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In this Issue:

FOCUS ON . . .
MENTAL HEALTH, ADDICTION AND LAW

Law & Health Care Program (L&HCP) faculty members are currently leading two significant initiatives relating to mental health and the law. The first, under the direction of Professor Ellen Weber, is an Open Society grant-funded project looking at the implementation of substance abuse and mental health laws under the Mental Health Parity and Addiction Equity Act and the Affordable Care Act. The second project, a joint initiative of the law school's Center for Dispute Resolution (C-DRUM) and the L&HCP, is an interdisciplinary project to study and make recommendations regarding assisted outpatient treatment (AOT) for individuals with mental health disorders. These two projects are described in more detail below.

Advancing Access to Addiction Treatment Project

Under a two-year $350,000 grant from the Open Society Institute, the School of Law's Drug Policy and Public Health Strategies Clinic led by Professor Ellen Weber is undertaking an expanded leadership role in policy development, advocacy and public education relating to the implementation of federal health reform in Maryland. Paige Lescure, a healthcare law attorney with over twenty years of experience in private practice, has joined Professor Weber as a Senior Healthcare and Policy Fellow in the Drug Policy Clinic to carry out the Advancing Access to Addiction Treatment initiative. The grant work focuses on health related issues of individuals with substance use disorders or a history of addiction, including the enforcement of the Mental Health Parity and Addiction Equity Act, the provision of comprehensive benefits under the new reform payment and insurance models and the coordination and integration of addiction and other health services.

During the 2011 Maryland General Assembly Legislative Session, Weber, Lescure and their clinic students worked actively to promote the inclusion of persons with expertise in addiction treatment as well as consumers in developing the

Diane Hoffmann, Director of the L&HCP, at table with members of the AOT Project Legal Subcommittee.

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State's Health Benefit Exchange structure and to ensure that legislation implementing the Affordable Care Act's claim review and appeal procedures provided full protections for consumers. The Clinic also developed a set of principles to guide the State's initiative to integrate the financing and delivery of addiction and mental health services and has been working with State health officials to secure the release of Medicaid data that is necessary to inform that effort.

With State agencies moving forward with plans to improve preventive services and care coordination, the Clinic has taken an active role to ensure that the State recognizes the cost savings available through early identification of problematic alcohol and drug use. Lescure is leading a multi-partner effort to expand the Maryland Patient Centered Medical Home Pilot to appropriately include early identification and screening for alcohol and drug problems and to expand screening and intervention practices in secondary school based health centers in Baltimore City and across the State. Under federal health reform law, school based health centers will play an increasingly important role in primary care and preventive care for children and adolescents.

As Maryland moves forward with its development of the State Health Benefit Exchange, the Clinic is taking an active role with its partners to ensure that persons with chronic health conditions and limited income will have their health care needs adequately addressed in the Exchange. Professor Weber has been named to the Exchange's Navigator and Enrollment Advisory Committee, which will assist in developing options for the navigator program and other consumer assistance tools.

On a separate track, as the State and advocates are awaiting decisions by the federal government on the essential health benefit package for health plans that will be offered through the Exchange, the Clinic is working to ensure that federal parity standards are being enforced by existing health plans. Weber has been educating treatment providers around Maryland about the federal insurance parity protections, developing materials to facilitate self-enforcement of the law and investigating large self-insured employers whose health plans may be in violation of the parity law. These efforts are designed to ensure that plans provided through the Exchange are compliant with parity standards.

Beginning in January 2012, students in the Drug Policy Clinic will work with Weber and Lescure to actively engage with state health and planning agencies, addiction and mental health organizations, community-based partners, and the Maryland General Assembly to promote specific policy innovations and reform implementation legislation that support the rights and health needs of persons with substance use disorders. In addition, students will participate in provider education efforts relating to health privacy and security issues for addiction treatment under new federal laws as well as broader community education regarding the clinical and economic benefits inherent in preventive and comprehensive addiction treatment services.

Assisted Outpatient Treatment

As we reported in the Spring 2011 edition of the newsletter, on April 25, 2011, the L&HCP and the law school's Center for Dispute Resolution (C-DRUM), in conjunction with the UMD Schools of Medicine and Social Work, held an interdisciplinary meeting of stakeholders and academics to discuss the emotional and controversial topic of assisted outpatient treatment (AOT) - also known as "mandatory outpatient treatment" and "civil commitment". L&HCP Professors Diane Hoffmann, Richard Boldt, Roger Wolf, and Amanda Pustilnik organized

Paige Lescure joined the law school as Senior Health Law & Policy Fellow in the Drug Policy and Public Health Strategies Clinic in 2010 after a 20-year tenure in private practice at the Maryland law firm, Miles & Stockbridge, P.C., where she specialized in health care law. Lescure brings to the Drug Policy Clinic her extensive expertise in health regulatory matters with a concentrated focus on federal self-referral and anti-kickback law; health care privacy issues; and health care advocacy. As a patient rights advocate, she was a lead author of the Health Freedom bills in Maryland and adjunct faculty at Goucher College and Tai Sophia Institute. Lescure received her law degree from the University of Connecticut School of Law and an LL.M. in Health Care Law from the New York University School of Law

the conference along with Dr. Steven Sharfstein, President and Chief Executive Officer of Sheppard Pratt Health System in Baltimore, Dr. Anthony Lehman, Chairman of the Department of Psychiatry at the UMD School of Medicine, and Dr. George Unick from the School of Social Work. The conference was designed to educate stakeholders in Maryland regarding the issue of AOT.

In follow-up to this first meeting, a smaller group of stakeholders met on June 1st and discussed initial conclusions regarding how to move forward with reforms to improve access to care in Maryland for mentally ill patients.

As background on the issue, AOT refers to laws and regulations that permit courts to require certain individuals with mental illness to take medication or to comply with other restrictions or face the risk of involuntary outpatient commitment in a psychiatric facility. This concept of involuntary outpatient commitment goes beyond the traditional concept which only permits involuntary commitment of an individual if he or she presents a harm to himself or others. The concept of AOT arose in the psychiatry community in the 1980s following widespread deinstitutionalization during which large numbers of people with mental illness were released from psychiatric institutions. While most individuals benefit greatly from treatment in the community, a small number of patients fall through the cracks and are noncompliant with their medication for various reasons. Noncompliance can lead to frequent relapses, repeated visits to emergency departments, repeated inpatient psychiatric admissions, and frequent contact with the criminal justice system.

High profile crimes such as the murders of Laura Wilcox in California and Kendra Webdale in New York led to the passage of laws in those states that allow AOT. Proponents believe that AOT regimes increase adherence to medication and thereby prevent deterioration and subsequent harm to the individual and others. Since the 1980s, all but a few states have passed some form of AOT although the states that have such laws vary considerably in their willingness and ability to implement and fund necessary community treatment once an individual is placed under a legal requirement to access care. According to UMD Law Professor Richard Boldt, there are three models of AOT currently in use in the United States:

1. Conditional release, which permits outpatient commitment only after some form of inpatient commitment.
2. Front-end commitment of an individual to community-based outpatient treatment without any preliminary requirement of inpatient treatment, using the same criteria as used for inpatient commitment.[1]
3. Preventive commitment which, while also a front-end outpatient commitment approach, utilizes eligibility criteria that depart from the jurisdiction's inpatient commitment provisions. States with well developed AOT statutes like New York's Kendra's Law use this approach.

For those states that use criteria for outpatient commitment that go beyond the traditional "harm to self or others" standard for inpatient commitment, the AOT criteria generally include the following:

- The individual is unable to make a rational, informed decision about treatment.
- The individual has a history of mental illness that has either: (1) at least twice within a specified period of time been a significant factor in necessitating hospitalization or receipt of mental health services in a correctional facility; or (2) resulted in one or more

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Professor Ellen Weber's Work Cited in 4th Circuit Opinion

Judge Andre Davis of the U.S. Court of Appeals for the 4th Circuit cited Professor Ellen Weber's work in a concurring opinion in the case of *U.S. v. Gregg* (2011 WL 2420267 (C.A.4 (Va.)). Judge Davis cited Weber's scholarship when discussing the harsh effect of drug law policies on communities of color, especially the disproportionate impact on female offenders. He noted a 2005 article by Weber as support for this proposition, "Bridging the Barriers: Public Health Strategies for Expanding Drug Treatment in Communities," 57 Rutgers L.Rev. 631, 644–48 (2005)).

