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Health Law Journal

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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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PACE UNIVERSITY SCHOOL OF LAW
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A Message from the Section Chair

Changes in the *Journal*

Greetings! You've already noticed the first of several changes taking place in the Health Law Section: a new look and new features in the Health Law Section *Journal*. For example, starting this issue, the *Journal* will point out recent health law developments in the NYS courts, the NYS legislature, NYS agencies and various law reviews. The *Journal* will also reproduce excerpts from important NYS governmental reports, such as a DOH-appointed task force Report on Human Subject Research. And it will carry reports by committees of the Health Law Section. These features will be in addition to the valuable substantive articles on health law topics that the *Journal* will continue to provide.

I thank our editors, Professors Barbara Atwell and Audrey Rogers of Pace Law School, for accomplishing these changes. I'd also like to thank three law firms for taking responsibility for the new regular features: Cadwalader, Wickersham & Taft; Garfunkel, Wild & Travis; and Kalkines, Arky, Zall & Bernstein.

New Section Officers

Another change is that the Section has new elected officers. I am proud to be your new Section Chair, and am delighted to be part of a strong slate of Section officers:

- Tracy E. Miller—1st Vice-Chair/Committees.
- Robert Abrams—2nd Vice-Chair/Professional Education.
- Linda J. Nenni—Secretary.
- Salvatore J. Russo—Treasurer.

I intend to use my time as Chair toward two purposes: to seek ways to better serve the Section members, and to seek ways for the Section to better serve the public. I'll speak more to both points below.

Changes in Committees

I'd contend that the most important change in the Section—and a key improvement in service to Section members—is an effort now underway to reform and revitalize the committees in the Section. Armed with four years experience (the Section was created in 1996) and the preliminary results of a membership survey developed under the leadership of my predecessor Jerry Levy and Membership Chair Robert Corcoran, we now have a clearer sense of what committees will best reflect the section membership's interests.

Accordingly, in June the Executive Committee decided to create three new committees (Fraud, Abuse and Compliance, Securing Health Care for the Uninsured and a Special Committee on Medical Information) and to close four others (Legislation, Liaison with the Health Professions, Professional Education and Public Health). The Executive Committee also identified two basic expectations for all committees: (1) each committee will meet at least three times annually; (2) each committee will identify and strive to accomplish one or more objectives annually. Moreover, we are making a concerted effort to find ways to overcome the geographic impediments to committee participation.

I am also delighted to welcome several new committee chairs to the Health Law Section. They bring with them a wealth of experience, and will add new energy and ideas to the Section:

- Biotechnology and the Law—James K. Lytle, of Kalkines, Arky, Zall & Bernstein (Albany and NYC)
- Ethics in the Provision of Health Care—Professor Larry Palmer of Cornell Law School (Ithaca)
- Fraud, Abuse and Compliance—James Horwitz of Glens Falls Hospital (Glens Falls)
- In-House Counsel—Patrick Taylor of Albany Medical Center (Albany)
- Managed Care—Frederic Bodner of Hinman, Straub, Pigors & Manning (Albany)
- Payment Issues—Ross Lanzafame of Harter, Secrest & Emery (Rochester)
- Securing Health Care for the Uninsured—Peter Millock of Nixon Peabody (Albany and NYC)
- Special Committtee on Medical Information—Anne Maltz of Stroock, Stroock & Lavan (NYC)

The full roster of committees and chairs is set forth on page 39 of the *Journal*.

Professional Education

The Section will also continue to provide you with the high level of health law professional education programs that we have become known for. The next scheduled program is "Health Law and the Internet—The Basics and Beyond: A Must for Health Law Practitioners," which will be at four locations in November and December. A program is also being planned on Managed Care for the January NYSBA annual meeting. Our periodic Health Law Primer and Update will be held in spring 2000. Other programs are under discussion as well.

Section Website

The Section's website is yet another area being enhanced. We want to make this a more useful tool for members, to do a better job of keeping it up-to-date, and to add new features. For example, we are looking into starting a listserve, which members can use to post health law questions to their colleagues throughout the state, and to contribute responses. But we need a website editor, and want to recruit a health care lawyer who will take on this task. Any volunteers?

Serving the Public

As I mentioned earlier, the Section leadership also plans to promote ways for the Section to better serve the public. For example, our Consumer / Patients Rights Committee, chaired by Jeff Gold and Susan Slavin, will continue to develop a program under which attorneys provide pro bono advice to managed care enrollees who have coverage disputes with their HMOs.

Moreover, I am especially proud to note that the Section has just created a new Committee on Securing Health Care for the Uninsured. The purpose of this new, important committee is described on page 36 of this edition, along with an invitation to join it.

Get Involved

This is an exciting, dynamic time to practice health law, and an exciting, dynamic time to participate in the NYSBA Health Law Section. I urge you to join a committee, and take the initiative on a committee project. Contribute an article to our *Journal*. Get involved.

And while you are at it, fill out the survey form posted on the Section's website (www.nysba.org/sections/health) to give us more data on how to better serve the members. In fact, feel free to send me your ideas directly as well. My e-mail address is swidlerr@nehealth.com. I look forward to hearing from you.

Robert N. Swidler

Important Announcement to All Health Law Section Members

Due to the fact that anticipated legislation was not passed as expected, the seminar entitled *Protecting Health Information and Technology: New Requirements and Risks*, originally scheduled for this fall, is going to be temporarily postponed. The following half-day program has been substituted in its place:

Health Law and the Internet—The Basics and Beyond: *A Must for Health Law Practitioners*

Friday, November 5, 1999	Melville, L.I.
Friday, November 19, 1999	Albany
Friday, December 3, 1999	New York City
Friday, December 3, 1999	Rochester

To register or for more information call toll free 1-800-582-2452. In Albany and surrounding areas dial (518) 463-3724. Or fax your request to (518) 487-5618. Internet Connection: http://www.nysba.org

For more information on the program, please see page 17.

In the New York State Courts

Medical Providers Not Exempt From Consumer Fraud Statute

Karlin v. IVFA, 93 N.Y.2d 282 (1999). In a ruling of first impression, the Court of Appeals held that General Business Law §§ 349 and 350 (prohibiting deceptive trade practices and false advertising) can apply to providers of medical services.

