreat marked the first time that faculties from both programs had the opportunity to meet and discuss current research interests. The day's schedule included brief presentations from faculty on their research in three areas: new and emerging technologies, infectious diseases, and opioids and pain. The presentations focused not only on current progress but encouraged discussion on the relationship of the different topic areas to issues of justice and the identification of research questions that would benefit from interdisciplinary collaboration.



“The retreat is the first of hopefully many such events bringing together the health law and Berman faculties. There was a lot of enthusiasm from the retreat attendees about possible collaborations. I am looking forward to the continued development of these ideas with our Berman colleagues,” remarked Diane Hoffmann, Director of the Law & Health Care Program.

LAW & HEALTH CARE PROGRAM NEWS

LESLIE HENRY

Leslie Henry was a co-author on the research white paper “Biorepositories: Addendum to Registries for Evaluating Patient Outcomes: A User’s Guide, Third Edition” prepared for the Agency on Healthcare Research and Quality.

Professor Henry was also a co-author on an article in the journal *Obstetrics & Gynecology*, “Ethical Considerations Concerning Amnioinfusions for Treating Fetal Bilateral Renal Agenesis,” 131(1):130-134, 2018.

DIANE HOFFMANN

Diane Hoffmann and campus colleagues published “Improving Regulation of Microbiota Transplants,” in *Science* in December 2017.

Diane Hoffmann was quoted and her article, “The Girl who Cried Pain,” was cited in the *Atlantic* on January 23, 2018 in the segment “Larry Nassar and the Impulse to Doubt Female Pain.”

Hoffmann was a guest on NPR’s *All Sides with Ann Fisher* appearing with Abby Norman, author of *Ask Me about My Uterus: A Quest to Make Doctors Believe in Women’s Pain* (April 26, 2018).

The *Washington Post* published a Letter to the Editor by Hoffmann and Kate Nicholson on efforts by Human Rights Watch to investigate the impact of opioid limits on chronic pain patients (May 6, 2018).

KATHLEEN HOKE

Kathleen Hoke was appointed to the Food and Drug Law Institute Tobacco Products Committee for 2018.

Prof. Hoke was quoted in “From Opioids to Guns: Cities, Counties Step Up Civil Suits,” an article published on *Bloomberg News* in March 2018.

FRANK PASQUALE

Prof. Frank Pasquale was featured in the December 2017 issue of the *ABA Journal* in the article “Defense lawyers want to peek behind the curtain of probabilistic genotyping.”

KAREN ROTHENBERG

Prof. Rothenberg was quoted in “Is DNA testing telling us more than we want to know? The untold story of Ancestry.com,” on *Deseret News* on May 30, 2018.

Prof. Rothenberg will serve as an Advisory Panel Member for a National Palliative Care Research Center Pilot and Exploratory Grant titled: “What it means for our family – Video Decision Supports for Parents Considering Chronic Pediatric Mechanical Ventilation,” a multicenter collaboration with the Johns Hopkins School of Medicine, the University of Mississippi Medical Center and Seattle Children’s Hospital.

AMANDA PUSTILNIK

Amanda Pustilnik published “The Law’s Responses to the Opioid Epidemic: Legal Solutions to a Unique Public Health, Criminal Law, and Market-Related Crisis” in *Confronting Our Nation’s Opioid Crisis: A Report of the Aspen Health Strategy Group*.

Amanda Pustilnik published “Legal Evidence of Subjective States: A Brain-Based Model of Chronic Pain Increases Accuracy and Fairness in Law,” 25 *Harv. Rev. of Psychiatry* 279 (2017).

Amanda Pustilnik published “Brain imaging tests for chronic pain: medical, legal and ethical issues and recommendations,” with Karen D. Davis, Herta Flor, Henry T. Greely, Gian Domenico Iannetti, Sean Mackey, Markus Ploner, Irene Tracey, Rolf-Detlef Treede, & Tor D. Wager, 13 *Nature Rev. Neurology* 624 (2017).

L&HCP STUDENTS

Health law student Mena Gaballah ‘18 co-authored a March 2018 op-ed in the *Baltimore Sun* with colleagues from the R. Adams Cowley Shock Trauma Center at the University of Maryland Medical Center, warning of abuse of the popular over-the-counter drug, Imodium.

Public Health Law Clinic student Adrienne Thomas (3L) testified before the Maryland General Assembly in support of House Bill 315 (Maryland Cares for Kids Act), a bill that would require the State to cover costs associated with reduced breakfast and lunch to expand access for low-income students.



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