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acts, attempts, or threats of serious violent behavior toward self or others within a specified period of time.

- The individual, as a result of mental illness, is unlikely to voluntarily participate in treatment but would be likely to benefit from such treatment.
- The individual, if he or she does not receive treatment, will continue to deteriorate and will either become impaired in his or her ability to function independently or will become imminently dangerous to himself or herself or others.
- The individual is unlikely to survive safely in the community without support or supervision.

Professor Amanda Pustilnik, Co-Organizer and Speaker, AOT Conference

The exact form of these laws varies by county, and often by state. Some require court hearings and others require that treating psychiatrists comply with a set of requirements before compulsory treatment is instituted. When a court process is not required, there is usually a form of appeal to the courts or appeal to or scrutiny by tribunals set up for that purpose. Community treatment laws have generally followed the worldwide trend of community treatment.

One issue raised at the first University of Maryland AOT meeting was the pivotal question – does AOT work? A report by the RAND Corporation that was commissioned by the Senate Committee on Rules in 2001 in response to pending AOT legislation in California (Laura's Law) determined that there was no evidence that AOT worked as hoped by legislators and consumers. The study, led by UMD Law alum Susan Ridgely, reviewed the available studies, interviewed stakeholders in eight states, and analyzed administrative data on services provided by California's county mental health contract agencies. They concluded that:

- There is no evidence that a court order is necessary to achieve compliance and good outcomes, or that a court order, in and of itself, has any independent effect on outcomes.
- The attorneys, behavioral health officials, and psychiatrists who were interviewed support involuntary outpatient treatment as a way to make sure people get needed services, but many feel the services offered in their communities are inadequate for making involuntary outpatient treatment work.
- The data suggest that a significant percentage of people with mental illness who need services aren't getting them, and those who do, get very few.[2]

However, more recent research conducted by Duke School of Medicine psychiatrist Marvin Swartz regarding Kendra's law in New York has shown that AOT is effective when funded adequately (as has been the case in New York). The New York law – popularly known as Kendra's Law – was created in 1999 and authorizes court-ordered treatment in the community for people with severe mental illness at risk of relapse or deterioration absent voluntary compliance with prescribed treatment. To be eligible for the program, individuals must be at least 18 years of age, diagnosed with mental illness and assessed to be unlikely to live safely in the community without supervision. In addition, recipients must have a history of treatment noncompliance that has resulted in (1) psychiatric hospitalization or incarceration at least twice in the past 36 months, or (2) committing serious acts or threats of violence to self or others in the past 48 months. Finally, these individuals must be found, as a result of their mental illness, to be unlikely to voluntarily participate in treatment and to be in need of AOT to prevent deterioration that would likely result in harm to themselves or others. Once an AOT order is finalized by a court, recipients are engaged in a comprehensive community-based treatment plan and extensively monitored for adherence to the plan.

Swartz, who spoke at the April 25 meeting at the law school, determined that a well-funded AOT program can be successful. Specifically, the final report published by his team noted that

> *We find consistent evidence that during AOT there is a substantial reduction in the number of psychiatric hospitalizations and in days in the hospital if a person is hospitalized. We also find moderately strong evidence from lifetime arrest records of AOT and EVS [enhanced voluntary service] recipients from the NYS Division of Criminal Justice Services that AOT reduces the likelihood of being arrested. We find substantial increases in receipt of intensive case management services during AOT. We also find that AOT recipients are far more likely to consistently receive psychotropic medications appropriate to their psychiatric conditions. Case man-*

agers of AOT recipients also report subjective improvements in many areas of personal functioning, such as managing appointments, medications, and self-care tasks.[3]

Notwithstanding evidence of its effectiveness and the arguments on behalf of AOT proponents that outpatient commitment improves mental health outcomes, increases the effectiveness of treatment, and reduces costs – a vocal number of opponents argue that these laws criminalize behavior of individuals with mental illness, unnecessarily limit freedom, force people to ingest dangerous medications, or are applied with racial and socioeconomic biases.

The Working Group brought together by the UMD interdisciplinary team includes members with varying viewpoints on this issue who have agreed to work together to see if areas of consensus can be reached and, if so, develop policy recommendations that reflect the areas of consensus. At the June 1st meeting, the Working Group did not agree on an AOT proposal but rather agreed to work together to design a model program that would engage and provide support in the community to individuals with serious mental illness whom the system has had difficulty engaging.

The Working Group created three subcommittees – Program, Legal and Data Subcommittees to pursue a model program. The first task of the Program Subcommittee created at the meeting was to define the target population of the model program. The target population is likely to be individuals who are high-utilizers of acute mental health care resources, the criminal justice system and homeless services, as well as individuals who may not be high-utilizers but who could benefit from an enhanced, targeted and comprehensive treatment approach. The subcommittee is also studying existing programs and evaluation data, identifying successful program elements in existing programs and using this information to design a model program for Maryland.

The Data Subcommittee is studying the data currently available in Maryland to provide information on cost and utilization of current programs and to develop evaluation measures for the program(s) developed by the Program Subcommittee. Finally, the Legal Subcommittee is studying legal issues relating to implementation of the model program in Maryland, including confidentiality, HIPPA, liability, and harassment issues.

References

[1] The traditional standard for inpatient commitment is the finding of mental illness and dangerousness or grave disability.

[2] http://www.rand.org/pubs/research_briefs/RB4537/index1.html.

[3] http://www.macarthur.virginia.edu/aot_finalreport.pdf.

Externship Leads to Prescription Drug Monitoring Advisory Council Appointment

Thelma Wright, a practicing physician and third year law student, was recently appointed by the Secretary of the Maryland Department of Health and Mental Hygiene (DHMH) to serve as a member of the state's Advisory Council on Prescription Drug Monitoring. Dr. Wright, a Board-Certified Anesthesiologist and palliative care specialist, has a long-standing interest in the regulatory and legal issues surrounding the treatment of pain and prescription drugs. In the Summer of 2011, she externed for the American Pain Foundation in Maryland and helped draft a survey for Foundation members (mostly pain patients) regarding prescription monitoring and how it would affect the members' pain care needs. This interaction with Maryland's new Prescription Drug Monitoring Program (PDMP) led Dr. Wright to seek membership on the advisory council. After an interview with DHMH Secretary Joshua Sharfstein, MD, she was officially appointed to the Advisory Council in September.

The intent of monitoring programs, which have been enacted in other states, is to decrease diversion and abuse of prescription medications. PDMPs help identify and track health care professional prescribing activities as well as the recipients of these prescriptions. A PDMP allows health care providers and/or law enforcement officials to identify individuals who obtain prescriptions from multiple providers and who may be "doctor shopping" for medications that can be abused or diverted for monetary gain. Since its creation, the Advisory Council explored other states' PDMP programs and advocated the creation of such a program in Maryland. At the close of the 2011 Maryland legislative session, a bill was signed into law by the Governor to enact a PDMP. The Advisory Council will monitor the implementation of the new program.

Dr. Wright was supervised during her externship by Mary Vargas, an attorney and Vice-Chair of the American Foundation Board of Directors & Pain Community Advisory Council Representative to the Board.

Professor Karen Rothenberg Teaches Genomics Workshop with NIH Colleague

In the Spring 2011 semester, Law & Health Care Program Professor Karen Rothenberg joined together with NIH bioethicist Benjamin Berkman, J.D., M.P.H., to teach a new Health and Science Policy Workshop. Berkman is the Deputy Director of the Bioethics Core at the National Human Genome Research Institute and a faculty member in the NIH Department of Bioethics. The Workshop – formally titled " Health and Science Policy Workshop: The Regulation of Genomic Research" – was a five credit intensive experience for students who were given the opportunity to spend many hours at NIH in Bethesda, Maryland attending institutional review board (IRB) meetings and interviewing experts in the field of genomics.

