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Focus on...

Health, Technology and the Law

Since its beginnings, health law has been, at least in part, a response to new medical and other technologies affecting the delivery of health care. These technologies have generated laws in the areas of privacy, assisted reproduction and genetics, and end-of-life care. Faculty at the University of Maryland School of Law and its Law & Health Care Program (L&HCP) have been at the forefront in thinking about how the law should respond to these technological developments. This article describes the response of the law to these various technologies and the participation of the L&HCP and its faculty in the development of the law in some of these areas.

The Internet Revolution

The development of and reliance upon the internet, by both patients and providers, is a new technological advance that has had tremendous impact on the delivery of health care services and health law. The practice of cybermedicine, internet sales of prescription drugs and medical devices, the creation of electronic medical records, and an explosion of medical information on the internet have markedly changed the way that medicine is practiced in the United States. These internet advances provide people with the ability, among other things, to purchase needed prescriptions and learn about medical conditions without leaving the house or picking up a medical text. In addition, telemedicine has allowed for the electronic transmission of x-rays, magnetic resonance imaging (MRI), and other test results to physicians across the country and throughout the world. A general practitioner in rural Maryland, for example, can con-

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suit with a radiologist in Pennsylvania to analyze a cranial-tomography (CT) scan. However, these new technologies also present new regulatory challenges. Though existing laws in some states permit doctors to consult with each other telemedically, there is a catch when it comes to diagnosing and treating patients remotely: each individual state requires that physicians practicing medicine in that state be licensed in that state. Unless the Pennsylvania radiologist is licensed in Maryland, where the patient is physically located, providing diagnostic or therapeutic services directly to the patient constitutes the impermissible practice of medicine without a license. In addition, these new technologies have raised issues regarding reimbursement by Medicare and other third party payors.

Software advances have also had an impact on the health care industry. For example, they have allowed medical professionals to maintain patient records in electronic form. Though some health care practice groups still maintain paper records, electronic medical records have become increasingly common. These records are also easier accessible and are more manageable than a paper medical chart, which is often a voluminous, well-worn stack of paper. With electronic medical records, a physician may check the dosage he last prescribed for a patient at the nearest computer terminal without having to locate the patient’s medical record. In addition to simplifying the administration of patient care, electronic medical records have streamlined the medical billing process. The same electronic patient record used to manage patient care also serves as a basis for the generation of an electronic bill to a clearinghouse or insurance company.

Electronic medical record-keeping and physician payment procedures might likely solve problems associated with the administration of health care services, such as lost bills, inaccurate patient information and long waiting periods for physician reimbursement. However, health care providers, health care plans, and clearinghouses currently use over 400 different electronic claims formats which utilize different transaction codes (detailing what services the patient received), making electronic processing of claims both costly and time-consuming.

To ensure that existing computer technologies are fully utilized in the health care services field, Congress passed the Health Insurance Portability and Accountability Act (HIPAA). One purpose of HIPAA is to promote the electronic transfer of health information by mandating a specific format for records of health information. HIPAA is comprised of three sets of complex regulations. The first set of regulations, the “transaction” standards, went into effect in October 2002. These regulations mandate specified transaction code sets for enrollment, claims and authorization. After the effective date (which could be delayed for one year upon request), if a provider submits a claim in a HIPAA compliant format, the payor must process the claim. HIPAA’s second set of regulations, regarding patient privacy rights, went into effect in April 2003. The third set of rules, which describe required security measures for electronic medical transactions, were just published in February 2003 and are not yet in effect.

HIPAA is frequently criticized as a morass of complicated federal regulations and critics complain that HIPAA implementation will cost health care providers and administrators more money than Y2K readiness measures. Alternatively, it is argued that these forward-looking regulations will provide long-term cost savings to providers, clearinghouses and insurance.
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companies. Medical billing will require less time and staff to administer, with savings eventually being passed down to the health care consumer.

In response to the legal issues that have arisen out of internet-based health care, computer technology, and other technological developments, last fall the L&HCP offered an eHealth seminar. (See related article p. 5.) The seminar was taught by Alan Goldberg, Esq., one of the country’s foremost experts on HIPAA and other issues brought about by the introduction of technology into the practice of medicine and the delivery of health care.

Reproductive Health Technologies and Genetics

In the 1970’s, the field of reproductive technology saw much progress. By 1995, nearly 15% of all women of reproductive age sought some type of fertility treatment. Currently, three of the most commonly employed reproductive technologies include artificial insemination, in vitro fertilization (IVF), and cryogenic preservation.

While these breakthroughs have allowed hundreds of thousands of women to conceive, the law has been slow to respond to our increased dependence on assisted reproductive technology (ART) and few states require insurance companies to pay for the technology. While there has been considerable public discussion about the regulation of ART, legislators have been unable to reach consensus about new laws in this area. There is reason to believe, however, that the push for government intervention will continue. Legislation and legal battles in the assisted reproductive area may involve the amount of time that frozen embryos are permitted to be stored in fertility clinics and limitations on pre-implantation genetic screening to determine embryo characteristics such as sex, skin color, disease or disability.

The mapping of the human genome has had a significant impact on assisted reproduction, as well as on medicine more generally. As a result of the Human Genome Project, health care providers now have the capability to test for a large number of genetic traits and abnormalities both prenatally and after birth.

Francis Collins, Director of the Human Genome Research Institute (HGRI), has said that by 2010 predictive genetic tests will be available for as many as a dozen common conditions, “allowing individuals who wish to know this information to learn their individual susceptibilities and to take steps to reduce those risks for which interventions are or will be available.” The availability of this technology has raised a multitude of legal and ethical issues from privacy to discrimination to access to tests and therapies.

