

LAW & HEALTH CARE

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UNIVERSITY OF MARYLAND HOSTS 30TH ANNUAL HEALTH LAW TEACHERS CONFERENCE

On June 1-3, the University of Maryland School of Law hosted the 30th Annual Health Law Teachers Conference (HLTC). The event, co-sponsored by the American Society of Law, Medicine & Ethics (ASLME), is attended by academics and practitioners who teach health law or bioethics in schools of law, medicine, public health, health care administration, pharmacy and nursing. Conference participants hear presentations on issues at the forefront of law and medicine and have the opportunity to share strategies, ideas, and materials with their colleagues. A record 172 attendees participated in this year's conference which featured over 90 speakers and poster presenters, four plenary sessions, 16 breakout sessions, and three updates.

Benjamin Moulton, Director of ASLME, kicked off the conference by

welcoming everyone and introducing Karen Rothenberg, Dean of the University of Maryland School of Law. Rothenberg reminisced about the first time she attended the HLTC in 1983. Throughout her early career, the conference was a place where she met many of the leaders in the health law field who later became her colleagues and friends. She hopes that this tradition is continuing and encouraged long-time teachers to reach out to the new attendees. Rothenberg also introduced Diane Hoffmann, Director of Maryland's Law & Health Care Program, who organized this year's conference.

In her welcoming remarks, Hoffmann provided a bit of history about the annual event. While this year's conference was billed as the 30th annual meeting, during

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FROM THE DIRECTOR

In this issue of the L&HCP Newsletter, we focus on the recent Health Law Teachers Conference and share highlights of the conference plenary sessions along with presentations made by L&HCP faculty. In addition, we report on the 10th Anniversary of the *Journal of Health Care Law & Policy*, the activities and appointments of several Program faculty, a recent bioethics conference, and the numerous accomplishments of our 2006 graduates in health law.

Diane Hoffmann, JD, MS
Director

**Law & Health Care
Newsletter**

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L&HCP Faculty:

Diane E. Hoffmann, JD, MS
Director, L&HCP and Associate Dean,
University of Maryland School of Law

There are a number of law school faculty
who contribute to the diversity of the Law
& Health Care Program through their
teaching and scholarship.

They include:

Richard Boldt, JD
Irving Breitowitz, JD
Kathleen Hoke Dachille, JD
I. Michael Greenberger, JD
Deborah S. Hellman, JD, MA
Thomas Pérez, JD, MPP
Karen Rothenberg, JD, MPA
Lawrence Sung, JD, PhD
Allyn Taylor, JSD, LLM
Ellen M. Weber, JD
Deborah J. Weimer, JD, LLM
Robin F. Wilson, JD
Roger C. Wolf, JD

Adjunct Faculty (2006-2007)

Barbara Billauer, JD, Foundation for
Law and Science Centers, Inc.
Ellen Callegary, JD, Callegary and Steedman
Marc Charmatz, JD, National Assn. of the Deaf
James Doherty, Jr., JD, Pecore & Doherty, LLC
W. Lawrence Fitch, JD, Maryland Dept. of
Health and Mental Hygiene
Gail Javitt, JD, MPH, Phoebe R. Berman
Bioethics Institute, Johns Hopkins University
John Lessner, JD, Ober |Kaler
Kevin McAnaney, JD, Law Office
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Robert T.M. Phillips, MD, PhD, Forensic
Consultation Association, Inc.
Frank Palumbo, PhD, JD, University of
Maryland School of Pharmacy
Jack Schwartz, JD, Maryland Office of the
Attorney General
Sanford Teplitzky, JD, Ober |Kaler

Program Coordinator

Virginia Rowthorn, JD



UM Hosts Health Law Teachers Conference

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the planning stages of the conference, Hoffmann uncovered a 1984 invitational flyer inviting teachers to the 4th annual HLTC. George Annas, a founding organizer of the conference and host of next year's meeting at Boston University, promised attendees a written history at next year's gathering. This promise notwithstanding, he attempted to set the record straight about the meeting's history, noting that he organized the first HLTC in 1975 (it was by invitation-only, therefore, no brochure). According to Annas, the founders originally intended to hold the conference every two years, but after ASLME assumed responsibility for the meeting, it was made an annual event.



***Benjamin Moulton, Director of ASLME,
welcoming conference attendees***

A peek at the 1984 brochure is illustrative of how much both the field of health law and, following suit, the HLTC have changed over the years. The topics highlighted at that early conference (e.g., Antitrust and the Health Care Industry, Health Care Funding Issues, Medical Malpractice Causation) now seem like exceedingly general overviews in comparison to the complex and discrete issues covered at this year's conference (e.g., Concierge Medicine; The Application of Personhood Theory to Embryos and Fetuses; Confidentiality and Privacy Implications of Functional MRI). In addition to addressing increasingly specialized issues, recent conferences have focused on scholarship, while early conferences tended to focus on teaching.

The Last 30 Years: From the Right to Die to the Culture of Life

In organizing the event, Hoffmann and her colleagues included plenary sessions on topics that have both historical and contemporary significance. Keeping in mind the history of the HLTC, the idea for the first plenary session came about when Hoffmann and Rothenberg looked back 30 years to what was significant in the field of health law in 1976. Notably, 1976 was the year that the New Jersey Supreme Court decided the case of Karen Ann Quinlan, a watershed in the jurisprudence on the right to die. With the Terri Schiavo case so present in the minds of current health law practitioners, Hoffmann and Rothenberg chose to make end-of-life decision making the subject of the first plenary session. The session included four experts on end-of-life issues. Two of the speakers were newcomers to the conference – Jack Schwartz, Adjunct Professor at the University of Maryland School of Law and Director of Health Policy at the Maryland Attorney General's Office and Cathleen Kaveny from the University of Notre Dame Law School. The other two included long time attendees Sandra Johnson, from Saint Louis University School of Law, and George Annas from Boston University School of Public Health.

Professor Johnson, who also spoke at the first HLTC conference, delivered a talk entitled, "Karen, Nancy & Terri: The Changing Faces of End-of-Life Care Jurisprudence." Johnson focused on the now-famous trio of patients: Karen Ann Quinlan, Nancy Cruzan and Terri Schiavo, all young white females in a persistent vegetative state (PVS) who died very public deaths. She explored the question of why every 15 years a case like this (i.e., termination of life support from a patient in a PVS) surfaces and asked does it have to do with the "alignment of the stars" or is there some kind of trajectory. She sees each of the cases as raising questions about PVS and

the role of the family in making these decisions. Johnson reminded us that PVS was “born” at the time of the *Quinlan* case. In fact, there was disagreement at the time as to whether Karen Ann Quinlan was dead or alive. *Quinlan* also represented a case where there was consensus among the family and the experts. *Schiavo*, in contrast, represents the fractured family, one that does not fit our ideal. To Johnson, the full implications of the *Schiavo* case are not yet clear. She intrigued the audience by calling the case “expressionist art” – something dark, stark, and powerful, the meaning of which evolves over time. While Johnson believes *Schiavo* illustrated the difficulty we have deciding cases involving fractured families, in her view it also showed us that Americans continue to have a “dis-ease” with cutting off artificial nutrition and hydration from PVS patients.

In his talk, “The Kulturkampf in the States: End-of-Life Legislation,” Maryland Assistant Attorney General Jack Schwartz also addressed post-*Schiavo* issues and concerns. Schwartz emphasized that if *Schiavo* is going to have any impact on the law it will most likely come from state legislatures because, despite recent cases, most end-of-life decision-making is steered by statutes or by health care providers’ understanding of the statutes.

According to Schwartz, most end-of-life statutes reflect a mildly libertarian consensus, one that gives little practical effect to the formulaic state interest in the preservation of life. He pointed out that nearly all state statutes allow, even encourage, decisional advance directives. In addition, most state statutes authorize end-of-life decision-making, including artificial nutrition and hydration for a patient, like Terri Schiavo, in a persistent vegetative state. Will the reverberations of the *Schiavo* case change any aspects of this consensus? In Schwartz’s view, a change in the law about advance directives is unlikely. Advance directives are generally adored by liberals and conservatives alike.

Schwartz believes the most significant fall-out of the *Schiavo* case will relate to

family decision-making, artificial nutrition and hydration, and PVS. One initiative, from the National Right to Life Committee, is a model law entitled the “Starvation and Dehydration of Persons with Disabilities Prevention Act.” This model law which would make artificial nutrition and hydration, like the provision of conventional food and water, obligatory care, is unlikely to gain traction. Although introduced in 12 states, it has not been enacted anywhere. Schwartz observed, however, that over the long term, the alliance of right to life and disability rights groups may force a reexamination of the consensus that families should be able to make decisions about life support both for a PVS patient and for a patient with a genuinely terminal condition.

Ultimately, if disability rights groups gain the ear of legislators, one possible outcome is greater insistence on actually



Jack Schwartz
Maryland Assistant Attorney General

having clear and convincing evidence of the patient’s wishes, which implies a shift from clinic to courtroom. Another option could be a “best interest of the family” criterion (at least if the patient left no advance directive). Rather than guessing what the patient would want, the patient would conclusively be presumed to want whatever the family decides.

