

LAW & HEALTH CARE

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LAW & HEALTH CARE PROGRAM HOSTS ROUNDTABLE ON LEGAL IMPEDIMENTS TO THE DIFFUSION OF TELEMEDICINE

- *A radiologist interprets medical images coming from four clinics across the state.*
- *A consumer uses a wireless phone to automatically upload vital signs and send it to a remote monitoring center.*
- *A cardiologist checks up on a heart transplant patient while away on a business trip, reviewing the patient’s chart, looking at live heart rhythms and talking to the patient.¹*

These three scenarios are examples of a growing trend in medical practice called telemedicine – which refers to the use of technology to provide health care to patients where distance separates the participants. Although, in many ways, the use of telemedicine is poised to expand dramatically in the coming years, the current legal framework may be a significant barrier to its further diffusion, especially on a national scale. To further the dialog on this important issue, on April 16, 2010, the Law & Health Care Program held a Roundtable on the Legal Impediments to the Diffusion of Telemedicine. The Roundtable focused on three issues – physician licensure, credentialing and privileging, and medical malpractice – and brought together over 20 telemedicine stakeholders, including telemedicine experts, government regulators, and health care providers, along with several policy makers and legal academics.² Using case studies in each focus area as a springboard for analysis and discussion, the Roundtable was organized to bring the stakeholders and academics together to discuss the legal impediments to a more robust implementation of telemedicine; identify regulatory and legal options to address the identified impediments; and develop recommendations that might be used to establish new guidelines to govern the practice of telemedicine.



The Growth of Telemedicine

Although telemedicine is not new, changes in the health care system and ongoing concerns about access, quality and cost of health care are making telemedicine more and more attractive to health care providers, insurers and patients. Some

**UMDLAW
RECEIVES \$1.3
MILLION FROM RWJ
TO BE REGIONAL HQ
FOR PUBLIC HEALTH
LAW NETWORK**

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Telemedicine

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of the potential benefits of telemedicine include increased access to health care (especially in underserved areas and among underserved populations), expanded utilization of specialty expertise, system coordination and integration, ready availability of patient records, and reduced opportunity costs of care for patients.³

Telemedicine is generally thought to include two modalities: store-and-forward (or asynchronous communication) and real time.⁴ Services include remote consultations, in-home monitoring and remote mentoring. Store-and-forward telemedicine involves transmitting medical data (such as radiological images and EEG readings) to a medical specialist for assessment offline. Store-and-forward services do not require the sending and receiving parties to communicate at the same time and these services are most commonly used for diagnosis and treatment decisions.

Dermatology, radiology, and pathology are specialties that are conducive to using store-and-forward asynchronous telemedicine. Remote monitoring, also known as self-monitoring, allows medical professionals to monitor a patient remotely using various technological devices. This method is primarily used for managing chronic diseases or specific conditions, such



as congestive heart failure, chronic obstructive pulmonary disease, diabetes mellitus, and asthma. Real-time interactions between patient and provider (or provider and provider) include phone and videoconferencing. Remote monitoring involves interaction between providers performing medical procedures and surgeries to ensure quality and patient safety.

The Roundtable

The genesis of the Roundtable was a confluence of factors that came together to convince Law & Health Care Program faculty that providing a forum to discuss the legal impediments to telemedicine was both timely and important. The Law & Health Care Program has a long history of collaborating with the health sciences schools at the University of Maryland Baltimore (UMB) on issues of mutual interest. Telemedicine presented an opportunity to examine an issue that has both wide-ranging medical and legal implications. UMB was an early leader in the deployment of telemedicine, particularly in emergency care. Telemedicine programs in the university's Brain Attack Center, Greenebaum Cancer Center, and Department of Psychiatry are providing health care to individuals outside of the four walls of the hospital.

Another reason for the L&HCP interest in telemedicine is a number of initiatives currently underway at the state and federal level to promote the use of the technology. In Maryland, the State Office of Rural Health within Maryland's Department of Health and Mental Hygiene and the Rural Maryland Council are currently focusing on the issue. At the federal level, in addition to research funding, the FCC promoted use of telemedicine in its 2010 National Broadband Plan. In addition, the Health Information Technology for Economic and Clinical Health Act (HITECH) enacted under the American Recovery and Reinvestment Act (ARRA) of 2009 provides both incentives for the adoption of technology

MARYLAND TELEMEDICINE GROUPS USING L&HCP EXPERTISE

Representatives of the State Office of Rural Health within Maryland's Department of Health and Mental Hygiene and the Rural Maryland Council attended the April 16 Telemedicine Roundtable at the law school and are currently focusing on telemedicine. Roundtable organizers, Diane Hoffmann and Virginia Rowthorn, prepared a white paper summarizing recommendations from the Roundtable. The DHMH group will incorporate the Roundtable white paper in their upcoming telemedicine report and Hoffmann and Rowthorn have been invited to speak in Annapolis in December at a Rural Roundtable including legislators and state health policy makers organized by the Rural Maryland Council to present issues and conflicts related to licensing and credentialing of telemedicine practitioners.

and penalties for non-adoption.

To encourage a robust exchange of ideas at the Roundtable, the organizers prepared case studies in each of the three topical areas, namely licensure, credentialing and privileging, and malpractice, for discussion. A summary of the discussion along with background information and areas of consensus and recommendations for each topic are presented below.

Physician Licensure

State laws regarding physician licensure perhaps present the greatest legal challenge to the interstate practice of telemedicine. Every state and U.S. territory has enacted laws relating to the practice of medicine within that state's boundaries, including laws that delegate authority for enforcing licensure laws to a state board of medical licensure. All medical boards perform essentially the same services but have different administrative structures and rules, including the tests and procedures required for licensure in that state. A telemedicine practitioner who seeks multiple state licenses may find the current system burdensome because of the time and expense of applying for multiple licenses. A patchwork of medical record, patient confidentiality, continuing medical education requirements, and mandatory reporting laws, along with differing medical practice acts, complicate the process.

In recent years, individual state boards, the Federation of State Medical Boards (FSMB), physician organizations, and academics have studied the issues that are raised by state licensure for telemedicine and made recommendations. Some states have enacted laws to facilitate telemedicine, whereas others have tightened their laws to ensure that anyone practicing medicine (whether in person or remotely) in their state has a full medical license – therefore making it harder for out of state telemedicine practitioners to practice in that state.