The Karlins were treated at an in vitro fertilization program managed by a corporate entity and operated at a New York hospital (the "Program"). Despite undergoing numerous in vitro fertilization cycles, Mrs. Karlin never became pregnant. The Karlins, as representatives of a putative class of patients treated at the Program, sued the corporate owners of the Program, the hospital at which it was operated, and the physician who treated them. The lawsuit alleged that the Program had disseminated, through brochures and seminars, false statistics that inflated the actual success rate in making infertile couples pregnant. Accordingly, the Karlins alleged that the Program had engaged in false advertising and deceptive practices prohibited by GBL §§ 349 and 350.

Reversing an appellate division decision that exempted medical providers from the consumer fraud sections of the General Business Law, the Court of Appeals focused on allegations that the Program's promotional materials (i.e., brochures and seminars) "contained misrepresentations that had the effect of deceiving and misleading members of the public." Based on this alleged conduct, the Court held that healthcare providers who "choose to reach out to the consuming public at large to promote business—like clothing retailers, automobile dealers and wedding singers—subject themselves to the standards of an honest marketplace," and may be found liable under the General Business Law.

Entirety of Proceeds of Personal Injury Suit Is Available To Satisfy Medicaid Lien

Calvanese v. Calvanese, 93 N.Y.2d 111 (1999). In settlement of a personal injury case, the parties allocated the entire settlement proceeds to pain and suffering, in an attempt to avoid outstanding Medicaid liens. The Court ruled that the entire amount of the proceeds of a personal injury settlement is available to satisfy a Medicaid lien for services provided to persons over the age of 21, not just that portion of the settlement allocated to past medical expenses. Thus, parties may not defeat or compromise a Medicaid lien by allocating settlement proceeds as payment for pain and suffering. The Court also ruled that Medicaid liens must be satisfied before any part of the settlement proceeds can be transferred to a supplemental needs trust.

Hospital Not Vicariously Liable For Alleged Sexual Abuse of Patient

Judith M. v. Sisters of Charity Hospital, 1999 WL 353069 (Ct. of Appeals June 3, 1999). Affirming a decision rendered by a sharply divided appellate division, the Court of Appeals recently held that a patient could not hold a hospital vicariously liable for alleged sexual abuse by a hospital employee. The patient claimed that the hospital, as the employer of the alleged perpetrator, was vicariously responsible under the legal doctrine of *respondeat superior*.

The Court found the hospital could be held vicariously liable only if the employee's conduct was within the scope of employment. Sexual abuse of a patient, ruled the Court, was such a departure from the employee's duties and so unrelated to furtherance of the hospital's business that no vicarious liability could be found.

ERISA Does Not Preempt Malpractice Claims Against HMO Primary Care Physician

Nealy v. U.S. Healthcare, 93 N.Y.2d 209, 689 N.Y.S2d 406 (1999).

See article on *Nealy* in this issue of the Health Law Journal.

Podiatrist's "Whistleblower" Suit Dismissed; Related Claims Waived; Attorney's Fees Awarded to Defendants

Rotwein v. Sunharbor Manor Residential Care Facility, 1999 WL 639853 (Sup. Ct., New York Co. July 15, 1999). Plaintiff was an attending podiatrist at a nursing home. The nursing home terminated plaintiff's privileges for failure to follow its policies. Plaintiff sued the nursing home, its administrator, and its medical director for (1) unlawful retaliatory discharge under Labor Law § 740 (the New York "whistleblower" statute), (2) breach of contract, (3) breach of bylaws and (4) defamation. Nearly two years after filing suit, plaintiff moved for leave to discontinue his § 740 claim. Defendants cross-moved for summary judgment dismissal of plaintiff's lawsuit in its entirety. Defendants argued that by filing the § 740 claim, plaintiff waived his right to assert other claims arising out of his termination, and plaintiff could not avoid the waiver effect of Labor Law § 740(7) by discontinuing the claim. Plaintiff argued that his voluntary discontinuance of the § 740 cause of action negated the waiver effect of § 740(7).

The Court denied plaintiff's request to withdraw the § 740 claim and instead dismissed it with prejudice. One of the grounds for dismissal was the lack of an employer-employee relationship, in that the plaintiff podiatrist was a member of the nursing home's attending staff but was not employed by the nursing home. The Court also held that, as a matter of law, the alleged billing

improprieties plaintiff claimed to have opposed did not support a section 740 claim, because they did not create a substantial danger to the public safety (a required element under the statute). Because this should have been clear at the beginning of the action, the Court held that defendants were entitled to an award of attorney's fees under § 740(6).

The Court also ruled that plaintiff's institution of an action containing a Labor Law § 740 claim resulted in a waiver of claims related to his termination, and that plaintiff's attempt to discontinue the § 740 claim did not nullify the waiver. The Court found that plaintiff's claims for breach of contract and breach of bylaws were related to the termination, and thus were waived.

The Court found that plaintiff's defamation claims were not waived, as they were based on the nursing home; response to a credentialing inquiry from a hospital several months after plaintiff's termination, and thus were not related to the termination. However, the Court dismissed the defamation claims on numerous other grounds, including statutory immunity conferred by Public Health Law § 2805-k. PHL § 2805-k immunizes good faith communications from hospitals and nursing homes in response to inquiries from other hospitals or nursing homes as to the status of a practitioner's professional privileges.

Examination Room in Private Doctor's Office Not Public Facility Under New York Civil Rights Law

Albert v. Solimon, 684 N.Y.S.2d 375 (4th Dep't 1998). A disabled patient who used a "service dog" sued physician for violation of New York Civil Rights Law § 47, which prohibits discrimination in "public facilities" against persons requiring accompaniment of a "guide dog, hearing dog, or service dog." The patient alleged that the defendant physician yelled at her in his examination room and refused to treat her because she had taken her service dog with her into the examination room.

The Court ruled that Civil Rights Law § 47 was not applicable because an examination room in a physician's private office was not a public facility, even though the office itself could be so considered. The Court found inapplicable *Cahill v. Rosa*, in which the Court of Appeals ruled that a private dentist's office was a public facility under New York Executive Law § 292 (prohibiting discrimination in a public facility against, inter alia, persons with a disability). *Albert* has been appealed to the Court of Appeals, and is scheduled for argument in September 1999.

