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From the Director

In this issue of the Law & Health Care Program Newsletter, we take the opportunity to share with our readers the diversity of health law—a diversity that extends to teaching, research, and practice. The newsletter includes articles on the state of the guardianship system in Maryland, prenatal testing and genetic technology, health care reform, mandatory testing of HIV-positive pregnant women, and the FDA's Orphan Drug Act. We hope you enjoy the newsletter, and as always, we welcome your comments and suggestions.

Have a happy holiday season.
Karen Rothenberg, JD, MPA

Guardianship Problems and Solutions Debated

An elderly man has been moved by his son from the place he has lived most of his life to an out of state nursing home. Separated from his relatives, he is disoriented and confused. He only partially understands that his son is trying to obtain guardianship—and while he realizes that he needs help managing his affairs, he is adamant that that help not come from his son. An attorney investigating this case on behalf of the father uncovered a long-standing pattern of monetary abuse by the son, and fortunately, the son was denied guardianship.

This case raised some of the many issues discussed at “Guardianship in Crisis: Discussion of the Problem and Proposed Solutions,” held on November 16, 1994 at the University of Maryland School of Law. About one hundred and fifty people attended the conference, which was co-sponsored by the Law & Health Care Program, the Geriatrics and Gerontology Education and Research Program and the Maryland Office on Aging.

The guardianship system in Maryland is, in fact, growing rapidly. As the population ages, more problems arise over the care of disabled adults. Dilemmas such as consent to medical care, patient discharge from hospitals and the lack of affordable home nursing care are being addressed in guardianship hearings. The sheer number of cases threatens to overwhelm the system. Social service agencies appointed as public guardians are inundated, making meaningful oversight difficult. Judges often issue all-encompassing orders that needlessly deprive disabled persons of civil rights—orders which are difficult to modify, revoke or terminate even after the disabled person dies.

In late 1993 the Maryland Office on Aging organized a task force to investigate these problems. It quickly became apparent that there was little data
L&HCP Student Wins Food and Drug Law Writing Competition

Third year evening student David Clissold walked away with the top prize—$3,000—and all of the prestige associated with winning the Food and Drug Law Institute’s 1994-95 H. Thomas Austern Writing Competition. Clissold’s paper, “Prescription for the Orphan Drug Act: The Impact of the FDA’s 1992 Regulations and the Latest Congressional Proposals for Reform” was submitted at the urging of L&HCP adjunct professors Lars Noah and Ellen Flannery. Clissold was a student in their Food and Drug Law Seminar.

Prior to entering law school, Clissold obtained a B.S. in Psychobiology from U.C.L.A. and a Masters in Psychology from Indiana University. He came to Baltimore to work for Nova Pharmaceuticals in the field of pre-clinical drug testing. When Nova was acquired by another corporation, Clissold went to work for the Johns Hopkins School of Medicine doing (in his words) “clinical trials of drugs no one has ever heard of which are used for diseases few people have.” Hence his interest in “orphan drugs.”

Orphan Drugs are those which are intended for a patient population of under 200,000 and which are unprofitable for drug companies to produce. The F.D.A. approval and clinical trials process for these drugs are far different (less stringent) than those for more widely used drugs.

Fueled Clissold’s interest in this issue was the recent failure of legislation introduced to govern orphan drugs. While tracking the legislation, he became involved with the National Organization for Rare Diseases (NORD) an umbrella organization which represents people taking orphan drugs. All of these occurrences combined to lead Clissold to write his award winning paper.

Clissold entered law school because he became interested in intellectual property and technology licensing issues while working at Nova, and he hopes to work in the field of biotechnology/ intellectual property law after graduation. He is “very interested in the process of getting an idea from the hospital or lab into the marketplace.”

Clissold encourages all L&HCP students to enter the Austern Writing Competition, which offers three awards—$3,000, $2,000 and $1,000.

Women & Prenatal Testing

Reproductive and genetic technologies have a tremendous impact on women’s lives. This book is an important and thought-provoking discussion of the issues, from the legal to the personal, that must be considered by scholars, policymakers and individual women,” states Congresswoman Patricia Schroeder about the recently published “Women and Prenatal Testing: Facing the Challenges of Genetic Technology.” This book contains a series of articles co-edited by Professor Karen Rothenberg that focus on the major women’s issues surrounding the development and application of reproductive genetic testing.