Roundtable participants, with L&HCP Director Diane Hoffmann as moderator, considered a range of licensure models that have been proposed by various groups and individuals. The models fall along a continuum of maximum state control of physician licensure (full state licensure) to minimum state control (national licensure).

As a foundational matter, Roundtable participants agreed

that any alternative to current licensure laws must preserve the fundamental goals of licensure – to protect the public from incompetent physicians or sub-standard care. However, participants expressed a wide range of views regarding which model would be considered “ideal.” FSMB (which was represented at the meeting) has proposed an “expedited endorsement” model for licensure supported by a uniform application form. Thirty-three state medical and osteopathic boards are now using (at some level) the uniform medical license application developed by FSMB. Although the uniform application was developed to encourage uniformity across the boards rather than to promote telemedicine, FSMB believes that the uniform application will make it easier for states to license out of state practitioners in a consistent and expedited manner.

Other advocates of telemedicine, such as the American Telemedicine Association (ATA), support a compromise between full state licensure and a national licensing system. ATA supports two approaches to physician licensure. The first is national preemption of state licensing laws for all physicians providing federally funded health services, i.e., services provided under Medicare and/or Medicaid. The second approach is an interstate collaboration model which requires the establishment of a national multi-state clearinghouse where out-of-state physicians can register with other states. This model is currently used by a number of nursing boards across the country. Jim Puente, an Associate with the Nursing Licensure Compact (NLC) of the National Council of State Boards of Nursing spoke at the Roundtable about his experience with the “compact” licensure model that many nursing boards have used since 2000. The NLC allows a nurse to have one license (in his or her state of residency) and to practice in other states (both physically and electronically), subject to each state's practice law and regulation.⁵ The compact was not established for the purpose of facilitating telenursing per se, but it could be used to allow the practice of telemedicine across state lines. After a decade of experience, the Council considers the Compact a success and has found that the early concerns were not warranted.

Finally, some Roundtable participants supported a

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UMDLAW TO ESTABLISH REGIONAL PUBLIC HEALTH LAW NETWORK

At a public health law conference held in Atlanta on September 13-15, James Marks, MD, MPH, Vice President of the Robert Wood Johnson Foundation (RWJF), announced a new \$12.5 million dollar investment to create a Public Health Law Network. The Network, which will consist of five Regional Headquarters and a National Coordinating Center, is designed to provide public health legal expertise to local, state, federal, and tribal officials and their legal counsel to help develop, implement and enforce laws that help solve public health problems. Marks also announced that RWJF selected the University of Maryland School of Law to receive a \$1.3 million grant to operate the Eastern Region of the newly-created Network. The Johns Hopkins Bloomberg School of Public Health (JHSPH) will serve as a collaborating partner for the Eastern Region. The long term goal of the Network is to increase the use and effectiveness of public health laws in protecting, promoting, and improving public health by helping policy makers apply the law to pressing public health issues.

Professor Kathleen Dachille who runs the law school's Legal Resource Center for Tobacco Regulation, Litigation and Advocacy, will serve as the Director of the Eastern Region. Dachille, who has written extensively on tobacco-related issues, joined the faculty in 2002 after serving for eight years with the Office of the Attorney General of Maryland. During her tenure as an Assistant Attorney

General, Dachille served in the Civil Litigation Division and the Opinions and Advice Division and as counsel to the Worker's Compensation Commission and counsel for election law.

In addition to two full-time attorneys, a part-time public health practitioner, and the JHSPH resources, the Eastern Region will benefit from students working through a new Clinic course to respond to the needs of the public health community.

The Network as a whole will provide legal technical assistance on many public health topics, including food safety, health-care reform, and health information data sharing but each Regional Network has been designated as providing front line information on selected topics, for example, the UMD Headquarters will provide expertise in the areas of environmental health,

injury prevention and food safety. Anyone working in the fields of public health or law can call or e-mail the Network (either the Coordinating Center or any of the Regional Headquarters) for guidance on how best to apply the law to their particular public health concern. The phone number of the University of Maryland center is 410-706-5575 or visit the following website for more information: www.publichealthlawnetwork.org



Professor Kathleen Dachille

FACULTY HIGHLIGHTS

Amanda Pustilnik is speaking on "Embodied Morality: Physiology and Normativity" at a symposium titled "Brain Sciences in the Courtroom" that will be held at Mercer Law School on October 21-22. She will also be submitting a piece to *Nomos* commenting on the work of Professor Nita Farahany on the relevance in law of neurobiological arguments about free will.

Leslie Meltzer Henry was appointed an Associate to the Consortium for Emerging Technologies, Military Operations, and National Security (CETMONS). She also recently published an article titled "Deciphering Dignity" in the *American Journal of Bioethics* (10 AM. J. BIOETHICS 59 (2010)) and has made several presentations including, "Health Care Reform and the U.S. Constitution," at the law school's September 17 Constitution Day Program and "Ethical Approaches to Allocating Scarce Medical Resources," at the Department of Pediatrics, Sinai Hospital of Baltimore on October 4.

Diane Hoffmann is participating on an Institute of Medicine committee to plan an upcoming IOM meeting on end of life care. She is also participating on an RWJF funded public health law research project with faculty from George Mason University regarding the impact of state childhood vaccination regulations on both vaccination uptake and communicable disease rates and is PI on an NIH ELSI grant to develop recommendations on the regulation of probiotics. Recently, she has made several presentations on the laws regarding medical marijuana based on an article she co-authored that was published last spring in the *NEJM*. She has a book chapter coming out this fall in *Reconsidering Law and Policy Debates: A Public Health Perspective* (John Culhane ed.).

FIRST MEETING OF NIH PROBIOTICS GRANT TEAM HELD AT UMDLAW IN JUNE

- In March 2010 the U.S. Food and Drug Administration issued warning letters to 17 food and beverage manufacturers concerning false or misleading health and nutrition claims on their products.
- In July 2010, the Federal Trade Commission (FTC) entered into its first probiotics-related consent agreement with Nestlé Healthcare Nutrition on false advertising charges for its probiotic product *BOOST Kid Essentials*.
- In a September 2010 *Scientific American* article entitled “Snake Oil in the Supermarket,” the magazine’s editors advocate for better substantiation of health claims by food makers.