Hospital Quality Management Report Exempt From Disclosure

Spradley v. Pergament Home Centers, 1999 WL 275702 (2d Dep't 1999). In this personal injury action, the trial court granted plaintiff's motion to compel non-party hospital to produce its quality management department report and file that assessed the medical care provided to plaintiff. The appellate division reversed, ruling that the quality management report was exempt from disclosure under Education Law § 6527(3); and that the underlying file should have been reviewed by the court *in camera* to determine which documents were similarly protected by the statute.

Psychiatric Hospital Incident Reports Exempt From Disclosure

Katherine F. v. State of New York, 684 N.Y.S.2d 243 (1st Dep't 1999). Plaintiff, a patient in a psychiatric hospital, filed a personal injury suit based on allegations of sexual abuse by a hospital staff member. Plaintiff sought pretrial discovery of the hospital's investigation files (including incident reports, an investigative report, and a safety department report). The Court of Claims directed production of the files for *in camera* inspection.

The appellate division reversed, ruling that Education Law § 6527(3) and Mental Hygiene Law § 29.29 protect from disclosure not only records relating to performance of a medical or quality assurance review function, but also "reports required by the Department of Health pursuant to Public Health Law § 2805-l . . . including the investigation of an incident pursuant to section 29.29 of the Mental Hygiene Law." Accordingly, the Court held exempt from disclosure the documents created by the hospital concerning its investigation of alleged sexual abuse of a patient by a hospital staff member.

All Incident Reports Required By Mental Hygiene Law Are Exempt From Disclosure

Finnegan v. State of New York 179 Misc.2d 694, 686 N.Y.S.2d 589 (Ct. of Claims, 1999). Under Education Law § 6527(3), exemption from discovery for incident reports required under Mental Hygiene Law § 29.29 is not limited to reports concerning malpractice or misconduct, but applies broadly to all types of incident reports.

Hospital Not Vicariously Liable For Acts Hospital-Based Radiology P.C.

Culhane v. Schorr, 686 N.Y.S.2d 105 (2d Dep't 1999). Patient's survivor sued for medical malpractice injuries, alleging negligent failure to detect, diagnose and treat recurrence of patient's cancer. Plaintiff sued the patient's treating physician, the hospital where patient was first admitted, and the radiology laboratory where subsequent CAT scans were performed.

The hospital moved for summary judgment arguing that it had not rendered any medical treatment to the patient; instead, all treatment was rendered by the affiliated, but non-employed physician, and by the

radiology laboratory. The hospital asserted that on those facts, it could not be held vicariously liable for the physician's or the lab's negligence.

The appellate division agreed and reversed the Supreme Court's order denying summary judgment. The Court found that although the patient was admitted through the hospital's emergency room, the suit was based on follow-up visits to monitor the cancer, not the initial emergency room visit, and there was no proof that the patient believed he was receiving care from the hospital.

The Court also held that the hospital was not vicariously liable for the alleged medical malpractice of the radiology professional corporation that provided services at the hospital, because the hospital did not exercise direction or control over the radiology laboratory.

Hospital's Compliance With Peer Review Laws Is Not State Action

Croy v. A.O. Fox Memorial Hospital, 1999 WL 342796 (N.D.N.Y. 1999). Plaintiff, a licensed psychiatrist previously employed by contract with the defendant hospital, sued the hospital, alleging defamation, negligent misrepresentation, and violation of 42 U.S.C. § 1983. Plaintiff's claims were based on reports made by the hospital to the Alaska State Medical Board and the Kansas State Medical Board in response to their requests for information after plaintiff applied for licensure in those states. The hospital and the individual administrators moved for summary judgment.

The Court dismissed plaintiff's 1983 claim because the hospital was not acting under color of state law in responding to medical board inquiries. The Court held that New York's "peer-review" statutes "are insufficient to convert the Hospital's conduct in this matter into state action."

The Court also dismissed the plaintiff's defamation and negligent misrepresentation claims against the hospital administrators, based on (i) the "common interest" qualified privilege; and (ii) the qualified immunity provided by New York Education Law § 6527(5). The Court held that the communications to the medical boards were made in the scope of the individual's duties, and were to persons who have a common interest in the subject matter. Accordingly, both the common law privilege and the statutory immunity applied, plaintiff having provided no proof that the communications were made with malicious intent.

Court Upholds Revocation of Physician's License

Larkins v. DeBuono, 682 N.Y.S.2d 732 (3d Dep't 1999). A hearing committee and the Administrative Review Board (AARB) of the State Board for Professional Medical Conduct voted to revoke a physician's medical license, based on findings that the practitioner engaged in a pattern of ordering tests that were not medically indicated, and failed to maintain proper medical records. The Court held that expert testimony to the contrary merely raised credibility issues that the AARB was free to resolve.

The Court also held that the standard for determining if the penalty of revocation was too severe is "whether it is so incommensurate with the offense as to shock one's sense of fairness." In this case, the Court held that findings of a pattern of medically unindicated tests and treatments, and failure to maintain appropriate patient records, supported the penalty of license revocation.

Compiled by Leonard Rosenberg, Esq. Mr. Rosenberg is a partner in the firm of Garfunkel, Wild & Travis, P.C., a full service health care firm representing hospitals, health care systems, physician group practices, individual practitioners, nursing homes and other health-related businesses and organizations. Mr. Rosenberg's practice is devoted primarily to litigation, including medical staff and peer review issues, employment law, disability discrimination, defamation and directors' and officers' liability claims.

In the New York State Legislature

On August fifth, the New York State Legislature concluded (at least for now) one of the longest legislative sessions in its history, prolonged primarily as a result of a four month standoff in reaching agreement on the state budget. In the health care arena, several major issues have not yet been addressed by the legislature, including the allocation of the proceeds of the tobacco settlement, the governor's program legislation that revamps the states's assisted living program and a host of bills that would have established new requirements governing insurers' and health maintenance organizations' payment practice and financial status. The legislature is, in addition, expected to return this fall to consider, among other things, the extension and/or revision of the Health Care Reform Act (HCRA), which is scheduled to expire at the end of this year. HCRA governs the now largely deregulated hospital reimbursement system, establishes funding for graduate medical education and indigent care and otherwise has a profound impact on health care finance in New York State.

