

LAW & HEALTH CARE

N E W S L E T T E R

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Focus on . . .

HUMAN SUBJECTS RESEARCH

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L&HCP Provides Forum for Debate Over Human Subjects Research

Over the last decade, the state of Maryland has been the focal point for significant policy and legal debate regarding the regulation of human subject research and the Law & Health Care Program (L&HCP) and its faculty have participated in and provided a forum for intellectual debate and exchange of perspectives on this issue. Most recently, the state of Maryland became the focus of attention on a question of adequate protection of children who participate in nontherapeutic research. On August 16, 2001, Maryland's highest court, issued a groundbreaking opinion in the cases of *Grimes v. Kennedy Krieger* and *Higgins v. Kennedy Krieger* (see article on page 3). The Court overturned a summary judgement decision by the trial court and held, among other things, that "in Maryland a parent,

appropriate relative, or other applicable surrogate, cannot consent to the participation of a child or other person under legal disability in nontherapeutic research or other studies in which there

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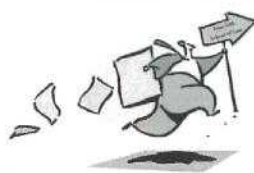
From the Director

This issue of our Newsletter covers the many ways in which the L&HCP has been involved in the topic of human subjects research from L&HCP conferences to faculty research to seminars and student field placements dedicated to the issue.

We've included articles on the L&HCP's long history of involvement in policy and legal issues related to human subjects research, a detailed analysis of the Maryland decision in the Kennedy Krieger case involving children in research, and the highlights of our recent conference, "Children in Research: The New Legal and Policy Landscape."

We hope you enjoy reading about these cutting-edge topics. Have a great summer!

Diane Hoffmann, JD, MS
Director



We're moving—the University of Maryland School of Law will relocate to its new facility at 500 West Baltimore Street effective July 8, 2002.

**Law & Health Care
Newsletter**

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

L&HCP Faculty

The following law school faculty contribute to the diversity of the Law & Health Care Program through their teaching and scholarship. We share some of these faculty's selected publications, presentations, and appointments in

Faculty Notes:

Taunya Lovell Banks, JD
Richard Boldt, JD
Irving Breitowitz, JD
Karen Czapanskiy, JD
Susan J. Hankin, JD, MPH
Deborah S. Hellman, JD, MA
David A. Hyman, MD, JD
Susan P. Leviton, JD
Joan L. O'Sullivan, JD
Thomas Pérez, JD, MPP
Karen Rothenberg, JD, MPA
Lawrence Sung, JD, PhD
Deborah J. Weimer, JD, LL.M.
Mary Webster, JD, MS
Roger C. Wolf, JD

Adjunct Faculty (2001-2002)

Ellen Callegary, JD, Callegary & Steedman
John R. Catizone, JD, The St. Paul Company
James Doherty, Jr., JD, Pecore & Doherty, LLC
W. Lawrence Fitch, JD, Community Forensic Services
Kevin McAnaney, JD, Office of Counsel to the Inspector General, Dept. of Health and Human Services
Lewis Noonberg, JD, Piper and Marbury
Frank Palumbo, PhD, JD, University of Maryland School of Pharmacy
Robert T. M. Phillips, MD, PhD
Forensic Consultation Association, Inc.
Sanford V. Teplitzky, JD, Ober, Kaler, Grimes & Shriver

**Director of Health Law Externships
Coordinator, Law & Health Care Program**
Lisa Ohrin, JD

Administrative Assistant
Carole Marshall

*Comments and letters should be
forwarded to the above address.*

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L&HCP Provides Forum
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is any risk of injury or damage to the health of the subject." The research community was devastated by the opinion and two of the major research institutions in the state, Johns Hopkins and University of Maryland, were instrumental in efforts to request that the Court reconsider its decision—an unusual request and one that is infrequently granted. The Court, in fact, refused the request but clarified its opinion by stating that "by 'any risk' we meant any articulable risk beyond the minimal kind of risk that is inherent in any endeavor."

Pending the outcomes of the two cases (the cases were remanded for a determination of liability), the L&HCP, in collaboration with the American Society of Law, Medicine & Ethics, took the initiative to host a conference that would provide a forum to debate the appropriateness of existing policies and practices regarding research with children (see article on page 5). The conference, held May 3rd, explored the pros and cons of recent federal efforts to expand research with children, the potential implications of the Kennedy Kreiger case for future research with this population, and the ethical issues arising from the National Children's Study, a study that will attempt to enroll 100,000 children and follow them for 20 - 30 years. The law school's *Journal of Health Care Law & Policy* will provide a vehicle for

publication of the conference papers in a forthcoming symposium issue.

This involvement is just the most recent in a longer history of Program involvement in policy development and implementation on issues of research with human subjects. In the mid 1990s, Karen Rothenberg, now Dean of the Law School, served on an Institute of Medicine committee on the inclusion of women in clinical research.

Rothenberg has also taken a leadership role in federal and state policy issues related to genetics research, in particular issues of privacy and discrimination and the role of group risk and benefit when studying a population and its unique genetic attributes. From 1995 to 1997, Professor Diane Hoffmann participated as a member of a Working Group appointed by the Maryland Attorney General on research involving individuals with decisional impairments. The Working Group issued a report that included proposed legislation that would provide additional protections for this vulnerable population. The report was the subject of several public meetings as well as the focus of a session of the Human Subjects Subcommittee of the National Bioethics Advisory Commission. The report caught the attention of researchers and advocates of the disabled and decisionally impaired both in Maryland and across the nation. Based on reactions to the Working Group's efforts it was clear that there was a need to educate the community about the recommendations and to provide an

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opportunity for stakeholders to debate the issues. The L&HCP stepped in to provide such an opportunity and on May 28, 1997 the Law & Health Care Program held a day long conference entitled "Conducting Medical Research on the Decisionally Impaired." Papers presented at the conference provided the content for the first issue of the *Journal of Health Care Law & Policy (JHCLP)*.

