Women's Health and Genetics Research: Panacea or Pandora's Box?

On October 25, 1996, fourteen experts from the fields of genetics, epidemiology, endocrinology, neurology, pharmacology, psychiatry, psychology, and law gathered at the Renaissance Harborplace Hotel in Baltimore to present their views at a conference, "Women's Health and Genetic Research: Panacea or Pandora's Box?" The Law & Health Care Program, together with the Women's Health Research Group, the School of Medicine's Department of Epidemiology & Preventive Medicine, and the University's Graduate School co-sponsored the conference in an effort to share current knowledge and establish a collaborative framework for future research in women's health.

Law & Health Care Program Director, Karen Rothenberg presented the keynote address, "Women and Genetic Testing: Predictions and Precautions" at the symposium, which was the third such interdisciplinary symposium of its kind. Symposium speakers examined the legal and ethical issues raised by a variety of women's health problems, including breast cancer, osteoporosis, cardiovascular disease and obesity, and how the prevention and treatment of those diseases are being influenced by the field of genetics. A particularly lively discussion was stimulated by Maimon Cohen, Chief of the Division of Human Genetics at the University of Maryland Medical Center, on the practice of commercialization, patenting and marketing of biotechnology. Obviously, as genetics research moves forward, there will be new social, legal and ethical challenges to be met.

Nearly 150 participants attended the all-day conference.
P

rofessor Karen Rothenberg, Director of the Law & Health Care Program, returned to the law school after a nine-month leave working as special assistant to Dr. Vivian Pinn, director of the Office of Research on Women’s Health (ORWH) at NIH. As Pinn’s assistant she served as an advisor on a variety of legal and ethical issues arising from research on women’s health, including the inclusion of women in clinical trials and genetic testing.

Rothenberg’s efforts at ORWH focused on education, outreach and consultation addressing unresolved issues arising from implementation of guidelines to require the inclusion of women in clinical research. ORWH established the Task Force on the Recruitment and Retention of Women in Clinical Studies to address barriers to women’s participation in research, and commissioned the Institute of Medicine (IOM) to establish a committee on the Ethical and Legal Issues Relating to the Inclusion of Women and Clinical Studies. Rothenberg served on both the Task Force and IOM committee.

She says, “It became clear to me that the scientific community and Institutional Review Boards (IRBs) needed to become more familiar with the recommendations of the task force and the IOM.” Rothenberg convened a workshop of IRB members and other experts to discuss these recommendations and new challenges and concerns emerging during the first phase of implementation.

Rothenberg says that there are both practical and ethical challenges to be met in addressing inclusion/exclusion criteria and recruitment practices. Historically, the fear that some women may become pregnant during the duration of the study contributed to the rationale to exclude all women of childbearing potential. The NIH guidelines state that women of childbearing potential should not be routinely excluded from clinical research, but do not specifically address the participation of pregnant women. Currently, data are compiled to determine the number of women enrolled in NIH-supported studies, but do not categorize whether these women are pregnant or of childbearing potential. Thus, it is not possible to document the extent of their participation or whether there have been any changes in the way IRBs now address this issue.

The IOM concluded that both women of childbearing potential and pregnant women should be presumed eligible for participation and recommends that pregnant women be excluded only when there is no prospect of medical benefit or significant risk of harm to the fetus. It recommended that the Department of Health and Human Services regulations for the protection of human subjects be significantly revised and reissued to reflect those conclusions.

IRBs also face special challenges with respect to the recruitment and retention of minority women in clinical studies. Many IRBs are concerned that we not repeat the historic exploitation of minorities and the poor being used as commodities in clinical research. With all of these challenges to be addressed, Rothenberg intensified her efforts, co-authoring several articles on inclusion issues and making numerous presentations and consultations on the topic.