Among the more significant bills enacted by the legislature was "Kendra's Law" (A8477A/S4536A), which will permit courts to order outpatient treatment to mentally ill individuals who have not complied with treatment and who satisfy certain other criteria, including a history of serious violent behavior toward themselves and others. If the patient fails to comply with treatment ordered by the court, a physician may seek involuntary commitment of the patient.

A summary of other bills that passed both houses and await the governor's action follows:

- **A194-C/S5328-B.** The bill makes technical corrections with respect to the allocation of funds to the spinal cord injury research trust fund; provides that such fund shall be credited with an amount, not to exceed $8.5 million, from monies collected by the mandatory surcharge imposed upon persons convicted of a felony or misdemeanor alcohol- or drug-related driving offense; provides that monies shall be payable from such fund on vouchers approved by the commissioner of taxation and finance, rather than the commissioner of health.
- **A921/S4055.** The bill requires continuing health insurance coverage for full-time students on a medical leave of absence for up to one year; requires medical documentation of the illness requiring a leave of absence; premiums for coverage must be at the same rate as if the student was still in school.
- **A4152-A/S2824-A.** The bill directs the commissioner of health to establish a program for the screening of newborn infants for hearing problems; makes related provisions.
- **A4600-A/S982-A.** The bill requires children entering any public, private or parochial child caring center, day nursery, day care agency, nursery school, kindergarten, elementary, intermediate or secondary school to be immunized against varicella (chicken pox).
- **A5600-A/S1502-A.** The bill provides that mental health services provided by certified voluntary free-standing day treatment programs to medical assistance recipients shall not be provided through managed care programs and shall continue to be provided outside of managed care programs and in accordance with applicable reimbursement methodologies.
- **A6509-A/S2937-A.** The bill makes provisions for health care insurance and HMO coverage to include coverage for acute care facilities or programs specializing in treatment of terminally ill patients; provides for external review of disputes.
- **A6909-A/S1922-A Chapter 397.** The bill authorizes pupils afflicted with asthma to carry an inhaler during the school day if authorized by a physician or other health care provider.
- **A6955-A/S4585-B.** The bill makes provision for coverage for services by non-participating home facilities which are facilities not participating in the network of the provider; makes related provisions on rates for such services and scope of services.
- **A7225-A/S5160-A.** The bill authorizes the waiver of penalties and interest in respect to certain assessments against hospitals.
- **A7631-A/S4537-A.** The bill authorizes insurers to issue stop-loss policies to employers who provide self-insured health benefit plans for their employees; specifies what such policy shall describe; authorizes rules and regulations by the superintendent of insurance.
- **A7886-A/S4597-A.** The bill provides office of professional medical conduct access to criminal information when investigating a licensee.
- **A7963/S5086 Chapter 151.** The bill extends expiration date to July 31, 2001, for chapter 693 of the laws of 1996, relating to authorizing patient discharge to hospices and residential health care facilities, under the medical assistance presumptive eligibility program.
- **A7965/S4925 Chapter 152.** The bill extends provisions relating to

authorizing bad debt and charity care allowances for diagnostic and treatment centers and certified home health care agencies.

- **A8157-A/S4511-A.** The bill requires children to be immunized against hepatitis B prior to enrollment in the seventh grade when such enrollment occurs on or after September 1, 2000.
- **A8320-A/S5462-B.** The bill enacts the long-term care resident and employee immunization act; requires every employee of a long-term care facility to be immunized against influenza and pneumococcal disease.
- **A8426/S4536.** The bill authorizes the provision of hospice supplemental financial assistance to persons receiving care in hospice residences.
- **A8477-A/S5762-A.** The bill enacts "Kendra's Law"; enhances the supervision and coordination of care of persons with mental illness in community-based settings by providing assisted outpatient treatment; provides for the establishment of assisted outpatient treatment as a permanent mode of treatment, improved coordination of care for mentally ill persons living in the community, the expansion of the use of conditional release in psychiatric hospitals and the improved dissemination of information between and among mental health providers and general hospital emergency rooms.
- **A8551/S5712 Chapter 303.** The bill permits NYS medical care facilities finance agency to lease or purchase one or more health facilities financed through loans secured by an existing local development corporation.
- **A8685-B/S4591-A.** The bill authorizes use of epinephrine auto-injector devices under prescribed circumstances; limits liability for their use by emergency health care provider; makes related provisions.
- **A8686/S4869-A.** The bill directs the commissioner of health to develop educational materials on the diagnosis, treatment and prevention of hepatitis C for health care professionals and persons at high risk for contracting hepatitis C.
- **A8851/S5936.** The bill implements the master settlement agreement provisions governing non-participating tobacco manufacturers.

Compiled by James W. Lytle, resident partner, and Ami Schnauber, legislative coordinator, from the Albany office of Kalkines, Arky, Zall & Bernstein, LLP, a firm that devotes a substantial part of its practice to health care and government relations.

In the Agencies

The New York State Department of Health has promulgated five regulations of note since January 1999:

- **External Appeal Program.** This adds a new subpart 98-2 to title 10 NYCRR, and implements the External Appeal Program enacted as chapter 586 of the laws of 1998, which amended article 49 of the Public Health Law. The legislation and these regulations give enrollees of heath care plans the right to an external appeal to review adverse determinations with regard to medical necessity or experimental and investigational treatments. The appeal is available to members of licensed health care plans, but not to those associated with self-insured plans or Medicare (which already has an external review program in place). Appeals will be reviewed by external appeal agents at the New York State Insurance Department (SID) upon completion of an application within 45 days of an adverse determination by the health care plan's internal reviewer, unless both the patient and the plan waive the internal appeal process. Filing date: June 21, 1999. Effective date: June 21, 1999. *See* NYS Register, July 7, 1999.

- **Methadone Maintenance Treatment Programs No Longer Preferred.** This enactment effectively repeals the regulation permitting physician-sponsored methadone maintenance treatment programs to qualify as preferred providers and receive enhanced Medicaid rates. The DOH delayed the new regulation's effective date to give providers of this treatment ample time to modify its services and arrange for new sources of reimbursement. Filing date: June 9, 1999. Effective date: 180 days after publication. *See* NYS Register, June 30, 1999.

- **Radiation Output for Fluoroscopic X-ray Systems.** A new amendment to title 10 NYCRR places limits on the radiation output for fluoroscopic X-ray systems in order to reduce the risk of radiation injury. Filing date: May 11, 1999. Effective date: May 26, 1999. *See* NYS Register, May 26, 1999.