Schwartz concluded by stating that short-term legislative inaction may give way to a longer term debate in the states

over the right way to frame decision making standards when the patient is, and always will be, silent.

In her talk, “The Religious Right and the Right to Die,” Professor Kaveny drew on her background as a Christian ethicist to provide conference attendees with an enlightening explanation of the Catholic Christian view on artificial nutrition and hydration, a historical view that she believes greatly informs current religious dialog on the issue of end-of-life care. On end-of-life decision-making, the church believes that death must not be hastened and that no life is more valuable than another (i.e., a PVS patient’s humanity is equally as valuable and worth preserving as that of a healthy individual). However, moral theology holds that only ordinary, as compared to extraordinary, methods are required to preserve human life. Ordinary care implies care that offers a reasonable possibility of a cure. So, while the church is ambivalent about quality of life issues, there is an internal debate in religious circles regarding artificial nutrition and hydration because on the one hand such care is routine and non-painful but on the other, it offers no reasonable possibility of a cure and is burdensome to the family. In keeping with the historical theme of this first plenary session, Professor Kaveny concluded by reminding attendees that the right to die issue, while relatively new as a legal topic, is something that religious groups have studied for years and continue to debate internally.

George Annas provided a lively analysis of the *Schiavo* case in his talk, “The Culture of Life and the Politics of American Bioethics.” He called *Schiavo* an unimportant legal case given that “the approximately 40 different judges that heard the case agreed on the legal standard.” Instead, he called it a legal ethics case about how many appeals a party should be able to initiate when the law is clear. To Annas, the case is about the abortion debate and is “emblematic of what is wrong with American politics.” Provocatively, Annas commented that, in the United States,

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VIRGINIA ROWTHORN JOINS L&HCP

On August 1st, Virginia Rowthorn, joined the University of Maryland School of Law community as the new Coordinator and Director of Externships for the Law & Health Care Program (L&HCP). Virginia, who takes the place of Cindy Tippett, is a 1997 graduate of the Law School. Although she graduated before the School of Law awarded the health law certificate, she took every health law class available at the time. She was also Notes and Comments Editor for the *Maryland Law Review* and a teaching assistant for Professor Richard Boldt's Legal Theory and Practice course. According to L&HCP Director Diane Hoffmann, "Virginia has had a number of job experiences which undoubtedly will make her a valuable asset to the L&HCP." Before law school, Rowthorn was a Legislative Assistant for the Senate Veterans Affairs Committee working directly with the General Counsel to



*Virginia Rowthorn
Coordinator, L&HCP*

conduct hearings and secure the passage of legislation relating to the provision of counseling services to veterans who have been victims of physical assault or sexual harassment while serving on active duty.

After law school, she worked for three years at DLA Piper as an associate with a focus on estates and trusts. In 2001, she had an opportunity to work in the Office of the General Counsel at the Department of Health and Human Services (HHS). At HHS, she provided legislative legal services to the Department's client agencies and assisted the agencies in the development of policies and negotiations with the Executive Branch and Congress. Most recently, she was living in Uruguay with her family working as a member of the Board of Directors of the Uruguay-United States Bi-National Center and actively volunteering for various non-governmental organizations. At the Law School, Virginia will be advising students about course selection, certificate requirements, externships and practicum placements, dual degree programs in health care and law, and career options.

UNIVERSITY OF MARYLAND FACULTY SPEAK AT HEALTH LAW TEACHERS CONFERENCE

The University of Maryland School of Law faculty was well represented at the 30th Annual Health Law Teachers Conference. Topics addressed by both full-time and adjunct professors ranged from disaster relief to relief from the high cost of prescription drugs under the Medicare Modernization Act. In addition to the presentation by Maryland adjunct professor Jack Schwartz, at the plenary session "From the Right to Die to the Culture of Life" (see story, p. 1), Maryland law professors Frank Palumbo, Michael Greenberger, Sanford Teplitzky, Allyn Taylor, and Robin Wilson spoke at the conference breakout sessions.

Drug Coverage under the Medicare Modernization Act

Frank B. Palumbo, Executive Director of the University of Maryland School of

Pharmacy's Center on Drugs and Public Policy and an adjunct professor at the School of Law who teaches *Food and Drug Law*, spoke to attendees about the implementation of the Medicare Modernization Act.

Before delving into the nitty-gritty of drug coverage under the Act, Palumbo gave listeners a brief history of Medicare prescription drug benefits. He explained that adding an outpatient prescription drug benefit to Medicare was the topic of much debate and study over many years. Finally, in 1988, Congress passed the Medicare Catastrophic Coverage Act (MCCA), offering such a benefit to those Medicare eligibles who needed catastrophic coverage. This benefit was designed so that in any given year only 17% of those eligible would actually receive any benefit. The benefit was to be financed by increasing Part B premiums for the elderly and by charging



Professor Frank Palumbo

them a surtax on their federal income tax. Senior citizens rebelled and the MCCA was repealed the following year. Almost 20 years later, Congress passed the

Medicare Modernization Act and the outpatient drug program (Part D) became effective in January 2006.

Palumbo set forth the basic provisions of the Act noting that the law provides for a standard drug coverage plan or alternative coverage with actuarially equivalent benefits. Coverage is offered through Prescription Drug Plans (PDPs) and through Medicare Advantage (MA) plans, the latter referring to managed care organizations. PDPs are private plans, although the law does provide for the government to establish its own plan where there is no PDP coverage. So far, the government has not had to create its own plan because enough PDPs have come into the Medicare Part D market.

The standard terms for each one year benefit period include:

1. A deductible of \$250;
2. Coinsurance of 25% for drug costs between \$250 and \$2,250;
3. Coinsurance of 100% (essentially no coverage) for drug costs between \$2,500 and \$5,100 (this is known as the “doughnut hole”); and
4. Catastrophic coverage for drug costs over \$5,100 (the patient pays the greater of 5 percent coinsurance or a co-payment of \$2 for generic/preferred drugs and \$5 for brand name drugs).

All plans require cost sharing until the beneficiaries reach their true “out of pocket” expense (referred to as TrOOP). Once a beneficiary has reached the TrOOP amount (\$3,600 in 2006), the catastrophic component is activated. Palumbo commented that what counts as TrOOP has raised a number of concerns. Certain payments made by the beneficiary may not be TrOOP. For example, payments for a brand name drug when the generic is available, payments for drugs excluded from the plan formulary, or payments from Medigap policies, do not count. On the other hand, payments made by another individual on behalf of the beneficiary, as well as payments made by a state pharmaceutical assistance program, are considered TrOOP.

Each Part D plan has a formulary including generic and brand name drugs. Formularies must include at least two drugs from each therapeutic category. However, some drugs are actually excluded from the program. These include drugs used for weight loss or gain, cosmetic purposes, symptomatic relief of cough and colds, and fertility; over the counter drugs; barbiturates and benzodiazepines; prescription vitamins and minerals (except prenatal vitamins); and certain lifestyle drugs.

Medicare eligibles are comprised of many subgroups such as retirees with no drug coverage; retirees with coverage through an employer-sponsored plan; and dual eligibles – those eligible for both Medicare and Medicaid. Retiree health benefits continue to erode in the U.S. and one of the major questions in the wake of Part D implementation is whether employers will discontinue retiree drug coverage now that a Medicare drug program is in place. The law provides for financial incentives for employers to retain this benefit but it remains to be seen whether they will prove adequate in the long run. Unless a retiree has an equivalent employer-sponsored benefit, at age 65 or at retirement if after 65, he or she must enroll in Medicare Part D or incur a penalty of a one percent per month increase in premium payments. Dual eligibles must find their own plan among the choices in their area or they will be assigned to one by the state Medicaid agency. Dual eligibles have full coverage (e.g., no doughnut hole applies) but are subject to plan formularies.

Since the Act went into effect, there have been many implementation issues. Enrollment was “frantic” and many people were confused about the details including whether it would be financially advantageous to enroll and, if so, which plan would serve them best. Plans differ in premiums, cost sharing, formularies, and other features. The government provided a “calculator” on the CMS website to assist Medicare enrollees but visitors to the website reported that the calculator was of very limited value. The calculator requires some level of

computer savvy and, while elderly users might be able to input the drugs they are currently taking, they do not know what other drugs they might need in the future or whether those drugs would be covered and at what level. PDPs marketed aggressively and enrollment volume was larger than anticipated. Accessibility to the government’s website was difficult because of the large numbers of interested beneficiaries. Moreover, there were problems with transmission of eligibility files from CMS to the PDPs. Because of transmission problems, PDPs were required to provide at least a 30-day supply of medicines during the transition period. Some states and local governments found it necessary to step in during those early days and pay for drugs for low income or dual eligibles who slipped through the cracks.

PDPs also created problems. Providers expressed concerns about PDP payments. These concerns still exist, especially with regard to timeliness of payment. In fact, this has prompted some states to pass legislation requiring payment to providers within specified time periods. PDP performance is a major factor CMS is taking into account in deciding whether to allow a PDP to continue in the program for 2007.