In addition, attempts to produce human embryos through somatic cell nuclear transfer, or cloning, have evoked a strong response from scientists, legislators and ethicists. Though no federal money may be used to fund cloning projects, the public outcry based on non-government scientists’ cloning attempts has prompted legislators in Congress and some states to try to enact a complete ban on cloning for reproductive and medical research purposes. In the summer of 2002, the President’s Council on Bioethics urged a temporary moratorium on both reproductive and medical research cloning.

A number of members of the Maryland General Assembly took notice of the controversy but rather than moving directly to propose legislation, the House Environmental Matters Committee, through Chairman John Hurson and Delegate Sandy Rosenberg, an adjunct professor at the School of Law, requested a study of the ethical dilemmas and scientific opportunities presented by embryonic stem cell research. The Department of Legislative Services, charged with authoring the study report, contacted Associate Dean Diane Hoffmann and the L&HCP for assistance. Hoffmann recruited second-year law student Sarah Richardson to work on the project which involved drafting a section of the report on legal issues involved with the storage and disposition of embryonic stem cells. (See related article p. 8.)

Last fall, the L&HCP also sponsored a panel discussion entitled “Beyond Dolly: Human Cloning and Human Dignity.” (See related article p. 7.) Moderated by Dean Karen Rothenberg, the panelists, two members of the President’s Commission on Bioethics and a leading stem cell researcher, engaged in a lively give-and-take that brought some clarity to the complex, urgent ethical and legal problems created by this particular technology.

In response to the legal and ethical questions created by the Human Genome Project, several Maryland faculty members have focused their scholarship on this topic and/or have become advisors to state or federal government policy makers concerned about these issues. For example, last fall, Professor Lawrence Cont. on page 4
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Sung organized a conference co-sponsored by the Intellectual Property Law Program and the Law & Health Care Program entitled "At the Crossroads—Public/Private Priorities Concerning Access to Genetic Information." (see article p. 7) Professor Sung will be publishing an article based on remarks he made at the conference in an upcoming issue of the Journal of Health Care Law & Policy.

Dean Karen Rothenberg and Professor Deborah Hellman have written articles on genetic discrimination and related issues. Professor Hellman’s article, "What makes Genetic Discrimination Exceptional?" was recently published in the American Journal of Law & Medicine. Rothenberg has published numerous articles on the misuse of genetic information in the insurance and employment context and proposed a legislative framework to prevent such misuse. This framework has been used as a guide by a number of states as well as Congress. In addition, Rothenberg’s research on the stigmatizing impact of a genetic predisposition that is common to a particular racial or ethnic group led to her participation in the recent PBS special, "Genes on Trial: Genetics, Behavior, and the Law." (See article p. 6.)

The L&HCP offers a number of new and continuing courses that incorporate these cutting-edge issues. Professor Lawrence Sung has created several courses on new technologies, addressing intellectual property, biotechnology, and bioethics. Also, this semester, Professor Irving Breitowitz taught a new seminar on Jewish law and reproductive technology. The course examined selected ethical issues posed by the development of assisted reproductive technologies through the prism of a body of religious law that is over 3000 years old. In addition, the law school continues to offer a very popular seminar on Principles of Bioethics which addresses these and other legal/ethical issues associated with developing scientific technologies.

End-of-Life Care

Judicial opinions and statutes on advance directives and end-of-life care were largely a reaction to the ventilator. The "breathing machine," patented in the 1950s, was a less cumbersome, more effective version of the iron lung. It allowed doctors to help a greater number of patients who lacked the capacity to breathe without assistance.

The benefits of the increased use of the ventilator were numerous; however, a unique set of problems developed with its proliferated use. Where before the 1950s a patient who suffered extensive brain damage and was unable to breathe without assistance would have likely died, the invention of the ventilator allowed patients to indefinitely sustain the life of a patient who held minimal chance of ever regaining consciousness. Thus, use of the ventilator presented two interrelated issues: Does the patient have the right to determine, in advance, that in the case of terminal illness or PVS, use of the ventilator should be terminated? Do the patient’s relatives and other loved ones have the right to make that decision for the patient?

Some of these issues were resolved in Cruzan v. Director, Missouri Department of Health. In Cruzan, the Supreme Court implied that mentally competent people have a fundamental right to refuse life-sustaining measures (the measure at issue in Cruzan was the provision of artificial hydration and nutrition). Further, the Court stated that a surrogate may exercise the patient’s right to die for the patient, but that a state may place limitations on the role of the surrogate and require that the patient, at some previous point in time, clearly and convincingly have expressed his/her desire to refuse such life-sustaining measures.

Because of life-sustaining technologies like the respirator and in response to "a green light" from the Supreme Court in Cruzan, legislatures were faced with the task of creating a system by which incompetent patients could exert their right to refuse medical treatment. Though California was the first state to enact an "advance directive" statute in 1976, Cruzan prompted many state legislatures follow suit.

Professor Diane Hoffman played a key role in the development and passage of legislation that became the Maryland Health Care Decisions Act (the "HCDA"). At the time the HCDA became law in 1993, it was a cutting edge model for legislating end-of-life care decision making. It remains so today.

In addition, Hoffman founded and directs the Maryland Health Care Ethics Committee Network. (See related article p. 9.) The Network serves as a resource for hospitals, nursing homes, and other health care providers on ethical issues, including the withholding or withdrawal of life sustaining technology. With its recent transition to the School of Law, MHECN is another example of how the L&HCP has responded to the changes in health law resulting from technology in health care.

Students in the L&HCP have also seen firsthand how technological advances such as the "breathing machine" have created new areas of health law. Several L&HCP students have studied the laws related to health care decision making both in class and out, and have made presentations to the community on advance directives and related issues. (See article p. 6.)