According to Rothenberg, the goal of the Workshop was to study the cutting edge bioethical issues raised by whole genome sequencing which is increasingly available and affordable. The first few decades of

Professor Karen Rothenberg (far left), Professor Benjamin Berkman (far right) and students at NHGRI

Student Presentation Topics

Category 1: The contours of an ethical obligation to return incidental research results

1. How should we define and determine what constitutes clinically useful information?
2. How much effort is required to satisfy an obligation to look for incidental findings?
3. To what extent does the "resource excuse" mitigate the obligation to look for and return incidental genetic research results?

Category 2: Legal issues raised by incidental research results

1. In addition to an ethical obligation to return incidental research results, are there any legal arguments (e.g., duty to warn, contractual, professional responsibility, right to access personal information) that might support an obligation to return findings?
2. Is there a legally enforceable right not to know genetic findings, and is it ever appropriate to override an individual's desire not to know?
3. How does CLIA (the Clinical Laboratory Improvement Amendments) interact with the return of incidental research findings, and does the law need to be revised given new genomic research technologies?

Category 3: Ethics review of genomic research

1. Is it necessary to revise the current human subject research regulatory framework given advances in genomic research technologies?
2. Do advances in genomic research technology raise new concerns about group harms, and are the current regulations adequate to protect against possible group harms?

genetic research were characterized by a targeted genetic research paradigm; the ethical, legal and social implications (ELSI) associated with this "first phase" genetic research were focused primarily on concerns about informed consent, stigma, privacy (both individual and group), and genetic discrimination. Rothenberg was at the forefront of academics who studied these initial concerns and much of the current public policy surrounding genetic research is based on her work.

The past couple of years, however, have been marked by a transition into a new phase of research that focuses on the genome as a whole. The increasing availability of next generation sequencing makes it easier for laboratories to engage in genomic research. The ELSI concerns previously associated with targeted genetic research are amplified by the magnitude and types of information generated by large-scale genomic sequencing. Concerns that had been rare now are becoming more prevalent and more complex, and IRBs are being called upon to review the ethics of research involving the use of these emergent, cutting edge technologies in research with human subjects prior to the development of ethical consensus and regulatory guidance about the use of these technologies. For example, genomic research with human subjects raises complicated questions about the management of incidental or secondary findings. Incidental findings are research results concerning an individual research participant that have potential health or reproductive importance and are discovered in the course of conducting research but are beyond the aims of the study. There are controversial questions about how, to whom, and under what circumstances to return incidental results. Genomic research also raises questions about the nature and magnitude of individual and group risks associated with genetic and genomic information.

Students in the Workshop worked with Rothenberg and Berkman to examine these and other ethical, legal, and social issues and to develop a regulatory framework for genomic research. The students presented their findings to a group of NIH researchers including the Director of the National Human Genome Research Institute, Eric D. Green, M.D., Ph.D. Rothenberg and Berkman are now in the process of converting several of the presentations into articles for publication.

Professor Karen Rothenberg Spends Academic Year 2011-2012 at NIH

Professor Karen Rothenberg, founding Director of the University of Maryland School of Law's Law & Health Care Program, is spending the year at the National Institutes of Health (NIH) as Special Advisor to the Director of the National Human Genome Research Institute and as a Visiting Scholar in the Bioethics Program at the NIH Clinical Center. This will be Rothenberg's second special assignment at NIH – in 1995-1996, she served as Special Assistant to the Director of the Office of Research on Women's Health at NIH. Over twenty years ago she also spent her sabbatical at the National Institute for Child and Human Development

Rothenberg will be working on the following major projects:

- Evaluating the Ethical, Legal and Social Implications (ELSI) Program and directions for the future of the program; assessing the program's research portfolio and grant process; exploring strategies for better integration of extramural, policy and intramural initiatives; researching global ELSI issues; reaching out to the research community and public, including a fact-finding visit to Australia where she will also make a number of presentations.
- Co-authoring a number of research papers that build on the Science and Health Policy Workshop Rothenberg taught in the Spring in collaboration with Berkman. The Workshop students studied the regulation of genomic research and the return of research results and incidental findings from whole genome sequencing and a number of them (all recent graduates) are continuing to work with Rothenberg and Berkman on their research toward joint publication.
- Mentoring legal fellows and UM Carey Law externs in the NIH Bioethics Program and NHGRI.
- Exploring how theatre vignettes can enhance our understanding of ELSI issues in genetics and other cutting edge technologies. She is leading a number of sessions with NHGRI staff and trainees using vignettes to stimulate discourse on such issues as the return of research results and incidental findings. In addition, Rothenberg will continue her long-term research project on theatre and science and health policy.

Professor Diane Hoffmann Speaks on Medical Marijuana

On June 27, Diane Hoffmann, Director of the Law & Health Care Program, spoke as part of an ABA Health Law Section Teleconference entitled, "Medical Marijuana: A Public Health Legal Conundrum?" Hoffmann reviewed the laws in the 17 jurisdictions that have decriminalized medical marijuana, comparing and contrasting them and considering their approaches to patients, dispensers, and growers. Hoffmann's talk was based on the *New England Journal of Medicine* article she published with her colleague Professor Ellen Weber regarding the decriminalization of medical marijuana. In the teleconference, Hoffmann noted that the policy issues surrounding decriminalization of medical marijuana continue to evolve, particularly in the area of federal/state interaction.

Professor Diane Hoffmann

One issue gaining increasing attention is the backlash by local governments against medical marijuana dispensaries for a number of reasons, including fear of increased criminal activity surrounding dispensaries. In California, for instance, where dispensaries are regulated on the local level, a number of court cases have arisen especially when local governments have tried to ban dispensaries. A question often raised in these cases is whether the state law that allows medical marijuana dispensaries preempts local jurisdictions from banning them.[1] In other locations, for example Billings, Montana, the local government approved a temporary moratorium on the opening of new marijuana storefronts shortly after firebombs were tossed at two such businesses and the town of Kalispell, Montana banned any new medical marijuana stores following the bludgeoning death of a patient that authorities believe was related to the theft of medical marijuana plants. Concerns relating to dispensaries appear to be leading states to more tightly control the availability of marijuana through dispensaries by, among other things, limiting the number of dispensaries that can be established, requiring dispensaries to obtain licenses from state agencies, and/or requiring numerous security measures. However, as Hoffmann noted during the teleconference, there has been pushback from the U.S. Department of Justice (DOJ) to the dispensary approach to making marijuana available to qualified patients.

Recently, DOJ has written letters to Governors in over half of the states that have decriminalized marijuana regarding their laws, proposed laws or regulations that set up a licensing scheme for the establishment of dispensaries or "grow houses" (entities that grow medical marijuana). These letters have stated that such licensing schemes may permit large scale marijuana cultivation and distribution of marijuana and that DOJ would consider imposing civil and criminal legal remedies against those who set up marijuana growing facilities and dispensaries for violating federal law. These letters have prompted some states to put a halt to licensing plans for dispensaries or growing facilities. After receiving such a letter, the state of Arizona filed a complaint seeking a declaratory judgment against DOJ and requesting a determination as to whether the Arizona state law complies with federal law or whether it should be declared preempted in whole or in part. The ACLU and others have filed a motion to dismiss the case.

Another issue that has arisen in the medical marijuana legal arena relates to whether the Americans with Disabilities Act (ADA) protects users of medical marijuana from workplace discrimination. Hoffmann addressed this issue in the teleconference. She noted that many people taking medical marijuana would likely meet the definition of disabled under the ADA but the more difficult issue is whether the individual can perform the "essential functions of the position" either on her own or with the help of a reasonable accommodation. While a person actively affected by marijuana would arguably present a safety threat to herself or others on the job, a more difficult issue arises if an individual smokes marijuana outside of the job but tests positive for marijuana or marijuana metabolites. The ADA states that the term "a qualified individual with a disability" does not include any employee or applicant who is currently engaging in the illegal use of drugs – so the law expressly provides that an employer may prohibit the illegal use of drugs at the workplace by all employees. The "illegal use of drugs" is defined in the ADA as "the use of drugs, the possession or distribution of which is unlawful under the Controlled Substances Act. But, such term does not include the use of a drug taken under the supervision of a licensed health care professional." Hoffmann believes that one could argue that medical marijuana use -- if outside the workplace and if the person can otherwise do their job -- should not be grounds for discharge if recommended by the patient's physician. In such a case, an employer might have to make reasonable accommodations such as using a functional test to measure the effects of the drug rather than a test to measure the mere presence of the drug in the individual's body.