Rothenberg also worked on issues arising from predictive genetic testing—she had recently completed a policy analysis of state legislative approaches addressing genetic discrimination and health insurance for a workshop she helped organize for the National Action Plan for Breast Cancer (NAPBC) in collaboration with NIH. As a result of the workshop, recommendations were drafted for state and federal policy makers. She was then given major responsibility at ORWH to inform health professionals, as well as state and federal legislators, on the ethical and legal issues raised by the flow of genetic information. Partly as a result of her providing an analytical framework, many state and federal proposals have now been drafted which integrate to varying degrees the workshop recommendations.

One offshoot of her research on genetic information concerned the implications of discovery of mutations in the BRCA1 gene that places women who inherit the mutated gene at higher risk for breast and ovarian cancer.

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Judges Educated in Health Care Law Issues

In response to the increasing complexity of health care law and technology issues, federal and state judges are seeking further education in these areas. At the request of Superior Court judges in the District of Columbia, the Washington Metropolitan Area Bioethics Network, in cooperation with the D.C. Hospital Association, organized a half-day seminar for the judges on issues such as the withholding or withdrawal of artificial nutrition and hydration, Do-Not-Resuscitate orders, surrogate health care decision making and guardianship. The program was so successful that the judges requested that a similar program on "Critical Health Care Decisions and the Law" be included in their 21st Annual Judicial Conference of the District of Columbia Courts on June 21, 1996. L&HCP Professor Diane Hoffmann participated in both conferences—first as a panel member, informing judges of the role of ethics committees in health care decision making, and in the second, as a keynote speaker on "Legal Conflicts Over the Use of Life Sustaining Treatment."

J udges at the federal level have also indicated an interest in more education on health law issues. In response to this interest the Federal Judicial Center organized a three-day conference for federal and state judges on June 6, 1996 on "Health Care and the Legal System." Hoffmann participated in this conference as well, speaking on ethics committees as an alternative mechanism for resolving disputes over patient care in health care institutions.

Hoffmann says, "Several thousand cases involving disputes over life and death medical decisions have come to the courts in the last two decades, invoking an increasing need for judicial education in health care law and technology issues."
L&HCP Faculty Notes . . .

PROFESSOR KAREN ROTHENBERG

Publications:
"Feminism, Law and Bioethics," 6 Kennedy Institute of Ethics Journal 69 (1996)


Selected Presentations:


"Advances in Genetics Research and Technologies: Challenges for Public Policy," Testimony, Hearing of the U.S. Senate Committee on Labor and Human Resources (1996)


ASSISTANT PROFESSOR DIANE HOFFMANN

Publications:
"Mediating Bioethical Disputes," (with N. Karp), ABA Dispute Resolution Magazine (1996)

Selected Presentations:

"Emergency Care and Managed Care," Emergency Medicine Specialty Conference, University of Maryland Medical Systems, Baltimore, MD (1996)


"Emergency Care and Managed Care A Dangerous Combination for Patients," Shock Trauma Grand Rounds, University of Maryland Medical Systems, Baltimore, MD (1996)

"Mediating Bioethical Disputes," Plenary Session - Ethics Consultation in the Nursing Home Society for Bioethics Consultation Conference: Workshop, University of West Virginia Medical Center, Morgantown, W. VA (1996)

ASSOCIATE PROFESSOR DAVID A. HYMAN

Selected Presentations:
"Public Sector Managed Care: A Forum on Corporate Responsibility, Ethics, Public Policy and the Law," Conference Co-Chair, American Society of Law, Medicine & Ethics, University of Maryland Law School, Hastings Center (1996)

"Values and Ethics in Health Care," Guest Lecturer, Loyola College (1996)


"Legal and Business Issues in Dentistry," University of Maryland Dental School (1996)

VISITING ASSISTANT PROFESSOR JOAN O'SULLIVAN

Publication:
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, AIDS and the elderly.

Sooner or later, all lawyers come face to face with a client whose legal goals directly conflict with the lawyer's personal beliefs. The lawyer must decide which is more important, the obligation to the client, or those personal beliefs. A recent case in the Health Law Clinic put me in the middle of such a dilemma and gave me a chance to model the struggle for my students.

