

FOCUS ON PROFESSOR LESLIE MELTZER HENRY . . . TIRELESS ADVOCATE FOR THE ETHICAL CONDUCT OF MEDICAL RESEARCH

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Essential Medicines symposium speakers (from l to r) Prof. Peter Danchin, Ambassador Necton D. Mhura, Prof. Diane Hoffmann and Prof. Leslie Meltzer Henry

On October 29-30, 2015, Law & Health Care Professor Leslie Meltzer Henry, along with colleagues Diane Hoffmann and Peter Danchin, Director of the Maryland Carey Law's International and Comparative Law Program, organized a unique symposium that brought together legal academics, IRB members, and medical researchers from North America and southern Africa for an “International Symposium on Clinical Trials and Access to Essential Medicines in African Countries.” The symposium, co-sponsored by the Faculty of Law at Chancellor College in Malawi, examined ethical and legal challenges to developing and distributing essential medicines for diseases such as HIV and malaria in African countries.

The symposium was the latest in a long collaboration between Maryland Carey Law and the Faculty of Law at Chancellor College in Malawi which began in 2010 when University of Maryland, Baltimore’s (UMB) Center for Global Education Initiatives sent an interprofessional team of faculty and students to Malawi to study the health and legal needs of orphans and vulnerable children. The Honorable Necton D. Mhura, Ambassador from

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Malawi to the United States, opened the roundtable by recounting the history of the collaboration. In the summer of 2013, Hoffmann and Danchin traveled to Malawi and worked with Malawian law professor Chikosa Banda to organize a workshop for students and faculty from both universities on the subject of HIV/AIDS. Since that time, faculty members from both schools have conducted visits and workshops in both Baltimore and Malawi.

Professor Henry was brought into the Essential Medicines symposium because of her expertise and her extensive scholarship on clinical research ethics. Based on her work in this area, she is frequently asked to provide expert commentary for federal and local agencies, organizations, and the media on ethical issues that arise in human subjects research. She has also served as a bioethics consultant for the Department of Defense and has presented to panels of experts at the Department of Health and Human Services, the Food and Drug Administration (FDA), and the National Institutes of Health Bioethics Advisory Committee. Professor Henry is also a core faculty member at the Johns Hopkins Berman Institute of Bioethics. Her recent scholarship in this area ranges from compensation for research subjects who sustain research-related injuries and commentary on changes to the Common Rule. She also teaches both the survey and advanced bioethics courses at the law school.

Selected Articles by Professor Leslie Meltzer Henry

- *Respect and Dignity: A Conceptual Model for Patients in the Intensive Care Unit*, 5.1A Narrative Inquiry in Bioethics 5A (2015) (with C. Rushton, M.C. Beach, and R. Faden).
- *Just Compensation: A No-Fault Proposal for Research-Related Injuries*, Journal of Law & the Biosciences (2015).
- *Moral Gridlock: Conceptual Barriers to No-Fault Compensation for Injured Research Subjects*, 41 Journal of Law, Medicine & Ethics 411 (2013).
- *Revising the Common Rule: Prospects and Challenges*, 41 Journal of Law, Medicine & Ethics 386 (2013).

Henry's interest in international human subjects research is largely focused on what researchers from the United States owe host countries and research subjects in those countries based on the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* published by the Council for International Organizations of Medical Sciences (CIOMS). The guidelines, published in 2002, provide guidance on the ethical justification and scientific validity of research, ethical review of research, and informed consent, among other topics. Her expertise in this area added greatly to the conference planning.

The four collaborators – Henry, Hoffmann, Danchin and Banda – organized the conference around four panels:

- 1) Access to Essential Medicines as a Human Right;
- 2) The Law and Ethics of Clinical Trials: What Rules Should Govern Clinical Research in Africa;
- 3) What do Clinical Researchers and Sponsors Owe to Host

Communities?;

4) Legal Regimes and Obstacles: Free Trade, Intellectual Property, and Access to Medicine.

Each panel was composed of an interprofessional and international group of speakers who shared their academic and personal perspectives of conducting research in southern Africa where such research brings both enormous promise and the potential for grave ethical conflicts.

Professor Henry moderated the third panel on the responsibilities of clinical researchers to host communities. Research conducted in lower income countries often involves ethical issues that are more complex than in developed countries because of power differentials, lack of health care outside of clinical trials, and the potential for exploitation of research subjects. Professor Henry's panel discussed several frameworks that aim to create more equitable interactions between researchers and participants and host communities. Joining her on the panel were Dr. Joseph Mfutso-Bengo, Professor of Bioethics and Director of the Centre for Bioethics at the University of Malawi College of Medicine and Dr. David Wendler, Head of the Section on Research Ethics in the Department of Bioethics at the National Institutes of Health. Both Dr. Mfutso-Bengo and Dr. Wendler have written extensively on these topics and brought perspectives from both sides of the Atlantic.

The first issue tackled by Professor Henry's panel related to the interpretation of the requirement to provide "reasonable availability" of any product developed during the trial to the host country/ research population. The idea of making interventions reasonably available emerged in 1993 from guidelines issued by CIOMS (and later strengthened in 2002). The guidelines stress that the sponsoring agency conducting the research should make any product developed through the research "reasonably available" to the community in which the research is conducted. How these guidelines should be interpreted – including such issues as who should make the decision as to what is reasonable and what constitutes "available" – was tackled by the panelists and others.