It is only fitting that five years after its initial issue, the *JHCLP* will revisit the topic of human subjects research and produce an issue that may serve as a resource for public policy makers and the courts.

Children as Research Subjects: Grimes v. Kennedy Krieger Institute, Inc.

by Lisa Ohrin, JD

On August 16, 2001, the Maryland Court of Appeals shocked researchers who conduct investigational studies involving children and the institutions that sponsor them when it held that, "in Maryland, a parent . . . cannot consent to the participation of a child or other person under legal disability in nontherapeutic

research or other studies in which there is any risk of injury or damage to the health of the subject." In such cases, according to the Court, "parental consent, no matter how informed, is insufficient." The legal world was equally shocked because the Court ruled on this issue without the request of the parties in the case.

Two separate lawsuits were brought against Kennedy Krieger, an internationally known pediatric treatment and research facility, by the parents of two children involved in a study of the effectiveness of different lead paint abatement techniques. The cases filed in Baltimore City Circuit Court claimed that the mothers of the children allegedly harmed by their

participation in the study were not properly or timely informed by Kennedy Krieger of the risks to their children or of elevated levels of lead in their children's blood or their homes. The Circuit Court dismissed both cases on summary judgment, stating that Kennedy Krieger had no legal obligation to make houses safe or to notify the families about the dangers they faced because Kennedy Krieger was not a landlord and never promised to provide medical care.

The Circuit Court rulings were

appealed to the Court of Appeals. The plaintiffs merely wanted the Court to order that trials be conducted to determine

According to the Maryland Court of Appeals, "parental consent, no matter how informed, is insufficient."

whether Kennedy Krieger was negligent in the way it conducted the studies with respect to Ericka Grimes and Myron Higgins and whether it breached its duty of care to the children. The Court of Appeals remanded the case for trial, but extended its opinion to admonish the research methods of Kennedy Krieger and accuse the Johns Hopkins University institutional review board (which reviewed the protocol) of protecting the interests of the researchers at the expense of children by instructing the researchers to circumvent federal regulations designed to protect children participating in nontherapeutic research. In its scathing opinion, the Court compared the actions of

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Children as Research Subjects Cont. from page 3

Kennedy Krieger to those of the Tuskegee Syphilis Study, the intentional exposure of soldiers and Navajo miners to radiation, the secret administration of LSD to soldiers, the injection of chronically ill patients with cancer cells without their consent, the typhoid experiment conducted by the Nazis at Buchenwald, and the use of "plague bombs" by the Japanese military in World War II. Following its comparisons, the Court stated that

[i]t is clear to [the] Court that the scientific and medical communities cannot be permitted to assume sole authority to determine ultimately what is right and appropriate in respect to research projects involving young children free of the limitations and consequences of the application of Maryland law.

Moreover, the Court noted its belief that Institutional Review Boards are, primarily, "in-house organs" and cannot be trusted to be sufficiently objective to protect the interests of children and determine the ethicality of the experiments they review.

The holding of the case—that parental consent is not sufficient for nontherapeutic research that poses any health risk to the child—aroused great concern among researchers in Maryland. According to numerous medical institutions and associations that reviewed the opinion, the Court's decision halted virtually all nontherapeutic research in the State involving children. In September

2001, as a result of these concerns, Kennedy Krieger and others asked the Court to reconsider the part of its August ruling prohibiting parental consent for the participation of children in nontherapeutic research citing numerous public policy concerns regarding the likely unintended and damaging outcomes of the Court's ruling. In addition, Kennedy Krieger questioned the ambiguous "any risk" and "nontherapeutic" terms used by the Court in its opinion and asked for clarification. It also requested that the Court withdraw its "similar problems" historical comparisons to the Tuskegee Syphilis Study and other horrific protocols noted above.

The Court of Appeals denied Kennedy Krieger's motion for reconsideration and modification of the original opinion, stating that "the *only* conclusion [it] reached as a matter of law was that, on the record currently before [the Court], summary judgment was improperly granted." (emphasis added). Yet, the Court refused to retract its holding that a parent "cannot consent to the participation of a child . . . in nontherapeutic research or studies in which there is any risk of injury or damage to the health of the subject." The Court did note, however, its belief that the definition of "any risk" was clear and meant "any articulable risk beyond the minimal kind of risk that is inherent in any endeavor." The Court defined "nontherapeutic" as a study that "promises no medical benefit to the child whatever, so that any balance between risk and benefit is necessarily negative."

Given the Court of Appeal's

confirmation of its holding in *Grimes v. Kennedy Krieger Institute, Inc.*, it was not unexpected when the Maryland General Assembly took up the issue during the 2002 session. House Bill 917, which requires all researchers conducting human subjects research in the state of Maryland to comply with federal standards on the protection of human subjects regardless of funding source, was passed unanimously by the legislature. In addition to extending federal protections, the bill requires IRBs to make their minutes available to the public upon request once all confidential information has been redacted. This provision was included specifically to promote public confidence in research following the death of a healthy research subject at Johns Hopkins and the case against Kennedy Krieger Institute.

The issue of liability of Kennedy Krieger in the two cases has yet to be determined by the lower courts. These decisions will also be important for the research community in Maryland.

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SPRING CONFERENCE

Research With Children

The New Legal and Policy Landscape

On Friday, May 3, 2002, a group of national experts and 175 participants from across the country explored the legal and ethical issues raised by research studies that use children as subjects. The conference, "Research With Children: The New Legal and Policy Landscape," was held at the University of Maryland Baltimore campus and was co-sponsored by the University of Maryland Schools of Law and Medicine, and the American Society of Law, Medicine and Ethics. Diane Hoffmann, Associate Dean and Director of the Law & Health Care Program at the School of Law, and James Nataro, Director of Pediatric Research at the School of Medicine, worked jointly on the conference format and bringing together the speakers.