Although much has been written about the biological safety and efficacy of these technologies, “Women and Prenatal Testing” addresses the psychological, sociocultural, ethical, legal and political impact on women and their pregnancy experience.

Women’s health has been one of Rothenberg’s primary research interests. During the fall of 1991, she organized an NIH interdisciplinary workshop to provide a forum for dialogue among the providers of genetic services, social scientists, ethicists, and lawyers on how best to address the issues and challenges created by the expansion of reproductive genetic testing. This book represents the latest in a series of publications on the issues first raised at the NIH workshop.
A Professor on Capitol Hill

On June 15, 1994, Professor Diane Hoffmann left her comfortable and relatively secure position in the Law & Health Care Program to spend a year in the turmoil of Capitol Hill, where by comparison nothing seems secure. Hoffmann left to become a Senior Fellow at the Senate Subcommittee on Aging—a Subcommittee of Senator Kennedy's Labor and Human Resources Committee, chaired by Senator Barbara Mikulski (D-MD). She arrived on Capitol Hill in the midst of the heated debate on health care reform. The Labor and Human Resources Committee had just become the first Congressional committee to pass a major health care reform proposal and the Subcommittee staff was anxiously awaiting action on the part of Senator Moynihan's Finance Committee.

Much of Hoffmann's work during June and July involved meetings with constituents and monitoring those parts of the health care reform proposals of most concern to Senator Mikulski. These included aging issues such as home and community based care and prescription drug coverage under Medicare, and women's issues such as what types of services would be included in a standard benefit package. Most controversial of the issues was whether abortion would be covered. Because of her legal background, Hoffmann also became responsible for tracking and reviewing the malpractice antitrust and due process provisions of the proposals.

By the end of July, health care reform was near the boiling point. The Finance committee had passed its own version of a health care reform bill and the Subcommittee staff became involved in attempting to influence the "compromise" proposal being prepared by Senator Mitchell and his staff. They were successful in having some favorable provisions on home and community-based care and women's health incorporated into the Senate bill, but their success was short-lived when it became clear that Senator Mitchell's bill was unlikely to move forward.

During August, Hoffmann and her colleagues attempted to follow the development of the "Mainstream" coalition proposal that was being developed as a "bipartisan" alternative to Senator Mitchell's bill. The unfolding events were like a high speed roller coaster ride. One day Hoffmann and her colleagues were optimistic that a compromise could be reached. The next day they felt that even if a compromise was reached, it would not achieve the goals of the Subcommittee for real reform.

The final demise of comprehensive health care reform was a disappointment to Hoffmann who had hoped to witness the passage of a historical piece of legislation during her year on the Hill. But this was not to be.

In September, Hoffmann began to work on tasks related to the White House Conference on Aging and the reauthorization of the Older Americans Act. In the midst of this focus shift, Hoffmann also became the acting staff director of the subcommittee while the staff director was on maternity leave. As acting staff director, Hoffmann began the effort to reevaluate the Older Americans Act, the federal law which establishes numerous services for senior citizens including meals on wheels, senior centers, congregate meal sites, transportation services and legal services. Hoffmann diligently went about meeting with constituency groups and aging advocates to get their input on the Act when her work was disrupted by the November 8th elections.

While Hoffmann went to Capitol Hill to learn more about health care reform and aging policy issues, she is also learning about the complex and sometimes baffling workings of government and Congress. Her role on health and aging policy issues will diminish as staff to a minority subcommittee, but the change may offer her an opportunity to see things from a different perspective—that of the underdog. According to Hoffmann, "As the minority, the Democrats will be playing in a whole new ball game and may have to rethink some of the approaches they have taken to policy making over the last decade. Without a doubt, it will be a time of significant change for the Democrats."

Hoffmann will continue her work on Capitol Hill through the middle of May, 1995.
Is Mandatory Testing of HIV-Positive Pregnant Women Legal?

On November 2, 1994, third-year students Lena Robins and Russell McClain and second-year students Jeannette Bisson and Andrea Imredy argued the constitutionality of a hypothetical Maryland statute mandating HIV testing and AZT counseling for all pregnant women seeking prenatal care. The argument was part of a moot court competition honoring the inauguration of new UMAB President, Dr. David J. Ramsay.