Professor Henry's panel members also discussed the issues of ancillary care obligations, or obligations to provide care to research participants that is not related to the research question, and the provision of "fair benefits," another ethical framework for research.

The fair benefits framework requires that research be conducted in developing countries only if three conditions are met: 1) the research addresses a health

problem of the developing country population, 2) the research objectives provide a strong justification for conducting the research in the chosen community, and 3) the research poses few risks to the participants or the benefits to them clearly outweigh the risks.

Conference Speakers, Moderators & Supporters

Chikosa Banda, Professor, Faculty of Law at Chancellor College in Malawi

Mark Barnes, Partner, Ropes & Gray, LLP

Danwood Chirwa, Professor, University of Cape Town Law Faculty

Peter Danchin, Professor and Director of the International and Comparative Law Program, University of Maryland Carey School of Law

Sean Flynn, Associate Director, Program on Information Justice and Intellectual property, American University Washington College of Law

Lisa Forman, Assistant Professor, University of Toronto

Diane Hoffmann, Professor and Director of the Law & Health Care Program, University of Maryland Carey School of Law

Heinz Klug, Professor and Director, Global Legal Studies Center, University of Wisconsin

Miriam Laufer, Associate Professor, University of Maryland School of Medicine

Joseph Mfutso-Bengo, Professor of Bioethics and Director of the Centre for Bioethics, University of Malawi College of Medicine

The Honorable Necton D. Mhura, Malawian Ambassador to the United States

Victor Mwapasa, Associate Professor, University of Malawi College of Medicine

Seema Shah, Faculty Bioethicist, NIH*

Hilda Kaluwa Soko, Law Lecturer, University of Malawi Chancellor College of Law

David Wendler, Senior Investigator and Head of the Section on Research Ethics, NIH

Lucie White, Professor, Harvard Law School

*Ms. Shah was unable to attend the conference, but her remarks were given by David Wendler

The symposium was supported by the UMB Center for Global Education Initiatives, Alan & Nancy Eason, the Stuart Rome Lecture Fund, the Reuben Shiling Mental Health Law Fund, the Leonard C. Homer/Ober|Kaler Law and Health Care Fund, and the Dr. Richard H. Heller Fund.

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Other Collaborations

In addition to organizing the Essential Medicines symposium this year, Professor Henry has been working intensively as a co-investigator on two projects relating to the ethical conduct of medical research. The first project is an NIH-funded, multi-year project called PHASES (Pregnancy & HIV/AIDS: Seeking Equitable Study), which is designed to establish ethically and legally acceptable strategies for conducting research about HIV treatment and prevention during pregnancy. Henry's collaborators include Ruth Faden at the Johns Hopkins Berman Institute of Bioethics, Maggie Little at Georgetown's Kennedy Institute of Ethics, Annie Lyerly at the University of North Carolina, and Anna Mastroianni at the University of Washington School of Law.

The project was created to address a gap in the diagnosis and treatment needs of pregnant women, a key population affected by HIV/AIDS. In November 2014, the PHASES team met with former FDA regulators, pharmaceutical company representatives, IRB chairs, and legal academics to begin the process of creating an ethical framework that would permit research with pregnant women with HIV. Research under the PHASES grant has been conducted in the United States to date, but the research team recently

received four more years of funding to continue their research in South Africa, Botswana and Malawi. The PHASES team is currently conducting engagement meetings at these sites with community members, local investigators, and local IRBs.

Henry and her PHASES collaborators also were recently funded by the Wellcome Trust to develop ethical and legal guidance for conducting research with pregnant women during public health emergencies, like the Zika crisis, where there is an urgent need to attend to the health needs of pregnant women and their offspring. The project is called "Conducting Ethical Research with Pregnant Women in the Emerging Zika Pandemic and Beyond: Challenges Arising in Public Health Crises." The goals of the project are to engage key experts in order to understand the needs and challenges of conducting research on women whose pregnancy may be affected by Zika and to develop a framework to conduct research with this population. The project will include working with medical researchers to determine when research requires participation of pregnant women and what the barriers are to conducting such research in certain target countries. Ultimately the team hopes to create guidance documents intended to be of real-time utility in the Zika crisis and future public health crises.

PROFESSOR ELLEN WEBER: FRONT AND CENTER ON PROTECTION OF INDIVIDUALS WITH MENTAL HEALTH AND SUBSTANCE USE DISORDERS



Professor Ellen Weber

The Drug Policy Clinic at University of Maryland Carey Law is working to address Maryland's heroin and prescription drug problem by helping individuals gain access to health insurance coverage and tackling systemic barriers to drug treatment. The Clinic was created by Professor Ellen Weber to address practices that inhibit the expansion of drug treatment in communities and the criminal justice system and that discriminate against individuals with histories of drug dependence. To identify the most pressing client issues, the Clinic established medical-legal partnerships (MLPs) at two Baltimore drug treatment programs – Man Alive and Institutes for Behavior

Resources in August 2015. Both programs provide methadone maintenance treatment and outpatient counseling services to hundreds of patients with substance use disorders, and offer “health homes” for patients with Medicaid who have multiple chronic health issues. Two student teams from the clinic assisted patients with problems obtaining Medicaid or private insurance coverage and accessing health care. They also looked for system-wide standards that could be the source of client problems. Weber described the value of this type of advocacy clinic to law students - “the collaboration has exposed our students to the complex financing system for drug treatment, and they have learned to help patients navigate multiple public and private health insurance programs.”