The conference explored the legal and ethical issues raised by recent regulatory policies, judicial opinions, and government studies on children. Specifically, the sessions addressed:

- the recent policies adopted by the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) to encourage research with children;
- the National Children's Study (formerly the Longitudinal Cohort Study) that is being organized by NIH's National Institute of Child Health and Human Development (NICHD), the Centers for Disease Control and the Environmental Protection Agency that

will attempt to enroll 100,000 children and follow them for 30 years; and

- the Maryland Court of Appeals decision in the case of *Grimes v. Kennedy Krieger Institute* articulating an enhanced legal duty on the part of researchers and calling into question the practice of conducting non-therapeutic research with children that poses "any articulable risk beyond the minimal kind of risk that is inherent in any endeavor."

Speakers included Duane Alexander, MD, Director of NICHD who discussed the evolution of research with children, and the trend from exclusion to inclusion; Michael Labson, Esq., an associate in the law firm of Covington and Burling who spoke on the FDA's policy on patent incentives for expanding such research; and Lainie Friedman Ross, MD, PhD, of the MacLean Center for Clinical Medical Ethics at the University of Chicago, whose presentation, "Women and Children First: Applicable to Lifeboats? Applicable to Medical Research?" questioned the direction of these new federal policies and addressed the question "What is the morally appropriate balance for the role of children in research?"

A panel discussion on the *Kennedy Krieger* case (see article on page 3) included the following faculty: Gary Goldstein, MD, President and CEO, Kennedy Krieger Institute; Jonathan M. Smith, Executive Director, The Public

Justice Center; Jack Schwartz, Assistant Attorney General and Director of Health Policy, Maryland Office of the Attorney General; and Joanne E. Pollak, Vice President and General Counsel, Johns Hopkins Medicine.

The afternoon included a series of breakout sessions and a presentation by Karen Rothenberg, Dean of the University of Maryland School of Law, on the implications of the *Kennedy Krieger* decision on the duty of researchers. The conference closed with a session at which Benjamin Wilfond, Head of the Section on Genetics in the Department of Clinical Bioethics at NIH and a member of the Ethics Working Group of the National Children's Study, discussed the ethical issues raised by the National Children's Study.

According to Rina Hakimian, JD, MPH, of the National Cancer Institute, an attendee of the conference, the conference was "informative, stimulating, and timely." Hakimian said the presentations sparked a lively conversation between her and her NIH colleagues.

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Spotlight on . . .

HEALTH LAW PRACTICUMS AND EXTERNSHIPS: Office of the General Counsel, Office for Human Research Protections

by Karena Cooper, 2D

I was drawn to the University of Maryland School of Law by the Law and Health Care program, and now that I am here, I have found that I am able to pursue my exact area of interest—the intersection of law and biomedical research-related legal issues.

Law is not my first career. For 12 years, I was a professional pianist/piano teacher/music director. In 1994, I obtained a Master's Degree in Social Work at the University of Maryland Baltimore. After working briefly as a child protective services case manager, I began working at the National Institute of Mental Health as a research assistant on a longitudinal study about the biological and psychological effects of child sexual abuse.

Later, I became the Regulatory Affairs Coordinator for a cancer institute and then the Institutional Review Board (IRB) Administrator for its affiliated hospital. I was appointed to the joint IRB for the two institutions.

When I moved back to Maryland to attend law school, I also became a board member of a private, independent IRB called Chesapeake Research Review, Inc. based in Columbia, Maryland. I attend weekly board



Karena Cooper and husband, Mark, on their honeymoon in Paris. The two were married in December, 2001.

meetings in which we review between two and six new scientific studies per week.

I wanted a research-related placement for the Health Law Practice Workshop (to satisfy the experiential requirement for the Health Law Certificate). With the approval of L&HCP Director and Dean, Diane Hoffmann, the L&HCP created a new placement at the recently created Office of Human Research Protections (OHRP) and I started working there in the fall under the supervision of Susan Sherman.

Susan Sherman is an attorney in the Office of General Counsel (OGC) of the Public Health Division in the

The Law & Health Care Program's Health Law

Practicums provide an opportunity for students interested in health law to obtain credit by working for organizations and government agencies dealing with health care issues. Students spend at least 10 hours per week at their placement and additional hours throughout the semester in the classroom participating in the Health Law Practice Workshop. Placements have included the American Nurses Association; the Equal Employment Opportunity Commission; Johns Hopkins Health System Corporation; Legal Services to the Elderly; Med-Chi of Maryland; Maryland Board of Physician Quality Assurance; the National Health Law Program; NIH; U.S. Senate Subcommittee 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 also offers several full semester externships—The National Health Law Program externship in Washington, D.C.; The University of Maryland Medical System externship, located in University Hospital's General Counsel's office; Blue Cross/Blue Shield of Maryland (BCBSM), The Federal Trade Commission, The Maryland Health Care Commission; and the NIH General Counsel's Office.

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L&HCP Adjuncts

Jack Schwartz, JD
*Director, Health
Policy Development,
Maryland Office of the
Attorney General*

*Law and Biomedical
Sciences Seminar:
Medical Research*

In the Fall of 2001, the Law & Health Care Program again included "Medical Research" in its *Law and Biomedical Sciences Seminar* offerings. Jack Schwartz, Assistant Attorney General and Director of Health Policy Development within the Maryland Office of the Attorney General, brought his extensive knowledge and personal experience to this "exhilarating and challenging" course and its students.

Jack Schwartz wears many hats when it comes to human subjects research. In addition to teaching the Medical Research seminar, his roles in human subjects research include advocate, institutional review board member at the National Cancer Institute, and research subject. In addition, in his role as Assistant Attorney General, he headed a working group that designed legislative recommendations for dealing with research in which the subjects lack decisional capacity to

give informed consent, wrote an amicus brief in the *Kennedy Krieger* case (see article, page 3), briefed the Maryland General Assembly on issues related to human subjects research, and worked on recently passed legislation that applies federal ethical and informed consent standards to all research in Maryland, regardless of funding source.