The Legal Aid Bureau case referral sounded innocuous enough—it involved the imminent involuntary discharge of a resident from a nursing home because of the resident’s dangerous behavior. We readily accepted the case, but soon learned that the dangerous behavior in question was the resident’s habit of smoking in her bathroom at night. This was prohibited by state law as well as the nursing home’s rules. Our client wanted to stay in the facility, and she wanted to be able to continue smoking. Our job was to represent her and advocate for that position.

The irony of the Health Law clinic advocating for a client’s right to smoke in a long term care facility was not lost to any of us. But the conflict between client goals and personal ethics was more a problem for me than for my students. I have long been an avid anti-smoking campaigner, and strongly supported Maryland’s new smoking ban. I see tobacco smoking as a public health problem, and think that nonsmokers should be protected from the unwanted smoke of others. However, we had solid law and good facts with which to argue that the nursing home could not discharge our client for smoking. We had made a commitment, and the time before the threatened discharge was short. Despite my personal aversion, I felt we had to advocate for the client as strongly as we could. My students agreed.

Our client’s predicament was precipitated by Maryland’s recently amended smoking laws, changes for which I had lobbied. The governor approved regulations which listed cigarette smoke as a dangerous substance in the work place, and thus banned it from all situations in which employees would be exposed to it. The legislature, in response to heavy lobbying from the hotel and restaurant industries as well as Maryland’s strong tobacco lobby, modified the regulations to allow smoking in some restaurants and bars. The passage of the regulations and the legislation was controversial, and ultimately a compromise, but I felt Maryland had made significant steps in the right direction. Our new case however, brought home to me the human cost of instituting this change.

Our client was 78 years old, a veteran who had served as an Army nurse in World War II. She was a resident of a Veteran’s Administration nursing facility, where, the administrator pointed out to us, 80% of the residents smoked, as did the administrator. Our client told us, “They gave us free cigarettes while we were in the war... I have been smoking ever since. What else do I have to give me pleasure now?... I’ve tried to quit, but I can’t. And if they kick me out of here, where am I going to go?”

She had a good point. As a result of the changes in the law, many nursing homes have become smoke free buildings, meaning that residents must go outside to smoke or quit smoking. State regulations do allow smoking in buildings such as our client’s nursing home, but only in closed rooms with direct outside ventilation. But if our client were discharged from this facility, she might well end up in one where she could not smoke inside at all. It was very important to her that we win this case.

The student attorneys working on the case, Raj Goel and Eric DeVito, diffused the emergency situation by convincing the nursing home that the discharge notice it sent the client did not comply with state law. They next persuaded the administrator that rather than reissue the discharge notice, he should set up a care plan meeting with the resident and her family to try to negotiate a solution to the problem. The meeting went well; the facility came to see that it had a greater responsibility to help the resident cope with her smoking problem than it had admitted in the past.

Using provisions of federal nursing home regulations, Raj and Eric pointed out that the facility should be treating our client’s smoking problem as an addiction to nicotine, not as defiant behavior. The client admitted that she would like to try to stop smoking, and we established a trial period with a nicotine patch and addiction counseling. The facility agreed to order neuropsychological testing for our client, to determine how brain damage she had suffered due to strokes had impaired her ability to resist the urge to sneak a cigarette at night in the bathroom. If all else failed, we agreed on a plan that...
T he L&HCP has always sought to balance a well-structured health law curriculum with innovative experiential training, and the Health Law Practice Workshop seems to be a perfect union of the two concepts.

Professors Karen Rothenberg and Diane Hoffmann alternately have taught the Workshop, which was originally structured as a one-credit course required for students enrolled in the L&HCP Practicum and Externship Programs. Expanded this semester to two credits, the Workshop is now available to students who have some type of experience in the health care or health law field, as well as remaining a requirement for Practicum or Externship students.