One of the newest and most promising developments in recent AIDS research is the possibility of reducing HIV transmission from mother to fetus during pregnancy. The results of a large NIH-funded study of perinatal transmission, released in April of this year, indicate that the transmission rate in HIV-infected women taking the AIDS treatment drug zidovudine (AZT) during pregnancy and birth was reduced from 25 percent to 8 percent, a two-thirds reduction. Although many questions about AZT treatment of pregnant women remain unanswered by the study, including the long-term effects on the infant and the effectiveness of treatment for women with full-blown AIDS, the results have raised a number of difficult issues for public health policymakers and healthcare providers. One of them is the question whether states should mandate HIV testing of all pregnant women. The current state of the law is that HIV testing and treatment require an individual’s informed consent, but several states have already introduced legislation requiring forced testing for pregnant women. No such legislation has passed so far, but observers of state legislation predict that many other states will take up the issue during the next legislative session.

In light of the controversy engendered by these attempts at mandated HIV testing, the topic seemed to be perfectly suited to a moot court argument. Law & Health Care Program Director, Professor Karen Rothenberg devised the program, and the panel of Maryland appellate and circuit court judges was headed by Court of Appeals Judge Lawrence F. Rodowsky, who was joined by Baltimore City Circuit judges Ellen M. Heller and Andre M. Davis.

The justices took a very active stance with regard to the constitutional questions raised by the students in their briefs. Is the forced taking of a blood sample and the subsequent laboratory analysis a reasonable search and seizure under the Fourth Amendment? Does such a law violate equal protection guarantees under the Fourteenth Amendment’s Equal Protection Clause and the Maryland Equal Rights Amendment? Lastly, do forced testing and counseling impermissibly impinge upon fundamental rights of privacy and liberty protected by the Fourteenth Amendment’s Due Process Clause? These were the primary issues debated; others, such as the statutory waiver of the informed consent requirement, possible violations of the Americans with Disabilities Act, problems with confidentiality of information, difficulties with statutory enforcement, and the possible negative effect on utilization of prenatal care by women already having difficulties obtaining healthcare, though clearly essential to a full consideration of the issue, could only be touched upon in the time permitted.

Attended by a large contingent of School of Law faculty, students, and staff, as well as representatives from other UMAB schools and the University Hospital, the half-hour argument was followed by a lively question-and-answer period while awaiting the judges’ decision. Perhaps foreshadowing the outcome of an actual challenge to a real statute in the not-too-distant future, the panel upheld the hypothetical statute by a two to one margin.

L&HCP Faculty Notes

Since our last newsletter L&HCP faculty have engaged in the following selected activities:

Professor Karen Rothenberg
Publications:
• “The Good Mother: The Limits of Reproductive Accountability and Genetic Choice,” (with A. Charo).

Presentations:
• “Pregnancy and Clinical Trials: Legal Issues,” Conference on FDA Regulated Products and Pregnan
Women, Crystal City, VA.
• “Partner Notification, Domestic Violence and Women with AIDS,” American Public Health Association Annual Meeting, Washington, D.C.

Assistant Professor Diane Hoffmann
Publications:

Women: Policy Implications,” University of Chicago, Chicago, ILL.
• “Women's Health Issues,” Women Legislators of Maryland: Annual Retreat, Annapolis, MD.

Appointments:
• Interim Editor-in-Chief, Journal of Law, Medicine & Ethics.
• Forum Participant, "Meeting the Challenge: Health, Safety and Food for America," White House Office of Science and Technology Policy, Washington, D.C.

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IN THE HEALTH LAW CLINIC

by Joan O'Sullivan, JD

The law school offers, as part of its regular curriculum, a clinical law program in which faculty members who are practicing attorneys supervise law students in the representation of actual clients. For those students with a general interest in health law, the clinic represents clients in cases involving health care for children, legal issues of the handicapped, mental illness and AIDS.

The clinical law component of the L&HCP has been awarded a three year grant by the U.S. Department of Education to conduct a guardianship clinic. The aim of the clinic is to prevent unnecessary guardianships and to work with the guardianship system to make it more effective.

Students study the law of guardianship and the legal needs of those who, because of age, illness, poverty, or inadequate medical or social support systems or are at risk to be, subjects of guardianship proceedings. They provide direct representation to clients, learn how the guardianship system works, investigate ways to improve it, and seek alternative ways to solve problems which are now addressed by filing a guardianship petition.

Guardianship cases present thorny legal and social issues to law students and to practicing attorneys alike. One of the most troublesome is the question of how to represent a client who is questionably competent.

The clinic teaches a client-centered approach to lawyering. Students learn to focus on the client's goals and motivations in conducting a case and to take direction from the client in all aspects of the representation. This approach becomes difficult, however, when the client is disabled to some degree and may be able to give only limited direction and information.