Students in the Medical Research seminar benefitted greatly from Schwartz's diverse experiences and accomplishments in human subjects research. According to Karen Smith Thiel, a student in the seminar, "the course's emphasis on ethics, law and the principles of biomedical research provided a very full treatment of the issues involved in human subjects research." Seminar students examined the legal and ethical issues raised by medical research, studying the history of research on human subjects, including some of its worst abuses, such as the Tuskegee Syphilis Study. In addition, the students explored the federal regulations on the conduct of human subjects research, the function of institutional review boards, ethical standards and informed consent requirements, inclusion of certain groups in research, conflict of interest and accountability in research, and the impact of tort litigation on the research enterprise. "Because the students had a rich background in various aspects of the research enterprise, their contributions were key to the seminar's success," noted Schwartz.

The Medical Research seminar was particularly timely. In June 2001, a healthy research subject died during participation in an asthma-related



Jack Schwartz

clinical trial at the Johns Hopkins Medical Institutions located here in Maryland. Shortly thereafter, federal funding of research at Johns Hopkins was temporarily suspended following an investigation by the Office for Human Research Protections. Finally, in August and October 2001, the Maryland Court of Appeals handed down its decision and clarification in the case of *Grimes v. Kennedy Krieger Institute*. According to Schwartz, following these events, medical research issues became more prominent than ever in Maryland. In fact, "no topic could have been more timely, and it sometimes seemed as if the course could be taught from the day's newspaper." Yet, despite the coincident nature of the course, it "also required that students be firmly grounded in the historical development of research regulation and gain command of difficult regulatory material."

In addition to writing a seminar paper, students gave "very impressive" final presentations. Thiel, whose paper

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Spotlight on Practicums

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U.S. Department of Health and Human Services. The OGC attorneys function as in-house counsel for specific client agencies and provide legal services, such as statutory interpretation, preparation and review of regulations and other legal documents, and advising on the issues that arise.

For the first half of the semester, I worked with Susan Sherman at the OGC Office on the NIH campus in Bethesda, Maryland. I was able to observe federal administrative rule-making at close range as my supervisor, in conjunction with representatives from other federal agencies, handled the public comments submitted during proposed rule-making for an amendment to 45 CFR 46, Subpart B. The final rule was published in the Federal Register on November 13, 2001.

In early November, OHRP moved to a new location in Rockville, where my supervisor became their designated attorney and the only attorney in the midst of M.D., Ph.D. and R.N. staff who administer the regulations that pertain to human subject research. Apparently, this is a unique arrangement for an OGC lawyer.

Throughout the semester, I spent much time researching and discussing the August 2001 Maryland case *Grimes v. Kennedy Krieger Institute*. Many issues affecting pediatric research were raised by that case and it was very interesting to get the federal perspective on the possible ramifications on federally-funded research conducted on the NIH campus and in states other than Maryland.

I found my practicum to be a very positive learning experience. I recommend it to anyone considering legal employment with the federal govern-

ment. Also, it was no doubt instrumental in helping me land my upcoming summer federal internship.

L&HCP Adjuncts

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topic "Parental Consent for Children's Participation in Biomedical Research" was particularly timely, commented, "I have recommended this class to my colleagues in the Law & Health Care Program. Even if they do not intend to work in the area of law and biomedical research, the issues are important and likely to become even more so in the coming years." Professor Schwartz will teach the Medical Research seminar again in the Fall of 2002.

L&HCP Student Wins GGear Award

L&HCP student Teresa Lancaster was recently awarded the 2002 Geriatrics and Gerontology Education and Research Award. In presenting the award to Lancaster, L&HCP Professor Joan O'Sullivan made the following remarks:

"Teresa Lancaster represented a long time client of the Health and Elder Law clinic this year, a person with mental retardation who was sexually and physically abused when she was in a mental hospital. She succeeded in finding her a new apartment, [removing her from a group home that had eight residents in it], restoring her art therapy, finding her physical therapy

after she had been confined in a wheelchair for some months, and finding her occupational therapy.

Ms. Lancaster also took on the Social Security Administration in several cases, restoring the clients' SSA money for her clients. In addition, she restored the Supplemental Security Income of a disabled woman.

Ms. Lancaster worked tirelessly with a man who is kept at Spring Grove Hospital, trying to get him into a DDA setting where he will be able to work and can improve his situation.

Ms. Lancaster devoted many hours of her time this year to improving the lives of her geriatric clients. She worked

without fail on many of her geriatric cases, often putting in more hours than the clinic requires. She is a tireless advocate for her geriatric clients, and is willing to take on any administration or court.

Teresa Lancaster is an ideal candidate for the 2002 Geriatrics and Gerontology Education and Research Award. She will make the University of Maryland proud of her when she graduates in December, 2002."

Webster Directs New Intellectual Property Resource Center

A recent partnership between the Montgomery County (MD) Department of Economic Development and the University of Maryland School of Law has resulted in the establishment of the Maryland Intellectual Property Legal Resource Center (MIPLRC or Center) (see article, Fall 2001 L&HCP Newsletter). In January 2002, Mary Webster, a patent attorney with eighteen years combined experience in microbiology and biotech patent law, was appointed as the Director of the new venture. According to Diane Hoffmann, Associate Dean of the School of Law and Director of the L&HCP, "With a background as a molecular virologist and patent attorney, Professor Webster has a real feel for the issues that biotech researchers face when moving their products from the lab to the marketplace."

The only Center of its kind in the United States, the MIPLRC was officially established in February 2002 to provide low-cost intellectual property services and other legal assistance to start-up technology companies and, in collaboration with faculty in the L&HCP, to explore emerging ethical, legal and policy issues in the field of biotechnology. Webster has been working to establish the infrastructure of the MIPLRC so that in its first year,

the Center will be able to offer academic courses for students at the School of Law, present workshops and lectures on intellectual property and

other legal issues to start-up technology and biotech companies, and provide legal information to such companies on site at the Maryland Technology Development Center (MTDC), an "incubator" for early-stage business enterprises. Once fully operational, the Center will be comprised of three components: an academic program, a clinical program for law students, and a public policy and ethics program to be

run in conjunction with the L&HCP.