However, notwithstanding this statutory analysis, Hoff-

mann noted that in cases in which someone who is using medical marijuana in a state that has decriminalized it has been fired because of a positive drug screen, the courts have sided with the employers. Only two of those cases referred specifically to the ADA but, nonetheless, the courts sided with the employers. Hoffmann believes that the bottom line with respect to the ADA and similar state laws is that the law in this area is still evolving and therefore it is still difficult for employers to determine what they must do to minimize their legal risk in this area.

Reference

[1] See e.g., *Montana Caregivers Assoc. LLC and MCM Caregivers, Inc. v. United States*, U.S. Dist Court, Dist. Of Montana, (Case 9:11-cv-00074-DWM) (2011).

Professor Barbara Olshansky Litigates Coerced Sterilization with Students in Namibia Clinic

In Spring 2010 and 2011, under the direction of Visiting Professor Barbara Olshansky, the Namibia team of UMDLaw's International and Comparative Law Clinic (ICLC) spent a semester in Namibia working on a number of legal projects, one of which focused on the highly charged issue of the compelled sterilization of HIV-positive women.

Professor Barbara Olshansky (in red) working with students in Namibia.

The students' legal work developed from an investigation commenced in 2008 by Olshansky in her prior position as an Associate Professor of Human Rights at Stanford University Law School. In collaboration with the Legal Assistance Centre of Namibia ("LAC") and the International Committee of Women and Children Living with HIV/AIDS ("ICW"), Olshansky and her students working in the 2008 Namibia Clinic began investigating complaints received by their local partner, the LAC, that HIV-positive women had been coerced into signing a document, which although unknown to them at the time, appears to have authorized their doctors to perform a sterilization procedure after each of the women gave birth by caesarean section.

Following the preliminary investigation, Olshansky and the LAC decided to further investigate, and then ultimately litigate the first thirteen cases in which HIV-positive women were subjected to involuntary sterilization when they sought health care services in rural public clinics and urban public hospitals. According to Professor Olshansky, the information collected from field interviews indicated that the women who have been sterilized were all HIV-positive, poor, living in traditional communities, and treated in the public clinics and hospitals which serve nearly all of the country's black Namibians. In most of the cases, the women came to the hospital while they were in labor in an attempt to follow their HIV treatment protocol and the protocol to prevent mother-to-child transmission of the virus.

In a number of the cases, the nurses who were assigned to handle the women's labor and delivery told the women that they would not be permitted to see the doctor who would perform their c-section until they signed a form consenting to sterilization. The extent to which the nurses explained the purpose of the consent form, the type of procedure that it authorized, or the permanency of the type of sterilization procedure that would be used differs from case to case. However, as far as researchers have been able to ascertain, in all cases the consent form was only provided in English and no effort was made to translate it or to explain its meaning to women who spoke Namibian languages other than English (there are five official languages in Namibia). As a result, the women did not understand that they were going to be subjected to a sterilization procedure, that the procedure would significantly reduce or eliminate their ability to have more children, that there were health risks associated with the procedure, and that there were alternatives to sterilization that would virtually ensure that there would be no mother-to-child transmission.

The ICLC students, under Olshansky's leadership, researched the law on extinctive prescription (Namibia's version of the statute of limitations bar), the law of informed consent, the parameters of damage awards, and most importantly, the meaning of the constitutional guarantees to life, liberty, and due process, three foundational rights that had not yet been interpreted by Namibia's Supreme Court. In addition to drafting memoranda on these issues, the students also drafted a number of the pleadings in the case,

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Maryland Health Care Ethics Committee Network Studies Medical Futility and Maryland Law

The Maryland Healthcare Ethics Committee Network (MHECN), a membership organization created by the L&HCP to provide informational resources to ethics committees in Maryland,[1] has turned its focus to the issue of medical futility and how the concept plays out in Maryland law and practice. Medical futility typically refers to a type of conflict over end-of-life medical treatment, usually the type of treatment provided in a hospital's intensive care unit. In these disputes, the patient almost never has capacity to understand and make treatment decisions, so health care decisions are made by the patient's substitute decision makers. A typical medical futility dispute pits a surrogate decision maker who wants all available treatment for a relative who is either in a terminal, end-stage condition, or persistent vegetative state against the patient's health care providers who have concluded that further treatment would be medically ineffective.

Maryland, unlike many other states, defines "medically ineffective treatment" by statute pursuant to the Maryland Health Care Decisions Act (HCDA). The fairly narrow definition is as follows:

> "Medically ineffective treatment" means that, to a reasonable degree of medical certainty, a medical procedure will not:
>
> 1. Prevent or reduce the deterioration of the health of an individual; or
> 2. Prevent the impending death of an individual.[2]

The statute further states that, while a physician is not required to render medically ineffective treatment,[3] the physician must inform the patient or his family of the decision and assist them to transfer the patient, if the patient or family desires a transfer. Pending the transfer, the physician must comply with the instructions of the patient or his health care agent or surrogate.[4] Over the past several years, MHECN has received feedback from some Maryland physicians that differing interpretations of the HCDA are affecting patient care decisions at the end of life. Specifically, interpretations between physicians and hospital counsel or risk managers may differ as to when a treatment may be withheld or withdrawn based on medical ineffectiveness.

Professor Hoffmann and MHECN Coordinator Anita Tarzian conducted a survey of hospital attorneys, risk managers, and ICU physicians on the issue of medical futility. The survey revealed that physicians comply with surrogates' request for medically ineffective treatment for dying patients in part due to fear of liability. Survey participants also noted that inconsistencies and lack of clarity in the HCDA complicates decision making in these situations.

In terms of specifics, the survey of ICU physicians revealed that:

- A majority of respondents (57%) recalled frequent situations over the previous two years in which family members wanted maximally aggressive life support for an ICU patient but the attending physician disagreed with that approach.
    - o The most frequent source of disputes in these cases, in order of perceived prevalence, were: code status (84%), switching to "comfort care" as the main goal of patient care (73%), ventilator use (59%), dialysis use (34%), disagreement about who is the appropriate decision-maker (32%), and feeding tube use (23%).
    - o Respondents reported that a facility's ethics committee became involved in such cases "frequently" at 28% of hospitals represented, "occasionally" at 33%, and "never" or "rarely" at 35%.
- A slight majority of respondents (56%) recalled one or more cases in which they thought a treatment could have been certified as medically ineffective but was not.
- In terms of their views regarding Maryland's Health Care Decisions Act:
    - o Almost half of respondents (46%) agreed with a statement that medically ineffective treatment provisions of the Maryland Health Care Decisions Act are difficult to interpret and apply.
    - o Almost a third (31%) of respondents agreed to a statement that the medically ineffective treatment provisions are too narrow and do not allow physicians enough discretion in withholding or withdrawing treatment. Substantially more respondents (59%) neither agreed nor disagreed with this statement; 10% disagreed.
    - o A third of respondents (34%) felt the medically ineffective treatment provisions of the Maryland Health Care Decisions Act support ethically appropriate care, 18% felt they do not, and 47% were undecided.

On November 20, 2010 MHECN held a well-attended conference to study the law and share ideas and suggestions for how to improve conflict resolution relating to medical futility disputes. Many participants seemed to agree that revisions to the Maryland HCDA are in order.

On September 28, MHECN will convene a group of hospital counsel and risk managers to whom the survey was sent to discuss whether regulatory changes to the Maryland HCDA might be helpful in responding to the uncertainties and complications caused by the law relating to medical futility.

REFERENCES

[1] More information about MHECN is available at this website: http://www.law.umaryland.edu/programs/health/mhecn/.

[2]Md. Code, Health General §5-601(o).