The law recognizes that there are varying degrees of competency, but determining whether or not a client is competent enough is difficult. This can be especially tricky with someone in the early stages of Alzheimer's Disease, when competency waxes and wanes. A client may have "good days and bad days," or good times of the day and bad times of the day, a phenomenon known as "sundowning." How can a representative act without clear directions from the one she represents?

The rules of ethics give lawyers some direction. One rules says that if a client has impaired decision making ability, the lawyer shall, as far as possible, maintain a normal client-lawyer relationship with the person. This means that the student lawyer must take special care in communicating with the client and must explain in simple terms the choices to be made. Clinic students seek to interview their client in a quiet, non-threatening setting, at the best time of day for the client. If the client is confused or not responsive, students investigate the reasons for that, attempting to rule out causes such as the "four D's": drugs (heavy medication or combinations of medications can cause confusion and lethargy in the elderly), diet (malnutrition may result in pernicious anemia in which treatable dementia may be present), depression (a common occurrence in the elderly which too often goes untreated), or...
National Health Lawyers Association Co-Sponsors Career Panel

On November 21, 1994, the National Health Lawyers Association (NHLA) joined with the Law & Health Care Program and its Student Health Law Organization (SHLO) to present a panel discussion, “Practicing Health Law: A ‘Real World’ Perspective.” Brent Henry, President of the National Health Lawyers Association and VP and General Counsel of the Medlantic Healthcare Group, Elizabeth Kameen, Assistant Attorney General for the State of Maryland and Leonard Homer of the Baltimore law firm, Ober, Kaler, Grimes and Shriver served on the panel. Local members of NHLA and the Health Law Section of the Maryland Bar were invited to attend together with SHLO members. Approximately fifty people attended the event.

Law & Health Care Program Director Karen Rothenberg commented, “The students learned a great deal about how diverse health law practice can be and the attorneys who attended took this opportunity to exchange information, as well. We hope to make such career panels an integral part of our Program.” The panel discussion also marked the beginning of the Health Law Mentoring Program. In cooperation with NHLA’s Career Counseling Program, the Mentoring Program will pair students and health law attorneys, allowing students an even greater access to the ‘real world’ of health law practice.

SHLO News

On September 21, 1994, SHLO held its first organizational meeting of the semester. The structure of the organization has been changed to allow for a more effective team effort, and the general membership of the organization is one of the most diverse in SHLO’s history. Current members include a medical corps member, an RN, an epidemiologist, an HMO employee, a sports medical specialist and others comprising a vast amount of experience in the health care field.

This semester SHLO events included participation in an Alzheimer’s Association Walk and bake sale; a “Meet the Professors” meeting, enabling new students to meet the school’s health law faculty; and the health law attorney career panel described above. The group will meet again in 1994 to discuss plans for next semester which tentatively include a repeat of “Control Your Own Destiny Day,” a day during which health law students encourage and assist the law school community in the preparation of living wills, durable powers of attorney for health care and distribute sign-up cards for the organ donation program; inviting a state legislator to visit the campus to discuss health care issues; a panel discussion on bioethical issues; and inviting Professor Diane Hoffmann, currently serving as a Senior Fellow in Senator Barbara Mikulski’s Office, to speak to the group on health care reform.
Spotlight on . . .

ASPER FELLOWSHIPS AND EXTERNSHIPS: A "Hands-on" Experience at the Medlantic Healthcare Group

Second year law student Barbara Fuller spent part of the summer of 1994 practicing as an Asper intern at The Medlantic Healthcare Group, a major health care organization that includes Washington Hospital Center, National Rehabilitation Hospital, the Cancer Institute, Medlantic Medical Research Institute and several other health care facilities in the Washington, D.C. area.

Fuller worked in the general counsel’s office under the direction of Brent Henry, Vice President and General Counsel for Medlantic, and was supervised by Risk Management Manager, Trueman Haskell, and Staff Attorney, Greg Murad. She found the Medlantic Asper a unique learning experience, “Working in this environment as an intern rather than an employee afforded me varied learning opportunities and allowed me the flexibility of seeking out different experiences within the Legal Affairs Office of Medlantic. It also allowed Medlantic’s staff members the flexibility of involving me in new and interesting issues as they occurred.”