As the market for probiotic products grows, so does concern about the safety and effectiveness of these products. These concerns are being studied by an interdisciplinary University of Maryland Baltimore (UMB) team, headed up by Law & Health Care Program Director Diane Hoffmann. The probiotics project – formally titled *Federal Regulation of Probiotics: An Analysis of the Existing Regulatory Framework and Recommendations for Alternative Frameworks* – is being funded by a grant from NIH’s Human Microbiome Project (HMP). The goal of the project is to look at the current regulatory framework for probiotics in the United States and to determine if it is appropriate and adequate and, if not, to recommend improvements and/or an alternative regulatory framework. To assist them in this work, the UMB team established a Working Group composed of scientists, bioethicists, legal academics, federal regulatory experts, and consumer representatives.

The Working Group came together for their first meeting on June 14th. At the meeting, participants focused on the science of probiotics; took a preliminary look at how drugs, foods, dietary supplements and other products are regulated by the FDA under current law; and began to discuss whether the current regulatory structure is a good fit for probiotics.

In the morning session, Dr. Mary Ellen Sanders, a food science microbiologist and consultant in the area of probiotics, provided attendees with an overview of the history of probiotics – from their earliest use in products such as fermented milk to current commercial formulations. She noted that, while probiotics were historically found in dairy products, they are increasingly found in other prod-

ucts such as juices, nutrition bars, infant formulas, relishes and condiments, sweeteners, waters, pizza crust, lozenges, toothpaste, gum and tampons as well as many products for pets and animals. Dr. Claire Fraser-Liggett, Director of UMB’s Institute for Genome Sciences and recipient of two HMP grants, gave an update on the HMP and discussed her thoughts on how HMP-funded research will influence the development of probiotics in the future.

Finally, Dr. Patricia Hibberd, an infectious disease physician, epidemiologist and clinical probiotic researcher at Massachusetts General Hospital for Children, described the current state of probiotic research, gaps in that research, and potential products that might develop from current and future research. She noted the increase in the number and

amplitude of probiotic research studies currently underway. Although many of the studies in the 1990s and early 2000s were done in the European Union, we are now starting to see more US studies – a number of them publicly funded. Moving beyond the narrow studies of the past, these studies are looking at probiotic use across the age spectrum, in an ever-increasing range of diseases, and using a variety of routes of administration

After these talks, the Working Group divided into small mixed-profession groups to discuss the following predetermined questions:

- What concerns relating to probiotics do participants have that they hope this project will address?
- From each participant’s professional vantage point, what are the gaps in the science relating to the risks and benefits of probiotics?
- Is there anything we should consider regarding risks and benefits that is not addressed in the literature, e.g., family, community, environmental concerns?

Responses to these questions were roughly grouped into the following categories – concerns with current FDA regulation of probiotics, gaps in the current research on probiotics, probiotic research-related concerns, ethical issues, consumer and claims issues, and issues for future consideration of the Working Group.

In broad terms, Working Group members are concerned that probiotic products do not fit squarely in the current FDA regulatory categories and this leads to confusion in both the research, regulation and marketing of probiot-



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PROFESSOR DEBORAH WEIMER PREPARES REPORT ON HIV/AIDS AND THE MILITARY FOR UNAIDS

This year, Law & Health Care Program (L&HCP) Professor Deborah Weimer and L&HCP Adjunct Professor Janet Lord were awarded a grant from UNAIDS to study existing jurisprudence throughout the world addressing the hiring, retention and deployment of soldiers and peacekeepers living with HIV. While the L&HCP has had a long-standing relationship with UNAIDS – each year several of our students undertake externships at the organization under the supervision of Susan Timberlake, UNAIDS Senior Human Rights Advisor – this is the first time L&HCP faculty have provided technical assistance to the organization.

Professor Deborah Weimer led the project. Weimer helped to create one of the first law school clinics in the United States to bring legal challenges against employers and health care providers for HIV discrimination. She is a leading scholar and researcher on the impact of HIV illness. The AIDS Legal Clinic provides legal services to individuals with HIV and engages in “impact work” with the legislature and through litigation. This is the first time the clinic has undertaken work in the international arena. Adjunct Professor Janet Lord, who also worked on the project, is a leading international human rights lawyer who has written extensively on discrimination against persons with disabilities, including people living with HIV/AIDS. She is a partner in the firm Blue Law International LLP, a service-disabled, veteran owned international law and development firm. Blue Law has designed and implemented programs throughout the world in Central and South America, Africa, the Middle East, Asia, and Central and Eastern Europe.

Weimer and Lord worked with Clinical Fellow Sabra Jafarzadeh, Blue Law Attorney Allison DeFranco, and clinic

students on the project. The team identified and reviewed legal cases from countries around the world involving discrimination based on HIV status (actual or perceived) in the military. The study includes an analysis of the legal reasoning in such cases including the main components of law and fact at issue in the identified decisions.

Although the study has not been finalized, the team found that, in general, there is an international trend toward recognition that people can live for a long time with HIV with no adverse impact on ability to work and that an individualized assessment of health is more appropriate than a general prohibition against infected service members. Based on this reasoning, military institutions and the courts have found that people living with HIV should not be excluded from military service unless medical evidence indicates they are too ill to do the job required of them. However, in at least two cases the team uncovered, courts have taken the position that

the military is not covered by statutes protecting individuals from discrimination on the basis of a perceived or actual disability. An Australian case raised the question of whether being able to “bleed safely” in a combat zone should be considered an inherent requirement of the position of being a soldier. The team found that military laws and policies automatically excluding, terminating or denying promotions to personnel who are found to be HIV positive have been rejected by courts in Mexico, South Africa, Canada, Columbia and Namibia. Earlier decisions by courts in Venezuela and the United States upheld such provisions.

The team’s report, “Review of Jurisprudence Related to the Hiring, Retention and Deployment of Soldiers and Peacekeepers Living with HIV,” is scheduled to be submitted to UNAIDS later this year.



PROFESSOR KAREN ROTHENBERG GOES “BACK TO THE FUTURE”

In September, Law & Health Care Program Professor Karen Rothenberg presented a talk titled “Back to the Future: Research Ethics for the Genomic Era” as part of the National Institutes of Health (NIH), Division of Intramural Research (DIR) biweekly seminar series. Rothenberg’s talk was the first in the DIR series this year. The series is open to the entire NIH community and covers a broad range of topics in genetics and genomics. Rothenberg’s talk is part of a larger collaborative project with the National Human Genome Research Institute (NHGRI) to evaluate the future of the Common Rule in the genomics era. As part of this project, Rothenberg, along with a member of the bioethics community at NIH, will teach a new Health and Science Policy Workshop for students in the Spring. In the workshop, law students will work on genomics-related ethical issues and present their findings to the Director of the NHGRI at the end of the semester.