Webster currently maintains an office at the MTDC in the same building with the start-up companies the Center is intended to support. Located in what has been called "DNA Alley" the MTDC houses a mix of biotech and information technology companies, internet service and access providers, and bioinformatics companies. These entities are at various stages of funding, with some ready to sell their products and services under multi-million dollar contracts and others in their infancy. However, according to Webster, no matter how big or small the company or what stage of operation it is in, all of the companies at the MTDC have the

same basic question: what type of intellectual property protection do I need?

According to Webster, the companies at the MTDC also have other legal needs, including assistance with trademark and domain name issues, patent application drafting help, and certain non-intellectual property issues such as corporate structure and employment concerns. Many of the School of Law's faculty have affiliated with the Center to help with the business, employment, and ethical issues facing the start-up companies at the MTDC. Students at the School of Law will also provide legal services to the start-up companies through a newly-established clinic to assist the MTDC entities.

In addition to assisting the companies at the MTDC, Webster and Professor Lawrence Sung (who heads the School of Law's developing Intellectual Property Law Program), have teamed to assist Dr. Francis Collins of the Human Genome Institute with issues related to biotech patenting. Webster and Sung recently spoke to Dr. Collins and his staff about the subtle nuances of the law surrounding biotech patenting, current issues in high technology, and the status of pending legislation in the area.

Webster notes that she has begun a "great adventure" at the MIPLRC and looks forward to the Fall when the Center "hits the ground" operationally and we see what unfolds.



Mary Webster, JD, MS, directs the Maryland Intellectual Property Legal Resource Center

Law & Health Care Program Graduates Receive Prestigious NAPIL and Skadden Fellowships

Lucy Shum and Luciene Parsley, May 2002 law school graduates and recipients of the L&HCP's *Health Law Concentration Certificate*, were each awarded prestigious fellowships to continue their public interest work.

Lucy Shum, a long-time advocate for health care for the underserved, was recently named a 2002-2004 National Association for Public Interest Law (NAPIL) Fellow. Only a handful of law students, recent law graduates, and attorneys dedicated to public interest law receive these annual fellowships. NAPIL Fellowships for Equal Justice began in 1992 when two federal judges gave NAPIL over \$3.1 million in unclaimed funds from two class-action settlements. According to NAPIL, now called Equal Justice Works, a fellowship provides the law graduate with "the unique opportunity to create [his/her] ideal job." In Shum's case, that job will be expanding the project she created as a Schweitzer Fellow with the Maryland Disability Law Center (MDLC) into a full-time program.

Beginning in September 2002, Shum will be working with MDLC to help special needs children from low-income families receive the medical and mental health services they need. Specifically, her work will focus on educating the parents, guardians and health care providers of low-income special needs children regarding community-based mental health services, Medicaid's Early and Periodic Screening, Diagnosis and Treatment (EPSDT) program, and other available services of significance to this underserved population. Shum's NAPIL Fellowship project will consist mainly of community outreach, a direct

extension of her Schweitzer Fellow work where she visited people in their homes to perform intakes and coordinated services with different care providers, but could eventually lead to litigation.

Luciene Parsley will also be working with the MDLC, but as a Skadden Fellow. The Skadden Fellowship Foundation was established in 1988 as a sort of "legal Peace Corps" by Skadden, Arps, Slate, Meagher & Flom

developmentally disabled and other vulnerable persons, when she became an intern with MDLC. Through her previous professional positions and work in the Law School Clinic, Parsley has developed relationships with several individuals who will remain her clients even after her graduation from law school. These individuals include two residents of nursing homes whom she has assisted with their domestic and guardianship needs.

Parsley has achieved great successes for her clients by putting forth the extra effort that made the difference in their cases. In one case, as a student-attorney in the Health and Elder Law Clinic, Parsley negotiated a settlement agreement with the State of Maryland for her disabled client to receive all services she requires for the rest of her life. Parsley's advocacy resulted in, among other things, the woman being moved to an apartment closer to her mother (who cannot drive) and having a one-on-one contact guard all night because the client frequently wakes at night with fearsome dreams.

Parsley considers herself extremely lucky. "Since Skadden encourages you to design your 'dream job' and design a two-year project to work on, I was able to structure exactly the kind of job I want. It's an exciting opportunity, and I am looking forward to starting work in September." She also credits L&HCP faculty Professors Stan Herr (deceased) and Joan O'Sullivan and Teresa Schmiedeler of the School of Law's Career Development Office with helping her obtain the Skadden Fellowship. Parsley notes that the support, information and encouragement of Herr, O'Sullivan and Schmiedeler were invaluable. "Knowing they were behind me made all the difference."



Lucy Shum



Luciene Parsley

to affirm its commitment to public interest law. Only 25 of these prestigious fellowships are awarded each year. Other 2002 recipients of this competitive award included graduates of Harvard, Georgetown, New York University, Columbia, Stanford, Yale, Fordham University, American University, Boalt Hall, UCLA, the University of Michigan, and the University of Chicago. Parsley is the second University of Maryland School of Law graduate to receive this award. The first recipient, Professor Susan Waysdorf, represented individuals with HIV at the Whitman Walker Clinic during her Skadden fellowship before going on to become a faculty member at the University of the District of Columbia.

Parsley's Skadden project will allow her to continue the work she began in June 2000, advocating on behalf of

Student Health Law Organization Has Successful Year

by Nisha Wagle, 3D
2001-2002 SHLO President

The 2001-2002 school year proved to be a success for the Student Health Law Organization (SHLO). Plans are underway for the next school year to build upon these achievements.

This past year, SHLO's membership exceeded 100 students from the law school's day and evening programs. Our membership was positively affected by the first year class who became some of our most enthusiastic members. In addition, the majority of our returning students remained active contributors to SHLO's success.