Failure in the Implementation of the National Response Plan following Hurricane Katrina

Michael Greenberger, a professor at the School of Law and Director of the School’s Center for Health and Homeland Security, spoke at the session on “Public Health: The Next Pandemic.” Professor Greenberger discussed the wholly ineffective governmental response to Hurricane Katrina and its broad national implications for the coordination of federal, state, and local governments in reacting to a catastrophic public health crisis.

Greenberger noted that in December 2004 to great fanfare, the Department of Homeland Security (DHS) rolled out its National Response Plan (“NRP”), the function of which was to ensure a high level of coordination, not just among all

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of the federal agencies that need to respond to a catastrophe on the magnitude of Katrina, but among all levels of government responding to what the NRP refers to as an “incident of national significance.” When Katrina made landfall, however (and for several days thereafter), the federal government, despite all of its ballyhoo about the document, never triggered the NRP. Indeed, when the NRP was finally deployed, many of its critical organizing principles were never used.

The NRP contemplates that all of the cabinet heads or their principal deputies would convene in a single “operations center” under the leadership of the Secretary of Homeland Security to monitor and respond to the incident. Affected states and localities were to be embedded into this process by advanced communication technologies on a real time basis. Yet, remarked Greenberger, not once during the crisis did high level federal officials ever meet in a single room. Indeed, there is scant evidence that any cabinet officers or the leadership of DHS, for that matter, ever personally met with each other. Much of the business of coordination was done by scattered emails and phone calls.

According to Greenberger, the most startling aspect of the Katrina response was the misuse of the substantial assets of the active military to assist Katrina victims. The military quickly deployed personnel and resources to neighboring states in the Gulf Coast region, but were delayed in providing that help while the Justice Department spent days researching the question of whether that assistance would violate the federal Posse Comitatus Act (“PCA”). This was in spite of the plain language of the NRP which provided that that issue had already been resolved and that the Secretary of Defense had, in compliance with the PCA, pre-signed orders in conjunction with the publication of the NRP so that no time would be lost in using military help to respond to an “incident of national significance.”

In the wake of Katrina, sparring has broken out between the federal

government and the states about the role each level of government is to play in such a crisis. The President has made it clear that the federal government will play



Professor Michael Greenberger

a much larger role in the future, including deploying the active military. This view is buttressed by the theory that emergencies of this nature simply overwhelm states and localities, making it impossible for them to lead the response. Through the National Governors’ Association, however, the states have made it clear that they will resist such a large and prominent federal role, which they see as an infringement on their constitutional rights. They see no crisis as being too large for states’ exclusive hands.

Yet, Greenberger believes, if the NRP were used as intended, adept federal leadership could maintain the equivalent of “control” over disaster response without ever publicly commandeering the leadership of the states. This would require a high level executive working group overseeing the crisis with a real time and effective link up with the affected states and localities. In such a system, the federal government could “support” the state response by being ready to quickly “supplement” the states’ resources with the full approval of the states, thereby assuring that, as far as the public is concerned, the states are still in charge. It is the very failure of the federal government to establish any effective coordinated federal response mechanism that aggravates tensions between the various

levels of governments and increases substantially the financial and social havoc of the crisis itself.

Update on Federal and State Fraud and Abuse Investigations

In a session focusing on business issues in health law, Maryland adjunct professor Sanford (Sandy) Teplitzky, who also chairs the Health Law Group at Ober|Kaler, a prominent Baltimore law firm, provided conference attendees with an update on federal and state fraud and abuse investigations. Teplitzky began by noting that any review of a health care transaction involving one or more health care professionals or entities who are in a position to refer patients and/or business to each other must be reviewed under three federal and a number of state statutes. The federal authorities include the federal anti-kickback statute, the Stark II self-referral statute, and the federal False Claims Act.

According to Teplitzky, over the last couple of years, federal and state authorities have become increasingly more aggressive in their review of business transactions in the health care field. In many respects, a significant percentage of current investigative and enforcement initiatives are being driven



Professor Sanford Teplitzky

by whistleblowers, or “relators” under the False Claims Act, with the possibility of substantial recoveries for the whistleblowers. In fact, statistics indicate that the fastest growing source of investigations result from current employees, former employees, and

competitors. Teplitsky reviewed the basic elements of each of these statutes, provided a summary of recent enforcement efforts, and highlighted those considerations which appear to play an important role in determining whether an investigation may ultimately turn into a prosecution. When evaluating a health care transaction, he stated that authorities focus on:

- (1) any unnecessary increase in cost to the payors;
- (2) any diminution in the quality of care;
- (3) any inappropriate impact on the utilization (either over or under) of health care services;
- (4) the effect on access to health care services in the community;
- (5) the effect on competition in the community;
- (6) the effect, if any, of the business relationship on a patient's freedom of choice; and
- (7) any situation in which a financial interest may cloud the judgment of a health care professional.

Teplitsky made clear that any law under which a sanction may be imposed requires proof of inappropriate intent. (Of course, the extent of the required intent varies based upon the specific sanction authority and whether it is a criminal or civil sanction.) He recommended that participants in health care business transactions remain aware of the seven considerations he discussed, as well as maintain thorough documentation regarding the parties' intent, to avoid potential exposure under the law.

International Framework Needed to Respond to Global Disasters

Allyn Taylor, who has a joint appointment at the University of Maryland Schools of Law and Medicine, specializes in international law, international public health, and human rights. She spoke at the conference during the breakout session entitled "Public Health: Responding to Domestic and International Natural Disasters."

Professor Taylor provided an analysis of the international legal framework for global disaster preparation and response with particular reference to the Indian

Ocean tsunami. The 2004 tsunami produced one of the largest humanitarian aid efforts in world history. Nevertheless, it exposed the underlying weakness of the existing legal framework. Namely, there is no comprehensive set of international standards to foster fast and effective relief in such emergencies.

The tsunami spurred governments, international organizations, and non-governmental organizations (NGOs) into quick action to provide relief for the millions of victims. In addition, \$13.4 billion was raised through the combined contributions of 92 countries in the form of private aid pledges and government aid packages. The international community also received praise for transparency and accountability when the United Nations (UN) developed an innovative and publicly accessible online database to keep track of aid dollars.

Because of the speed and generosity of the international reaction, as well as the sustained focus on reconstruction and prevention, the tsunami is widely considered a leading model for effective global disaster response. However, Taylor remarked, the success of the relief effort was not due to the effective implementation of pre-existing international legal standards which are remarkably underdeveloped in this area.

International disaster response law consists almost exclusively of isolated clauses scattered throughout agreements that are not specific to natural disasters. Moreover, there has been no systematic attempt to improve existing law or to develop new laws to strengthen global assistance efforts. Historically, international disaster response law has been neglected because disasters are seen as short-term, episodic events. As such, states are reluctant to address these events by codifying binding commitments that could restrict their sovereignty.

Despite the conventional resistance to the use of legal frameworks, a variety of factors suggest that the time has come to address the gaps in the international legal approach. First, the scale and the costs of natural disasters are increasing, thereby elevating the need for effective

international collaboration. Second, there has been significant growth in the scope of intergovernmental organization and NGO disaster relief efforts which demand greater coordination than currently exists. Finally, as the scale and scope of the international response to natural disasters has increased, the gaps in the existing legal fabric are increasingly apparent and seriously impede disaster response. Although the tsunami relief effort was considered a success, the initial response was hindered by legal issues that commonly plague international assistance operations and result in delay of relief to the victims. For example, most countries do not have a national legal framework for disaster response. In addition, the absence of coordination and communication among international responders and victim countries leads to delay and duplication that wastes limited time and resources. Finally, lengthy customs processes and tariffs on relief goods, inappropriate aid, difficulty in obtaining over-flight and landing rights, restrictions on visas, and protection of personnel are also common legal problems in disaster response.

Because of the growth in natural disasters as well as the expansion of international disaster actors and assistance, a new and more demanding governance environment for disaster response may be emerging. In 2005, Member States of the UN adopted a resolution calling for the strengthening and formalization of international frameworks, and the Association of Southeast Asian Nations (ASEAN) adopted an Agreement on Disaster Management and Emergency Response.

Although the international community has taken steps to address the gaps in international disaster response laws, according to Taylor, the window of opportunity is rapidly closing for governments to re-examine current regulatory structures and develop an effective international regulatory regime to address future disasters. As the tsunami and Hurricane Katrina reveal, no state can ignore the possibility that it might, one day, be in a position to need outside help.

PUBLISHING STRATEGIES FOR HEALTH LAW TEACHERS

This year's HLTC organizers added a new preconference session to the conference agenda primarily geared toward new health law teachers and scholars. One session focused on teaching and was moderated by Maryland faculty member Tom Pérez. The other, focused on publishing strategies for health law teachers and was organized by Professor Robin Wilson.

At the publishing session, in addition to Wilson, three seasoned health law faculty shared their experiences and gave suggestions to attendees on completing scholarship, from article development to final publication. These faculty members included Professor Judith Daar from Whittier Law School, Professor David Hyman from the University of Illinois College of Law, and Professor Barbara Noah from Western New England College School of Law.