Professor Karen Rothenberg

APRIL CONFERENCE FOCUSES ON DISABILITY & ETHICS IN HEALTH CARE

On April 28, 2010, the Maryland Health Care Ethics Committee Network (MHECN) and Kennedy Krieger Institute co-sponsored a one-day conference entitled, “Disability, Health Care, and Ethics—What Really Matters.” MHECN, which is part of the School of Law’s Law and Health Care Program, provides resources for Maryland health care ethics committee members, and other individuals interested in health care ethics. Given the increasing prevalence of persons with cognitive and physical disabilities, this conference addressed how health care providers and ethics committee members could improve their knowledge, skills, and insight related to disability rights and its impact on health care delivery and ethical decision-making.

Steve Eidelman, MBA, MSW, gave the opening plenary lecture. Eidelman is the H. Rodney Sharp Professor of Human Services Policy and Leadership in the Department of Human Development and Family Studies at the University of Delaware, where he is Senior Fellow of the Center for Disabilities Studies. He gave an overview of the history of disability prejudice and rights—both policy approaches and on-the-ground successes and failures related to integrating people with disabilities into mainstream society.

Eidelman pointed out that disability is a natural part of the human experience and should in no way diminish the right of individuals to live independently, enjoy self-determination, make choices, contribute to society, pursue meaningful careers, and enjoy full inclusion and integration in the economic, political, social, cultural, and educational mainstream of American society. He contrasted the medical model of disability (i.e., that disability is inherent in the person, and is directly related to an individual’s physical or mental limitations, which health care professionals try to cure or normalize) with the social model (i.e., that disability is a function of the environment, social issues and attitudinal barriers more than impairments, *per se*).

Eidelman reviewed several constructs of disability, including the “tragedy/charity” model (people with disabilities are seen as victims), the “religious/moral” model (disability is seen as punishment), the “customer/empowering” model (the disabled person is the expert on his/her own body), and the “rehabilitation model” (rehabilitation professionals work to “fix” the disabled person). Rather than adopt any one model, Eidelman acknowledged the need to blend from models with constructive elements.

Eidelman identified lack of health care provider training to care for individuals with disabilities as one of many reasons why disabled persons have poorer health outcomes. For example, 46% of Special Olympics athletes have untreated tooth decay, 25% have failed hearing tests, and 64% are overweight. Despite efforts to de-institutionalize people

with intellectual and developmental disabilities, thousands remain in institutions, although evidence shows that they do better in the community. Eidelman pointed out that if all supports and services available today in Maryland were as good as the best that are available with current technology and resources, the quality of life for people with intellectual and developmental disabilities would improve more than we have seen in the past 50 years. The challenge now is to finish the task of de-institutionalization and implement “second order development” of community inclusion for disabled persons.

Challenges include lack of federal support to train medical personnel to work with adults (most people with intellectual disability are adults), lack of caregiver knowledge and skills about disability, and reimbursement models that frequently do not account for the intensity of time required to work with disabled individuals. While the self-advocacy movement has been important and is growing, it lacks infrastructure. Persons with intellectual disability should be supported in efforts toward self-advocacy and incorporated into leadership, governance and planning. Their family members should receive appropriate support, including learning how to respect their loved one’s individual autonomy.

Eidelman ended his address by reviewing the “Statement of Common Principles on Life-Sustaining Care and Treatment of People with Disabilities,” available at <http://thechp.syr.edu/endorse/index.htm>.

A panel of speakers followed Eidelman’s address. Panelist Janice Jackson, MS (Creator and Program Director of Women Embracing Abilities Now; W.E.A.N.) and William Peace, PhD (Independent Scholar and Adjunct Faculty at SUNY Purchase College) spoke about how being paralyzed and using a wheelchair affects their quality of life—more due to others’ negative attitudes, judgments, and physical access barriers than to Jackson’s and Peace’s physical impairments *per se*. Panelist Elizabeth Weintraub, Quality Enhancement Specialist at the Council on Quality and Leadership, an international organization that develops outcome standards for the assessment of quality of services for people with disabilities and surveys whether agencies meet those standards, gave a first-person account of what people with intellectual and physical disabilities want. Just like the non-disabled, they want to take risks, help others, make mistakes, have friends, advocate for themselves and others, and be respected. Weintraub underscored that people with disabilities are all different, and should not be put in one box. She addressed how we as individuals can support a person with a disability to find quality in his or her life. Specifically, she suggested that we believe in them;

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teach them how to advocate for themselves, let them tell us what they want before we offer an opinion; be willing to stand back; encourage them to take risks; encourage them to “dig” for more choices; walk alongside them, and respect their right to change their mind.

The afternoon concurrent conference sessions included the following speakers:

- Judy Levy, MSW, MA, Director of Social Work and Ethics Committee Chair at Kennedy Krieger Children’s Hospital.
- Alicia Ouellette, JD, Associate Professor at Albany Law School.
- Theodosia Paclawskyj, PhD, BCBA, Faculty at Kennedy Krieger Institute and Assistant Professor in the Department of Psychiatry and Behavioral Sciences at The Johns Hopkins University School of Medicine.
- William Peace, PhD, an Independent Scholar and Adjunct Faculty at SUNY Purchase College and recent Hastings Center Scholar.

- Elizabeth Pendo, JD, Professor of Law at Saint Louis University School of Law’s Center for Health Law Studies.
- Nancy Pineles, JD, Managing Attorney of Developmental Disabilities at the Maryland Disability Law Center.
- Anita Tarzian, PhD, RN, MHECN Program Coordinator and Associate Professor at the University of Maryland School of Nursing.

Rebecca Garden, PhD, Associate Professor of Bioethics and Humanities at Upstate Medical University, gave the dinner plenary address, “Who is Disabled? Chronic Illness, Disability and Medicine.” She ended her talk with a provocative examination of alternative perspectives for viewing and understanding disability as “difference.”

This conference was supported by the Professor Stanley S. Herr Fund for Disability Rights and Social Justice, established in March 2001 through the generosity of Professor Stanley S. Herr, members of his family, and his friends.