- **Expedited HIV Testing of Women and Newborns.** These new regulations amend §§ 58-8.1—58-8.3 and 69-1.3 of title 10 NYCRR, pursuant to the authority of §§ 2500-a, 2500-f and 576 of the Public Health Law. The amendments require hospitals to perform HIV tests on newborns whose mothers were not tested during pregnancy and to report the results within 48 hours of birth to the mothers. Filing date: April 29, 1999. Effective date: August 1, 1999. *See* NYS Register, May 19, 1999; December 23, 1998.

- **Schedule II and Certain Other Controlled Substances/ Pharmacists.** This recent amendment of §§ 80.67, 80.69, 80.73 and 80.74 of title 10 NYCRR, pursuant to the authority of § 3308(2) of the Public Health Law, allows pharmacists to complete certain missing information on official New York State Prescriptions. Among the categories of information that pharmacists are entitled to modify is the "quantity" of the prescription. In fact, the DOH reports that the intent of the enactment is to "allow pharmacists, with authorization of a practitioner, to change information such as directions for use or dosage . . ." Filing date: May 4, 1999. Effective date: May 19, 1999. *See* NYS Register, May 19, 1999.

Compiled by Francis J. Serbaroli, Esq. Mr. Serbaroli is a partner in Cadwalader, Wickersham & Taft's 20-attorney health law department. He is the Vice Chairman of the New York State Public Health Council, writes the "Health Law" column for the *New York Law Journal*, and serves on the Executive Committee of the New York State Bar Association's Health Law Committee. He is the author of a forthcoming book entitled "The Corporate Practice of Medicine Prohibition in the Modern Era of Health Care" to be published later this year by BNA as part of its Business and Health Portfolio Series.

In the Law Journals

1. Brett Schlossberg, *The Bankruptcy of Allegheny Health System and Its Consequences*, 32 J. of Health Law 155 (Winter '99).
2. Lisa M. Kerr, *Can Money Buy Happiness? An Examination of the Coverage of Infertility Services Under HMO Contracts*, 49 Case W. Res. L. Rev. 599 (1999).
3. John V. Jacobi, *Canaries in the Coal Mine: The Chronically Ill in Managed Care*. 9 Health Matrix: J. of Law-Medicine (Winter '99).
4. P.L. Brown, *Contracting on Behalf of Physicians: Some Considerations in the Age of Managed Care.* 45 Prac. Law 69 (March '99).
5. Nichole J. Starr, *The Conversion and Settlement of Georgia Blue: Are Consumer Groups Still Singing the Blues?* 32 J. of Health Law 115 (Winter '99).
6. Shelley A. Sackett, *Conversion of Not-For-Profit Health Care Providers: A Proposal for Federal Guidelines on Mandated Charitable Foundations*. 10 Stan. L. & Policy Rev. 247 (1999).
7. Dwayne A. Banks, Stephen E. Foreman, Theodore E. Keeler, *Cross Subsidization in Hospital Care: Some Lessons From the Law and Economics of Regulation*. 9 Health Matrix: J. of Law-Medicine (Winter '99).
8. Joel Ferber and Jo Anna King, *A Cure for the Blues: Resolving Nonprofit Blue Cross Conversions*. 32 J. of Health Law 75 (Winter '99).
9. Wm. Horton and F. Hampton McFadden, Jr., *Disclosure Obligations of the Newly Public Healthcare Company: Practical Strategies for the Company and Its Counsel*. 32 J. of Health Law 1 (Winter '99).
10. Elizabeth M. Apisson, *Double Jeopardy and the Civil Monetary Penalties Dilemma: Is Hudson the Cure for Health Care Fraud and Abuse?* 51 Admin. L. Rev. 283 (1999).
11. Mary Terrell White, *Guidelines for IRB Review of International Collaborative Medical Research: A Proposal.* 27 J. of Law, Medicine and Health Care 87 (Spring '99).
12. J. Murray, *Disclosure of Corporate Compliance Matters By Healthcare Providers.* 45 Prac. Law 45 (March '99).
13. *Electronic Medical Information: Privacy, Liability and & Quality Issues* (special edition—ten articles). 25 Am. J. of Law and Medicine 191 (1999).
14. J. K. Locke, *The ERISA Amendment: A Prescription to Sue MCOs for Wrongful Treatment Decisions.* 83 Minn. L. Rev. 1027 (April '99).
15. Jane M. Mulcahy, *The Erisa Pre-Emption Question: Why Some HMO Members Are Dying for Congress to Amend ERISA*. 82 Marq. L. Rev. 877 (1999).
16. Linda C. Fentiman, *Health Care Access for Children With Disabilities*. 19 Pace L. Rev. 245 (Winter '99).
17. Patricia I. Carter, *Health Information Privacy: Can Congress Protect Confidential Medical Information in the "Information Age?"* 25 Wm. Mitchell L. Rev. 223 (1999).
18. Frank Serbaroli, *Health Law: Areas of Career Specialization.* N.Y. Law J., March 31, 1999 at 1. Health law symposium. 43 St. Louis U. L.J. 1 (1999).
19. Joseph C. Mandarino, *Intermediate Sanctions Flow Charts*. 32 J. of Health Law 169 (Winter '99).
20. *The Judicial Legitimization of Horizontal Price-Fixing Among Partially Integrated Health Care Providers: An Antitrust/Health Care Case Study.* 50 Ala. L. Rev. 465 (1999).
21. Thaddeus Mason Pope, *The Maladaption of* Miranda *to Advance Directives: A Critique of the Implementation of the Patient Self Determination Act.* 9 Health Matrix: J. of Law-Medicine (Winter '99).
22. B.J. Caveny, *Managed Care and Emergency Care: Issues of Access, Compatibility, and Regulation.* 45 Med. Trial Tech. Q. 177 ('99).
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'Net Worth

By Margaret Moreland Murray

What are the functions of law firm web pages? Are they public relations tools? Do they also satisfy a legal research function for clients, researchers and other attorneys? In this issue I will briefly describe several websites that might be interesting models for other firms. Additionally, some of these contain useful research data. If you think that your web site should be included in a future column, please send the Internet address to: mmurray@lawlib.law.pace.edu.