Both teams quickly learned that patients with Medicare coverage face significant barriers accessing drug treatment, particularly methadone maintenance treatment. The teams launched several projects to assist patients, including identifying those who were eligible for programs that reduce the cost of Medicare premiums and prescription drugs. Student-attorneys Brenda Kathurima and James Cook also conducted training programs about Medicare coverage to help program administrators assist patients and to educate policymakers about the need to secure stable funding for the growing population of patients with Medicare coverage.

Man Alive identified a group of patients who should have been able to use their private secondary insurance policy – often a retiree policy – to cover their drug treatment, but faced administrative barriers imposed by both the Center for Medicare and Medicaid Services (CMS) and private carriers. Student-attorneys Isabel Coello and Mike Martin worked with the clients and the program’s clinical and administrative staff to document treatment and claims histories and then make the case to insurance carriers that the private policies should pay outstanding and future claims. The team’s efforts have resulted in positive outcomes for each client. The carriers have reimbursed over \$4300 in unpaid claims, some dating back many months, and are now paying all claims without delay. The team has also developed a toolkit that will help treatment programs around the state address these reimbursement issues for their patients.

The Clinic has also helped individuals with private insurance challenge discriminatory reimbursement decisions and advocate for better enforcement of

the federal Mental Health Parity and Addiction Equity Act. One hospital-based treatment program discovered that a national insurance carrier had repeatedly denied reimbursement for methadone treatment services for patients with both individual and small employer plans sold on the State’s health benefit exchange. Student-attorney Kris Corwin has represented one patient whose plan denied coverage for methadone treatment in violation of state law. In the course of his investigation, Kris identified plan standards that impose more restrictive utilization review requirements for substance use and mental health treatment than for medical services. The Clinic reported these potential Parity Act violations to the Maryland Insurance Administration, which has launched an investigation of the carrier’s practices. In the meantime, the carrier admitted, in response to the Clinic’s insurance appeal, that it had incorrectly denied coverage for the client’s methadone treatment. The carrier reimbursed the methadone clinic \$2700 for the client’s care.

The Drug Policy Clinic has also identified Parity Act violations in the Maryland Medical Assistance program and has looked to the Maryland General Assembly to require compliance. Beginning in September 2014, the Clinic and its partners began to work with the State’s Medicaid officials to develop a comprehensive substance use disorder benefit that complied with the Parity Act. When discussions failed to resolve outstanding benefit problems, the Clinic drafted legislation (HB 1217/SB 899), introduced in the 2016 legislative session, to require the State to bring its Medicaid benefit into compliance with federal law. The Clinic and its partners advocated successfully with members of the General Assembly, resulting in overwhelming support and passage of the bills. The State is required to adopt regulations by July 1, 2017 and those standards should result in more comprehensive services for the State’s most vulnerable youth and adults.

PROFESSOR KAREN ROTHENBERG CREATES UNIQUE NIH FIELD PLACEMENT FOR HEALTH LAW STUDENTS



Dr. Eric Green, Director, NHGRI Speaks to Professor Rothenberg's Externship Students

In Fall 2015, Law & Health Care Program faculty member and former Dean of the law school, Karen Rothenberg, created an opportunity for four students to work and study at the National Institutes of Health (NIH) through a new externship program that, based on its positive response, she will lead again in Fall 2016. Rothenberg, a national expert in the ethical, legal and social implications of genetic testing and genomic research, developed the externships with colleagues at NIH whom she met during her four years as Senior Advisor to the Director of Genomics & Society at the National Human Genome Research Institute (NHGRI). Rothenberg is now back at Maryland Carey Law and continues to serve as a Visiting Scholar in the Department of Bioethics at NIH's Clinical Center. According to Rothenberg, the externship program "provides a unique opportunity for law students to experience the making of health policy at the most prestigious medical research institution in the world while having opportunities to delve into cutting edge research topics at the intersection of ethics, law, and science. In addition to working with world renowned health policy makers, the students had the opportunity to round in the Clinical Center and meet the patients who hope to benefit from the advances in genomics research."

The four students were placed in different offices in NIH and NHGRI: the Technology Transfer Office, the Division of Genomics and Society, the Department of Bioethics at the NIH Clinical Center, and the Social and Behavioral Research Branch with the Senior Advisor for Genomics and Health Disparities. Their diverse research projects included the ethical and legal implications of the use of legacy samples, gene editing, the Precision Medicine Initiative, and health disparities in access to designer drugs. The students spent two days a week at NIH in Bethesda, Maryland attending Undiagnosed Diseases Program rounds and NHGRI Institutional Review Board (IRB) meetings, conducting research and writing memos for their supervisors and developing an extensive written research project.