**The Maryland Health Care Ethics Committee Network
and the Law & Health Care Program
at the University of Maryland School of Law
invite you to attend**

MEDICAL FUTILITY & MARYLAND LAW



Tuesday, November 30, 2010
Southern Maryland Corporation Campus Center
Room 349
University of Maryland
621 W. Lombard St., Baltimore, MD
8:30 a.m. – 4:00 p.m.

The conference will examine two provisions of the 1993 Maryland Health Care Decisions Act that allow physicians to withhold or withdraw treatments considered “medically ineffective” or “ethically inappropriate,” as long as specified due process procedures are followed. The conference will explore the role of these concepts in providing good end-of-life care that does not waste critical care resources and discuss whether revisions should be made to the Act or whether education is needed as to how these laws should be interpreted.

For more information or to register, contact Anita Tarzian at atarzian@law.umaryland.edu.

national licensing system as the optimal solution for the interstate practice of telemedicine. Such a system would ensure that physicians meet the knowledge and experience requirements necessary to protect patients and assure quality while leaving the policing powers to the states to deal with unscrupulous behavior and substandard practice. Licensing fees would be allocated between the states and the federal government.

Roundtable participants Carl Ameringer, Professor of Health Policy and Politics, Virginia Commonwealth University, and John Blum, Professor of Law, Loyola University Chicago School of Law, while acknowledging the need for more flexibility in physician licensure laws to facilitate telemedicine practice, raised concerns about proposals to nationalize or federalize medical licensure for telemedicine practitioners. Ameringer urged caution in separating out telemedicine from the practice of medicine for separate licensure questioning the ability of regulatory authorities to disentangle the standards of diagnosis, treatment, and follow-up care when a physician breaches a standard of care while diagnosing a patient using electronic means. John Blum, similarly, did not think that a federal licensing scheme would be the solution to the challenges faced by interstate practice of telemedicine. He pointed to the strong federalism tradition in the licensing arena and the need to change laws at both the state and federal levels if we were to adopt a national preemption of licensure authority.

Roundtable participants focused on the merits of the different licensure models without reaching a consensus on a single model. However, several principles emerged from the discussion. Many participants agreed that any model adopted on the state or federal level should be based on uniform licensure rules across the United States and integration of licensure with national databases. In addition, although not uniformly embraced, a majority of those at the meeting believed that telemedicine is not a separate medical specialty and should not be singled out as a special area of medical practice because it is part and parcel of many other medical specialties. Participants also reacted favorably to the idea of a national clearinghouse for all medical licensure and generally agreed that uniform up-to-date national databases that are interoperable with electronic health records and other forms of medical information technology are critical to ensure seamless and accurate licensing and policing of physicians.

Credentialing and Privileging

A second legal impediment to the successful dissemination of telemedicine services are the current CMS rules regarding credentialing and privileging of health care providers. The process of credentialing and privileging refers to the policies and procedures that health care organizations

use to determine whether a health care professional has the qualifications to be employed and practice at the organization. Credentialing refers to obtaining, reviewing and confirming the credentials and professional documentation of health care providers including documentation of education, licensure, certifications, medical professional liability insurance and malpractice history. Most hospitals engage the services of “credentials verification organizations” to check the credentials of their providers.

Privileging is the process whereby a specific scope and content of patient care services are authorized for a health care practitioner by a health care organization, on the basis of its evaluation of the individual’s credentials and performance. Unlike credentialing, privileging is conducted by peer review and is thus considered a more subjective process than credentialing and a process that might therefore be harder to do externally by a third party organization.

Credentialing and privileging are routinely conducted at the institutions in which the health professional is providing service. Given that most telemedicine services involve two hospitals, the question for hospitals in the telemedicine context is which hospital is responsible for credentialing and privileging the practitioner – the originating site receiving the telemedicine consult or the distant site giving the assistance?

Most hospitals follow the nationally accepted standards regarding credentialing and privileging that are provided by the Joint Commission. For years, the Joint Commission permitted “credentialing and privileging by proxy” for telemedicine services. This meant that the originating Joint Commission accredited hospital (i.e., hospital receiving telemedicine services for its patients) could rely on the credentialing and privileging decisions of the distant Joint Commission accredited facility (where the telemedicine provider was located). Although the Joint Commission’s policy was widely used, the policy conflicted with long-standing Medicare Conditions of Participation requirements and Joint Commission-accredited hospitals were at risk of citation by the Centers for Medicare and Medicaid Services (CMS). Under CMS regulations, all Medicare practitioners must undergo credentialing and privileging by each originating site. In practice, most hospitals have used credential verifying organizations, but have relied heavily on privileging by proxy notwithstanding the CMS rule. Therefore, although “credentialing and privileging” are often considered in tandem, it is privileging of telemedicine practitioners that is of greater concern to telemedicine stakeholders.

The long-standing practice of ignoring this CMS rule against privileging by proxy came under scrutiny with the passage of the Medicare Improvements for Patients

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and Providers Act of 2008. In 2009, the Joint Commission informed hospitals that, as of July 15, 2010, the Commission would enforce the longstanding CMS credentialing and privileging requirements found in the Medicare Hospital CoPs. This decision caused an uproar in the telemedicine and hospital administration worlds.

Roundtable participants, including representatives from CMS, discussed the CMS rule against privileging by proxy and its impact on rural and critical access hospitals. The theme that emerged during the Roundtable is that privileging is a complex and difficult process for small hospitals. Privileging requires peer review of a physician's qualifications and abilities which is difficult if the hospital has no other similar practitioners on staff. In fact, this lack of onsite professional expertise is often why small hospitals seek out telemedicine services. As more telemedicine services have become available to small hospitals, the burden of privileging numerous physicians has grown.

If small hospitals were required to privilege all practitioners that provide telemedicine services, Roundtable participants raised the following concerns:

- Small hospitals may choose not to use telemedicine because of the cost and administrative burden of privileging all telemedicine practitioners. If so, telemedicine may be performed outside of hospitals in facilities where privileging is not required.
- Small hospitals may privilege practitioners based on little or no background information about the actual qualifications of the practitioner.
- Physicians will not seek out telemedicine opportunities because of the administrative burden associated with becoming privileged in numerous sites and maintaining those privileges over time.