[3]Md. Code, Health General §5-611(a).

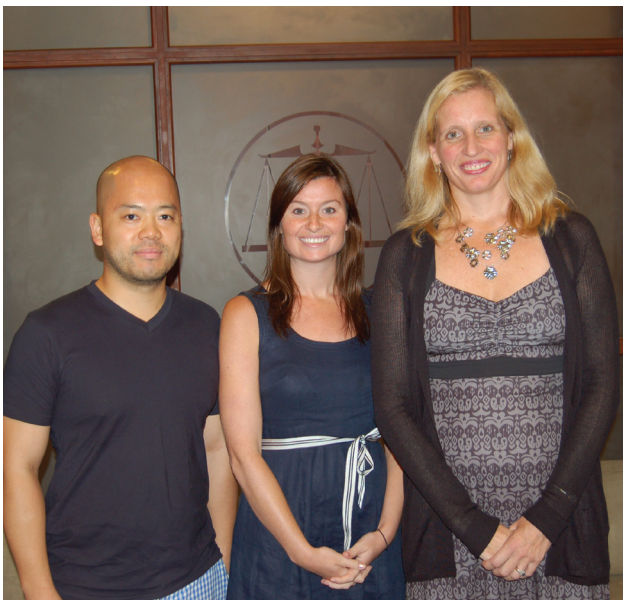
[4]Md. Code, Health General §5-613.

Students Participate in Regulation Drafting Workshop with Maryland's Department of Health and Mental Hygiene

In academic year 2010-2011, two UM Carey Law students had the opportunity to study and draft regulations with attorneys at Maryland's Department of Health and Mental Hygiene (DHMH). The program was created jointly by DHMH's former Chief Counsel Daniel O'Brien and the Law & Health Care Program's Managing Director, Virginia Rowthorn.

The project, for which the students received externship credit, was designed to give students the practical opportunity to study how health-related regulations are developed. During the first two weeks of the semester-long workshop, Rowthorn provided a tutorial in administrative law with a focus on Maryland law, regulations, and drafting protocols. As part of the tutorial, the students looked at an influenza regulation now on the books to learn how the need for the regulation was raised, how it was researched and drafted and the steps necessary to implement the final regulation.

O'Brien then provided the students with their projects. One project required the students to study latent TB reporting requirements. This project involved looking at how mandatory reporting standards are structured in other states; options for specific reporting and follow-up requirements; and options regarding who the information is reported to and how. Student Michelle Brunner '12 conducted extensive research on these issues and presented her findings to attorneys and program staff at DHMH. The other student, Peter Chin '12, worked with the Office of the Inspector General on regulations relating to Medicaid fraud – specifically regulations on extrapolation audits, surety bonds, civil money penalties, and other administrative enforcement tools. Peter did extensive research in these areas and presented his findings to DHMH attorneys and was then asked to write the draft regulation. This regulation is on track to go through the administrative process to become a formal regulation. Both Peter and Michelle found this hands-on experience to be both valuable and informative and both were able to gain a great deal of insight into the administrative workings of Maryland's health department.



Regulatory Workshop Students Peter Chin and Michelle Brunner with Virginia Rowthorn, Managing Director of the Law & Health Care Program (right)

Health Law Alumni News

Cori Annapolen Goldberg '06, Senior Associate at Fulbright & Jaworski LLP, was honored as an industry "Rising Star" by the Healthcare Businesswomen's Association, at its 22nd annual Woman of the Year award luncheon on May 5th in New York City. Cori joined the Washington D.C. office of Fulbright & Jaworski L.L.P. in 2007. As a senior associate, she focuses her practice on health law matters, food and drug law issues, government and internal investigations, and white collar criminal defense. Her practice includes the representation of health care clients in compliance matters, including internal investigations and self-disclosures. Prior to joining Fulbright, Cori served as a judicial law clerk to Judge Clayton Greene, Jr. on the Court of Appeals of Maryland. Cori earned her J.D. from the University of Maryland School of Law, M.P.H. from the University of Maryland School of Medicine, and B.A. from Emory University.

Clark J. Lee '06, a Senior Law and Policy Analyst at the University of Maryland Center for Health and Homeland Security and an Associate Member of the Work and Health Research Center at the University of Maryland School of Nursing, was invited to participate in two recent academic events on the use of legal and public policy tools to address health and safety hazards posed by sleep loss and fatigue in society. In May 2011, Clark participated in an exploratory seminar on Translating Sleep Research to the Real World: Developing a Regulatory Framework for Drowsy Driving held at the Radcliffe Institute for Advanced Studies at Harvard University. At this event, Clark co-led a panel discussion on current legislative and administrative approaches to tackling drowsy driving. On June 14, 2011, Clark co-chaired a well-attended discussion group at the SLEEP 2011 25th Anniversary Meeting of the Associated Professional Sleep Societies, LLC in Minneapolis. Entitled Sleep Science and the Law: The Legal State of Mind of Drowsy and Sleeping Parties in Legal Proceedings, the discussion group focused on how sleep complicates the issue of "state of mind" in legal proceedings, how courts and legislatures have attempted to address this issue; and how sleep science can inform and contribute to the development of this area of law and public policy.

Health Law Student Abe Gitterman '13 won a scholarship to attend Seton Hall University School of Law's Healthcare Compliance Certification Program. He is pictured here with Simone Handler-Hutchinson (left), the Executive Director of the Center for Health and Pharmaceutical Law & Policy at Seton Hall, and a fellow scholarship student.

including the summons (Namibia's version of a complaint), the heads of argument (the supporting memorandum of law), and the declarations for all of the individual plaintiffs. In 2009, the court proceedings relating to these initial cases began. The government admitted that the women had been sterilized after the completion of their c-section surgery while they were still under anesthesia, and the parties consequently agreed that the only remaining factual issue was whether the circumstances surrounding each individual plaintiff's signing of the consent form warrants a finding of informed consent.

The first matter to come to trial in the case was whether the statute of limitations barred the women's claims. The High Court of Namibia found that the Public Service Act of 1995, which requires that persons wishing to institute legal action against the federal government must do so within 12 months of the action arising and only after written notice has been given to the government within one month of that action, did not apply to the women's lawsuit for damages. With this final legal hurdle out of the way, the women were free to proceed with the merits of their claims of unlawful involuntary sterilization. The first three women's cases went to trial on the sole remaining factual issue of informed consent during the end of 2010 and the beginning of 2011. The ICLC students participating in the spring 2011 clinic wrote the opening argument for the trial and played a second chair role in the trial. The clinic students, the LAC, and the three women plaintiffs are now awaiting a decision in this first round of cases. According to Olshansky, much work remains for future clinical students in order to identify other women who may have been subjected to compelled and unknowing sterilization during a c-section delivery because of their HIV status. Once identified, court filings must be prepared.

While everyone awaits the decision, the ICLC law students have taken part in a joint public education effort with the LAC to develop training manuals and videos for public education campaigns. Some of these materials were gathered together for a public education kit for train-the-trainer programs that are still being held throughout the country and may be reconfigured for use in other southern African countries.

In addition to the coerced sterilization project, Professor Olshansky and her students assisted the Namibia Paralegal Association (NPA) with the design and implementation of the first comprehensive needs assessment of the NPA's paralegals and the communities they serve around the country. The ICLC research team interviewed thirty-seven paralegals and fifty-one community members who live and work in ten of Namibia's 13 regions. Unlike the situation here in the United States, the paralegals in Namibia serve a much different purpose: they are the lay public educators for the country. Because of the extreme poverty in the country, many adults who were deprived of full educational opportunities under the Apartheid system remain ill-informed about their new constitution and the rights and privileges it provides. The paralegals provide public education programs wherever they can find a spot to sit and invite everyone in the community to attend. Often while travelling through the country, visitors will see classes of 50 or more adults sitting under an Acacia tree learning about how to start a parliamentary political party.