The expanded course provides an opportunity for students to share their experiences and to explore the ethical, legal and practical challenges raised by health law in a variety of settings, including hospitals, insurance and managed care organizations, government (the Maryland Office of the Attorney General and state and federal legislative offices), law firms. Each week, one or more health law attorneys participate in the Workshop and share their perspectives on the pressures and dilemmas they face in carrying out their practice. Workshop students are also assigned mentors with whom they work on a final project and presentation. Course presentations are supplemented by readings and discussions focusing on questions about the client in various settings, the role of politics and how it affects the lawyer's role, and the changing nature of the health care industry and how that affects the lawyer's work in various settings.

Ten students are enrolled in the fall 1996 Health Law Practice Workshop class—students drawn from a wide variety of backgrounds and experience. Michele Lillie is a physician who practiced in the field of pediatrics and worked at NIH before her interest in religious liberties led her to law school. Bruce Currie worked in computer distribution and became interested in health care law when he had to negotiate the health care system as a consumer when he was injured during his first year of law school. An undergraduate degree in psychology and the desire to work in a people-oriented profession, led Janet Heald, a visiting student from Wake Forest University, to law school and the Law & Health Care Program. For Wanda Hicks, a pharmacist, it was her work as a sales representative for a pharmaceutical company and in policy development for a pharmacy association that stimulated an interest in health care law.

The students' Practicum placements and mentor assignments are equally diverse.

Three of the Workshop students are pursuing special projects at the Maryland Hospital Association, a hospital trade organization, the Maryland Office of the Attorney General-Medicaid Fraud Unit and at the University of Maryland President's Office, working for a University Counsel.

Five students are currently enrolled in Practicums at the Maryland Office of the Attorney General-Department of Health and Mental Hygiene, the Maryland Department of Legislative Reference, the Johns Hopkins Health System Corporation, NIH, and the Helix Health System. The remaining two Workshop students have been assigned a mentor at Dimensions Healthcare System.

Malka Scher's Practicum at the Department of Health and Human Services' Office of the General Counsel, NIH Branch, involves matters relating to technology transfer, a fascinating area of health care law. Scher has had the opportunity to review cooperative research and development agreements (CRADAS), as well as licensing agreements between NIH and the companies though which NIH moves the results of their own intramural research into the
public sector. She recently began a large research project involving investigation of intellectual property rights and materials on the Internet.

Many students commented on the "real-world" value of their practicum/mentor experiences and the high degree of practicality of the information passed on by the speakers.

The health law attorneys who participated in the Workshop are equally enthusiastic about its value. At the first class session, Sigrid Haines, an attorney with Lerch, Early and Brewer and current head of the Health Law Section of the Maryland Bar provided the class with an overview of the practice of health law. Haines said she was impressed with "the high degree of interest and motivation exhibited by the students and the diversity of their prior work experiences," and she felt the Workshop explored "the exciting opportunities [available in health care law] for long-term career prospects."

The Health Law Practice Workshop will be offered again during the fall 1997 semester.

In The Clinic
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would allow the nursing home staff to control our client's cigarettes so that she got only one at a time.

Like any good compromise, everyone got something, but not all of what they wanted. Our client got to stay in her home and to get some help to control her smoking. My students got a lesson in advocacy. They learned that being an advocate for a client often means putting aside one's personal feelings and beliefs for the good of the client. While there are limits to this, a line which a lawyer must draw, beyond which she will not go, this case did not approach that line. My discomfort was minimal compared to the value of a satisfactory outcome for our client.

What I got was yet another lesson in the complexities of life. While it is simple to say that smoking is bad and everyone should stop, the consequences of a sweeping change such as Maryland's work place smoking ban are much more intricate than that.

Student Health Law Organization (SHLO) News

The Student Health Law Organization began the fall semester with an informational meeting for new members, and held elections for the coming year. The 1996-1997 SHLO officers are: Michele Saba (3D) and Heather Connolly (1D) - Co-Chairs; Chris Coffin (1D) - Secretary; Jennifer LaRoche (1D) - Treasurer; Melissa Feliciano (1D) - Events Chair; Eric DeVito (2D) - Networking/Bar Liaison; and Emily Koschanski (3E) and Alice Legat (1D) - At-Large Members.