Roundtable organizers asked participants to describe the optimal process for privileging telemedicine physicians that would protect patient safety and would be reasonable for small hospitals. Although a single process was not agreed upon by Roundtable participants, a number of suggestions and recommendations emerged. While diverse in nature, the underlying theme of the recommendations is that the privileging process must ensure that hospitals are accountable for the telemedicine practitioners that provide services to the hospitals' patients while protecting smaller hospitals from burdensome privileging processes that may inhibit access to care.



Not long after the Roundtable, on May 26, 2010, CMS proposed new regulations in the Federal Register addressing the credentialing and privileging of physicians and practitioners providing telemedicine services. The proposed rule would allow a form of privileging by proxy under certain circumstances and is streamlining the process that Medicare-participating hospitals use to credential and grant privileges to telemedicine physicians.

Medical Malpractice and Professional Liability Insurance

The third set of topics addressed by Roundtable participants were the medical malpractice and professional liability insurance issues raised by telemedicine. To date, there has been a lack of telemedicine malpractice cases from which to draw some ground rules about legal risks associated with telemedicine. The majority of legal actions that have been associated with telemedicine were brought against providers who prescribed medication over the internet, rather than claims brought against providers for negligent care administered through telemedicine. Although there are few legal cases involving telemedicine, there is a widespread assumption that telemedicine may pose new complications to traditional medical malpractice claims, in particular jurisdictional, choice of law, procedural issues and duty of care concerns.

Roundtable participants agreed that telemedicine raises questions both about the source and scope of informed consent and that patients should be provided with information specific to telemedicine in the process of obtaining informed consent. What that specific information must

include depends on the particular telemedicine intervention, but Participants agreed that it should include the risks of any proposed treatment or procedure and possibly the risks associated with providing the services remotely, e.g., interruption of lines of communication

There was a general consensus among Roundtable participants that telemedicine may not present many unique challenges in the area of medical malpractice. In terms of jurisdiction, there are numerous situations in which a plaintiff can sue for damages in more than one state. For instance, in a product liability case, a plaintiff can sue in the state he or she resides or in the state the product is manufactured. However, the participants did raise issues relating to medical malpractice and telemedicine that may require additional study and provided some suggestions to practitioners providing telemedicine services, including possible components of informed consent.

Medical Professional Liability (Malpractice) Insurance

Another issue that may affect the widespread dissemination of telemedicine is the availability of medical professional liability (MPL) insurance coverage for the practice. The industry is still relatively young so there is not a great deal of published literature about liability risks associated with telemedicine or how the professional liability insurance industry is responding to the practice. Also, there are few published case opinions in which a telemedicine practitioner has been sued.

Because telemedicine is a relatively new field, it is still unclear whether the professional liability insurance industry will treat telemedicine differently from other medical practices. If telemedicine is treated differently, premium rates may be increased and additional types of insurance may be required. Divya Parikh, a representative of the Physician Insurance Association of America (PIAA) who participated in the Roundtable and has studied the issue, agreed that telemedicine presents unique challenges for MPL insurers in terms of how it will affect malpractice litigation and

Probiotics Grant Team

Cont. from p. 5

ics. Many noted that the current regulatory framework is focused on the drug model and doesn't contemplate the role of foods in preventing and maintaining wellness and that there are gaps in our understanding of the science and safety of probiotics and their impact on human health. Working Group members also noted that there are gaps in our understanding of the science and safety of probiotics and their impact on human health and also considered ethical questions such as the impact of probiotic research and products on different populations.

The purpose of this first meeting was to engage in critical issue spotting and therefore no firm conclusions or recommendations were reached by the group. However, a general

standards of care (including standards relating to quality of care, quality of technology, and quality of training for providers).

PIAA is continuing to collect data on telemedicine practice and associated liability claims and may respond if cases against telemedicine practitioners create an additional burden on insurers.

Telemedicine is moving ahead on many fronts—the technology is there, the willingness of practitioners to provide and patients to accept telemedicine is there, and even the funding is there. However, in some ways, the law is not there. The goal of the Roundtable was to move closer to resolving the legal barriers that stand in the way of robust implementation of telemedicine.

This article was developed from a white paper article that will be published in a forthcoming addition of the Journal of Health Care Law & Policy by Virginia Rowthorn and Diane Hoffmann.

References

¹American Telemedicine Association document, “What Is Telemedicine & Telehealth?” available at http://www.american-telemed.org/files/public/abouttelemedicine/What_Is_Telemedicine.pdf.

²For more information about the Roundtable, visit <http://www.law.umaryland.edu/telemedicine>.

³Agency for Healthcare Quality and Research, *Evidence Report/Technology Assessment: Number 24*, “Telemedicine for the Medicare Population,” AHRQ Publication Number 01-E011, February 2001.

⁴*Id.*

⁵*Response to Licensure Case Study*, Submitted to Roundtable organizers by Jim Puente, Associate, Nurse Licensure Compact, National Council of State Boards of Nursing, and Joey Ridenour, RN, MN, FAAN, Chair, Executive Committee, Nurse Licensure Compact Administrators.

consensus emerged that the Working Group should consider the creation of an authoritative entity within the FDA Commissioner's Office that would determine if an IND is necessary to perform probiotic research and/or the creation of a new regulatory pathway for some probiotics within FDA.

The project's next meeting is scheduled for February 3-4 at the law school. For more details about the project, please visit <http://www.law.umaryland.edu/programs/health/events/probiotics/>.

HEALTH LAW STUDENT STUDIES GLOBAL HEALTH IN MALAWI

Second year law student Yewande Ajoke Agboola spent six weeks this summer in Malawi as part of a University of Maryland Baltimore (UMB) multidisciplinary global health research team. Ajoke was one of five UMB students who traveled to the Salima District of Malawi as part of a project designed to evaluate access to health, legal, and psychosocial services available to orphans and vulnerable children (OVCs) and their families. She was joined by students from the Schools of Pharmacy, Medicine, Nursing and Social Work. Five UMB faculty members and administrators traveled to Malawi for various lengths of time to support the students during the six-week project. Virginia Rowthorn, Managing Director of the Law & Health Care Program, helped organize the project and spent 10 days in Malawi supporting the student team.

The project was developed by UMB's Global Health Resource Center (GHRC), which was created in 2004 to promote international health education and research through multidisciplinary cooperation. Faculty members from the six professional schools on campus form the GHRC.