Olshansky, who also teaches International Health and Human Rights at the law school, has extensive experience in international legal work. Prior to coming to the law school, she was the Leah Kaplan Distinguished Visiting Professor in Human Rights at Stanford Law School for three years. Previously, she was Deputy Legal Director for the Center for Constitutional Rights (CCR) and Director Counsel of the Guantánamo Global Justice Initiative at Stanford. She was one of the lead attorneys who brought the landmark U.S. Supreme Court case that resulted in a decision allowing the nearly 800 detainees held at the Guantánamo Bay Naval Base in Cuba to challenge their unlawful indefinite detentions. She has appeared on numerous television and radio shows and has been interviewed by the press from around the world. She's the author of Democracy Detained (Seven Stories, 2009), the coauthor of The Case for Impeachment: The Legal Argument for Removing George W. Bush from Office (St. Martins, 2006), among other titles, and author of Secret Trials and Executions: Military Tribunals and the Threat to Democracy (Open MediaSeries/Seven Stories Press, 2002). Olshansky graduated from Stanford Law School in 1985, was an associate editor of the Stanford Law Review, and clerked for three years for Rose E. Bird, Chief Justice of the California Supreme Court.

L&HCP Graduates Record Number of Health Law Certificate Students

This Spring, the 14th year that the Law & Health Care Program (L&HCP) has been granting a certificate to those students who concentrated in health care law, a record 37 students qualified for the Health Law Certificate. This sizeable number of students focusing on health law left an indelible mark on the L&HCP and the law school in many ways, including the number and variety of health law externships the students completed, their loyal attendance and participation in health law conferences and symposia, the notes and articles they wrote on cutting edge health law topics, and the variety of student health law activities they organized.

To celebrate the students' accomplishments and give the group a proper sendoff, L&HCP faculty and administrators hosted a graduation breakfast on May 18 for the students and their family members. At this breakfast, faculty members spoke about the individual accomplishments of this record-breaking group and their contributions to the Program. Several faculty members noted that, while the milestone of their graduation was a wonderful reason to celebrate, it was bittersweet to say goodbye to the students whom the faculty got to know in so many contexts – as students, research assistants, student leaders, and *Journal of Health Care Law & Policy* staff members. Below are highlighted six students who represent the breadth and variety of students who earned the Health Law Certificate in 2011.

Nancy Bonifant

Nancy Bonifant graduated magna cum laude in 2008 from Wake Forest University where she majored in Chemistry. Her science major and externships during college prepared her well to join the L&HCP when she arrived at the law school. In college, Nancy interned in the Office of Regulatory Policy in FDA's Center for Drug Evaluation and Research. In this position, she had her first real exposure to health lawyers whom she assisted in regulatory matters. She then served as a Science Policy Intern at NIH in the Office of Biotechnology Activities where she worked on projects relating to informed consent and genetic exceptionalism. These experiences provided Nancy with a broad initial understanding of health law and policy that was evident during her time at the law school. In Spring 2011, Nancy externed at MedStar Health, a non-profit, community-based health system serving the Baltimore/Washington region. Her supervisor, Carl Jean-Baptiste (UMD Law '97), praised her legal skills and said she "set the bar for future externs." In addition to her externship, Nancy took part in the Civil Rights for Persons with Disabilities Clinic and wrote a scholarly note on the Blackwell v. Wyeth case that was published in the Maryland Law Review. Of the L&HCP, Nancy told the editor of the newsletter, "I think Maryland's health law program addresses and meets a critical need in the legal profession: preparing practice-ready attorneys. My time both in the classroom and externing for MedStar Health introduced me to the current problems facing health care corporations and the tools necessary to solve those problems." This Fall, Nancy is beginning her legal career as an Associate at the law firm of Reed Smith in the Life Sciences Health Industry Group in the Washington, DC office.

Professor Leslie Henry, Michael Ulrich '11, and Professor Karen Rothenberg at Health Law Certificate Celebration

Peter Nicewicz

Peter Nicewicz is another recent graduate who exhibited a strong interest in health policy before coming to the law school. As an undergraduate student at Yale ('08), Peter had the opportunity to extern at Keren Pharmaceutical, Inc. in New Haven, CT. When he arrived at the law school, Peter immersed himself in the L&HCP. He was a student attorney in the Drug Policy and Health Strategies Clinic and externed for the House of Representatives Committee on Veterans Affairs, Subcommittee on Disability Assistance and Memorial Affairs. His supervisor, Kimberly Ross, said in her evaluation of Peter, "Peter could find anything if it had ever been written and was outstanding at verifying facts and locating hard to find documents. He performed

far above expectations." Peter also served as Co-President of the Student Health Law Organization (SHLO) during his third year. In this role, he planned a number of successful events for health law students including a "What is Health Law?" panel that he organized at the beginning of the school year to familiarize students with the wide range of careers under the umbrella of health law. Peter found his time at the law school enriched by his involvement with the L&HCP stating, "I think that some of my fondest memories from the health law program were working with SHLO. The relentless energy and passion of fellow health law students was infectious and inspired me to always try to put my best foot forward. It was a great chance to interact with and, in many cases, develop deep relationships within the larger health law community." Peter recently started his career as the Assistant Director of Social Concerns and Parish Social Ministry at Catholic Charities of Baltimore. In this position, he will advocate on behalf of vulnerable Marylanders by lobbying on interrelated issues of poverty – such as housing, energy assistance, access to health care, and employment.

Serra Schlanger

Serra is a 2005 graduate of Vassar College where she majored in Science, Technology, and Society. Like Nancy and Peter, Serra also demonstrated a strong interest in health policy issues as an undergraduate. She was a member of the Vassar College Environmental Risks and Breast Cancer project where she compiled information for the development of an award-winning CD for breast cancer education. She also served on the Committee on Disability Issues at Vassar and wrote her senior thesis on "Social and Medical Transformation: From Siamese to Conjoined Twins." After college, Serra worked as a Clinical Assistant to the Chief of Breast Medical Oncology at the Memorial Sloan-Kettering Cancer Center in New York. In law school, Serra continued to pursue her interest in health and science policy. She was a summer intern in the Center for Science in the Public Interest in Washington, DC, an extern in the Office of the General Counsel, Public Health Division, Department of Health and Human Services, and an extern in the Office of the General Counsel, University of Maryland Medical System. She also served as the Executive Editor of the Journal of Health Care Law & Policy, was a member of the National Health Law Moot Court Team, and took part in the Tobacco Control Clinic. Her clinic professor, Kathleen Dachille, who remembers Serra as incredibly bright yet unassuming, stated, "I suspect Serra will become a fine advocate for her clients and will quickly earn an excellent reputation among her professional colleagues as she has done among her peers and faculty here at the Law School." A paper that Serra wrote in her final year of law school entitled "Putting Together the Pieces: Recent Proposals to Fill in the Genetic Testing Regulatory Puzzle," will be published in Volume 21, Issue 1 (Winter 2011) of the *Annals of Health Law*. This Fall, Serra is starting her career as an Associate at the health law firm of Epstein Becker & Green in Washington, D.C.

Professor Kathleen Dachille, Mariestela Buhay '11 and her mother at Health Law Certificate Celebration

Nishamarie Sherry

Nisha graduated from University of Notre Dame with a BS in Biological Sciences in 2007. Since graduating from college, she has moved from a focus on science to one on health policy with a number of impressive externships and experiences. In the Summer of 2007, she was an Intellectual Property and Human Rights intern in the HIV/AIDS department in the United Nations Development Program in Geneva. In the Summer of 2008, she worked on a project comparing adolescent health legislation in Pan American Countries for the Pan American Health Organization. In Spring 2009, Nisha externed at the Department of Health and Human Services in the Office of Counsel for the Inspector General and later for the Senate Health, Education, Labor and Pensions Committee. In addition to these experiential learning opportunities, Nisha was also active in the SHLO during her second year and was part of a particularly active group of SHLO leaders who were able to organize a myriad of educational activities for health law students. Nisha was a joint JD/MPH student and earned her public health degree at the Johns Hopkins Bloomberg School of Public Health at the same time she received her JD. Her tobacco control clinic teacher – Professor Kathleen Dachille

Cont. from page 15

- said of her, "as a clinical student, Nisha employed not only her deep research and analytical skills but served as a translator for her group, putting in overtime to prepare for a global tobacco control conference. At the conference, she was an asset to our client and really engaged on the international stage with complete confidence." In the Fall, Nisha will start her career as a staff attorney at the University of Maryland Center for Health and Homeland Security, a non-profit think tank housed at the law school.