The organization held two events thus far this semester—a meeting with L&HCP faculty to provide new students with information on spring 1997 courses and to obtain feedback on plans for the future direction of the Program, and a panel discussion featuring attorneys from both the public and private sectors who provided SHLO members with information on choosing a career in health law. Future events include a reception for the Maryland Health Law Section of the Bar and a Career Day Exposition. The Career Day Exposition is being planned to attract a variety of representatives from both health law firms and public and non-profit organizations to the law school to discuss the practice of health law.

As always, SHLO has attracted a diverse group of students to its membership, as well as an unusually large number of first year students. For information on the organization, please contact any of the SHLO officers named above or the L&HCP Program Office at (410) 706-7239.

Program news . . .

Law & Health Care Program

Director, Karen Rothenberg was presented with the 1996 Joseph Healey Health Law Teachers Award at the American Society of Law, Medicine & Ethics' Annual Health Law Teachers Conference held in Wilmington, Delaware on June 7, 1996.

Did you return your questionnaire? . . . The L&HCP recently mailed 850 questionnaires to members of the Health Law Sections of the Maryland and District of Columbia Bar Associations in an effort to update a 1988 survey of health law practices in the area. Survey responses and analysis of data will be included in a spring 1997 newsletter article. To date, approximately 150 questionnaires have been returned.

As a follow-up to The Nursing Home Handbook, Health Law Clinic Director, Joan O'Sullivan, recently wrote and published, The Guardianship Handbook: A Guide To Adult Guardianship and Guardianship Alternatives in Maryland. Several thousand copies of the 68-page book will be distributed to consumers.
Director Returns
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Rothenberg made over thirty presentations throughout the United States to both provider and consumer groups on the ethical, legal and social challenges raised by predictive genetic testing. Rothenberg says, “A number of assumptions have been made about the positive value of predictive testing, including the potential to reduce cancer morbidity and mortality, and enabling individuals with both positive and negative test results to better plan for their future. On the other hand, the negative values that have been associated with testing are anxiety, guilt, stigmatization, discrimination and being labeled as precancerous in the context of the family and society. In reality, she emphasizes, “we really know very little about the benefits and risks.”

Since her return, Rothenberg has testified on genetics and public policy before the U.S. Senate and House of Representatives, served as a U.S. delegate to draft recommendations on a variety of legal and ethical issues at the U.S.-Canadian Forum on Women’s Health, and continues to make presentations and author articles on genetics and women’s health issues. In October she chaired “Workshop on Genetic Information and the Workplace: Implications for Employment, Insurance, and Privacy,” co-sponsored by the NAPBC and NIH-DOE Working Group, and completed an analysis of state legislative approaches addressing genetic discrimination in the workplace.

This semester Rothenberg is teaching Seminar on Law and Biomedical Sciences: Genetics, a course which examines the legal, ethical and social implications raised by genetics and the Human Genome Project. That course will be followed, during the Spring 1997 semester, by Biotechnology and the Law, co-taught with Max Oppenheimer, which will examine the legal, ethical and public policy challenges raised by new developments in biotechnology, and the roles of industry, government and academic institutions in moving this technology to market. Both courses utilize many of the resources Rothenberg had access to while at NIH.

Faculty Notes
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Selected Presentations:
“Planning for Incompetency: Financial Affairs, Health Care Decisions, and Guardianship,” at Dilemmas in Dementia Symposium, Geriatric Research, Education and Clinical Center, Veteran’s Affairs Medical Center, Baltimore, MD (1996)

“Legal Issues Related to Nursing Homes,” Law Day for Older Adults, Wheaton, MD (1996)

“Determining Competency and Guardianship in Maryland,” Garrett County Memorial Hospital, Oakland, Maryland; Western Maryland Area Health Education Center, Cumberland, MD, Hagerstown Junior College, Hagerstown, MD (1996)

“End of Life Decision Making,” Baltimore County Department of Aging (1996)

Appointment:
Maryland Long Term Managed Care Committee, appointed by Department of Health and Mental Hygiene Secretary Martin Wasserman (1996)