The UMB student project was a collaborative effort between UMB, the University of Malawi College of Medicine, and Duke University's Malawi Orphans and Vulnerable Children Evaluation (MOVE) project. The MOVE project, based in the rural Salima District of central Malawi, was undertaken to evaluate the effectiveness of existing service programs that target OVCs in the region. MOVE project staff members are in the process of surveying 1,600 OVC households in different group villages throughout the Salima District using the Child Status Index survey instrument that was developed by Duke University. Duke University subcontracted with the College of Medicine to conduct the surveys. The task of the UMB team, via observation and supplemental surveying, was to obtain additional information regarding access to services that might not be picked up via the Child Status Index survey.

To begin the evaluation project, the Maryland team met with relevant government officials and health and legal professionals to develop a general understanding of the OVC situation in Malawi and the government programs designed to deal with this population. Ajoke met with members of the legal community in Malawi and Dr. Fidelis Edge Kan-yongolo, the Dean of Malawi's Law School, the Chancel-



Interdisciplinary Team in Salima, Malawi

lor College of Law. In addition to key interviews, the team spent time observing the MOVE project interviewers as they conducted interviews of families with OVCs in various villages in the Salima District. The team also visited community-based and faith-based organizations, Rural Health Centers, village leaders, and other stakeholders to further clarify the needs of OVCs and the services available to them. Based on the interviews, observations, and the MOVE survey instrument, the UMB team then evaluated the availability, awareness, access and utilization of services for OVCs and their caregivers. As the team's legal expert, Ajoke focused her research on laws and regulations relating to access to care, succession planning, and property rights.

The Malawi project was designed to bring together students from different disciplines to conduct global health research. This interdisciplinary perspective was very useful to the students' research because it closely mirrored the overlapping nature of service provision in Malawi. Ajoke said of her participation in the project, "Being able to work on this project was not only an enriching learning experience but also very practical lesson on how one should approach problem solving. People do not live within bubbles and the problems we face can rarely be neatly compartmentalized. As such, a multifaceted perspective or approach to problem solving often yields the best results."

27 GRADUATES EARN HEALTH LAW CERTIFICATE

At a breakfast reception held on May 19, 2010, 27 students were awarded the Health Law Certificate. In addition to meeting the classroom, experiential, and writing requirements of the Certificate, this year's group of students boasted an incredible and varied number of other health law accomplishments on their resumes - including participation in the University of Maryland Baltimore Interdisciplinary Patient Management and National Health Law Moot Court competitions; health-law related service trips; and publication of scholarly health law articles.

Professor Diane Hoffmann, Director of the Law & Health Care Program (L&HCP); and Virginia Rowthorn, Managing Director of the L&HCP, presented the Certificates to the students and spoke about each student individually based on comments elicited from other L&HCP faculty and externship supervisors. The picture that emerged at the reception was that of a group of students who will become vibrant and valuable members of the professional world of health lawyers. In her comments at the reception, Hoffmann called the 2010 class of health law students "the most dynamic, brilliant, and just plain fun group of health law students that I can remember in recent history."

This ceremony marked the 13th year that the L&HCP has been awarding the Health Law Certificate to those students who have concentrated their legal studies in the area of health law. In their three years at the law school, L&HCP faculty and staff got to know many of the certificate awardees well and will deeply miss the individual perspectives they brought to the Program. Each student pursued his or her interest in health law in a unique way and each student's story is worth recounting but, given the limits of space, in this article we focus on five certificate students whose various backgrounds and career aspirations highlight the breadth of health law and its future practitioners.

M. Jason Brooke

Prior to coming to the law school as a leadership scholar, Jason obtained a B.S. in Biological Resources Engineering at University of Maryland College Park and an MS from Johns Hopkins in Biomedical Engineering. Prior to attending the law school, Jason applied his graduate education in biomedical engineering as a Senior Scientist developing implantable pacemakers and defibrillators for Boston Scientific Corporation. During this experience in the medical device industry, Jason became aware of the importance of the law in bringing medical technology from bench to bedside.

As a law student, Jason externed at the Center for Devices & Radiological Health at FDA, participated in the Tobacco Control Clinic, and served as a research assistant for Professor Lawrence Sung working on biotechnology and

intellectual property issues. However, Jason was most well known in the Law & Health Care Program for his work as Editor in Chief of the Journal of Health Care Law and Policy. In his role as Editor in Chief, Jason helped plan a conference on privacy and health information technology (HIT) that morphed into a very successful roundtable on Telemedicine (see article p.



(from l to r:) M. Jason Brooke, Caroline Farrell and Keith Shebairo

1). Jason participated in several of the planning meetings for, and later participated in, the Roundtable.

Jason won a scholarship to attend the Healthcare Compliance Certification Program at Seton Hall Law School - a week long program that took place in June. Starting this year, Jason will work as an Associate at the health law firm of Epstein, Becker & Green in Washington D.C.

Lauren Brumsted

Lauren wanted to study health law long before she actually attended law school. She wrote her senior paper in high school on "The effects of the thalidomide crisis on the structure of the Food and Drug Administration." Lauren then went on to obtain a BA in Government from Dartmouth, where she won the Chase Peace Prize for an essay on the impact of militarization on food security.

Prior to coming to the law school, Lauren served as Health Care Legislative Correspondent and then Legislative Assistant to Senator James Jeffords. In that position, she advised Senator Jeffords on health and disability issues and represented the Senator in Finance and Health, Education, Labor and Pensions (HELP) Committee staff meetings and legislative negotiations.

With health policy experience behind her, she hit the ground running when she arrived at the law school and pursued every opportunity at her disposal to learn about, and practice, health law. She externed in two highly sought after placements—the U.S. Attorney's Office in the Civil Health Law Division and the Department of Health and Human Services in the Office of the Inspector General. In his evaluation, her OIG supervisor David Blank called Lauren "a fantastic law clerk ... I was continuously impressed

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with her intelligence and enthusiasm. She is articulate and well-read and continually demonstrated the ability to think clearly and creatively when tasked with complex assignments.”

Lauren also served as a summer associate at the Washington D.C. law firm of Keller and Heckman, where she had the opportunity to work on regulatory and statutory issues regarding national and international food and drug law. Through the Presidential Management Fellowship Program, Lauren starts work this Fall as a Public Health Analyst in the Office of the Associate Director for Policy at the CDC’s Washington office.