The panel members discussed a variety of ways to develop article ideas. They pointed out that the timeliness of a topic is important when deciding what to write about and that newspaper articles can be a great source of inspiration in choosing a topic. Choosing a “big target” – such as an important law reform proposal or an article by a well-known author with which the writer disagrees—can help place an article well and also allow the writer to get more than one piece out of her research. One panelist urged faculty not to be afraid to be the lone voice on a topic. Generally, the panel concluded that authors should write about whatever strikes them as interesting.

Panelists also gave advice on maximizing presentations and talks, which can be turned into an article or other form of scholarship, like a book chapter or essay. Talks often can serve as a “pre-commitment strategy,” forcing the faculty member to complete a certain amount of research by a fixed date. Co-authors can help to keep an author on a timetable and on track, and for this reason, co-authored scholarship sometimes works well.

Choosing the right type of journal to which to submit a piece is also crucial. This decision should be made based on the type of school at which the author teaches (whether, for example, it has an interdisciplinary focus or values such work) and whether the author is on the ramp up to



tenure or is post-tenure. Some panelists felt that overall, diversification is the best strategy and an author should attempt to publish in a number of different kinds of publications, including journals and policy reviews. One way to do this is through “knock-offs” – tweaking the same article to reach a number of different audiences. For example, a longer article may be published in a law review and then a shorter piece on the same topic in a policy journal or as an op-ed.

An author should spend at least some time developing a marketing strategy for his or her work, which can assist with placement and broaden the piece's impact. The cover letter that accompanies the article should explain why the article is important. A lot of health

law topics are inherently interesting and this should be conveyed. Frequently, a narrow piece can be framed as a test case for larger issues facing legislatures or courts.

A number of electronic databases can broaden the impact of an article. The Legal Scholarship Network within Social Science Research Network (SSRN) is a good way to advertise completed works and works in progress. SSRN's eLibrary contains approximately 124,000 publications, which represent the work of 63,000 authors. Because SSRN offers free submissions and downloads, SSRN speeds the distribution of legal research and creative ideas. Legal scholars throughout the world use SSRN as a research tool. In addition, the service delivers research to faculty working and writing on the same issues. SSRN's Young Scholars Law Abstracts, which is edited by Professors Wilson and Hyman, can be a great way to connect to other new scholars in the same field. Panelists suggested that authors also utilize the public relations people at their schools because raising the visibility of faculty is their job.

Finally, the panelists reminded attendees that books should not be overlooked. An article can sometimes be turned into a book, or a group of articles can be turned into a book with a bit of new material. At one time, casebooks were the traditional form of legal scholarship. Some schools now discount casebooks, while others continue to value them. If writing a casebook, especially a specialized casebook, marketing must also be considered. For specialized casebooks, the author will need to survey the potential market and see how many courses on the subject are being taught around the country. For academic books, as well as some casebooks, authors will need to submit three or four chapters before the publisher will commit to the project.

CHARITY SCOTT RECEIVES JAY HEALEY DISTINGUISHED HEALTH LAW TEACHER AWARD

Each year faculty at the Health Law Teachers Conference honor one of their peers by awarding a current health law teacher the Jay Healey Distinguished Health Law Teacher Award. Nominees are health law professors whose passion for teaching health law and their mentoring of students and other faculty honors the memory of Jay Healey.

Benjamin Moulton, Executive Director of the American Society of Law, Medicine and Ethics, in a letter to health law colleagues, solicited nominations for the award and shared some history about Jay, a beloved teacher of health law at the University of Connecticut Schools of Law and Medicine: “Jay, a 1973 graduate of Boston College Law School, was one of the organizers of the first Health Law Teachers Conference in 1976 and soon became the spiritual leader of the nation’s health law teachers, who honored him with the Health Law Teacher Award in 1990. Jay was the youngest recipient in the award’s history. A baseball fan, he was accurately described at the time as the ‘Roger Clemens of health law teaching.’ He was a teacher’s teacher, who cared deeply about his students and whose students were extraordinarily fond of him.”

This year, Professor Diane Hoffmann had the privilege of announcing the award recipient, Charity Scott, Professor of Law at Georgia State University’s College of Law. According to Hoffmann, it didn’t take long to agree on who should receive the award this year. Charity is “someone who for over a decade, since Jay’s death, has taken over for him at this conference and has moderated the Jay Healey Teaching Session. Each year she brings to life the memory of Jay Healey and shares with all of us the role he played in inspiring students and other health law



*Diane Hoffmann (right) presents
Health Law Teacher
Award to Charity Scott*

teachers. She spends many hours conceptualizing the panels for these conferences, coming up with excellent speakers and challenging the audience, making us think hard about what it means to be an effective and inspirational health law teacher. Her passion and enthusiasm for health law teaching shine through each year.”

In addition to teaching at Georgia State’s law school, Scott has a joint appointment at the University’s College of Business, in the Institute of Health Administration. She is also the Director of the Center for Law, Health & Society at the College of Law and teaches courses on health law and policy and bioethics. In addition, she is a Faculty Fellow in Health Law with Emory University’s Center for Ethics, where she joins an interdisciplinary faculty team to offer clinical ethics classes for third-year medical students.

Charity, like Jay Healey, has worked tirelessly to bridge the gap between

physicians and lawyers, providing opportunities for lawyers and health care professionals to work and learn together about issues at the intersection of law, health, ethics, and public policy. According to Steve Kaminshine, Dean at Georgia State, “Charity is passionate in her belief that health law is a vehicle that brings together a host of disciplines and allows for interdisciplinary collaboration. She is innovative, creative, enterprising, indefatigable and constantly thinking outside the box. The Center for Law, Health & Society at Georgia State is evidence of her vision that health law isn’t a silo but a topic that calls for interdisciplinary thought and participation.”

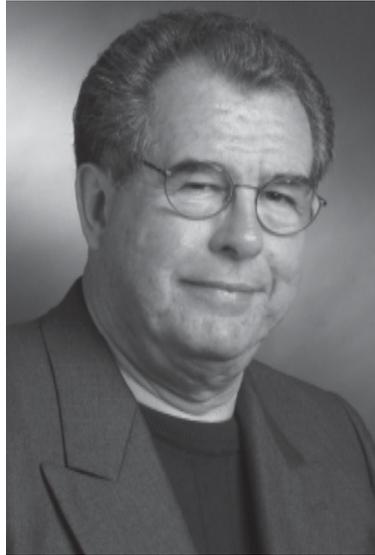
Charity also clearly has a passion for teaching. That passion, Hoffmann found out, just might be genetic. Charity actually comes from a long line of professors. She is a third generation law professor and a fourth generation professor. Hoffmann spoke with Jerri Nims, a former student and research assistant who now works for Charity at the Center. Jerri told her that “Charity is regarded by the students at Georgia State not only as an excellent health law teacher, but as one of the best teachers at the Law School.”

In terms of Charity’s commitment to health law, Hoffmann was most struck by something her son, Peter, shared with her. Several years ago, Scott spent a sabbatical year at a local hospital. But she didn’t just go and sit in an office, she spent her time doing rounds and actually following the doctors, mostly ob-gyns on their 36 – 48 hour shifts. It is this kind of dedication – spending 48 hours with the ob-gyns at the hospital—that made Professor Charity Scott an easy choice as the recipient of this year’s Health Law Teachers Award.

THE LEONARD C. HOMER/OBER | KALER LAW AND HEALTH CARE FUND

The University of Maryland School of Law was delighted to learn last spring that Ober | Kaler, a prominent Baltimore-based law firm, had created the Leonard C. Homer/Ober | Kaler Law and Health Care Fund to support the Law & Health Care Program (L&HCP) in developing the next generation of health care lawyers. The Fund was named in honor of Leonard C. Homer, a practicing attorney at Ober | Kaler who founded the firm's health law practice 31 years ago and served as its Health Law Chair for many years. Through the Fund, the firm made a pledge of \$30,000 over five years to provide financial support for initiatives of the L&HCP, the first \$5,000 of which was earmarked to support the 30th Annual Health Law Teachers Conference held at the Law School in June.

Last year, Ober | Kaler celebrated the 30th anniversary of the founding of its health law practice. The firm, which boasts more than 30 health care lawyers, ranks among the top 10 largest health law practices in the country. Considered a pioneer in health law, Mr. Homer represents hospitals, physicians, and other



Leonard C. Homer

health care providers in transactions, contracting, compliance, and litigation involving federal, state, and private health care programs. The Fund is a fitting homage to Mr. Homer, who has championed health law education and scholarship for years as a charter fellow of the American Health Lawyers Association

(AHLA), which he joined in 1976. Two years later, he co-founded the Institute on Medicare and Medicaid Payment Issues – one of the AHLA's most successful and longest running educational programs. He served as president of the AHLA's predecessor, the National Health Lawyers Association, from 1985 to 1986. In 1991, Homer received the David J. Greenburg service award for his "great loyalty...and significant contributions to the AHLA."

Karen Rothenberg, Dean and Marjorie Cook Professor of Law at the School of Law, said of the gift, "We want to thank Ober | Kaler for its generosity and support in creating the Fund. Leonard Homer has truly been an inspiration and a powerful figure in the health law field across the country, in Maryland, and at the University. We have worked closely with him for years and have benefited greatly from his knowledge and experience."