The four students divided their time between working with their NHGRI supervisors and participating in the accompanying workshop with Professor Rothenberg. The purpose of the split structure was to introduce students to the day-to-day work of NIH lawyers, to provide a structured opportunity for students to share their experiences, and to allow students to explore more deeply the ethical, legal, social and policy challenges raised by genomics research. The students were also required to keep a weekly journal reflecting on their participation in clinical rounds, their weekly assignments with their supervisors, and research related to research projects.

Apurva Dharia (3L), who was placed in the NHGRI Technology Transfer Office, reflected on the experience, "I was able to work closely with and learn from the licensing and technology transfer specialists within the National Human Genome Research Institute. As part of my experience I was able to draft licensing and transfer agreements, catalogue NIH patent portfolios, and research important bioethics and intellectual property issues related to the cutting edge of genomics research. As part of an incredibly enlightening externship and workshop we were privileged to learn from the Nation's foremost experts in bioethics in genomics research."

LAW & HEALTH CARE PROGRAM CELEBRATES 30TH ANNIVERSARY WITH “HEALTH LAW: PAST, PRESENT, AND FUTURE” PANELS



Sanford Teplitzky, Joanne Pollak ('76), Adjunct Prof. Jack Schwartz and Prof. Leslie Meltzer Henry (from l to r)

On October 30, 2015, the Law & Health Care Program celebrated its 30th anniversary with a panel discussion on “Health Law: Past, Present, and Future” followed by a gala celebration in the law school’s historic Westminster Hall. The panel discussion gave 120 program alumni and local health law practitioners the chance to hear from experts in different areas of health law about how health law has changed over the years from a loosely to a highly regulated industry, where we are now with the Affordable Care Act (ACA), and the way in which biotechnology and big data promise to transform the health care industry – and the field of health law – in the future. At the reception and celebration, attendees listened to a staged reading of a bioethics play written by Professor Karen Rothenberg and a song written by adjunct Professor Jaime Doherty and his law partner Jeff Pecore that revealed the more lighthearted side of the L&HCP.

The “Health Law: Past, Present, and Future” event started with a look back at how health law was studied and practiced a generation ago. The panelists who spoke about “Health Law: Past” were Joanne Pollak ’76, Senior Vice President and General Counsel at Johns Hopkins Medicine, Sanford “Sandy” Teplitzky, Principal at Ober|Kaler, and Jack Schwartz, Adjunct Professor and former Maryland Assistant Attorney

General and Director of Health Policy Development at the Maryland Office of the Attorney General. With questions from L&HCP Professor Leslie Meltzer Henry, all three panelists agreed that they “stumbled” into the practice of health law largely because it was not an established field of study or practice when they started their legal careers. Courses in Law & Psychiatry or Forensic Medicine existed, but beyond these meager offerings, the panelists described their providential entrance into health law by accepting law firm and governmental positions in which they were tasked with some aspect of regulation of the health care industry.

Pollak described learning about the regulation of the health care industry as a young lawyer at Piper & Marbury (now DLA Piper) when three important pieces of legislation were passed in Maryland– the Maryland Certificate of Need Law (1969), the law establishing the Maryland Health and Higher Educational Facilities Authority (1970) and the Health Services Cost Review Commission law (1971). These early regulatory laws trained Pollak in the complexities of the health care industry which have formed the basis of her career largely as counsel for Johns Hopkins Medicine.

Working on complex end-of-life care cases that arose in the 1970s when he worked at the Maryland

Office of the Attorney General set the stage for Schwartz's career as an expert in law and bioethics, particularly end of life care and the right of patients to refuse life sustaining treatment. Teplitzky and Pollak also described their work on early informed consent cases. Pollak recalled arguing a case at the bedside of a patient who did not consent to life saving treatment. Pollak argued – and the judge agreed – that the 1977 *Sard v. Hardy* case (379 A.2d 1014) that established the standard for informed consent in Maryland also provided patients with the option not to consent to medical treatment. The panel agreed that these informed consent cases and Jehovah's Witnesses cases during the same time period fundamentally changed patients' relationships with their doctors. Finally, Teplitzky talked about the evolution of the nation's body of fraud and abuse laws that also grew up in the last thirty years. His early work at the US Department of Health and Human Services in the office that supported the Medicare program led to a long career developing and interpreting fraud and abuse laws, which he now does at the law firm of Ober/Kaler.

The second panel was moderated by L&HCP Professor Ellen Weber and focused on current issues in health law through a Maryland lens. Panelists Carolyn Quattrocki, Executive Director of the Maryland Health Benefit Exchange, and Peter Parvis '77, a Partner at Miles & Stockbridge, focused on recent changes to Maryland's unique Medicare waiver and Affordable Care Act implementation in Maryland.