SHLO began the school year by co-sponsoring, with the Law & Health Care Program (L&HCP), a panel of speakers to expose students to the diversity that exists in the field of health care law. Five prominent attorneys from the local area shared their professional experiences and the evolution of their careers to a packed

audience of students and faculty. These attorneys included: Joanne Pollak, General Counsel for Johns Hopkins Hospital; S. Craig Holden from Ober, Kaler, Grimes & Shriver; Margaret Ann Nolan, Deputy Counsel, from the Maryland Office of the Attorney General; Kristin Jones, a Policy Analyst with the Department of Legislative Services/ Maryland General Assembly; and Tom Lewis, from Gallagher, Evelius & Jones.

SHLO also successfully sponsored a health law practice speakers series. This year SHLO welcomed Mark DiAntonio from Baxter Baker Sidle Conn & Jones, who discussed medical malpractice; Steven Stern from Ober, Kaler, Grimes & Shriver who talked to students about the ADA and the practice of health law; James Hodges, Project Director of the Center for Law & Public Health at Johns Hopkins School of Public Health who spoke on the model state emergency health powers act and state legislative activity; and Jim Botluk, Assistant Bar

2002-2003 Executive Board Members

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Counsel for the Maryland Attorney Grievance Commission, who presented the issue of drug and alcohol abuse in the legal profession. SHLO also had the privilege of hosting Congressman Benjamin Cardin, who addressed current health law topics on Capitol Hill.

A major fall event was SHLO's first (and hopefully annual) joint meeting with the Maryland Health Law Bar Section. SHLO also combined this event with its annual Alumni mixer. This informal dinner and the educational speakers at the meeting gave students the opportunity to socialize with working attorneys and further learn about the day-to-day practice of health law.

In the Spring, SHLO cosponsored, with the Law School's Career Development Office, the annual Health Law Career Fair which attracted a variety of prospective employers from government departments, in-house hospital counsel, boutique and medium-sized law firms, public interest groups, and private corporations.

SHLO is proud to announce that in March 2002, the University of Maryland became the first student health law organization to sign an affiliation

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IN THE CIVIL RIGHTS OF INDIVIDUALS WITH DISABILITIES

CLINIC

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 an interest in health law, the clinic represents clients in cases involving health care for children, legal issues of the disabled, mental illness, AIDS and the elderly. This issue's article is written by the instructor teaching the Civil Rights of Individuals with Disabilities Clinic.



by Marc Charmatz, JD

This past spring semester, student-attorneys in the Civil Rights of Individuals with Disabilities Clinic, had the opportunity to meet Mr. Joseph Heard, a deaf man, at the National Association of the Deaf (NAD) Law Center. Mr. Heard is represented by private counsel and attorneys at the NAD Law Center. Sign language interpreters were present. Mr. Heard has a complaint pending in a federal district court against the District of Columbia government and the District of Columbia Department of Corrections.

In October 1999, Mr. Heard was arrested in the District of Columbia on minor charges, which were eventually dismissed by a D.C. judge, and Mr. Heard was ordered released from custody. However, Mr. Heard was transported back to the D.C. jail without supporting documentation. For the next 670 days, Mr. Heard was held in solitary confinement by the District of Columbia at the District of Columbia Jail Mental Health Unit without any charges pending against him or any outstanding detainers against his release. The student-attorneys drafted

interrogatories and a request for production of documents.

This is one example of the learning experiences of the seven student-attorneys in the Civil Rights of Individuals with Disabilities Clinic. Four of the student-attorneys traveled each week to the NAD Law Center in Silver Spring. Three student attorneys worked at the Maryland Disability Law Center (MDLC) in Baltimore. Their outstanding work, chronicled in weekly time logs reflects practical legal knowledge gained and legal advice imparted to many individuals with disabilities. Along the way, two public interest organizations benefitted tremendously from this invaluable resource – student attorneys, under the supervision of the University of Maryland School of Law, attorneys at the NAD Law Center and MDLC, actively participating in a public interest practice.

The practice of the student-attorneys working in the Civil Rights of Individuals with Disabilities Clinic included:

- Researching and drafting a successful response to a motion to dismiss

dealing with the definition of public accommodation under Title III of the Americans with Disabilities Act and procedural issues;

- Investigating a shopping mall for failure to have TTY (telecommunication devices for the deaf) available along with public pay telephones (as a result, the shopping mall agreed to install a TTY);

- Corresponding with clients and Department of Justice (DOJ) officials in connection with pending Americans with Disabilities Act complaints filed with DOJ;

- Advising parents of a student regarding the school district's obligation under the Individuals with Disabilities Education Act to provide and pay for a hearing aid;

- Representing a client at a clinical review panel hearing regarding forced medication;

- Researching charitable immunity in a complaint against a hospital that failed to provide interpreter services to ensure effective communication with a deaf patient;

- Researching issues regarding Medicare and Medicaid, residential treatment, intermediate care facilities, and developmental disabilities; and

- Interviewing and providing legal advice to clients having complaints about employment discrimination and access to public accommodations.

At weekly meetings, the class jointly reviewed and analyzed the student

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L&HCP Faculty Notes . .

ASSOCIATE DEAN DIANE HOFFMANN

Publication:

"Law Ethics and Gender in Medicine: Undertreating Pain in Women: A Risky Practice," 5 The Journal of Gender-Specific Medicine 10 (2002)

Selected Presentations:

"Genetic Testing and the Law: Science Fiction v. Real Life," Conference on Genetic Testing and Public Policy: Preparing Health Professions, sponsored by the Secretary's Advisory Committee on Genetic Testing, Baltimore, Maryland (2002)

"Putting Mediation in the Elder Law Repertoire," National Academy of Elder Law Attorneys Symposium, Hyatt Regency, Baltimore, Maryland (2002)

"State Medical Boards' Attitudes and Practices Toward Physician Prescribing of Opioids," Mayday Scholars Program, Saint Louis University, Saint Louis, Missouri (2002)

"Legal Issues in End of Life Care – Futility and Pain Treatment," Symposium on End of Life Care, Sinai Hospital, Baltimore, Maryland (2001)

PROFESSOR DAVID A. HYMAN

Publications:

"Two Cheers For Employment-Based Health Insurance," (with Mark Hall) 2 Yale J. Health Policy, Law, & Ethics 23-57 (2001)

"You Get What You Pay For: Result-Based Compensation for Health Care," (with Charles Silver) 58 Washington & Lee L. Rev. 1427-1495 (2001)

Selected Presentations:

"You Get What You Pay For: Result-Based Compensation For Health Care," Carolina Seminar on Law and Public Policy, University of North Carolina Schools of Law & Public Policy, Chapel Hill, North Carolina (2002)

"Medical Malpractice: What Do We Know And What (If Anything) Should We Do About It?" What we Know and Don't Know About the Impact of Legal Services on the American Economy and Policy Conference, University of Texas School of Law, Austin, Texas (2002)

"Why Doesn't Medicare Care About Quality? Conference on Quality Health Care: Can We Identify It? Can We Achieve It?" University of Chicago School of Law, Chicago, Illinois (2001)

"Access to 'Free' Health Care: Restructuring the Safety Net," Cato Institute, Washington, DC (2001) (available on http://www.law.umaryland.edu/fac_hyman.asp)

ASSOCIATE PROFESSOR JOAN O'SULLIVAN

Publication:

"Informed Consent for Medication in Persons with Mental Retardation and Mental Illness," with Breck Borcharding, MD, Symposium: Barriers to Access to Health Care, Case Western Reserve, 12 Health Matrix 63 (2002)

Selected Presentations:

"Two Guardianship Cases: In Re: Sonny E. Lee and DHMH v. Minnie Campbell," Maryland State Bar Association, Elder Law Section, Baltimore, Maryland (2002)

"Challenges in Issues of Consent for Health Care for People with Developmental Disabilities," The Elizabeth M. Boggs Center on Developmental Disabilities, UMDNJ, The Robert Wood Johnson Medical School, Piscataway, New Jersey (2002)

"Surrogacy, the Health Care Decisions Act and Guardianship," Developmental Disabilities Administration, Laurel and Owings Mills, Maryland (2002)

Panelist, "Legal and Ethical Issues in the Progression of Dementia," National Aging and the Law Conference, Arlington, Virginia (2001)

ASSISTANT PROFESSOR THOMAS E. PÉREZ

Publication:

"The Civil Rights Dimension of Racial and Ethnic Disparities in Health Status," Institute of Medicine, National Academies of Science Press (2002)

Selected Presentations:

"Ensuring Access to Health Care for People with Limited English Skills," Annual Conference, National Health Law Program, Washington, DC (2001)

"Legal Framework Surrounding Cultural Competency in Health Care," American Public Health Association Annual Conference, Atlanta, Georgia (2001)

DEAN KAREN ROTHENBERG

Awards:

Honorary Fellow of the American College of Legal Medicine (2002)

Publications:

"Building Community, Recognizing Dignity: Beyond the ADA," with Professor Alan Hornstein) 25 Mental & Physical Disabilities Law Reporter 709 (2002)

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Selected Presentations:

"Grimes v. Kennedy Krieger Institute: Implications of the Decision – The Duty of Researchers," at the Research with Children: The New Legal and Policy Landscape Conference, University of Maryland Baltimore, Baltimore, Maryland (2002)

"Counseling and Confidentiality," and "Access and Availability Questions," Human Genome Project Colloquium: Challenges for Genetic Counseling & Testing, Washington University School of Law, St. Louis, Missouri (2002)

Panelist, "Biology, Destiny, Responsibility," Fred Friendly Seminars, "Our Genes/Our Choices," Washington, DC (2002)

"Consequences of Civil Actions in Human Subjects Research," Department of Health and Human Services, Meeting of the National Human Research Protections Advisory Committee, Bethesda, Maryland (2002)

Workshop Presentation "Beyond the Beginning: The Future of Genomics," National Human Genome Research Institute, Airlie, Virginia (2001)

Panelist, "Health Care Law and Litigation," 4th Annual Advanced ALI-ABA Course of Study, Washington, DC (2001)

**ASSISTANT PROFESSORS
LAWRENCE SUNG AND MARY
WEBSTER**

Selected Presentations:

"Partly Sunny or Partly Cloudy: A Forecast for Public Access to Genetic Information," The National Human Genome Research Institute, Bethesda, MD (2002)

**PROFESSOR
DEBORAH WEIMER**

Selected Presentation:

"New Research Issues: Aids Research and Children" at the Research with Children: The New Legal and Policy Landscape Conference, University of Maryland Baltimore, Baltimore, Maryland (2002)

**PROFESSOR
ROGER C. WOLF**

Selected Presentation:

"Putting Mediation in the Elder Law Repertoire," National Academy of Elder Law Attorneys Symposium, Hyatt Regency, Baltimore, Maryland (2002)

2002 Graduates Receive Certificate in Health Law

On May 24, 2002, twenty-six students were awarded the L&HCP's *Health Law Concentration* Certificate upon graduation from the School of Law. Students receiving this certificate satisfied requirements including health law course work, participation in health law seminars, experiential learning, and completion of a substantial health law paper.

Many of the students who received the Certificate have backgrounds in health care, knew they wanted to specialize in health law, and came to the School of Law specifically for the L&HCP. Other students came to the School of Law and made the decision to complete the Certificate requirements after taking the survey courses in Law & Medicine and Health Law. The experiences that led these students to the L&HCP are as diverse and varied as the career paths they have chosen.

Fred Mohre, who will be an associate with Epstein, Becker & Green in Washington, DC, has a background in pediatric intensive care nursing. He was attracted to the L&HCP, in part, because he believes that, with the state of health care law in continual flux, practicing in this area will afford him the opportunity to "leave his mark." According to Mohre, "we live in an era, specifically an economy, that relishes specialties. Having this

certificate . . . advertises your special qualifications to practice in the health law area."

Kristy Radio came to the L&HCP with a background in psychology. After completing two health law internships in the offices of hospital in-house counsel, she will be working in compliance and risk management at the Veterans Affairs Hospital in Philadelphia as a Presidential Management Intern. According to Radio, the requirements she completed for the *Health Law Concentration* Certificate paved the way for her internships which, in turn, will help her meet her future employment goals.