A reception was held at the School of Law on May 1st to announce the creation of the Fund and celebrate Mr. Homer's life-long contributions to the field of health law.

ROTHENBERG APPOINTED TO MARYLAND STEM CELL COMMISSION

During its 2006 legislative session, the Maryland General Assembly passed legislation designed to stimulate research on new therapies based on the use of stem cells. The controversial legislation, described by *The Washington Post* as the "most emotional and most divisive taken up by the Maryland General Assembly" in 2006, was first introduced in 2005. The earlier bill, which earmarked \$25 million a year for embryonic stem cell research and included fewer limitations than the recently-passed legislation, died on the final day of the legislative session last year under the threat of a filibuster on the Senate

floor. The current law, signed by Governor Robert Ehrlich in April, represents a middle ground, making available up to \$15 million in grants, but requiring that grants be available for work on adult stem cells, if scientists find such research promising.

The new law, the Maryland Stem Cell Research Act of 2006, calls for the establishment of a 15-member Stem Cell Commission composed of the Attorney General or his designate, three patient advocates, three individuals with experience in biotechnology, four scientists (who do



Dean Karen Rothenberg

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INAUGURAL MEETING OF THE NANOTECHNOLOGY REGULATORY WORKING GROUP

Nanotechnology is a subject about which we know less than we should but probably more than we think we do at first glance.¹ Like Rumsfeld's known unknown terrorists, we know enough to know what to know we should be concerned with.² Glimmers of risk associated with nanotechnology cropped up recently when German authorities recalled a bathroom cleaning product, "Magic Nano." The product was purported to contain nanosized particles and was on the market for only three days, after more than 100 people suffered severe respiratory problems in a 1-week period—six of whom were hospitalized with pulmonary edema.³ Although a subsequent analysis of "Magic Nano" found that the nanoliquid ingredient changed chemically in the production, the recall nonetheless turned a white hot spotlight on the risks of nanosized particles.⁴ Latching onto the risks posed to workers producing materials using nanotechnology, *The Washington Post* has labeled nanotechnology a "seat-of-the-pants occupational health experiment."⁵ A clear-eyed evaluation of the risks and benefits of nanotechnology is made all the more complicated by a very complex science—pushing the envelope of materials science—and by a venture capitalist-like hype about the potential of nanotechnology.

On Friday, April 28th Maryland Professor Robin Wilson, hosted a half-day meeting focusing on the role of regulation in promoting nanotechnology and addressing its risks. The Nanotechnology Regulatory Working Group (NRWG) included regulators, industry representatives, and academics who work in nanotechnology. Sitting at the table were representatives from FDA, the NY State Department of Health,



(left to right) Maryland Professors Fred Provorny, Robin Wilson, Frank Palumbo, and Visiting Professor Dan Gilman at first meeting of the NRWG

NIH, the Maryland Insurance Administration, and the Environmental Law Institute.

In this inaugural meeting, the NRWG considered a number of questions, including:

- ◆ How should we respond to the possible risks of nanotechnology without hampering its growth?
- ◆ Is there a need for a regulatory response to nanotechnology? If so, is new legislation necessary or can nanotechnology be addressed within existing statutory frameworks?
- ◆ What are the gaps in our knowledge base about nanotechnology that are relevant to an appropriate response?
- ◆ Is a regulatory response the exclusive province of the Federal government or is there a role for industry or the States?

The NRWG is part of Professor Wilson's ongoing work as a Co-Investigator on the National Science Foundation grant, "From Laboratory to

Society: Developing an Informed Approach to Nanoscale Science & Technology."

Footnotes

¹Robin Fretwell Wilson, *Nanotechnology: Regulating the Unknown*, ENVTL. LAW REP. (forthcoming 2006).

²Donald Rumsfeld, Secretary of Defense, Defense Department Briefing (October 17, 2002).

³Rick Weiss, *Nanotech Product Recalled in Germany*, WASH. POST, Apr. 6, 2006, at A2.; *Has all the magic gone?*, THE ECONOMIST, Apr. 12, 2006.

⁴Andreas von Bubnoff, *Study shows no nano in Magic Nano, the German product recalled for causing breathing problems*, SMALL TIMES, May 26, 2006, available at http://www.smalltimes.com/document_display.cfm?document_id=11586.

⁵Rick Weiss, *Nanotech Raises Worker-Safety Questions*, WASH. POST, Apr. 8, 2006 at A1.

SHOULD CONSCIENCE BE YOUR GUIDE? EXPLORING CONSCIENCE-BASED REFUSALS IN HEALTH CARE

A Clinician refuses to remove a dying patient from a ventilator . . . A pharmacist refuses to fill a prescription for emergency contraception. . . A nursing home medical assistant refuses to stop a patient's tube feedings. . .

Such refusals based on claims of conscience were the focus of a conference held on June 20 at the University of Maryland School of Law. The conference, sponsored by the Maryland Health Care Ethics Committee Network (MHECN), an initiative of Maryland's Law & Health Care Program, was designed for health care providers, administrators, labor lawyers, and policy makers who grapple with how to meet patients' health care needs while accommodating staff with diverse beliefs.

Keynote speaker James F. Childress, Ph.D., Professor of Ethics and Medical Education and Director of the Institute for Practical Ethics and Public Life at the University of Virginia, spoke on "Exploring Claims of Conscience: Making & Respecting Conscientious Refusals." He concentrated on what he calls the fundamental question in this debate – should society exempt conscientious objectors from some legally and ordinarily expected actions and practices? He believes that we should, as a society, have a presumption in favor of claims of conscience that could be overridden under certain circumstances.

Childress suggests that society strike a balance between protection of practitioners' conscientious objections on one side and protection of the interests of patients on the other. Possible approaches that have been offered to strike such a balance include:

1. Avoidance by the conscientious objector (CO) of employment where an offensive act (X) is required.
2. Requiring a CO to perform X when the CO has entered a profession where X is expected as a core duty.



(left to right) Conference organizers Anita Tarzian and Diane Hoffmann, and speakers James Childress and Carolyn McLeod, alongside Dean Karen Rothenberg

3. Requiring a CO to give advance notice to the patient that they won't perform X.
4. Requiring a CO to inform patients of the refusal coupled with a disclosure to the patient about other options for X.
5. Requiring a CO to inform patients of the refusal coupled with referral or transfer of the patient elsewhere for X.
6. Providing for a case-by-case review of conscientious refusals both before and after such refusals.

According to Childress, none of these approaches are without problems, especially options 4 and 5, as some COs may see disclosure and referral as equivalent to performing X itself. In making accommodations for conscientious refusals, Childress commented that providers must ensure performance of needed medical services in a timely and nondiscriminatory fashion while allowing COs not to perform certain acts. In addition, COs must avoid "surprising a patient" with a refusal to perform a certain act.

Maryland Professor Robin Wilson also spoke at the conference and updated attendees on legal trends in the field of conscientious refusal. Wilson, like Childress, struck a conciliatory note by proposing a "live and let live" approach. As background, she noted that nearly every state has a conscience clause that authorizes individual providers or entities to refuse to participate in certain procedures, usually abortion and sterilization. She commented that these conscience clauses date back to *Roe v. Wade*, when family planning advocates sought to force private, not-for-profit hospitals to provide sterilization and abortion services. In this early litigation, these advocates argued that the receipt of federal monies required an individual or institution to perform these controversial services. In what Wilson calls the "primogenitor" of the health care conscience clauses, the Church Amendment, Congress prohibited the government from using receipt of certain federal funds to force an institution or individual to provide a service contrary to



Professor Robin Wilson

their “religious beliefs or moral convictions.”

Following Congress’ example, state legislatures also carved out a space for medical providers to continue in their professional roles without participating in acts they find immoral. Conscience clauses vary from state to state, especially in the strength of the protection given to individuals and facilities that refuse to participate. Many insulate facilities and individual providers from suit by patients (what she calls “horizontal conscience clauses”), while others insulate providers from coercion by employers or the government itself (“vertical conscience clauses”).

With this background in place, Wilson argued that the conscience clause model has functioned well for over 30 years and should serve as a model to handle the conscientious refusal issue. In support of her policy of accommodation, she also commented that requiring pharmacists to dispense emergency contraception would actually be a radical departure from common medical practice. Under current law, providers often make their own decisions as to which services and practices they provide. For example, hospitals have always had the ability to choose (subject to licensure requirements) which services they provide, pharmacies generally stock only what is required by their local patrons (usually only stocking 15% of available pharmaceutical products), and doctors have always had latitude (subject to special discrimination clauses) to choose which patients they will serve.

In her view, a prudent solution would be for state legislatures to allow individuals to recuse themselves from acts and practices as long as such a recusal

would not create an undue hardship to the patient or employer.

Following Wilson’s update, several health care practitioners addressed the subject from their respective profession’s point of view in a session on “Conscience and Professional Duty – Considerations for Health Care Professionals.”