Under Maryland's "old" waiver which came into place in the mid-1970s, Parvis explained, Maryland hospitals received a waiver from federal Medicare payment methods (i.e., diagnostic related groups) if all payers were charged the same rate for services and the cumulative growth in Maryland inpatient payments was less than the growth of US government inpatient payments. This system was designed to ensure that uninsured patients were not charged the full amount for medical services but rather charged the negotiated rates paid by insurance companies. It also kept rates reasonably related to costs which, for many years, led to the lowest "markup" in the country for medical services. Parvis explained that Maryland has moved to a new waiver program that started January 1, 2014 as a five-year demonstration project. Under this new "global budgeting" waiver program, each Maryland hospital's total annual revenue and reimbursement amount will be known at the beginning of the fiscal year based on historic data adjusted to account for



Prof. Amanda Pustilnik, David Cade ('85), Marcus Wang ('08) and Prof. Frank Pasquale (from l to r)

inflation. The program limits the annual increase in total per capita hospital costs in Maryland to less than 3.58%. This program is designed to focus on population health, prevention, and cost savings by including measures that reduce readmissions, avoid preventable hospitalizations and complications, and increase wellness programs.

Ms. Quattrocki described the "big decisions" that shaped Maryland's implementation of the ACA. As soon as the law was passed, Maryland's Governor set up a task force that determined that the state should be a national leader in ACA implementation, expand Medicaid, and create a robust quasi-public health insurance exchange. Despite early computer problems that stalled the roll out of the exchange, as of October 2015, the reforms brought 750,000 people into either private insurance or Medicaid and decreased the percentage of uninsured from 10.9% of the population to approximately 4.9%.

Finally, the attendees were galvanized by the discussions of the "Future" panel. Speaking on the panel were L&HCP faculty members Frank Pasquale and Amanda Pustilnik, as well as prominent alumni David Cade '85, CEO of the American Health Lawyers Association, and Marcus Wang '08, Co-Founder of ZytoGen, LLC, a preimplantation genetic diagnosis company. Professor Diane Hoffmann, who moderated the panel, started off by asking Cade to comment on the biggest issues that would face health lawyers in the next decade. Looking toward the future, Cade noted that the health law issues that are likely to grow in prominence are regulation of privacy and data security, big data and data analytics, and digital technology such as mobile medical applications. Professor Pasquale, a

nationally-recognized big data expert, followed up on this point and urged the gathered health lawyers to defend professional autonomy from being overtaken by technology. He explained the risk that predictive analytics and pattern recognition may lead people to conclude that professional judgement is not necessary for physicians to diagnose and treat illness. The automation of disability determinations would also challenge fundamental rights to due process and undermine claimants' dignity. Based on his research on big data, predictive analytics, and artificial intelligence in fields where these technologies are more advanced, Pasquale believes lawyers need to be involved in their deployment in health care settings, to assure they are accurate, ethically sound, and economically fair across socioeconomic groups.

Professor Pustilnik, an expert in the intersection of the law and neuroscience, spoke about technology as a new frontier for lawyers that will require all of us to understand the law in new ways and to question if current law is adequate to address the legal and ethical issues that new technologies bring. Pustilnik focused on the use of neuroscience tools to diagnose and understand pain. Historically no tools have existed to measure pain and when the cause of pain is not clear physicians and legal bodies do not know how to assess it. The experience of pain has legal ramifications in terms of disability compensation, determination of tort damages, and health insurance benefits (among other things) but it is often poorly understood by the judicial and administrative bodies that encounter it. Misunderstanding of pain is particularly common when it is unrelated to an injury or separate disease state. Chronic pain that is not peripheral to another condition is often typically treated as a psychiatric disorder although neuroscience technologies are now able to demonstrate that chronic pain causes – and is caused by – changes in brain function. Pustilnik hopes to see pain considered a neurological disease from a medical, legal, and policy perspective. Pustilnik was recently invited to join a working group of the International Association for the Study of Pain to develop international standards for the legal uses of brain imaging.

Finally, Marcus Wang focused his comments on the promises and potential ethical complications of reproductive technologies. Although he sees the clear benefit of providing parents the opportunity to select healthy embryos for implantation, he is aware that the ability to control which embryo becomes a child raises

challenging ethical issues especially at the macro level where overuse of the technology could lead to gender imbalance and elimination of certain conditions and disabilities.

The give-and-take between panelists and audience highlighted the tension between the great promise of technology, its attendant ethical and legal dilemmas, as well as the clear role of lawyers to help ensure that an appropriate and just balance is reached between the two.

The evening – with its scholarly conversations and celebratory moments – was a reflection of the dream that Professor Karen Rothenberg had when she started the L&HCP in 1983. Four years later, Diane Hoffmann left a practice at Dewey Ballantine to help forge new ties with the health sciences on the University of Maryland, Baltimore campus. By 1988, the law school had 11 courses in everything from Civil Rights of Individuals with Disabilities to Legal and Ethical Issues in Biotechnology. The program now boasts 11 faculty members and has graduated over 400 students with the Certificate in Health Law.



Prof. Karen Rothenberg, L&HCP Director Diane Hoffmann and L&HCP Managing Director Virginia Rowthorn (from l to r)



Adjunct Professor Jamie Doherty and Jeff Pecore

HEALTH LAW STUDENTS PARTNER WITH MISSISSIPPI CENTER FOR JUSTICE DURING ANNUAL SERVICE TRIP

by: Reena Palanivel and Allison Best
(2016 Trip Leaders)



Mississippi Center for Justice team and MD Carey Law Health Law students discuss research projects

Maryland Carey Law students have been traveling since early 2006 to the Gulf region of the United States to help with the vast need for legal services created by Hurricane Katrina. In 2009, the Law & Health Care Program (L&HCP) approached the Mississippi Center for Justice (MCJ) in Jackson about creating a trip that focused on health law. MCJ has a well-established health law practice in Jackson and in the northern Delta region of Mississippi focused primarily on access to health care and the legal needs of individuals with HIV disease. Since 2010, groups of 10-12 health law students have spent a week in Mississippi during winter break working closely with MCJ attorneys on outreach and advocacy efforts.