Elyse Grossman '11, Director of the L&HCP Diane Hoffmann, Margaret Schuster '11, Managing Director of the L&HCP Virginia Rowthorn

Kylyn Deary

Kylyn is a 2007 graduate of Tufts University where she majored in Political Science. After graduation from Tufts, she worked at the law firm of Foley Hoag in Boston as a Litigation Case Assistant before taking the plunge into law school. Kylyn transferred to UMDLaw after her first year at University of Baltimore to take advantage of the L&HCP and she met this goal with vigor. Kylyn externed in the in-house counsel office at the Johns Hopkins Health System and later externed in a similar office at MedStar Health. In addition to these externships, Kylyn worked as a Research Assistant for Director of the L&HCP Diane Hoffmann on several projects including legal issues surrounding the de-criminalization of medical marijuana. She also helped with Hoffmann's NIH-funded project on the regulation of probiotics. Kylyn is originally from Michigan and has started her legal career as a temporary compliance officer at University of Michigan in Ann Arbor. About her experience as an L&HCP student she stated, "I really loved and valued my time at Maryland. As a transfer student, I was nervous that I would be lost in the mix because everyone had solidified their relationship during their first year. However, I found an instant family within the Law and Health Care Program. The information and critical thinking techniques I learned in the class room are invaluable when I'm assigned a task here at the University of Michigan. I now have confidence when communicating and interacting with a diverse group of professionals due to my externships (at Johns Hopkins Hospital and Medstar) and as my time at Dean Hoffmann's research assistant. In my opinion, if you have a passion for health care law then Maryland may be the best fit law school in the country."

Congratulations to the 2011 Health Law Certificate recipients!

Leila Ashkeboussi
Sarah Baum
Nancy E. Bonifant
Matthew Brenner
Mariestela Buhay
Jennifer Brigid Cohen
Athena Cymrot
Kathleen Davies (December 2010)
Kylyn Deary
Michelle Nicole Denton
Kaelyn Drumm
Elyse R. Grossman
Jack G. Haake
Kathleen Hildreth
Bryan Hull
Jessica Lana Hurst (July 2010)
Evelyn Knolle
Lauren Fusillo Levy
Vicki Lynn Lung
Rebecca Eve Mansbach
Natasha Mehu
Tabitha Nicole Mitchell
Kathleen Morris
D'Paul Nibber
Peter Nicewicz
Jennifer Lindsay Pike
Patricia Ramudo
Serra J. Schlanger
Steven David Scholz
Margaret F. Schuster
Rebecca E. Semcken (December 2010)
Nishamarie B. Sherry
Eric Stephenson
Nina Sun
Michael Ulrich
Matthew Alex Ward
Tristan Young

Michael Ulrich

Michael graduated from the University of Maryland with a BS in Biological Resources Engineering in 2004. After graduation he had an internship at NIH working on an MRI brain-imaging study before moving on to the EMMES Corporation, a Contract Resources Organization. At EMMES, he was a Data Manager/Protocol Monitor on the Herpevac project, working with NIH and GlaxoSmithKline to develop a herpes vaccine for women. It was in that position that he decided to pursue an advanced degree to address health policy and felt law school would be the best place to gain the skills to accomplish this goal. When Michael arrived at the law school, he immediately began focusing his studies and extra-curricular activities in the area of health law. In his first summer he worked at the Maryland Office of the Attorney General in the Medicaid Fraud Control Unit. Michael also served as a Research Assistant for the Director of the Law & Health Care Program, Diane Hoffmann, working with the Maryland Healthcare Ethics Committee Network on potential changes to the Maryland Healthcare Decisions Act. In his second summer, Michael interned with the Maryland Stem Cell Research Commission analyzing the new stem cell guidelines and their effect on Maryland law. His work with the Commission led to a joint publication with Professor Karen Rothenberg for the 2010 World Stem Cell Report. Michael was very active with the Student Health Law Organization -- serving as its President in his third year and as Chair of the Maryland Volunteer Service Corps' Health Law Trip to Mississippi. Michael recently accepted a position as Law and Policy Analyst with the Center for Health and Homeland Security, a center affiliated with the University of Maryland Francis Carey School of Law.

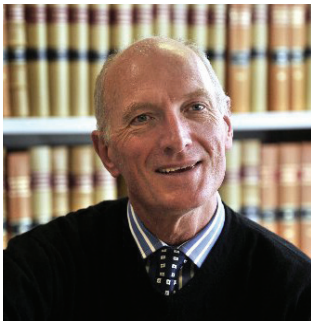
\'fort-nīt-lē\ IP

On September 14, the Law & Health Care Program co-sponsored the Intellectual Property Law Program's "Fortnightly IP" discussion. The discussion featured Professor Lawrence Sung, Director of the Program, who spoke on "The Future is Now: Personalized Medicine, Biologics, and Tissue Engineering." A schedule of future Fortnightly sessions is available at http://www.law.umaryland.edu/programs/iplaw/events.html

Distinguished Health Law Speakers

This semester the Law & Health Care Program has had two distinguished speakers in different areas of health law and policy speak at the law school.

Justice Cameron of South Africa Constitutional Court Speaks about AIDS Stigma



Justice Edwin Cameron

On September 13, the Law & Health Care Program and the UM Office of Global Health Initiatives co-sponsored a talk by Justice Edwin Cameron of the Constitutional Court of South Africa on "AIDS Stigma – the Personal and Political." Justice Cameron, who was at the law school as a Distinguished Visitor, has served on the Constitutional Court in South Africa since 2009. He is a leading human rights lawyer in South Africa and deeply involved in AIDS/HIV advocacy efforts. His book *Witness to AIDS* was awarded the Sunday Times/Alan Paton Prize, South Africa's premier literary award for non-fiction.

Columbia Law Professor Abbe Gluck Speaks to Legal Theory Workshop

Professor Abbe Gluck

On September 22, Abbe Gluck, Associate Professor of Law at Columbia University School of Law, presented a paper at a Legal Theory Workshop entitled "A Federalism Agenda for the Age of Statutes: Intrastatutory Federalism in Health Reform and Beyond." Professor Gluck is an expert in legislation and the role of state legal actors in the federal system. She joined the faculty at Columbia after serving in senior positions in the New York City and New Jersey State Governments. Most recently, she served in the Administration of New Jersey Governor Jon Corzine as the Special Counsel and Senior Advisor to the New Jersey Attorney General. Professor Gluck clerked for U.S. Supreme Court Justice Ruth Bader Ginsburg, and then-Chief Judge Ralph K. Winter, on the U.S. Court of Appeals for the Second Circuit.

Health Law Faculty Publications and Presentations,

May 2010 – August 2011

Kathleen Dachille

"Injury Prevention Policy in Maryland -- Legislators' Perspective" (a review of a survey of 87 members of the Maryland General Assembly on their interest in certain issues in injury prevention commissioned by the Maryland Department of Health and Mental Hygiene). Available at http://fha.maryland.gov/pdf/ohpetup/eip_Report_GA_Survey.pdf

"Addressing Client's and Communities' Problems through the Legislative Process," Presentation, AALS Clinic Law Teacher's Conference (June 2011)

Speaker, Annual Trauma and Injury Prevention Forum (Partnership for a Safer Maryland) (September 2011)

Don Gifford

"Suing the Tobacco and Lead Pigment Industries: Government Litigation as Public Health Prescription," Reader Meets Author Series, University of Maryland Francis King Carey School of Law, Baltimore, Maryland (February 24, 2011)

Michael Greenberger

"Intergovernmental Issues in the Response to H1N1," 33rd Health Law Professors Conference, Austin, Texas (June 3-5, 2010)

"Governance and Biosecurity: Strengthening Security and Oversight of the Nation's Biological Agent Laboratories Performance," Keynote Address Speaker, Campus Safety Health and Environmental Management Association, Baltimore, Maryland (July 21, 2010)