Venable, Baetmer and Howard, http://www.venable.com

This is a large law firm that uses their Internet presence primarily to promote its practice. Their web site, which has received a great deal of praise, is comprehensive and well organized. It gives an overview of the firm and recruitment information, as well as descriptions of its practice areas and brief biographies of the attorneys. A nice feature under each practice area is "Fax Alerts." The most recent in the area of health care were "Severe Sanctions for Dealing with Excluded Individuals or Entities" (4/13/99) and "Courts Continue to Hold Certain HIV-Positive Health Care Workers Not Protected by Federal Disability Discrimination Laws" (11/2/98). This firm highlights the activities of its attorneys. It lists their pro bono work, presentations and articles (with links to full text - for example, "OIG Compliance—Guidance for Hospitals" dated 2/98). Additional articles can be found in its newsletters under "Press," with press releases about the firm and its attorneys.

Latham & Watkins, http://www.lw.com

Latham and Watkins is another large law firm that makes excellent use of its website to market itself. The home page lists areas to explore, beginning with "firm overview" and "departments," has links to documents and press releases, and highlights its specialty practices. With regard to its health care practice there is a ten "page" profile, links to seminars featuring speakers from the firm, press releases, and articles written by firm attorneys. Many publications are included in full text format: Client Alerts (i.e., "Latham & Watkins Obtains Favorable Advisory Opinion 98-9: Practical Application of Employee Exemption and Safe Harbor"), Reprinted Articles and a firm newsletter published by the various practice groups. Most interesting, Latham and Watkins has developed an Internet-based system to aid their clients in implementing regulatory compliance programs. This area includes web access to compliance guidelines, policies, procedures and model documents.

Arent Fox, http://www.arentfox.com/

This international law firm has created an excellent research source, as well as a marketing tool. The website contains many of the usual sections, such as a firm brochure, attorney biographies and employment information, but also includes innovative features. The firm hosts seven interactive discussion forums "for the exchange of ideas and issues," including general law, advertising law, environmental law and patent law. It also provides an Interactive Client Tour allowing browsers to interact directly with a sampling of their client base. In terms of research, Arent Fox also publishes "Features of the Month"—some designed to show their expertise in particular practice areas (public finance and antitrust) and others that provide comprehensive, current information in developing legal areas (telemedicine, counterfeiting remedies, etc.). Previous features are continually updated. Other firm publications include newsletters, alerts and employment law brochures. The newsletters, including *Health Information Systems and Telemedicine* and *Health Law Trends*, may be subscribed to for online or regular mail delivery. The contents of current and previous issues are provided in full text format. Full-text Alerts cover all aspects of the firm's practice. Finally, Arent has begun publishing a monthly E-Tip Sheet to cover federal developments in the areas of privacy, pending legislation, licensing and trademarks, as well as international internet issues.

Crowe & Shanahan, http://www.crowe-shanahan.com

Crowe & Shanahan calls itself "The Social Security Law Group" and, not coincidentally, its website contains an comprehensive guide entitled: "What You Should Know about Your Social Security Disability Case." The guide covers proof of disability, kinds of benefits, the steps in applying for disability benefits, special restrictions, how long benefits last, and the functions of a lawyer on a social security case. Its newsletter, *Social Security Disability Update*, contains articles on obtaining benefits, specific medical conditions and legal and policy developments. The firm has also assembled a page of Internet links to social security law, practice and disability resources.

Anderson Kill & Olick, http://www.andersonkill.com

This firm really grabs you with their first page which just states: "We Are NOT The Enemy." The ensuing page opens with a riddle. "Why do testing labs prefer to use lawyers instead of mice? Because there are more lawyers than mice, the scientists don't get as attached to the lawyers, and there are some things mice won't do." It goes on to state: "It's no joke. We solve problems. We are not the enemy." This website defies categorization! It does cover the basics—a firm description, its practice groups and attorneys. It also includes current and archival copies of the firm's newsletters: *AKO Policyholder Advisor*, *Banking On Insurance*, *Commercial Litigation Advisor*, *Employment Law Insider*, *U.S. Insurance Report*, *AKO Practical Lender Advisor*, *U.S. Intellectual Property Law Advisor*, and *Nailing Down Coverage*. There is a long list of Internet resources, keyed to insurance but also including general legal resources on the web, Y2K issues, and search engines. However, AKO has gone further than most firms and created a number of unique resources. One is a guide to high-tech insurance issues. Another is its Vacatur Center that was created "to help preserve court decisions that have been wiped off the books by losing litigants." Some are insurance companies that "pay the winning litigants more than they won in court, but only if the winner will agree that the important precedent in their case will 'disappear.'" Another page, "Stopping Mismanaged Care: In Memory of Judy Packevicz," tells the story of an AKO pro bono client whose HMO would not authorize payment for a liver transplant. It includes documents filed in that case, as well as a pleadings generator which can take relevant data from other cases and mail-merge it into the documents. The stated purpose here is to reduce the time necessary to prepare pleadings in cases where time is critical. Finally, AKO has created a set of web pages dealing with *Jensen v. The White Star Line*. Do you know the event that gave rise to this case? The categories include: judicial process, plaintiff, defendant, basic facts, negligence law, defenses, witnesses, exhibits, links, jury charge, verdict sheet and awards and comments. A particularly delightful resource!

Margaret Moreland Murray is Lawyer/Librarian for Research Services at Pace University School of Law. Her e-mail address is mmurray@lawlib.law.pace.edu.

Health Law and the Internet—The Basics and Beyond:
A Must for Health Law Practitioners

Registration: 8:30-9:00 a.m.• Seminar: 9:00 a.m.-1:10 p.m.

Friday, November 5, 1999	**Melville, L.I.**
Friday, November 19, 1999	**Albany**
Friday, December 3, 1999	**New York City**
Friday, December 3, 1999	**Rochester**

The Internet is, first and foremost, an information universe where anyone with access can receive and/or offer information on almost any subject imaginable. Further, the quality of information and the timeliness in which it is delivered via the Internet continues to improve on a daily basis. Attorneys look to the Internet to conduct legal research, communicate with clients and colleagues and for other specific uses such as filing litigation papers with local courts or submitting information to regulatory agencies. Clients look to the Internet for information about many things, including information about their health. Throughout the web, there are many sites that give health related information. The health care industry uses the Internet to transact business and share information with consumers. Without question, those health care legal practitioners who do not understand and participate in this communication realm may find themselves at a distinct professional and competitive disadvantage.