On this year's annual Health Law trip, Maryland Carey Law students had the opportunity to work on several projects focused on HIV/AIDS advocacy and the Affordable Care Act in the Jackson, Mississippi region. To kick off the week, the group of twelve health law students visited a transitional group home for individuals living with HIV/AIDS in inner city Jackson. The residents of the home shared stories of the biggest challenges they have faced since learning of their diagnosis. In response to questions on a legal needs screening tool administered by the students, the residents identified the areas of the law that still need the most improvement. Every resident agreed that ending the stigma surrounding HIV/AIDS is the most important step to ensuring individuals can live well with HIV/AIDS and in ending the epidemic, altogether.

In addition to visiting the group home, half of the

health law students worked on research projects focused directly on the prevalence and impact of HIV/AIDS on different groups around Mississippi. One project focused on exploring how HIV/AIDS impacts the Latino population in Mississippi, many of whom are undocumented and do not have consistent access to health care. Another group compared HIV/AIDS statistics between Mississippi and Arkansas in order to identify which outreach strategies and programs have had the best outcomes on improving access to HIV/AIDS testing and medical care. The third group researched medical-legal partnerships that work with community health centers to improve access to care. The Mississippi Center for Justice plans to use all of the data and information collected by the Maryland Carey Law health law students to prepare its agenda for the coming year and adjust its focus to cover the unmet legal needs of low-income Mississippians.

The second project required legal research, data collection, and brainstorming ideas on the implementation of the Affordable Care Act. The deep south is an area in the country that has high poverty rates which correlates with a high number of uninsured individuals. Some of the major issues involve lack of understanding of the Affordable Care Act, awareness of the state's provisions and benefits, and services for health care. For this project, the students compiled data regarding the uninsured rates in the state of Mississippi and observed the correlation between different federal poverty levels. They also researched the Medicaid enrollment centers in the Delta, mapped out the eighty-four centers and discovered the very

limited days and times per month that individuals can visit them. Lastly, the students identified outreach and education organizations that the MCJ could team up with in order to teach families how to enroll their children into the Children's Health Insurance Program (CHIP). The research project will help the Mississippi Center for Justice focus on outreach and advocacy to increase the number of insured individuals in the state.

Throughout the week, the Maryland Carey Law students enjoyed experiencing Mississippi's culture. The students were able to explore not only the city of Jackson, but also the more rural Delta area. They

toured the Mississippi State Capitol and had the opportunity to meet with several congressmen. They met representatives of different health organizations and collaborated on ideas on how to improve the health system in the state. Finally, they ate delicious southern comfort food, listened to jazz music, and toured the BB King Museum. The Health Law trip provided the Maryland Carey Law students with an amazing, first-hand opportunity to learn about critical issues in health law in a rural setting very different from their home in Baltimore.

PROFESSORS PASQUALE AND HOFFMANN FOCUS ON SOCIAL MEDIA AND RISK MANAGEMENT



Professor Frank Pasquale

On January 13, 2016, the Maryland/DC Society for Healthcare Risk Management and the Maryland Bar Association co-sponsored a conference at the law school titled "When Worlds Collide: The Intersection of Healthcare, Law & Technology." Director of the L&HCP Diane Hoffmann helped organize the event which was developed with two themes in mind – the demonstrations related to the death of Freddie Gray and the role of social media and technology in health care. The symposium was attended by over 200 local risk managers and focused on four topics: the Public Behavioral Health Crisis; Medical and Policy Implications of Mental and Behavioral Health; Social Media and Privacy in Healthcare; and Anticipating Patient and Legal Risks Associated with Emerging Technology. The first two panels focused on heightening awareness of the specific issues faced by law enforcement officers when responding to individuals who are experiencing

a behavioral or emotional health crisis. These challenges in the field are then exacerbated by the lack of behavioral health resources and the lack of acute care beds and outpatient services for the behavioral health patient populations. The second two panels brought together risk managers, hospital attorneys and legal academics to discuss the unique challenges that technology brings to the provision of health care.

Professor Hoffmann moderated the Social Media and Privacy in Healthcare panel which included L&HCP Professor Frank Pasquale, a national expert in social media and health care privacy. Pasquale has an active Twitter presence with 11,700 followers at @FrankPasquale and is a contributing member of the *Concurring Opinions* blog which focuses on a broad range of legal topics including big data and social media issues. The panel looked at access by the media to information about a breaking story or newsworthy event involving an individual who becomes a patient at the hospital and how the hospital can get better control over the social media that is put out about such individuals or the hospital more generally. The panelists – a former television producer who now works in communications at a university, a hospital attorney and Pasquale – looked at the issue from their professional perspectives. Tim Parsons, now Director of Communications at Johns Hopkins Carey School of Business, spoke about his experience trying to get news from hospitals as a television producer and also, in his current role, acting as a gatekeeper of information from the media. Pamela Rayne, Associate Senior Counsel at Johns Hopkins Health System, spoke about navigating between the needs of the media and the legal needs of the hospitals and patients. Professor Pasquale discussed the kinds of things that have gotten on to social media that perhaps should not have and he related some problematic legal cases and news stories in which health care providers shared patient images or information on social media. Finally Pasquale suggested some policies that health care providers might want to think about for employees/staff as to their use of social media.