As new health technologies develop, policymakers will undoubtedly struggle to find a balance between regulating and encouraging their benefits. As the law responds, health lawyers will also face the challenge of keeping pace with the impact of technology on the delivery of health care services.
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L&HCP Offers New eHealth Course

Last fall, the L&HCP offered an "eHealth" seminar taught by Alan S. Goldberg, JD, LLM, of Goulston & Storrs. Goldberg was one of the first attorneys in the country to establish a practice that incorporated the issues created by technology into health law. He has been practicing health law (originally by being a business lawyer for clients who deliver or pay for health care) since the 1960s. Although familiar with computer technology—Goldberg was proficient in typing and "cutting messages" on what he calls an "early computer" while in the Navy—he had to wait for the computer to make its way into the mainstream before technology would become part of his area of legal specialization.

With the creation of the internet, Goldberg began his technology and eHealth law practice. The practice, while rewarding, says Goldberg, can be frustrating in that the technology (i.e., the computer) only says "yes" or "no," but the law recognizes shades of gray. Moreover, the "law" of technology has not kept up with technology's new creations.

Goldberg has been teaching for over 20 years, both at law schools and professional associations such as the American Health Lawyers Association and the American Bar Association. He has also written extensively on health care technology, the Health Insurance Portability and Accountability Act (HIPAA), telemedicine, and the use of technology in the practice of law.

"Any place law, health care and technology come together," says Goldberg, "I'm on that corner with my thumb out looking for a ride."

In an effort to expose students to some of the legal issues surrounding the impact of technology on the delivery of health care services, Goldberg brought his expertise and passion for teaching to the School of Law. His class, "eHealth Care, Privacy, Security and Technology," provided a timely and exciting opportunity for Goldberg to combine his vast knowledge of technology, health care, and the law. The course covered topics including telemedicine, e-signatures, ethical issues involved in the use of technology in health care, and HIPAA.

Students in Goldberg's seminar examined the notions of patient travel and physical presence being required for diagnosis and treatment and the challenge to such notions by telemedicine and the use of computer technologies. They surveyed health care information and technology from the perspectives of the health care professional, the patient, and the technology entrepreneur. Finally, students considered federal and state laws, including those relevant to the licensure of physicians and other health care providers, pharmaceutical dispensing, reimbursement systems, malpractice claims, and jurisdictional concerns. Goldberg placed particular emphasis on the Administrative Simplification Subtitle of HIPAA, the Gramm-Leach-Bliley Act, and the PATRIOT Act.

Goldberg was impressed with the quality of the students in his class, the sophisticated class discussion, and the papers the students wrote as part of the seminar. He believes that students must be willing and active participants in their health law education and training. There is no "history of health law" to read, and students need to be proactive about finding out the things they don't know. His students were proactive, writing papers on such diverse topics as "The End of the Medical Procedure Patent," and "Internet Pharmacies."

According to Julia Chu, a third year student in the class, "In this cutting edge course which dealt with an area where few laws have been developed, I was able to analyze how technology affects and plays a critical role in the industry and in the delivery of health care."

Julia Chu, 3D
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Genes on Trial: Rothenberg Plays Role in Fred Friendly Seminar

"He is an alcoholic and aggressive to the point of violence. But is he responsible for his behavior if it can be traced to a genetic marker in his DNA?" So reads the lead sentence describing the hypothetical case that Dean Karen Rothenberg and columnist Stanley Crouch acted out as part of the Fred Friendly Seminars—Genes on Trial series.

Rothenberg and Crouch's interaction was based on the implications of genetic research focused on undesirable traits such as alcoholism, drug addiction, and aggressive behavior. The two play members of a family with a history of alcoholism on both sides. Their 21-year-old son, Joseph, has been seen sipping champagne on Christmas morning. Brother-in-law Dean Hamer, a geneticist, wants the family to participate in a study of a genetic susceptibility to alcohol addiction in Tracy Islanders, a fictitious immigrant group to which the family belongs. Somewhat reluctantly, the family participates. As the case evolves, it becomes clear that the hypothetical research program has opened a genetic minefield as the test results could stigmatize everyone in the Tracy Island community.

Charles Ogletree, a former public defender and a professor at Harvard Law School, moderated the seminar. Other participants in the program included prominent attorney Johnnie L. Cochran, Jr.; Francis Collins, Director of the National Human Genome Research Institute; Nadine Strossen, President of the American Civil Liberties Union and a professor at New York Law School; and Dean H. Hamer, Chief of Gene Structure and Regulation in the Laboratory of Biochemistry at the National Cancer Institute.

The panelists struggled with the legal and ethical implications of publicizing the research conducted on Tracy Islanders debating such questions as: When genetic research focuses on a family, ethnic, or minority group, what consequences might such groups experience and what responsibility do scientists have to their research subjects? If Tracy Islanders are seen as genetically at risk for alcoholism, could a Tracy Islander who gets drunk and kills someone in a bar brawl be acquitted on genetic grounds? Does a genetic predisposition override free will?

Rothenberg's expertise in this area comes from her investigation of the implication of genetics research on the Jewish community. In her most recent study, she surveyed members of the Ashkenazi Jewish population (Jews from eastern or central Europe) regarding genetic predispositions to certain diseases and traits and their attitudes about the risks and benefits to the Jewish community of such participation.

Based on 20 years of cooperation between the Fred Friendly Seminars and PBS, the Genes on Trial series was televised by PBS in January 2003. For additional information, including video clips and transcripts, visit: www.pbs.org/fredfriendly/ourgenes/index.html.