Professor Cynda Rushton, Associate Professor at the Johns Hopkins School of Nursing and Co-Chair of the Ethics Service at Johns Hopkins Hospital spoke about what she termed the “special challenges” that nurses face carrying out the often-conflicting decisions of doctors, institutions, and families. She commented that for nurses, going against one’s conscience creates a loss of integrity and sense of alienation from what it means to be a nurse. She commented that many studies show that nurses often experience “moral distress” during performance of their duties – a sensation that stems in part from performing acts contrary to their consciences. Rushton believes nurses warrant special respect in this area because unlike doctors, they cannot pick and choose their patients. In Rushton’s view, a proper framework to handle these situations must include:

- 1) an understanding that the right to refuse is not absolute;
- 2) non-abandonment of patients and their families;
- 3) a requirement that the refusal be made in advance, in other words, not at the moment the act is contemplated;
- 4) a requirement that the refusal be consistent and not mask another labor/employment issue;
- 5) due process;
- 6) exploration of what reasonable accommodation looks like; and,
- 7) organizational structures and policies.

Dr. Michael Williams, Associate Professor of Neurology and Neurosurgery at the Johns Hopkins School of Medicine, who also co-chairs the Ethics Service with Cynda Rushton, started by commenting that while many call the physician/patient relationship a contractual one, for most physicians it is much more. He noted that while virtually all ethical guidelines require physicians to act in a patient’s best

interests, physicians can generally choose their patients. Furthermore, doctors usually work in teams with other types of health care professionals. Therefore, he recommended that policies regarding conscientious refusal be made at the institutional level. Williams particularly noted the importance of ethics committees in creating institutional policies, noting that such committees should provide guidance in protecting the patient and conscientious refuser, establishing processes for placing the conscientious refuser in the right job and for resolving unanticipated situations of conscientious refusal. In addition, ethics committees should see that their institutions have in place a mechanism to support people who were forced by



Professor Helen Norton

circumstances to perform acts against their conscience.

During the following session, “The Institution Role – Balancing Rights & Duties,” Helen Norton, a visiting Maryland professor with expertise in employment law, spoke on “Employment Laws & Conscientious Objection.” To begin, she noted that most employment relationships in the United States are presumed to be “at will” unless 1) a contract is in place that specifies other terms, or 2) federal or state law deviates from this presumption. An employer may fire an “at will” employee for refusing to perform any act required by the position. However, Title VII of the Civil Rights

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Conscience Based Decisions

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Act and (often more generous) state anti-discrimination clauses protect employees from termination based, among other things, on their religious beliefs. While Title VII generally imposes negative obligations, with regard to religion, it imposes a positive duty on an employer to take affirmative steps to reasonably accommodate an employee's religious beliefs unless doing so would cause an undue hardship. Generally, it is under this type of anti-discrimination clause that employees bring suits if they have been dismissed for conscientious refusal. Norton noted that there have been very few lower court and no Supreme Court cases on the issue.

According to Norton, it is easy for a plaintiff to make a prima facie case regarding discriminatory firing based on conscientious refusal, but employers generally win these cases because courts have made it quite easy for employers to show that they either offered a reasonable accommodation or that making any accommodation would cause an undue hardship to the employer. Professor Norton then discussed several cases (including *Bruff v. North Mississippi Health Services*, 244 F.3d 495 (5th Cir. 2001) and *Noesen v. Medical Staffing Network/Wal-Mart* (W.D. Wis. 2006)) that indeed show, thus far, that courts have been employer-friendly on this issue.

Other conference speakers included Edmund Howe, Professor of Psychiatry and Director of the Program in Ethics at the Uniformed Services University of the Health Sciences; Jamie Reuter, Clinical Specialist in Critical Care and Program Director of the Pharmacy Practice Residency at Union Memorial Hospital; Evan DeRenzo, a bioethicist at the Center for Ethics, Washington Hospital Center; Dennis Mahon, Assistant Professor at Seton Hall University; Brian Childs, Director of Ethics and Spiritual Care for the Shore Health System; and Carolyn McLeod, Assistant Professor in the Department of Philosophy at University of Western Ontario.

This year marks the 10th anniversary of the University of Maryland School of Law's *Journal of Health Care Law & Policy* (JHCLP). Over the last decade, the JHCLP has provided the legal community with scholarly publications on important national issues in health care and medicine through an interdisciplinary focus on timely and controversial issues in health law. The JHCLP, which works in conjunction with the school's Law & Health Care Program, incorporates articles from judges, attorneys, medical doctors, social workers, psychologists, economists, and other leading experts. Past issues have explored (among other things) the legal implications of medical research conducted on the decisionally impaired, genetic privacy and family disclosure, tobacco legislation and litigation, and end-of-life care.

In this important anniversary year, the JHCLP will be headed up by incoming Editor-in-Chief Amy Siegel, a third year law student who brings an impressive health-care related background to the task. Amy earned a Masters in Public Health at Columbia University in the area of Health Policy & Management in 2004 after receiving her B.A. from the University of Pennsylvania. Amy's work experience includes clerking at the

Bethesda, Maryland law firm of Bregman, Berbert, Schwartz & Gilday, working as a student attorney in the Law School's Drug Policy & Public Health Strategies Clinic, and interning for the Deputy Counsel to the Maryland Department of Health and Mental Hygiene.

The focus of the next issue of the JHCLP (10:1) will be articles stemming from presentations made at the Law, Medicine and Health Care section's session, "Public Health in Law" at the 2006 Association of American Law Schools (AALS) conference. Speakers at the session discussed how public health issues and perspectives, including epidemiology, can be introduced into health law classrooms. The issue will include articles by Professors Wendy Parmet,

Northeastern University School of Law; Lawrence Gostin, Georgetown University Law Center; Wendy Mariner, Boston University School of Public Health; Elizabeth Weeks, University of Kansas School of Law; and Nan Hunter, Brooklyn Law School. Plans are also underway for Issue 10:2, in which Amy and her staff plan to commemorate the tenth anniversary of the Journal by soliciting articles on a variety of health law topics to demonstrate how far the field of health law has expanded, even in the last decade. Articles in this issue will reflect the changes in policy and technology that continue to shape the field of health law.



Amy Siegel
JHCLP Editor-in-Chief

MARYLAND'S LAW & HEALTH CARE PROGRAM GRADUATES 29

At a reception held on May 17, 2006, at the School of Law, Professor Diane Hoffmann, Director of the Law & Health Care Program and Cindy Tippet, former Coordinator of the Program, recognized 29 students for fulfilling the requirements necessary to be awarded the Certificate in Health Law. This diverse group completed all the coursework required by the School of Law as well as the rigorous requirements necessary for the concentration in health law. The Certificate in Health Law was first awarded to students in 1998. After eight years, the Program continues to attract students with prior degrees from the nation's top universities and students with significant work experience as health care practitioners. This year's graduates formed a particularly strong group: their prior research and practical experience not only enriched their individual law school experiences but also enriched the education of the other students in the Program. Another hallmark of this year's graduates was the incredibly wide range of health law and policy internships and externships they participated in during their years at the law school. While all of the Program graduates are stars in their own right, we highlight six of our recent graduates below.

Brooke Courtney brought both a prior health-related degree and significant work experience to her law school career. Brooke earned her MPH from Yale University in 1999. Over the next four years, she worked on policy issues with the Lewin Group (a healthcare policy research and management consulting firm in Washington, D.C.), the American Red Cross, Pfizer, Inc., and the Maryland Health Care Commission.

While at law school, Brooke took full advantage of the many opportunities available to students to gain practical legal experience through intern- and



(left to right) *Health Law Certificate Recipients*
Linda Gousis, Monika Ras, and Mona Shah

externships. In the spring of her second year, Brooke was a fellow for two subcommittees of the U.S. Senate Committee on Health, Education, Labor & Pensions: the Subcommittee on Retirement Security & Aging and the Subcommittee on Bioterrorism & Public Health Preparedness. In this capacity, she provided legislative assistance to Ranking Committee Chair Senator Barbara Mikulski of Maryland. Brooke spent one summer in the Health Care Fraud Division of the U.S. Attorney's Office, another summer at the Department of Health & Human Services, Public Health Division, and a semester in the Office of Delegate Jon Cardin in the Maryland General Assembly. In addition, Brooke managed to gain practical experience outside the Law School as a mediator in the Community Mediation Program in Baltimore.

A paper Brooke wrote for her Tobacco Control Legal Theory and Practice class entitled "Is Obesity Really the Next Tobacco? Lessons Learned from Tobacco for Obesity Litigation," was selected as a finalist in the Epstein Becker & Green writing competition and was

published in *Annals of Health Law* (Volume 15 (2005-06) Issue 1, Winter 2006).

Brooke is now a Fellow at the Center for Health and Homeland Security here at the School of Law.

Clark Johnson Lee also brought a wealth of experience to his law school career. Clark earned his undergraduate degree in neurobiology from Harvard University. While at Harvard, he worked in the medical school's Division of Sleep Medicine researching the effects of long work hours and sleep deprivation on hospital interns. This work led to publication of his Comment, "Federal Regulation of Hospital Resident Work Hours: Enforcement with Real Teeth" in the *Journal of Health Care Law & Policy (JHCL&P)*, for which he later received the prestigious Burton Award. The Burton Award, created in 1999 in honor of William C. Burton, Esq., is awarded to law students and attorneys who have published a high quality legal paper in one of the nation's law reviews or journals. The award which is extremely competitive, recognizes excellence and clarity in legal writing. Award recipients were selected from nominations by deans of all of the law schools in the United States, as well as from nominations by managing partners of the country's 750 largest law firms.