HOFFMANN AND CO-INVESTIGATORS BRING TOGETHER WORKING GROUP TO DISCUSS REGULATION OF MICROBIOTA TRANSPLANTATION



Microbiota Transplantation Co-Investigators after May meeting

This year, in December and again in May, Diane Hoffmann, Director of the Law & Health Care Program (L&HCP) and her University of Maryland Baltimore (UMB) co-investigators held meetings supported by their NIH-funded grant, “Microbiota Transplantation: Recommendations for a Regulatory Framework.” As we reported in a prior newsletter, in June 2015, the UMB team was awarded a grant from the National Institute for Allergy and Infectious Diseases (NIAID) to study the legal and regulatory aspects of a cutting edge medical treatment called microbiota transplantation (MT). MT is the transplantation of communities of microorganisms from one individual to another. The two-year grant is facilitating a project to study regulatory options for fecal microbiota transplantation and other emerging MT options including vaginal, skin, anterior nares, oral, and whole body microbiome transplants.

At present, there is much interest and increasing evidence-based support for one type of MT - fecal

microbiota transplantation (FMT) - which involves the transplantation of fecal material obtained from a healthy individual into the gastrointestinal tract of a patient recipient to treat disease. FMT has been found particularly effective in treating recurrent *Clostridium difficile* infection (CDI), a virulent infection that causes inflammation of the colon and deadly diarrhea. According to the CDC, CDI causes almost half a million infections among patients in the United States every year. In 2011, approximately 29,000 patients died within 30 days of the initial diagnosis of CDI and of those, about 15,000 deaths were estimated to be directly attributable to CDI putting it among one of the top causes of infectious disease death in the United States. It is the most common microbial cause of healthcare-associated infections in US hospitals and costs up to \$4.8 billion each year in excess health care costs for acute care facilities alone. More than 80 percent of the deaths associated with CDI occurred among Americans aged 65 years or

older. Importantly, one out of every five patients with healthcare-associated CDI experience a recurrence of the infection.

FMT is used to treat patients with recurrent CDI who, in the past, had few treatment options. Before FMT was clinically available – and still to this day – desperate patients have resorted to “do-it-yourself” FMT at home in some cases relying on YouTube videos that provide detailed instructions. According to Catherine Duff, Executive Director of The Fecal Transplant Foundation, a nonprofit that is advocating for safer, more widespread access to the treatment, about 10,000 people perform at-home FMT in the United States each year, notwithstanding the infection risk associated with sharing stool.

As physicians have started to provide FMT to patients with recurrent CDI, stool banks have opened to provide fecal material to physicians performing FMT. While there are a number of stool banks in hospitals, larger stool banks have opened, including OpenBiome in Cambridge, MA and Advancing Bio in California, that provide screened frozen fecal material ready for clinical use. In addition, various applications of microbiome-based products to treat CDI and other conditions are currently being studied by pharmaceutical companies and biotechnology start-ups, such as Seres Health, Rebiotix, and Repopulate, that are developing specially-designed biotherapeutic products that treat CDI and other conditions by transferring microbial communities or cocktails to a recipient via enema, colonoscopy or orally in pill form.

The Food and Drug Administration (FDA) is actively considering how to regulate FMT. At present, FDA classifies FMT as a procedure involving live biotherapeutics (a category of drugs), but is exercising “enforcement discretion” for recurrent CDI if the donor is known to the recipient and if adequate informed consent is obtained from the patient. On March 1, 2016, FDA issued another draft guidance document on FMT which does not alter FDA’s current enforcement discretion policy. While the March 2016 draft guidance does not include the requirement that the donor be known to the recipient, it states that FMT may be used for recurrent CDI if “the FMT product is not obtained from a stool bank.” The draft guidance explicitly states that stool banks must have an IND application in place before distributing FMT product but – importantly – under the new guidance

an IND sponsor may request a waiver of certain IND regulations when it is providing FMT product to doctors treating patients with recurrent CDI. FDA is using the new March 2016 guidance to solicit feedback on this general proposal, and on which parts of the IND application would be appropriate to waive.

Under the grant, the co-investigators put together a working group of approximately 30 expert stakeholders including scientists, clinicians, patient and professional association advocates, bioethicists, academics, lawyers, and individuals from the biotechnology industries who have an interest in microbiota transplantation or expertise relevant to the project. In addition, representatives of FDA and NIH participate as observers.