Portions of this article have been excerpted from the PBS web site: www.pbs.org/fredfriendly/ourgenes/

The Fred Friendly Seminars' unique format forces participants to put rhetoric aside, as they deal with real life problems that raise a broad spectrum of ethical, legal and public policy issues. The seminars have won major broadcasting awards and have played host to such prominent participants as Supreme Court Justices, former presidents, journalists, scientists and corporate CEOs.

Fred Friendly, for whom the series is named, has a long history in broadcast news. He joined Edward R. Murrow to take on Senator Joseph McCarthy in their weekly program, See It Now. He tackled many controversial issues during his career, including the dangers of tobacco and government secrecy. When Friendly joined the Ford Foundation, he was one of the driving forces behind the creations of public television. In 1974, he used Socratic dialogue in a unique format in the Media and Society Seminars. The Fred Friendly Seminars are an outgrowth of these earlier productions.
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Fall Conferences Spotlight Genetics

During the Fall 2002 semester, the L&HCP sponsored two conferences which focused on genetics. "At the Crossroads—Public Private Priorities Concerning Access to Genetic Information" was held on October 21, 2002. Participants at this interdisciplinary symposium discussed the business, legal, scientific, and social implications of regulating access to genetic data.

Expert speakers such as Francis S. Collins, MD, PhD, Director of the National Human Genome Research Institute, Steven L. Salzberg, PhD, Senior Director of Informatics at The Institute for Genomic Research, and Alan Paau, PhD, Director of the Technology Transfer and Intellectual Property Service at the University of California, San Diego, explored the development of a consensus model for balancing the benefits of free public access to genetic information with those of protecting private investment-backed genetic research.

Speakers on two morning panels discussed the laws governing innovation in genomics and the technology transfer concerns generated by emerging biotechnology applications. In particular, they mentioned that emerging technologies, such as bioinformatics and proteomics, have challenged extant legal paradigms, which seem unable in these instances to strike a satisfactory balance between public access and commercial exclusivity to genomic data.

The afternoon sessions included discussions on the ethical and social implications of exclusivity in genetic knowledge and how companies can survive in the competitive biotechnology marketplace. The first panel explored the consequences of intellectual property protection on collaboration in the scientific community and the merits of a bona fide research use exemption to shield academic endeavors from patent infringement liability. The second panel, which was composed of biotechnology industry leaders, shared their views on the importance of an appropriate balance between commercial exclusivity and open access to facilitate continued growth in biotechnology.

Professor Lawrence Sung, JD, PhD and Associate Dean Diane Hoffmann, JD, MS co-chaired the conference. Papers from the conference will be published in an upcoming issue of The Journal of Health Care Law and Policy this year.

On November 21, 2002, the L&HCP and the Johns Hopkins University Phoebe R. Berman Bioethics Institute co-sponsored, "Beyond Dolly: Human Cloning and Human Dignity," a panel discussion on the report of the President's Council on Bioethics. Cloning—whether for biomedical research or to produce children—is one of the most hotly debated genetics issues of our time. For six months, the President's Council on Bioethics—a team of scientists, physicians, ethicists, lawyers, humanists, and theologians—studied both issues and published the result of their deliberations in July of 2002.

Council members Leon R. Kass, MD, PhD, and Rebecca Dresser, JD, MS, spoke at the event, along with Dr. John Gearhart, MD, a pioneer in stem cell research and the head of the Johns Hopkins Institute for Cell Engineering (ICE) Stem Cell Biology Program.

The panelists discussed the policy recommendations made in the Council's report: 1) that cloning to produce children is not only unsafe, but also morally unacceptable, and ought not to be attempted at this time, and 2) that cloning for biomedical research should be placed under a four-year moratorium with a federal review of current and projected human embryo research practices. The latter recommendation was endorsed by ten members of the Council. A minority of the Council (seven members) did not support a moratorium, but instead recommended regulation of the use of cloned embryos for biomedical research.
L&HCP Student Works on Stem Cell Report

Last summer, Sarah Richardson, a second-year student at the School of Law, worked with Associate Dean and Director of the L&HCP, Diane Hoffmann, on issues surrounding the disposition of unwanted embryos for the Maryland Department of Legislative Services. In this article, Richardson discusses her experience.

I enrolled in the University of Maryland’s School of Law because I wanted to build a new career in health. Before coming to the Law & Health Care Program, I worked as the Senior Development Associate at the national office of Physicians for Social Responsibility (PSR) in Washington, DC. Fundraising constantly tested my skills as an advocate, especially on the printed page. I spent many hours drafting reports to key funders, including the W. Alton Jones, Turner, and the John D. and Catherine T. MacArthur Foundations. My interest in the business of making a program happen, along with a knack for making good policy arguments, told me law school was right for me.

University of Maryland’s School of Law has opened up numerous opportunities for my academic and professional growth. I spent the summer of 2002 working as a Research Assistant to the Director of the L&HCP, Diane Hoffmann. Initially I sought work with Associate Dean Hoffmann on end-of-life issues, given her role in drafting Maryland’s Health Care Decisions Act. But in a curious twist, I was instead invited to explore legal issues surrounding the beginning of life. My research went to one of the most profound issues currently under debate—the ethics of stem cell research.

Despite severe restrictions on federal funding for stem cell research and a renewed effort by the U.S. House of Representatives to ban all cloning, even for biomedical research, the federal government has left the legal landscape on cloning relatively barren. No federal law has endorsed this emerging technology, nor have we seen a comprehensive ban. States have been scrambling to fill this gap. Towards this effort, Maryland delegates John A. Hurson (D-Montgomery) and Samuel I. “Sandy” Rosenberg (D-Baltimore City) commissioned a report by Maryland’s Department of Legislative Services (DLS) to survey the field. In particular, one of the sections in the requested report was to address the legal and ethical issues that arise from the storage and disposition of embryonic stem cells. As part of the expanding collaborative effort between the L&HCP and DLS, Associate Dean Hoffmann was asked to work on the chapter and she recruited me to serve as her research assistant.