Given his abilities as a legal writer, Clark was chosen as a Notes & Comments Editor for the *Maryland Law Review* in his third year. Clark also took advantage of numerous opportunities to gain experience in legal and health law settings while in law school. During much of law school, he worked for the Denial Research Group, which assists health care providers appeal denials of health care payment claims. In the summer of 2005, he clerked in the Medicaid Fraud Control Unit of the Maryland Office of the Attorney General and, in the fall of 2005, interned for

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Judge Handy on the Circuit Court for Baltimore City. In addition, Clark worked during his three years in law school as a General Assistant at the University of Maryland Center for Advanced Study of Language in College Park. Aside from English, Clark speaks six languages with varying levels of proficiency: German, French, Taiwanese, Portuguese, Spanish, and Chinese.

For the next two years, Clark will be a Governor's Policy Fellow for the State of Maryland. The Governor's Policy Fellows Program is a two-year, post-graduate program that attracts the nation's most distinguished policy graduates to serve in Maryland State Government. The Program provides participants with broad exposure to the development, implementation, and evaluation of public policy at the State level.

Cori S. Annapolen has the honor of being the first law student to receive the joint JD/MPH degree from University of Maryland's new Masters of Public Health Program. Cori was able to complete the required course work for her dual degree in three years, an impressive accomplishment given her involvement in a number of other law school activities. Cori was a Notes & Comments Editor for the *Maryland Law Review*, a member of the National Health Law Moot Court Team, and, most notably, won first place in the 2005 George Washington University Legal Research and Writing Competition with a seminar paper she wrote entitled, "Maternal Smoking During Pregnancy: The Harmful Effects on the Exposed Fetus and Proposed Legal Implications for the Mother's Actions." Her paper discussing this cutting edge issue was published in the *Virginia Journal of Social Policy & the Law* (12 Va. J. Soc. Pol'y & L. 744-778 (2005)).

Cori is bringing her wealth of skills to the chambers of Judge Greene at the



(left to right) Health Law Certificate Recipient Neil Sood, with Professors Diane Hoffmann and Jaime Doherty

Maryland Court of Appeals where she began a judicial clerkship this fall.

Like many of our other graduates, Oyeronke (Ronke) Bamiduro juggled multiple commitments during law school. In addition to completing her legal studies, Ronke worked as a program specialist for Covance Market Access Services, a reimbursement and health economics consulting firm. Despite her work and school responsibilities, Ronke was also an active member of the Student Health Law Organization (SHLO), the Black Law Students' Association (BLSA) and the Christian Legal Society. She also served as Articles Editor for the *JHCL&P*. In the fall of 2004, Ronke was able to spend a semester abroad in Cape Town, South Africa where she worked as a policy intern for the Children's Institute and the Institute for Democracy in South Africa.

For her law school clinical experience, Ronke enrolled in the Civil Rights of Persons with Disabilities Clinic where she worked at the National Association of the Deaf. For her dedication to providing legal services to underprivileged populations, Ronke was awarded the Monumental City

Bar Association's Juanita Jackson Mitchell Scholarship.

In the spring of her last year, Ronke did a practicum at MedStar Health's Integrated Legal Services Department working on policy revisions to MedStar's compliance plan. This fall, Ronke will be relocating to the Atlanta, Georgia area.

Kevin Madagan began his health law studies as soon as possible after finishing his required first year courses. In his second year he took the two health law survey courses and was also a student attorney in the Health Care Delivery and Child Welfare Clinic: The AIDS Epidemic. In the summer between his 2nd and 3rd years, Kevin clerked in the legal department of Kaiser Permanente. His supervising attorney Dinah Seiver enjoyed working with Kevin, calling him, "bright in spirit as well as intellect" and someone who "reminds you why you do what you do – because it's interesting, it helps people, it advances principles."

After his experience at Kaiser, Kevin externed at the U.S. Department of Health and Human Services, Office of the General Counsel for CMS (Center for Medicare & Medicaid Services) and then stayed on in the spring of his third year. His supervising attorney, Howard Cohen, praised Kevin for making "substantive contributions with respect to a number of important assignments, including a major issue associated with Part C (Medicare Advantage) and the new



(left to right) Health Law Certificate Recipients Maria Mojica, Erin Smith and Mikaela Rossman

Medicare Part D (drug benefit), and also contributions with respect to a case recently heard by the Supreme Court, *Ark. Dept. of Health & Human Services v. Alhborn.*”

Kevin served as Manuscripts Editor of the *JHCL&P* during his last year in law school, a very important and time-consuming position. Recently, Kevin began as an associate in the Health Care Group at the firm of Reed Smith in Washington, D.C.

Like other recipients of the Certificate in Health Law, Kristin M. Cline came to law school after having worked as a health care provider. As a registered nurse, Kristin started her career as a nurse clinician in the bone marrow transplant unit at Johns Hopkins Hospital. She then spent three years in the post-anesthesia care unit at Memorial Sloan Kettering Hospital in New York.

Kristin pursued her interest in health law from the moment she set foot in the Law School. She spent her first summer interning at the Maryland Office of the Attorney General in the Medicaid Fraud Control Unit. She spent the next spring as an intern in the legal department of Kaiser

Permanente. In her final year at the Law School, Kristen clerked at Civil Justice, Inc., a Maryland not-for-profit corporation formed for the purpose of increasing the delivery of legal services to clients of low and moderate incomes.

Kristin also served as Associate Editor of the *JHCL&P*. Her dedication and leadership abilities were recognized by



**Health Law Certificate Recipients
Travis Robey (left) and Steve Karon**

the Department of Health and Human Services, which selected Kristin to participate in the Department’s prestigious Emerging Leaders Program next year. The Emerging Leaders Program is designed for top university graduates with an interest in working for the federal government. While rotating through various departments within HHS, participants are provided with appropriate training, mentoring and tailored instruction based on their career interests.

Kristin recently started the Program in the National Institutes of Health (NIH).



**(left to right) Health Law Certificate Recipients
Kristen Farrell, Kristin Cline and Kristin Cilento**

2006 Health Law Certificate Recipients

Cori S. Annapolen
Bisma A. Al-Humadi
Oyeronke Bamiduro
David Robert Blazina
Kristin Carrie Cilento
Kristin M. Cline
Brooke Courtney
Kristen Leslie Dorsey
Kristen Astrid Farrell
Beck S. Fineman
Linda Souter Gousis
Morriah Holly Horani
Susan Janoski
Iyanrick Walton John
Steven Leonard Karon
Daniel Nathan Kassel
William Thomas Lawrie, Jr.
Clark Johnson Lee
Kevin Madagan
Maria de Lourdes Mojica Vazquez
Rahul Narula
Ann Monique Ras
Travis E. Robey
Mikaela Ivy Rossman
Alexandra Sasha Sagalovich
Delora Robin Sanchez
Mona Gulab Shah
Erin Bronwyn Smith
Neil Balwant Sood

only individuals on their deathbed have a right to health care. He would like to see the right to life sentiment expressed in support of Terri Schiavo channeled to support a recognized right to health care – the issue he believes (hopes) will be the focus of the next big national health law debate.

A Renewed Concern: Public Health Disasters

While the conference's first plenary session examined an issue that has faced health law practitioners for years, the concurrent plenaries on the second day of the conference dealt with two contemporary themes in the field of health law. The first, a plenary session entitled, "Public Health Disasters: Politics, Money & Ethics," was in large part a forum for addressing health care issues raised by Hurricane Katrina. Maryland Professor Robin Wilson moderated the session that included presentations by Professors Sara Rosenbaum from George Washington University Medical Center and School of Public Health and Health Services, Dayna Matthew from the University of Colorado at Boulder School of Law, and Peter Jacobson from the University of Michigan School of Public Health.

Professor Rosenbaum told attendees that she uses the Katrina disaster to teach her students seven lessons about health care financing. First, there is a public health care dimension to health care financing, whatever model is applied to a region or population. Second, health care financing can be (and in the case of Katrina, is) the source of huge legal battles with powerful interests arrayed on both sides. Third, health care plays an essential role in making a community feel safe, such that public safety and health care must be considered together. Fourth, there are consequences to denying people a right to health care coverage. Fifth, there are grave problems with the current Medicaid system that Katrina laid bare – it does not provide coverage to all low-income individuals, it is not portable, and it does not provide

for rapid enrollment. Sixth, Medicaid is a public benefit, not an insurance policy in the commercial contract sense. Finally, there are horrible gaps in governmental disaster management policies – most glaring from a health law perspective is the lack of plans for a provisional health care system in the event of disaster-related health care system failure.