Jennifer Sebor Thompson also came to the L&HCP with a background in psychology. While in law school Thompson developed an interest in the field of biotechnology and the law which she has been able to explore as a law clerk in the Northern Virginia office of Arnold and Porter. Following law school, Thompson will serve as a law clerk in the Prince George's County, Maryland, circuit court system. She notes that, not only was the course work required to obtain the *Health Law Concentration* Certificate enjoyable, because health law is an up and coming field, especially in Maryland, it was worth earning the certificate.

Prior to entering the L&HCP, **Vanessa Taneyhill** worked for 15 years in the health care industry with physicians in private practice. In addition, she is the parent of a disabled child. Taneyhill felt that the L&HCP allowed her to explore both of these elements of her background and appreciated the many elective courses and clinical offerings within the Program. She feels that the certificate, for which she completed

federal and state internships in the Medicare and Medicaid programs, combined with her previous experience, was a significant factor in her ability to secure a position after graduation with Callegary & Steedman, a Baltimore firm specializing in the representation of children with special needs.

Lucy Shum has a Masters Degree in public health. Prior to law school, she worked in hospital administration. Her post-graduation plans as an Equal Justice Works (formerly NAPIL) fellow are described in detail in the article on page 10. Shum notes that the *Health Law Concentration Certificate* was worth pursuing, as it led her to take some classes that she might not otherwise have taken, and those classes exposed her to different areas of health law. In fact, one of the reasons she chose the University of Maryland over other law schools is the strength of the L&HCP.



Secretary of Health and Human Services Tommy G. Thompson poses with Vanessa Taneyhill during her federal internship.

Steve Hudson, MD, JD, a December 2001 graduate of the L&HCP, entered the L&HCP because of his background in medicine and the outstanding reputation of the program. Hudson "was not disappointed" as he feels "able to tackle just about any health law issue, and potential employers are reassured by [his] training in the L&HCP."

The L&HCP introduced **Kelly Fitzpatrick** to "the legal and policy aspects of many important, cutting-edge issues that affect everyone's life at some point." After teaching at West Point, Fitzpatrick came to the L&HCP with an interest in bioethics and appreciates that she was able to learn from "people who are leaders in that field, such as Dean Rothenberg and Dean Hoffmann."

With a background in disability rights, **Luciene Parsley** (see article, page 10) entered the

L&HCP to better understand the health care system. Planning a career as a civil rights lawyer, Parsley believes that the training she received and courses she completed through the L&HCP will help her as she advocates for the rights of persons with disabilities.

Following graduation, **Sarah Browning** will be moving to Seattle to begin

her career as a health lawyer. Browning chose to participate in the *Health Law Concentration Certificate* program because "it offered [her] an opportunity to delve into the substantive areas [of health law] while still in school, as well as offering [her] a 'portable' way to show her experience."

Atinuke Fawole, RN, a nurse prior to beginning law school, is from a family of health care practitioners – her husband is a dentist and physician. Since law and health care issues have always been a part of their household discussions, being part of the L&HCP seemed a natural path for her law school career. Through practicing as a registered nurse, Fawole saw "first hand the great potentials of our health care system, but also the pitfalls, the waste and the abuse." Grateful for the "heads up" she feels the L&HCP provides its students, Fawole hopes to address some of these problems through a career in health care policy, especially as it relates to the elderly.



Recipients of the L&HCP's Health Law Certificate include (bottom row, left to right): Patricia Dougall, Christine McDaniel, Sarah Browning, and Lucy Shum. (Top row, left to right): Michael Pappas, Allison Guley, Kelly Fitzpatrick, Thanh Ly and Anitra Crump. Not pictured: Michael Barrett, Connie Beals, Atinuke Fawole, Joanna Fong, Anne Nichols Hill, Krista Horochena, Jean Kim, Dan McBride, Fred Mohre, Jonathan Morse, Luciene Parsley, Kristy Radio, Tamara Schmidt, Jeffrey Stickle, Vanessa Taneyhill, Jennifer Sebor Thompson, and Donald Wright. Dr. Steven Hudson received the award in December 2001.

Student Health Law Organization

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agreement with the American Health Lawyers Association (AHLA). SHLO has had a working relationship with AHLA for several years and was instrumental in drafting the affiliation agreement that other schools will use to join AHLA. SHLO also provided student volunteers at AHLA's Fall 2001 Fraud & Abuse Conference in Washington, D.C., and the Spring 2002 Medicare & Medicaid Institute on Payment Issues in Baltimore, Maryland.

Finally, SHLO's executive board amended the organization's constitution, adding new positions for board members, due to our growth over the past year and the myriad of activities planned for the upcoming academic year.

In The Clinic

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attorneys' cases and projects. During one class, we had a mock argument where student attorneys argued whether a non-profit organization was a public accommodation under Title III of the Americans with Disabilities Act.

We also had a number of guest speakers at our meetings. One former student attorney of the Civil Rights of Persons with Disabilities Clinic, who works at the Disability Rights Section of the DOJ, discussed the role of the federal government in ensuring compliance with the Americans with Disabilities Act. Another former student attorney in private practice, who handles special education matters, discussed legal advocacy on behalf of students with special education needs in administrative proceedings under the Individuals with Disabilities Education Act. An attorney in private

practice with a large law firm in Baltimore discussed pro bono services in Maryland, including representation of non-profit organizations which serve individuals with disabilities. An attorney in solo private practice described her representation of clients with disabilities in major housing and employment cases. MDLC attorneys discussed the role of the protection and advocacy system in Maryland in promoting the legal rights of individuals with disabilities throughout the state.

It continues to be an honor and privilege for me to serve as an Adjunct Professor at the University of Maryland School of Law. The dedication and hard work of the student-attorneys in the Civil Rights of Persons with Disabilities Clinic has helped promote equal and meaningful access for individuals with disabilities.

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