I immersed myself in the science and policy of stem cells and cloning. My research took me to several meetings of the President’s Council on Bioethics, including the July press conference where members released their policy recommendations on cloning. I was struck by the candor and thoughtful nature of the Council’s debates.

After working through the initial questions on cloning and stem cell research, I reached the topic of my chapter—embryo disposition. Stem cells come from adult and embryonic cells, making the legal status of these cells and their origin a flash point. In vitro fertilization (IVF) clinics provide one source of embryonic cells; some are donated, some are abandoned. I was asked to explore what becomes of “surplus” embryos that couples create and cryopreserve but never implant. More importantly, my research required me to address such questions as whether or not an embryo is a person, property, or something else? What becomes of a contract signed by a couple undergoing IVF treatment? Can public policy considerations tolerate contracts that would ultimately make an unwilling individual a parent? Can a couple desperate for children truly give consent to cryopreserve their surplus embryos when divorce or death seem remote? I spent the rest of my summer analyzing state and federal court decisions bearing on these questions and tracking down anyone in Maryland’s IVF community willing to share their consent forms and insight into the IVF process.

My efforts culminated in “Chapter Four” of the report and a request from the Department of Legislative Services to have other students work with them on future projects. The experience sharpened my research skills by large measure and built for me a healthy arsenal of cocktail talk surpassing the usual Aldous Huxley “Brave New World” variety.
Last fall, the Maryland Health Care Ethics Committee Network officially became a part of the Law & Health Care Program at the University of Maryland School of Law. The Network, established by Associate Dean Diane Hoffmann, had operated as an unincorporated association with its own Executive Board until September of last year. The change in affiliation came about as a result of financial concerns and a decision by the Board that a closer nexus with the L&HCP and the ability to use the School of Law’s experts and resources would be of significant benefit to the Network and its members.

The Network, a membership organization composed of health care institutions with ethics committees and individuals interested in medical ethics, provides informational and educational resources to ethics committees serving health care institutions in the state of Maryland. According to Hoffmann, “the Network is a good fit for the Law School and the L&HCP as a number of our faculty teach and conduct research on issues related to bioethics.”

Along with Dean Hoffmann, Anita Tarzian, RN, PhD and Emily Nothstein, a University of Maryland law student, help to oversee the Network’s services and provide administrative assistance.

Students Educate Seniors on End of Life Care Issues

Earlier this year, four L&HCP students traveled to the Edgemere Senior Center in East Baltimore to discuss issues of advance directives, wills, trusts, and estate planning with a group of seniors at the Center. Andrea Kirby, Julia Chu, Sarah Richardson, and Emily Nothstein fielded questions about the differences between living wills and durable powers of attorney, the advantages and disadvantages of wills as compared to trusts, and how one prepares an estate plan. The presentation provided the students with an opportunity to explain some complicated legal concepts to a group of seniors and to think on their feet as they responded to a number of questions. After the presentation, the students joined the seniors for a cowboy lunch of hotdogs, beans and applesauce.
ASSOCIATE DEAN
Diane Hoffman
Publications:


Selected Presentations:
"Researchers Under Attack: Legal Liability of Researchers and IRBs," Ethics Rounds, Dana Farber Cancer Institute, Boston, MA (Feb. 10, 2003)


PROFESSOR MICHAEL GREENBERGER
Publications:
"Ethical Issues in Cloning and Stem-cell Research," Chesapeake Nurse Attorneys and L&HCP, University of MD School of Law, Baltimore, MD (March 9, 2003).

PROFESSOR SUSAN LEVITON
Publication:

PROFESSOR TOM PEREZ
Selected Presentations:
Panelist, Institute of Medicine, One year anniversary of the release of the report, "Unequal Treatment: Racial and Ethnic Disparities in Health Care" (March 2003).


DEAN KAREN ROTHEMBERG
Publication:

Selected Presentations:

Appointment:

PROFESSOR LAWRENCE SUNG
Selected Presentations:
Hoffmann Completes Study of State Medical Boards

As part of her ongoing work on the issue of legal and regulatory obstacles to the management of pain, Professor Diane Hoffmann, along with colleague, Anita Tarzian, RN, PhD, recently completed a national study of state medical boards. The study, supported by funds from the Mayday Foundation and awarded by the American Society of Law, Medicine & Ethics, sought to better understand how state medical boards are evaluating and balancing the need for adequate pain treatment with concerns about drug diversion and inappropriate prescribing.

There have been several studies indicating that physicians fear potential disciplinary action for prescribing controlled substances and that, as a result, some physicians have inappropriately prescribed opioids. Prescribing opioids for chronic pain management has been controversial and boards have investigated and, in a few cases, disciplined physicians for such prescribing. Reports of such actions have fueled physician fears of regulatory scrutiny; however, news of cases where physicians have been sued or disciplined for insufficient treatment of pain and recent press and educational efforts about inadequate pain treatment have made physicians more sensitive to this problem. The renewed concern about drug diversion, in light of the abuse associated with Oxycontin, has led to much confusion and uncertainty among physicians about the appropriate course of action when dealing with patients with chronic pain.

State medical boards play a key role in this area as they have the authority to discipline physicians for both undertreatment and overtreatment (unnecessary or inappropriate prescribing of medication) for pain. Board member attitudes about pain management and knowledge of appropriate pain treatment are relevant to their actions on this issue. Prior surveys of state medical boards by the University of Wisconsin Pain & Policy Studies Group in 1991 and 1997 found that while board member knowledge and attitudes on this issue had improved during the time frame under study, in both years members overestimated the incidence of addiction to pain medications and were more skeptical about prescribing opioids for noncancer than for cancer pain.