The gaps in federal emergency management mentioned by Rosenbaum were also prominent in Professor Matthew's talk entitled, "Law and Disastrous Disasters: Controlling the Race and Class Disparities in Public Health Responses." Reminding attendees that the varied terrain of the United States makes it subject to all manner of natural disaster, Matthew analyzed the response of state and federal officials to disasters that have occurred in the United States in the last century. Using data obtained from these various calamities, she uncovered a pattern of disparate impact on vulnerable populations. For example, in the 1906 San Francisco earthquake Chinese immigrants were disproportionately targeted for looting and dwellings in Chinatown were indiscriminately and disproportionately razed to the ground. Justice in that case, however, was inadvertently served for some of these immigrants who were later able to make successful bids for citizenship because the San Francisco town hall collapsed, crushing records that might have invalidated their applications.

Katrina highlighted the unfair treatment of minorities before, during, and after a disaster. Matthews is currently studying legal methods to redress this issue. She observed that historically available federal litigation avenues have largely been closed, noting that Title VI of the Civil Rights Act, which might have provided relief, has been foreclosed by *Alexander v. Sandoval* which eviscerated the ability of private parties to bring disparate impact cases. On another front, there has been ineffective enforcement by the Office of Civil Rights. A novel theory that offers hope is the "school finance" litigation model used in state courts. This model, proposed by Robert

Klee, has been quite successful and may be applicable to the issue of health care disparities, although one difficulty Matthews anticipates is qualifying "the poor" as a suspect class. Cases under the Civil False Claims Act are another avenue Matthews is studying. While she acknowledges that none of these theories are safe bets, she concluded her talk by observing that "desperate times call for desperate measures."

Next, Professor Jacobson moved away from the gloom and doom of disasters and safely back to academic theory. His talk asked the question – are bioethical principles a distraction to thinking about public health ethics? Or, asked another way, can bioethics deal with public health challenges or is there a need for a new set of moral principles to guide public health policy? Recent trends in public health, such as bioterrorism, emerging infectious disease, and rising health care costs, make these questions more important than ever. The problem as Jacobson sees it is that medical ethics do not fit squarely within the public health model. While medical ethics focus primarily on individual autonomy, public health ethics must necessarily be concerned with multiple determinants of health, prevention, the central role of government, safety-net functions, a multi-disciplinary work force, and community participation. What principles underlie these ethical concerns? Jacobson believes that the principles of fairness, "population-level utility," social justice, cost effectiveness, and transparency are the principles upon which a unique framework for public health ethics can be constructed. Jacobson concluded by propounding the value of such a framework as long as it can be supported by solid empirical data.

After 30 Years: Rethinking Health Law

The second concurrent plenary was titled "Rethinking Health Law," suggesting an ambitious agenda. This panel discussion was an outgrowth of a workshop held in December 2005 at Wake Forest University that challenged

participants to propose new perspectives for approaching the field of health law. According to session moderator Lois Sheperd of Florida State University School of Law, the workshop was based on the assumption that health law is generally in a state of fatigue and that dominant paradigms of autonomy and market theory have “done their work and run their course.” Participants in the Wake Forest conference were asked to address four questions: Does health law have a core set of concerns? Is health law a distinct field of law that should have a unique set of doctrines? What new paradigms can best help us to reconceive health law? How can health law accommodate the unique psychological, physical, and moral aspects of its subject matter? Shepherd described the panel discussion at the HLTC as a “road show” of the issues raised at the Wake Forest conference.

Professor Mark Hall, from Wake Forest University School of Law, was the first to speak. He rejected the notion that health law is no more than the application of other fields of law to health-related cases, in the same way one could apply such laws to horses or bananas. In fact, he believes health law does have a unique core—the patient—and he argues that it is concern for the patient that makes health law practitioners care so deeply for the field in which they practice.

Einer Elhauge of Harvard Law School also agreed that health law can be a coherent field. Elhauge argued that, in fact, health law needs to be a coherent field in order to avoid dangerous and inefficient contradictions that exist under current law. He pointed to several inconsistencies that result from the complicated application of health law principles, e.g., the existence of antitrust laws that require competition alongside other laws that make it nearly impossible to employ competitive practices. He also pointed to statutes that create managed care organizations and other laws that prevent the same managed care organizations from actually managing the care they provide. What Elhauge calls the “powerful mismanagement” of health care

is the result of employing various paradigms to legal issues without thought to which paradigm best fits a given issue. The various decision making paradigms, e.g., the market model or the patient autonomy model, all have limitations. Therefore, Elhauge argues, we have to resign ourselves to the tension but allow for a more reasoned and consistent approach to resolving health law conflicts. He recommended organizing the field around decision making processes – or a “comparative process approach”.

Gregg Bloche of Georgetown University Law Center agreed with Elhauge that retooling the field of health law is critical and hardly a case of academic “naval gazing.” Professor Bloche noted that health law does have an image problem and that some legal professionals do not see it as a separate field of law. But Bloche argues that the complicated patchwork of health law reflects the complicated human emotions that underlie the field. Bloche calls the “core paradox” of health law the clinical encounter. It is this encounter that distinguishes health law from other fields. On one hand patients, even legally incompetent patients, are considered to have rights and dignity equal to the practitioners who treat them. On the other hand, the relationship is extraordinary in its one-sidedness in terms of knowledge and experience. This one-sidedness leads the patient to have an almost child-parent relationship with the practitioner – a relationship studied in the field of family law. This marketplace/family relationship tension is what is unique to health law. Bloche acknowledged that this relationship raises messy questions, including questions of responsibility that are unique to health law.

Bloche’s talk flowed smoothly into Professor Sheperd’s discussion of what practitioners in the field should do going forward. Sheperd told attendees she approached the issue of “rethinking health law” by looking at the relationship of health care to suffering. Within this

relationship, she believes, is a common moral perception that when someone is suffering we have an obligation, or responsibility, to do something. Therefore, she focused her talk on her current research regarding the notion of responsibility as a framework for reconceiving health law and organizations.

She based her presentation on three main points. First, with respect to health care, she believes that we (professionals, nonprofessionals and health care entities) are automatically in relationships of responsibility. Because health care is uniquely interpersonal, our health conditions, habits, and decisions have effects on other people and can lead to an increase in their suffering. Second, she asserted that there are some relationships within health care that carry a greater responsibility (e.g., large employers are responsible for providing health insurance to their employees; doctors for providing appropriate care; family members for caring for dependents; the government for caring for its citizenry). Finally, Professor Sheperd discussed the question of what this concept of health care responsibility means with respect to health law. She supports tying the concept of responsibility to accreditation standards, professional licensure standards, health care funding, tax status, and to the interpretation of existing law.

In addition to these plenary sessions, conference participants were able to attend a preconference session on teaching and scholarship (see article page 8), several updates describing recent developments in various areas of health law, multiple breakout sessions where colleagues described their recent scholarship or ongoing research, a poster session, and the Jay Healey Teaching Session and Award (see article page 9). Over half a dozen Maryland faculty and adjuncts participated in these sessions, addressing attendees on a variety of cutting-edge issues. A summary of their presentations can be found beginning on page 4.

Rothenberg Appointment

Cont. from p. 10

not engage in stem cell research), two individuals with experience in religious biomedical ethics, and two bioethicists. The legislation provided that three of the 15 Commission members were to be nominated by the University of Maryland System. Dr. David Ramsay, President of University of Maryland, Baltimore, immediately recognized that Karen Rothenberg, Dean and Marjorie Cook Professor of Law at the University of Maryland School of Law, would be an ideal member to serve on the Commission. On July 6th, Rothenberg, along with Dr. Jeremy Sugarman, professor at the Johns Hopkins Bioethics Institute, was appointed to fill one of the bioethicist slots.

Rothenberg, a national expert in genetics and public policy, was a natural choice for the Commission, having served as President of the American Society of Law, Medicine and Ethics, a member of the Institute of Medicine's Committee on Legal and Ethical Issues Relating to the

Inclusion of Women in Clinical Studies, as well as on several NIH panels on such topics as prenatal care, the recruitment and retention of women in clinical studies, and the ethical, legal and social implications of genetics. She also served as a member of the NIH Recombinant DNA Advisory Committee, the National Action Plan for Breast Cancer, the American Bar Association's Coordinating Group on Bioethics and the Law and on the Advisory Council to the National Institute of Child Health and Human Development.

The Commission is charged with establishing criteria, standards, and requirements to ensure that stem cell research financed by the Maryland Stem Cell Research Fund complies with state law. Working through the Maryland Technology Development Corporation (TEDCO), the Commission will appoint an independent scientific peer review committee to review, evaluate, and rank research proposals for state-funded stem cell research based on the

procedures and guidelines established by the Commission. The Commission will provide up to \$15 million in grants in 2007 to university-based and private researchers working with stem cells.

At the Commission's first meeting on July 27th, participants did not debate the morality of the highly-charged issue of embryonic stem cell research but agreed that it was appropriate for funds to be available for research on both adult and embryonic stem cells. The Commission focused instead on its immediate goals: to issue a request-for-proposals (RFP) within the next two months, seeking applications from both academic and corporate researchers, and the establishment of the scientific review panel (SRP). The School of Law hosted the Commission's second meeting on September 14th, at which the Commission moved forward on its work of drafting the initial RFP and regulations governing the process as well as creating the SRP.

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