This program is designed to provide the health care legal practitioner with both a fundamental and advanced knowledge of the private state and federal Internet resources available to practitioners in order to use the Internet effectively in their practices. Speakers will discuss issues such as, using the Internet to perform legal and health care related research and other communications via the Internet, the health care industry's uses of the Internet in several different areas, and privacy, confidentiality and ethical issues in using the Internet in both the medical and legal community.

We invite you to register for this timely half-day program. Bound course materials will be distributed to registrants on the morning of the presentation, **as well as a disk of internet sites referred to by many of the speakers**. Attendees staying for the entire program will receive a total of 4.5 MCLE credits, including .5 credit in ethics. This program will offer credits to newly-admitted attorneys.

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- **OVERVIEW OF THE INTERNET**
- **STATE AND FEDERAL LEGAL RESEARCH USING THE INTERNET**
- **INTERNET RESOURCES AND STRATEGIES FOR THE HEALTH CARE LEGAL PRACTITIONER**
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The Role of Hospital Legal Counsel in End-of-Life Treatment Decisions: A Review of the United Hospital Fund/Milbank Report

By Robert N. Swidler, James Horwitz and Donald Walker

For better or worse, decisions about medical treatment toward the end-of-life are affected—and sometimes skewed—by legal considerations. Physicians and nurses recognize that a complex and shifting web of statutes and cases may compel the provision of life-sustaining treatment in some circumstances and preclude it in others. Patients and families often recognize this as well, or soon learn it. Yet those most directly involved in end-of-life treatment decisions are often uncertain about the relevant legal principles, or about the application of those principles to their case.

Since most deaths occur in hospitals, in-house hospital counsel are sometimes asked to provide advice on the legal aspects of end-of-life treatment decisions. But involving hospital counsel can be problematic. On one hand, a hospital counsel may be knowledgeable about the pertinent statutes and caselaw, and comfortable in contributing that knowledge to help further a collaboratively reached, ethically sound, patient-focused resolution. On the other hand, counsel may be unfamiliar with the law in this area, uncomfortable with these issues, and excessively focused on protecting the hospital from liability. Indeed, clinicians sometimes avoid their involvement for just this reason.

Recently, United Hospital Fund and the Milbank Report issued a report, *End-of-Life Care and Hospital Legal Counsel: Current Involvement and Opportunities for the Future.* The report described the results of their study of the role of legal counsel in six hospitals in New York City. The study was conducted by interviewing both the hospital counsels and the clinicians at those institutions. Based on the interviews, UHF/Milbank arrived at seven observations, and made three recommendations.

This article summarizes the observations and recommendations in the UHF/Mibank study. Moreover, it adds comments that reflect the combined views of hospital counsels at Albany Medical Center, Glens Falls Hospital and Northeast Health—the parent corporation of Samaritan Hospital (Troy), Albany Memorial Hospital and The Eddy. For the most part, our upstate hospital counsel group found that the observations made at the New York City hospitals are applicable upstate as well. We also agree with the recommendations in the study, and are committing ourselves—both separately and collectively—to implement those recommendations.

UHF/Milbank Observations

1. Legal considerations, and the procedural decision framework created through the law, strongly influence how clinicians think about end-of-life decisions. The study observed that clinicians, when asked to discuss end-of-life care issues, focused on legal issues such as procedural requirements, rather than clinical/ethical issues such as pain control or autonomy.

Upstate hospital counsel group comments: To be sure, clinicians' thinking about end-of-life care is strongly influenced by their perception of legal requirements. However, it is an overstatement to say, as the study does, that "these considerations dominate the concerns of clinicians who care for these hospitalized patients." In our experience, clinicians tend to reach a firm view about the right course in end-of-life cases based on clinical and ethical considerations, and then give consideration to legal parameters.

2. Concern and confusion about what is, and is not, legally permissible are common components of clinical decisionmaking. Clinicians interviewed expressed a sense of uncertainty and insecurity about the relevant legal principles, such as the authority of family members to make decisions, particularly where there is disagreement among them.

Upstate counsel group comments: We too have found that clincians are uncertain and confused about the relevant legal principles, and often hold misconceptions. However, it is important to differentiate among sources of clinician confusion. To be sure, in some instances, the relevant legal principles are clear, and clinicians simply are unfamiliar with them. But in other instances, the law in this state is unclear—accordingly, clinician confusion is justified. For example, it is not always clear when treatment may be withheld or withdrawn, or a DNR order issued, on the basis of futility: physician uncertainty on this point is understandable. Finally, in some instances the law is clear, but at odds with clinical and ethical reality. For example, in New York, when a patient lacks capacity and did not appoint a health care agent or leave clear and convincing evi-

dence of a wish to forego treatment, family members have no residual authority to direct withdrawal or withholding of life-sustaining treatment. This principle, clearly enshrined in New York law, is unworkable in practice, and thus the source of considerable confusion, frustration, anger, disbelief and folklore about what might suffice to satisfy the standard.

3. Hospital clinicians are often unaware of the institutional policies and protocols that were created to assist them in end-of-life care decision making and delivery. Hospital administrators and counsel tend to regard hospital policies as shaping and reflecting their institution's approach to end-of-life care. Yet clinicians on the front lines tend to either be unaware of such policies, or to disregard them in real-life situations.

Upstate counsel group comments: We cannot say as a general matter that physicians in our hospitals are unfamiliar with or disregard the policies on end-of-life care; some are quite familiar and notably compliant. Nonetheless, there is always a need to improve knowledge and compliance with our institutions' end-of-life policies. To do so, it is not enough to disseminate policies and educate staff; we need to ensure that the policies are intelligible and practical, and reflect clinical realities.

4. Hospital clinicians have little formal training in the legal aspects of end-of-life care. Instead they often rely on a variety of informal educational outlets that often transmit inaccurate or incomplete information about the law in the acute care setting. The study found that most clinicians obtained their knowledge of the relevant legal principles from other physicians, and from "the occasional journal article passed on a by a colleague or an informational notice circulated through their department." Few mentioned seeking advice from hospital counsel, or educational programs offered by their hospital.

Upstate counsel group comments: This is consistent with our impression. The need for educational efforts is discussed further below.