In their survey, Hoffmann and Tarzian sought information regarding trends in the number and nature of complaints received by boards for inappropriate prescribing of opioids (both overprescribing and underprescribing), how boards evaluate such complaints, and under what circumstances boards would discipline physicians falling into one of those categories. Of the fifty states and the District of Columbia, thirty-eight state medical boards (75%) responded to the study questionnaire. While many of the results were qualitative rather than quantitative, significant findings included the following:

- regarding decisions to investigate physicians for overprescribing, many boards are now attempting to find the appropriate balance between identifying physicians who overprescribe and those who are appropriately treating patients with chronic pain;
- boards with state pain policies that address the treatment of chronic, nonmalignant pain appear to be more proactive — providing more pain-management related education to physicians than boards that do not have such policies;
- boards appear to be moving away from volume or quantity of opioids as a primary basis for investigating a physician for overprescribing opioids;
- boards are generally more likely to discipline for overprescribing than underprescribing for pain and seem to
As part of its regular curriculum, the School of Law offers a nationally recognized clinical law program in which faculty members who are practicing attorneys supervise law students in the representation of actual clients. For those students with an interest in health law, the clinic represents clients in cases involving, among other things, health care for children, legal issues of the disabled, mental illness, AIDS, and the elderly. Clinics in which health law clients are served include Civil Rights of Persons with Disabilities; Drug Policy and Public Health Strategy; Health Care Delivery and Child Welfare: The Challenge of the AIDS Epidemic; Tobacco Control; Civil Rights: Access to Health Care; and Children’s Issues and Legislative Advocacy. This issue of the L&HCP Newsletter focuses on a new Legal Theory and Practice Course (LTP) that is part of the clinic curriculum.

In this new LTP/Clinic course developed by Professor Deborah Weimer—Legal Issues in Health Care Delivery and Child Welfare—student attorneys have had a variety of opportunities to engage in problem solving with medical and social work professionals addressing cutting-edge issues in health care delivery and child welfare. These students have assisted the Adolescent HIV Clinic at the University of Maryland to address barriers to treatment and research with HIV positive teenagers and those at risk for HIV. They also participated in the Healthy Grandparents Project, a collaboration between the University of Maryland Schools of Law, Social Work and Nursing, to address the legal needs of families in crisis because of the death or illness of a parent. Through these projects, they experienced the benefits as well as the challenges of working as a part of an interdisciplinary team.

Working on medication adherence issues with HIV-positive adolescents is an even greater challenge than trying to assist families with young children deal with these issues. Adolescents are typically struggling to be independent, resistant to adult demands and engaging in a variety of experimental behaviors. They want to be like their peers and avoid anything that will make them feel appear different—e.g., being HIV-positive and having to take medication two or three times a day. To add to the complexity, the majority of HIV-positive adolescents are being raised by someone other than a parent. Forty percent are in foster care, and the balance are in the care of relatives.

The STAR Medical Clinic for Adolescents at the University of Maryland is working with two other premier research institutions, Children’s National Research Institute in Washington, DC and NYU School of Medicine, to identify what interventions with HIV-positive adolescents may bring positive results in medication adherence and preventing the spread of HIV among this age group. They sought the law school Clinic’s assistance in developing a protocol that would comply with state law and federal regulations and which would facilitate the potential enrollment of 60% of their patient population that might otherwise be ineligible for this study.

Among the questions Weimer and the students addressed were: Is parental consent essential for enrollment of adolescents in a research study involving only behavioral interventions? What if the adolescent is living with a relative who does not have legal custody? What if the adolescent is living with a parent but is unwilling to inform the parent of his HIV status? Can an alternative mechanism be used to safeguard the adolescent’s best interest in these circumstances? What would the alternative mechanism look like?

This new course arose in part out of work Professor Weimer was engaged in with students in the AIDS Litigation and Counseling Clinic, which she has directed for twelve years. One of the recent recurring issues has been the reporting of parents of HIV positive children for alleged medical neglect when they fail to adhere to the medication regimen for their children. Professor Weimer’s article on this subject, “Medical Treatment of Children with HIV Illness and the Need for Supportive Intervention: The Challenges for Medical Providers, Families and the State,” appeared in the Winter 2003 issue of the Juvenile and Family Court Journal published by the National Council of Juvenile and Family Court Judges. The article suggests that many families need additional support to meet the challenges of the highly active antiretroviral therapy (HAART) medication regimen, which is especially challenging. If the patient is not 95% compliant with taking three types of medication two or three times a day, she is likely to become resistant to a whole class of medications, seriously compromising future treatment options. Trust and communication issues between patients and providers are sometimes a barrier to effective treatment. The article proposes earlier preventative intervention to avoid harm to the child and unnecessary involvement by the juvenile court.
Student attorneys played a key role in addressing barriers to research and improved treatment for HIV positive adolescents. Working with the medical staff of the STAR Clinic, they were able to create an alternative consent mechanism to protect the interests of the adolescents, while facilitating the enrollment of those who wished to enroll.

Student attorneys also participated in an interdisciplinary conference focused on the medical and psychosocial needs of adolescents living with HIV. Two students addressed the conference participants regarding legal mandates of patient/provider confidentiality and partner notification and counseling of individuals who have tested positive for HIV. They were also asked to address potential criminal prosecution faced by sexually active HIV-positive adolescents, because of the recent experience of clinic patients.

In the Healthy Grandparent Project, students have been working as part of an interdisciplinary team trying to help stabilize and support grandparent families. These families typically have many unmet legal needs, many of which affect the welfare of the children. The students work with them and the interdisciplinary team to ascertain what legal assistance will be most effective in supporting the family. This may include appealing a denial of public benefits or assisting a grandparent in pursuing legal custody of her grandchildren so she can enroll them in school, obtain medical insurance, etc.