Dominic Cirincione

Dominic graduated from the University of Maryland Baltimore County (UMBC) *magna cum laude* in 2005 with a B.A. in Political Science and Sociology. He later earned a Master of Public Policy from UMBC. Prior to law school, Dominic worked as a Health Policy Analyst at Discern Consulting for such clients as the National Business Coalition on Health, the American Pharmacists Association, and the Leapfrog Group.

Along with Jason Brooke, Dominic took a leadership role in the *Journal of Health Care Law & Policy*. In his position as Managing Editor of the *Journal*, Dominic spearheaded an effort to ensure that Journal students assist with the conferences that lead to symposia issues of the *Journal*. He also had the opportunity to have his comment, “The Medical Home Model: Is There Really No Place Like Home?” published in the *Journal* this year.

Like so many of the students in the L&HCP, Dominic has taken full advantage of the Health Law Externship Program. In Spring 2009, he externed in the Maryland Office of the Attorney General at the Department of Health and Mental Hygiene. In Spring 2010, he externed in the Office of the General Counsel at Johns Hopkins Hospital. Outside of the Externship program, Dom was an Honors Legal Intern in the Office of the General Counsel at CMS and served as a student attorney in the AIDS clinic.

Dominic will be able to put all his experience and education into practice as he begins his career as an Analyst in the FDA Office of Special Health Issues.

Danielle Duszczyszyn

Danielle came to the law school with a Ph.D. in Neuro-molecular Immunology from McGill University in Montreal. As a student she studied multiple sclerosis and

completed her Ph.D. thesis on Perturbed naive CD4 T cell homeostasi with evidence of thymic abnormality in relapsing-remitting multiple sclerosis. For her research, she earned a scholarship from the Multiple Sclerosis Society of Canada and was named Outstanding Young Researcher at the 8th International Congress of Neuroimmunology.

Prior to entering law school, Danielle had two positions that created a bridge between her scientific training and future legal training. She served as a Marketing Assistant at Bayer, Inc. in Toronto working with clinical experts to develop marketing aids geared toward physicians. She then served as a Regulatory Affairs Liaison at the Canadian pharmaceutical company, Gattefosse Canada, where she investigated regulations and policies required to distribute foreign pharmaceutical, nutraceutical and cosmetic ingredients into the Canadian market.

Danielle came to the law school as a Maryland Leadership Scholar. While at law school, she translated her interest in science into an interest in health law and intellectual property law. She served as a Research Assistant for Professor Diane Hoffmann on Hoffmann’s NIH-funded grant to study federal regulation of probiotics. Danielle conducted a literature review and studied how other countries regulate probiotics. Danielle’s scientific background was a great asset to the study team. For her work on the project, Danielle was named an Aaron Fellow.

Danielle found a position that will enable her to call on both her science and law training. She will be working at the Washington D.C. intellectual property law firm, Finnegan.

Stephanie Mackowiak

As a registered nurse, Stephanie is the kind of student that any health law program would love to have. Prior to entering law school, Stephanie worked in a hospital as a critical care nurse. Her nursing background made her a valuable asset in all her health law classes and externships.

In Fall 2008, Stephanie externed at Johns Hopkins Hospital in their in house counsel office with L&HCP alum, Meg Garrett. Stephanie then clerked at the in house counsel office of MedStar Health with L&HCP alum and Senior Corporate Counsel, Carl Jean-Baptiste. Stepping out of the in house counsel setting, Stephanie interned at CMS as a law clerk for the Provider Reimbursement Review Board and



L&HCP Director Diane Hoffmann and Molly Grace '10

Office of Hearings. In that position, Stephanie drafted complex PRRB administrative decisions involving Medicare reimbursement issues, as well as retiree drug subsidy cases. Her CMS supervisor Ben Cohen said of her, “Stephanie displayed exceptional maturity and professionalism and was well-liked by all. Given her strong professional and interpersonal skills, I have confidence that she will be an asset to future employers regardless of legal setting.” The first “future employer” she is sure to impress is Johns Hopkins Hospital where she will work as an Associate Counsel with L&HCP alum Laura Callahan Mezan.



Dominic Cirincione and Melissa Ruff

Shanna Wiley

Shanna came to the Law & Health Care Program with the perfect undergraduate credentials to study health law - she graduated from University of North Carolina with a B.A. in Biology and Political Science, a Concentration in Public Policy, and a Minor in Interdisciplinary Health Studies.

During law school, Shanna interned in two highly sought after health policy settings—the CDC and the U.S. Congress. Shanna was an intern with the CDC’s Washington Office and then interned for Senator Barbara Mikulski on the Subcommittee on Aging. She also served as a Reproductive Rights Legal intern at the American Civil Liberties Union in their Washington legislative office.

To meet the experiential learning requirement for the Health Law Certificate, Shanna participated in the law school’s Drug Policy and Public Health Strategies Clinic with Professor Ellen Weber. As a student attorney in the clinic, she researched statutes, regulations, and case law to help women’s health organizations determine the validity of compulsory drug testing on newborn infants and the policy’s effect on pregnant women.

Shanna’s vast and varied experience in health law as a student will serve her well as she commences her career as a Health Insurance Specialist at CMS.

CONGRATULATIONS TO THE 2010 HEALTH LAW CERTIFICATE RECIPIENTS!

Anne Blackfield
M. Jason Brooke
Lauren Brumsted
Lola Burford
Yue Pui Chin
Dominic Cirincione
Heather Deckert
Danielle Duszczyszyn
Caroline Farrell
Fay La Frossia Gordon
Molly Grace
Brenna Higgins
Jessica Hurst
Noah Isserman
Rebecca Alice Jesada
Jensen N. Jose
Stephanie Lee Mackowiak
Cipriano Oudie Martinez III
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Rebecca Spence
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Joy Pritts, JD

Chief Privacy Officer

Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services



November 4, 2010

“Health Care Reform and the Constitution”

Gillian Metzger, JD

Professor of Law
Columbia Law School

Ilya Shapiro, JD, MSc

Senior Fellow in Constitutional Studies
Editor-in-Chief, *Cato Supreme Court Review*
Cato Institute

February 10, 2011

“Health Care Disparities and Health Care Reform”

Frank McClellan, JD, LLM

Professor of Law Emeritus
Temple University Beasley School of Law

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“Health Care Cost Control”

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