Fuller’s duties were extremely varied and included responding to a complaint from a deaf patient, researching an employee discrimination charge, revising Medlantic’s authorization for release of information form, and attending negotiations for a labor contract. The intern also attended a mediation conference for a medical malpractice case and was present during the private discussions between the mediator and the defense counsel—an invaluable learning experience. Fuller credits the variety of her assignments to the fact that she often initiated contacts during the course of her placement, as she felt she wanted to get as much from the Asper experience as possible during her time with Medlantic.

Commenting on the L&HCP Asper Program in general, Fuller says that the diversity of placements is a definite advantage to students, “The L&HCP’s Asper placements provide real world work experience for us, and the

In The Health Law Clinic
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disorientation (this can be a temporary condition brought on by a change in location, illness or a severe loss, such as the death of a spouse.)

The student attorney, as well as attorneys who represent children, the elderly and the disabled, must make an assessment of the client’s decision making ability to determine the direction the case should take. To do that, she will ask, does the client have reasons for his decision? Are the client’s decisions consistent over time? Does the client understand the consequences of such decisions? Are the decisions, though unwise in the lawyer’s opinion, reasoned and realistic? If the answer to these questions is yes, the student lawyer must follow the wishes of the client and advocate for them, treating that client just as any other.

The Law and Health Care Program’s clinic is the perfect place for students to consider ethical dilemmas raised by the unquestionably competent client. In this setting, they are able to explore issues at length, discuss the law and facts with each other and their supervising attorney, and resolve the kinds of ethical questions likely to arise in a health law practice. Their experience in the clinic should help to prepare them to make appropriate choices later, when they are in practice, and when time is of the essence.

The Law & Health Care Program’s ASPER Fellowship Program (named after Louis D. Asper, a Maryland Law School professor who advocated practical training for students) provides an opportunity for students interested in health law to obtain credit by working for non-profit and government agencies dealing with health care issues. Students spend 10 to 20 hours at their placement and additional hours throughout the semester in the classroom participating in a health law workshop.

Placements have included the American Nurses Association; FDA; Johns Hopkins Hospital, Office of the General Counsel; Med-Chi of Maryland; Medlantic Healthcare Group; National Health Law Program; NIH; U.S. Senate Special Committee on Aging; University of Maryland Medical System, Office of the General Counsel; and the Office of the Attorney General, General Litigation Unit and Medicaid Fraud Unit.

The Program has also offered three full semester externships—The National Health Law Program externship in Washington, D.C.; The University of Maryland externship, located in University Hospital’s General Counsel’s office; and Blue Cross/Blue Shield of Maryland (BCBSM), the state’s largest health insurer.

L&HCP has developed a comprehensive range of opportunities. Also, serving as an intern at Medlantic confirmed that work in a general counsel’s office is one career goal I will pursue after I receive my JD.”
Faculty Notes  
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Presentations:
• “Guardianship and Limited Orders: Actual Practice vs. Statutory Requirements” (with Visiting Assistant Professor Joan O’Sullivan and others), Joint Conference on Law and Aging, Washington, D.C.
• “New Issues for Ethics Committees,” AAHSA Annual Meeting, Orlando, Florida.
• “Statistical Analysis of Guardianship Files in Four Counties,” (with Joan O’Sullivan), Guardianship in Crisis Conference, Baltimore, MD.

Appointments:
• Member, Maryland’s Health Care Decision Act Advisory Council.

Visiting Assistant Professor Joan O’Sullivan
Presentations:
• “Legal Ethical and Medical Consideration in End of Life Medical Treatment;” Together We Serve: Spiritual Support and Social Responsibility Conference, Marriottsville, MD.
• “Guardianship: Representing the Alleged Disabled Person,” Maryland Institute for Continuing Legal Education for Lawyers, Baltimore, MD.
• “Guardianship and Limited Orders: Actual Practice vs. Statutory Requirements” (Diane Hoffmann and others) and “Teaching Health Law/Elder Law: An Interdisciplinary Approach,” Joint Conference on Law and Aging, Washington, D.C.
• “Elder Law: Planning and Problems,” Sandwich Generation, Caring for Aging Relative Conference, Anne Arundel County, MD.
• “Statistical Analysis of Guardianship Files in Four Counties,” (with Diane Hoffmann), Guardianship in Crisis Conference, Baltimore, MD.

Assistant Professor David A. Hyman
• Coached the University of Maryland Law School National Moot Court team to a win over Georgetown University Law School. Winner of “best brief” competition. The national competition will be held in January, 1995 in New York.