This project is currently providing services to 20 families. It also includes a research arm that will examine the impact of these interventions at set intervals. The goal is to identify what works and then replicate this project on a larger scale. In two current cases, student attorneys filed motions to intervene in CINA proceedings in Circuit Court on behalf of the grandparents who are the only stable presence in their grandchildren’s lives. The student attorneys have enabled the grandparents to have a voice in custody decisions being made by the Court.

### Professor Tom Pérez Elected to Montgomery County Council

Health Law Professor and civil rights advocate Tom Pérez was elected in November 2002 to serve as a member of the Montgomery County Council. Pérez, a Democrat, will represent the Council district which encompasses parts of Takoma Park, Silver Spring and Wheaton, Maryland.

Professor Pérez joined the Law School faculty in 2001. He works closely with the Law & Health Care Program on issues related to racial disparities in health care. Though his position on the Montgomery County Council will be the first elected office that Pérez will assume, Pérez is hardly a newcomer to government and politics. Pérez served as the Director of the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services from February 1999 until the conclusion of the Clinton administration. As the head of OCR, Pérez oversaw enforcement of antidiscrimination laws in the health and human services sector. From 1995 to 1998, Pérez was special counsel to Senator Edward M. Kennedy, serving as the principal adviser on civil rights.

Representing District Five on the Montgomery County Council, Pérez has placed addressing the mental health crisis in the County, enhancing access to services for people with limited English proficiency, and expanding participation in the State Children’s Health Program (MCHIP) at the top of his list of legislative priorities. In addition, Pérez hopes to improve affordable housing options in the affluent county and increase funding for schools.

During the 2003-2004 academic year, Pérez will co-teach the Civil Rights Clinic: Access to Health Care for Vulnerable Populations, which focuses on the tools—civil rights and otherwise—that an advocate can use to enhance access to health care for vulnerable populations. These tools include litigation, legislative advocacy, community organizing and other grassroots approaches, and administrative advocacy.

Steve Hitov, an attorney with the National Health Law Program (“NHeLP”) in Washington, DC, will co-teach the course with Pérez. NHeLP is a national public interest law firm that seeks to improve health care for America’s working and unemployed poor, minorities, the elderly, and people with disabilities. NHeLP serves legal services programs, community-based organizations, the private bar, providers, and individuals who work to preserve a health care safety net for the millions of uninsured or underinsured low-income people.
Spotlight on . . .

HEALTH LAW PRACTICUMS AND
EXTERNSHIPS: Johns Hopkins Health System

Since the early 1990s, the Johns Hopkins Health System ("JHHS" or the "System") Office of the General Counsel has hosted L&HCP students in practicum placements. JHHS has been recognized as a leader in patient care, medical research, and teaching for over a century. The System is made up of several acute-care hospitals (including the world-renowned Johns Hopkins Hospital) and, in conjunction with the Johns Hopkins School of Medicine, is a partner in the Johns Hopkins Home Care Group, Employer Health Programs, Priority Partners (an HMO for Maryland medical assistance patients), and Johns Hopkins Health care (an entity which manages contractual relationships between managed care organizations, employers, and health care providers). The Office of the General Counsel employs ten attorneys who provide legal advice and counsel to these prestigious health care entities.

Practicum students usually work under the supervision of Meg Garrett, Senior Counsel to JHHS, on projects covering diverse health law topics ranging from biomedical ethics to physician licensure to HIPAA, patient records, and more. These students gain invaluable experience as they work alongside top-notch attorneys to address emerging health law issues for one of the nation's most well-respected medical institutions.

A half-dozen current L&HCP students, as well as numerous graduates of the School of Law, have completed the experiential component of their Health Law Certificate at JHHS. All have been extraordinarily complimentary of the quality of both the work and the supervision they received.

Meg Garrett has been with JHHS since 1984 and is an integral part of the System's legal team. She does her best to make each student feel equally a part of the team by permitting them access to high level meetings, policy development sessions, and legislative advocacy activities. Inclusion in the Risk Management Committee meetings was one of the highlights of third-year day student Deborah Garibay's placement at JHHS. As a nurse, Garibay was able to understand the issues discussed and participate fully in the meetings along with Garrett (who is also a nurse).

In addition to being privy to the inner workings of the System's various committees, L&HCP students are assigned complex projects that hone their research and writing skills — and the pace at JHHS keeps them on their toes. According to Jessica Wills, who will graduate this spring, at the beginning of her placement, research projects could be "difficult and intimidating" but, with the active support of Garrett and the other JHHS attorneys, she developed new approaches to handling the tough assignments and now possesses skills which she believes will benefit her in her imminent legal career. As for the fast pace, Wills notes that the time constraints and variety of assigned work opened her eyes to what life is like in the in-house counsel's office of a large health care system. Despite the sometimes demanding schedule, Wills was very pleased with her overall experience and sees the positive impact a legal department can have on the hospital's operations.

Currently, two students are completing practicums at JHHS under Garrett's supervision: Rina Erhart, a part-time fourth-year day student, and Hayley Butera a second-year day student. Erhart is thrilled with the experience she has gained so far. She describes Garrett as a knowledgeable mentor who artfully handles the complicated, fast-paced work that the Office of the General Counsel must tackle. Erhart is confident that her experience at JHHS will give her an edge when she graduates and begins her job search. Butera, who would consider a career in the in-house setting, is also pleased with her choice of placements. According to Butera, "it is fascinating to be in the hospital setting and see firsthand what goes on behind the scenes. Meg Garrett is welcoming, insightful, and genuinely interested in hearing my point of view on different topics." Butera

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The Student Health Law Organization (SHLO) began the 2002-2003 academic year with a flurry of activities. The SHLO Executive Board's first task was to provide first-year students with information about SHLO at the Student Organization Fair held annually during orientation week. During the event, SHLO members were excited to meet many first-year students with strong backgrounds in various health-related fields. These first-year students have since become valuable participants in all of SHLO's activities.