"Immunity for Vaccination Design Defects: Laws and Recent Court Cases," Panelist, A Changing Landscape: The Constantly Evolving Legal & Ethical Challenges of Vaccination at the Middle Atlantic Regional Center for Excellence Public Health Emergency Meeting, Ellicott City, Maryland (February 28, 2011)

"Afterword: Learning Lessons from Maryland's RCPG Projects," Opening Remarks, Regional Catastrophic Preparedness Grant Final Summit, Baltimore, Maryland (March 1, 2011)

Interview, "Target Volunteers to Help in MD Emergencies," The Daily Record, WBAL-TV (April 29, 2011)

Leslie Meltzer Henry

"Commerce Games and the Individual Mandate," (with Maxwell Stearns) Georgetown Law Journal (forthcoming 2012)

"Deciphering Dignity," 10 American Journal of Bioethics 59 (2010)

"Visionary Pragmatism and the Value of Privacy in the Twenty-First Century," 108 Michigan Law Review 1107 (2010) (with Danielle Keats Citron)

"Health Care Reform and the U.S. Constitution," Constitution Day 2010 Program co-sponsored by the Maryland League of Women Voters and the University of Maryland Francis King Carey School of Law, Baltimore, MD, September 17, 2010

"Ethical Approaches to Allocating Scarce Medical Resources," Department of Pediatrics, Sinai Hospital of Baltimore, Baltimore, MD, October 4, 2010

Appointment, Consortium for Emerging Technologies, Military Operations and National Security (CETMONS), Ethics of Bio-Enhanced Warfighters Thrust Group

Appointment, Reviewer, International Journal of Feminist Approaches to Bioethics

Diane Hoffmann

"Dying as a Public Health Issue" in *Reconsidering Law and Policy Debates: A Public Health Perspective*, (John Culhane, ed.) (Cambridge Press, 2010)

"Federal Regulation of Probiotics: An Analysis of the Existing Regulatory Framework and Recommendations for Alternative Frameworks," Human Microbiome Project (HMP) Research Network meeting, Washington University, St. Louis, MO (August 31, 2010)

"The Legal Landscape for Medical Marijuana: What Physicians Should Know," and "The Legal Landscape for Medical Marijuana: What Patients Should Know," Plant Medicine Expo and Health Care Provider Conference, Denver, CO (September 25-26, 2010)

American Society for Pharmacy Law (ASPL) Conference, Speaker, "The Evolving Legal Landscape for Medical Marijuana", Palm Springs, CA, (November 21, 2010)

WYPR Midday with Dan Rodricks, "A Discussion of If, When and How to Stop Costly and Futile Treatments on Terminal Patients," Baltimore, MD (November 22, 2010)

Medical Futility & Maryland Law Conference, "Findings from a State Survey of Hospital Counsel, Risk Managers, and ICU Physicians Regarding Maryland's Health Care Decisions Act", sponsored by the Maryland HealthCare Ethics Committee Network, Baltimore, MD (November 30, 2010)

"Legal Obstacles to the Treatment of Pain," Barriers to Pain Management Staff Briefing for California Legislative Women's Caucus, (Webcast) (December 1, 2010)

"Legal Impediments to the Dissemination of Telemedicine," Maryland Telehealth Roundtable sponsored by Rural Maryland Council, Annapolis, Maryland (December 6, 2010)

Planning Committee Member & Facilitator, "Approaching Death, Fourteen Years Later: Where Are We Now?" Institute of Medicine, Washington, DC (January 14, 2011)

"Legal Impediments to the Diffusion of Telemedicine," 14 Journal of Health Care Law & Policy, 1 (2011) (with Virginia Rowthorn)

"Balancing Access, Safety & Quality in a New Era of Telemedicine," Panelist, Federation of State Medical Boards, Washington, DC (March 10, 2011)

"Federal Regulation of Probiotics," Probiotics and Clinical Metagenomics Working Group, Human Microbiome Project, Cleveland, Ohio (April 4-5, 2011)

"The Evolving Medical Marijuana Legal Landscape," The Annual Paul A. Pumpian Lecture, Department of Pharmaceutical Health Services Research, University of Maryland School of Pharmacy, Baltimore, Maryland (April 18, 2011)

"Federal Regulation of Probiotics" 34th Annual Health Law Professors Conference, June 9-11, 2011, Philip H. Corboy Law Center, Chicago, IL

ABA (Health Law Section) Teleconference: "Medical Marijuana: A Public Health Legal Conundrum?" June 27, 2011

Appointment, President of ASLME (January 2011-present)

Amanda Pustilnik

Rethinking Unreasonableness: A Comment on Professor Farahany's Rethinking Reasonableness, forthcoming in Nomos LII: Evolution & Morality (2010)

Pain as Fact & Heuristic: How Neuroimaging Illuminates the Moral Dimensions of Law, 97 Cornell Law Review (forthcoming 2012)

Karen Rothenberg

Appointment, Legal Advisory Board, Genetics Policy Institute (2010)

Member, Institutional Review Board, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland (2010)

"From Eugenics to the "New" Genetics: The Play's The Thing," National Human Genome Research Institute, National Institutes of Health, Bethesda, Maryland (June 9, 2010)

Participant, "Planning the Future of Genomics: Foundational Research and Applications in Genomic Medicine," National Human Genome Research Institute, National Institutes of Health, Airlie Center, Warrenton, Virginia (July 6-8, 2010)

Presenter, "Back to the Future: Research Ethics for the Genomics Era, DIR Seminar Series, National Human Genome Research Institute, National Institutes of Health, Bethesda, Maryland (September 21, 2010)

Presenter, "From Plays to Policy: Reflections on How to Make an Impact," Program in Bioethics, Columbia University, New York, New York (September 30, 2010)

"NIH Guidelines on Human Embryonic Stem Cell Research in Context: Clarity or Confusion," Speaker, World Stem Cell Summit, Detroit, Michigan (October 4, 2010)

"Gender, Eugenics and Genetics: Theatre and the Role of Women," Speaker, American Society of Bioethics + Humanities Annual Meeting, San Diego, California (October 22, 2010)

"NIH Guidelines on Human Embryonic Stem Cell Research in Context: Clarity or Confusion?," with Michael Ulrich, 2010 World Stem Cell Report 89 (October 2010)

"From Eugenics to the "New" Genetics: The Play's The Thing," 79 Fordham Law Review 407 (2010)

"Eugenics, Genetics and Gender: Theatre and the Role of Women," in Caulfield, Gillespie & Caulfield, eds., Perceptions of Promise - Biotechnology, Society and Art , Univ. of Washington Press (2011)

Panelist, "Perceptions of Promise -- When Pop Culture Intersects with Biotechnology: A Critical Look at Science & Art," Glenbow Museum, Calgary, Canada (March 3, 2011)

Lawrence M. Sung

"Genomic Patenting as Pop Culture," Johns Hopkins Medical Institute, Baltimore, Maryland (June 14, 2010)

"2011 Medical Device Patents," Thomson/West (2011)

"Medical Alert: Alarming Challenges Facing Medical Technology Innovation," 6 J. Bus.& Tech. L. 35 (2011)

"Frontiers in Stem Cells in Cancer," Intellectual Property Considerations, Washington, DC (March 18, 2011)

Jack Schwartz

"Building Esprit de Corps: Learning to Better Navigate between 'My' Patient and 'Our' Patient," Journal of Clinical Ethics 21 (2010): 232-37 (with Even DeRenzo)

"Advance Directives: Legal Issues," Washington Hospital Center, Washington, DC, April 15, 2011

"The Sometimes Partnership of Ethics and Law," Center for Ethics Clinical Ethics Intensive, Washington Hospital Center, Washington, DC, May 22, 2011

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LAW & HEALTH CARE PROGRAM FACULTY AND STAFF

(from l to r:) Deborah Hellman, Amanda Pustilnik, Deborah Weimer, Leslie Meltzer Henry, Ellen Weber, Jack Schwartz, Karen Rothenberg, Virginia Rowthorn, Diane Hoffmann, Kathleen Dachille (not pictured Michael Greenberger, Richard Boldt, Lawrence Sung).