At the first meeting in December, prominent microbiome researchers who are part of the working group discussed the microbiota communities that reside in the gut, vagina, nasal and oral cavities, and skin and the status and gaps in research about microbiota transplantation in those body sites. The working group also studied potential frameworks for regulation of FMT including the existing frameworks for blood and tissue. At the May meeting, the working group went beyond regulation of FMT and considered how vaginal and oral microbiota transplantation should be regulated by comparing the critical similarities and differences raised by transferring these microbial communities at different body sites. For instance, studies show that increased microbial diversity in the gut confers a health benefit, whereas a healthy vaginal tract is associated with colonization by a single *Lactobacillus* bacteria. The working group considered this and other differences that might influence how different forms of MT should be regulated.

At the May meeting, Dr. Rob Knight, a prominent microbiome researcher at University of California San Diego spoke to the working group via Skype regarding cutting edge research conducted by principal researcher Dr. Maria Dominguez-Bello, a New York University School of Medicine faculty member. In what some call a “whole body microbiome transplant” researchers swabbed babies born by Cesarean section with gauze covered in their mothers’ vaginal fluids. The concept is to confer the microbial communities the baby would have received if it had been born via the birth canal. The transfer of maternal microbial

communities is thought to help babies' immune systems develop. Only a small proof-of-concept study has been conducted to date, but there is excitement about this form of MT and the working group will consider how it should be regulated along with other forms of MT. Dr. Knight also discussed the potential use of MT to treat malnourished infants whose gut

microbiota may not be able to recover from the effects of malnutrition, thus leading to long-term negative health sequelae.

The working group will meet for the third and final time in December 2016 to finalize recommendations that will appear in a white paper.

UMB Microbiota Transplantation Investigators

- Diane Hoffmann, Law & Health Care Program, University of Maryland Carey School of Law (Principal Investigator)
- Dr. Frank Palumbo, Center on Drugs and Public Policy, University of Maryland School of Pharmacy
- Dr. Jacques Ravel, Institute for Genome Sciences, University of Maryland School of Medicine
- Dr. Mary-Claire Roghmann, Department of Epidemiology and Public Health, University of Maryland School of Medicine
- Dr. Erik von Rosenvinge, Division of Gastroenterology, University of Maryland School of Medicine and Veterans Affairs Maryland Health Care System
- Virginia Rowthorn, Law & Health Care Program, University of Maryland Carey School of Law

“FREDDIE GRAY’S BALTIMORE” – A NEW COURSE DESIGNED TO TEACH AND HEAL



On April 12, 2015, Freddie Carlos Gray, Jr., a 25-year-old African American was arrested by the Baltimore Police Department for possessing a switchblade. While being transported in a police van, Gray fell into a coma and died from injuries to his spinal cord. Mr. Gray was not secured inside the van while driving to the police station. On May 1, 2015, the Baltimore City State's Attorney filed charges against six police officers after the medical examiner's report ruled Gray's death a homicide on the grounds that Gray had died as a result of a 'rough ride'—a form of police brutality in which a victim is helplessly thrown around the interior of a police vehicle by deliberately abrupt police driving. The incident caused demonstrations in Baltimore primarily among African Americans who wanted to express their anguish about the specific incident and decades of inequitable treatment on a multitude of fronts. In response to the palpable distress of the city in the aftermath of the incident, eleven Maryland Carey Law faculty members, including Law & Health Care Program faculty members Michael Greenberger (course master), Diane Hoffmann, and Deborah Weimer, developed an 8-week course called *Freddie Gray's Baltimore: Past, Present and Moving Forward* to help students at the University of Maryland Schools of Law and Social Work explore the causes of, and possible solutions to, the unrest in Baltimore.

The course attracted almost 100 law and social work students as well as extensive media coverage when it was introduced in Fall 2015. The class was held in the law school's largest lecture hall and its leaders still needed to turn away applicants. The course was offered again in Spring 2016 at the law school as well as to undergraduate students at the University of Maryland in College Park.

The course focused on social, economic and other issues facing the citizens of Baltimore, including

policing practices, criminal justice, access to housing, health care, education, joblessness and community development. Professor Hoffmann organized the class module that discussed the intersection of poverty and health and worked with health law faculty members Deborah Weimer, Ellen Weber and Sara Gold to create a class that explained the impact of the social determinants of health (including socioeconomic status, education, the physical environment, employment, and social support networks) in Baltimore. During the fall class, Dr. Leana S. Wen, the City of Baltimore's Health Commissioner, spoke to the class about her efforts to improve the health of Baltimore's residents which she sees as a critical cornerstone of well-being and social justice. Following Dr. Wen's talk, the faculty team arranged for a "standardized patient" to interact with students. The "patient" was an actor taking on the role of a resident of the Sandtown Winchester neighborhood of Baltimore which suffers from a high level of poverty and need and was the home of Freddie Gray. Students interacted with the patient regarding her health care needs and were able, through the stories she related, to understand the impact of her life's challenges on her health and her ability to access health care. After hearing from the patient, the students were asked how they as lawyers or social workers could help the patient in ways that might affect her health. The takeaway message for the students was that the law itself can be a social determinant of health.

The Freddie Gray course arose from conversations among law school faculty about how to help students understand the many issues raised by Freddie Gray's death. The course is intended to be a springboard for further student and faculty involvement in citizen and government efforts to reform law and policy for the benefit of the city and beyond.



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forwarded to the above address.*

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

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