In September 2002, SHLO and the L&HCP invited four health law practitioners to participate in the second annual "What is Health Law?" panel discussion. Margaret Ann Nolan, JD (Deputy Principal Counsel with the Office of the Maryland Attorney General, Department of Health and Mental Hygiene), Pegeen Townsend, JD (Senior Vice President and Counsel with the Maryland Hospital Association), Frank Palumbo, PhD, JD (Director of the Center on Drugs and Public Policy at the University of Maryland School of Pharmacy), and Sanford Teplitzky, JD (Chair of the Health Law Department of Ober, Kaler, Grimes & Shriver) spoke to the students. These seasoned attorneys provided insight into the substantive work of health care attorneys in diverse practice settings such as academic institutions, advocacy groups, state government and law firms. The panelists' lively discussion also included information about available work in health care law that was particularly helpful for first-year students, most of whom were just beginning to think about a practice specialization.

In October, SHLO and the L&HCP asked Alan Goldberg, JD, with Goulston & Storrs in Washington, DC, and Adjunct Professor of Law at the School of Law (see article p. 7), to address students at the first of the "Brown Bag Lunch Speaker Series." This lunchtime speaker series is held to allow students to learn about discrete, contemporary health care law issues in an informal atmosphere. Goldberg talked to students about the Health Insurance Portability and Accountability Act (HIPAA). In November, Dr. Allyn Taylor, JD, LLM, JSD, Legal Adviser to the World Health Organization and Adjunct Professor of Law, engaged students in an animated discussion about International Public Health Law. The series continued in the spring semester when Richard Kidwell, JD, Director of Claims and Risk management, Johns Hopkins Health Systems, was the featured speaker. Kidwell discussed Johns Hopkins' groundbreaking work in mandatory (but not binding) malpractice claims mediation. The series concluded with John Lessner, JD, currently a shareholder at Ober, Kaler, Grimes & Shriver, who compared the practice of health law from both sides of the table. Lessner was formerly an Assistant Attorney General who counseled the health facility licensure and certification agency in Maryland.

As part of its ongoing affiliation with the American Health Lawyers Association (AHLA), SHLO student volunteers assisted AHLA at its "Fraud and Compliance Forum," held in Washington DC, September 29 - October 1, 2002. Students had the opportunity to attend many of the educational sessions and networking events at this annual conference sponsored by the Health Care Compliance Association. Maryland Law students again had the opportunity to assist the AHLA and enrich their bank of health law knowledge when they volunteered in a similar capacity at the "Institute on Medicare and Medicaid Payment Issues," in Baltimore in April 2003. This conference, the largest of AHLA's educational programs, attracted nearly 1000 health law attorneys to its more than 75 educational sessions, and SHLO members were given complete program access.

In October 2002, SHLO was privileged to host a meeting of the Health Law Section of the Maryland State Bar Association. Students and attorneys mingled during dinner and were then treated to an informative presentation by Constance Baker, JD, a partner at Venable, Baetjer, Howard and Civiletti, LLP. Baker offered a comprehensive vision of the impact of the latest updates to the regulations implementing the Emergency Medical Treatment and Labor Act (EMTALA).

During the spring semester, SHLO (with help from the L&HCP) focused on providing students with health law job search strategies. In January, a panel comprised of third-year law students discussed summer work experiences in health care law. Jason Caron and Valerie Webb, third-year day students with job experience in both the public and private sectors, offered valuable information to first-year students preparing to commence their summer job searches. In February, SHLO sponsored a "Movie Night and Resume Review." Students brought their resumes for individualized review and advice while "My Cousin Vinny."
apply a higher threshold of harm for undertreating pain (require greater evidence of patient harm) than for over-prescribing for pain.

An article based on the survey results was recently published in the *Journal of Law, Medicine & Ethics*. In addition, Hoffmann and Tarzian, along with other Mayday Scholars, presented their findings at a press briefing at the National Press Club in Washington, DC, on April 29th.

**Student Health Law Organization**
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played on the big screen television in one of the law school classrooms. Lisa Ohrin, Coordinator of the L&HCP and Teresa Schmeideler with the School of Law's Career Development Office generously donated their time to help students improve their resumes.

On March 19, 2003, SHLO hosted a "Health Law Networking Reception." Health law practitioners from Baltimore and Washington, DC, were invited to speak informally with students about the recent changes in health law, their opinions on course selection, law school activities relevant to health law, and their thoughts about securing a satisfying health law job for the summer and/or upon graduation. Both the attorneys and students benefitted from the opportunity to interact and discuss matters of mutual interest.

SHLO is proud of the wealth of opportunities that it has been able to provide students, with the help of the Law & Health Care Program, during the 2002-2003 year. Each of these events truly furthered SHLO's mission to increase student interest in health care law.

**Spotlight on Practicums**
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would recommend this placement to anyone interested in Hospital or Health Care Law.

The success of the L&HCP's practicum and externship program depends heavily on its field supervisors. Garrett takes her responsibility as a supervisor and mentor seriously. She takes the time to get to know students on a personal, as well as professional, level so that she can make their experience at JHHS more meaningful. In addition, she carefully chooses assignments that match students' skill levels and progression through law school and that will afford them opportunities to work in areas they have not attempted thus far in their careers. The L&HCP looks forward to a continued relationship with JHHS that is as mutually beneficial as the past decade has proved to be.

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