5. Hospital legal counsel are engaged in a variety of responsibilities and activities within the hospital, but their involvement in the hospital's clinical or educational activities related to end-of-life care is limited. These attorneys also differ in their level of comfort with, and interest in, being involved with such issues. Most of the hospital counsels interviewed by UHF/Milbank indicated that their primary responsibilities lie elsewhere. They believed that, for the most part, clinicians were resolving these issues without their involvement—and most did not regard the absence of their involvement as a problem. When they became involved in end-of-life situations, it was usually in response to a crisis brought to their attention by a clinician or—more often—an administrator. All counsel assigned a high priority to such issues when they were brought to their attention. In such cases, some counsel were comfortable providing advice and becoming actively involved. Others were not, and were concerned about the propriety of their invovement in such issues, or by their view that their role would have to be to protect the institution from liability. Hospital counsel differed greatly in the degree to which they were prepared to tolerate legal risk and uncertainty inherent in end-of-life decisions.

Upstate counsel group comments: These observations seem only partly true to our upstate hospital counsel group. Certainly, we have a broad range of responsibilites: we advise and represent our hospitals in matters relating to corporate law, Medicare/Medicaid law, NYS Public Health Law and state hospital regulations, tax-exemption law, contract law, real property law, employment and labor law, environmental law—and many other areas. Moreover, we agree that most end-of-life decisions are—appropriately—being resolved in our hospitals without counsel involvement. Like other counsel, we are occasionally called in for advice in end-of-life decisions, mostly when there is a dispute, or a greater-than-usual degree of legal uncertainty. We certainly assign a very high priority to these issues, and often set aside everything if that is necessary.

But unlike some of the downstate counsels interviewed, we think that our group has considerable knowledge, experience, comfort and interest in dealing with the legal aspects of end-of-life decisions. As important, we all agree that the paramount objective is reaching a decision that reflects the values and interests of the patient. Institutional liability exposure is not an overriding concern. Accordingly, we are willing to approach end-of-life issues with a reasonable degree of flexibility, and tolerate a reasonable degree of legal uncertainty, in furtherance of reaching an ethically sound resolution of the matter.

6. Hospital legal counsel currently have little contact with hospital clinicians, despite clinician's concerns about the law. Various approaches within hospital settings are being used to address and resolve legal concerns related to end-of-life care, and these rarely involve hospital counsel. The study found considerable divergence among clinicians, even within the same hospitals, with respect to the approach they would take in problematic cases. They might, depending on the circumstances, turn to patient advocates, ethics committees or consultants, risk managers or legal counsel.

Upstate counsel group comments: Actually, at Albany Medical Center and Glens Falls Hospital, hospital counsels have considerable contact with hospital clinicians, and work together in numerous settings. Northeast Health created the position of Corporate Counsel recently, and its counsel is now building such relationships. While clinicians use a variety of approaches to resolve problematic cases, we regard that as appropriate. Hospital counsel should be available to provide advice in all such cases, but we do not insist on our involvement in all such cases. Nor do we feel that we have been excessively or inappropriately excluded. However, frankly, we don't know what we don't know—there may well have been legally-sensitive cases at our hospitals where clinicians should have, but did not, call in hospital counsel.

7. Clinicians have high regard for hospital counsel and report that their advice and recommendations influence their own decisions about patient care. One common theme was that, in those instances where hospital counsel was brought in, they exercised considerable authority: Indeed, clinicians rarely acted over counsel's objection.

Upstate counsel group comments: This is consistent with our impression. It also serves as a cautionary reminder to hospital counsels to act within an appropriately limited sphere: our role should be to provide legal information, and to provide support for clinically and ethically sound decisions. We are not final decisionmakers and should not try to supplant clinical and ethical discussion with legal analysis. Of course, on occasion, the law may clearly prohibit what is clinically and ethically appropriate. In such situations, it is counsel's role and obligation to advise compliance with the law, or possibly to seek judicial intervention. But in our experience, these situations are rare.

UHF/Milbank Recommendation #1: Create Educational Opportunities. Counsel need to familiarize themselves more with the clinical reality in which decisions are made, and clinicians need a better understanding of applicable legal principles.

Upstate counsel group comments: We agree. While we have made efforts to understand the clinical reality, and to provide educational programs for clinicians, this study reminds us of the importance of these efforts and prompts us to commit ourselves to further efforts—both separately and collectively.

UHF/Milbank Recommendation #2: Promote Enhanced Communication and Advance Care Planning. Counsel and senior clinical leaders should collaborate in advance planning, for several purposes: to build a good working relationship, to prepare for problematic situations, and to develop strategies to work with patients and families to head off problems (for example by promoting health care proxies).

Upstate counsel group comments: We agree, and will strive to make further efforts at our institutions along these lines.

Recommendation #3: Translate between the clinical and policy arenas. Hospital counsel are ideally positioned to convey clinical issues to policymakers, and seek to reform policies to make them more practical, as well as more clinically and ethically sound.

Upstate counsel group comments: Not only do we agree, we think this recommendation is particularly relevant to our group: we are located in the state's Capital District, and we are experienced in the state legislative and regulatory process. Accordingly, to the extent we can do so consistent with the wishes of our governing bodies, administration and clinicians, we will seek to become more active in "translating the clinical to the policy" by working to improve state policies on end-of-life issues. In particular, we will strive to work harder to secure practical rules that give family members clear authority, in ethically appropriate circumstances, to authorize the withdrawal or withholding of life-sustaining treatment.

Originally printed in the Northeast New York Regional Ethics Consortium Newsletter (June 1999).

Robert N. Swidler is Corporate Counsel at Northeast Health; James Horwitz is General Counsel at Glens Falls Hospital; and Donald Walker is Senior Associate Counsel at Albany Medical Center.

Nealy v. United States Healthcare HMO: The New York Court of Appeals Rejects Expansive Application of the ERISA Preemption Clause

By Steven F. Seidman, M.D. and Mary O'Bryan, J.D.

The New York Court of Appeals recently ruled in *Nealy v. United States Healthcare HMO*[1] that the preemption clause in the Employee Retirement Income Security Act (ERISA) did not bar a plaintiff's action against a physician for medical malpractice, breach of contract or breach of fiduciary duty.[2]

Background

Malpractice actions are typically adjudicated in state court; however, in an attempt to minimize liability, health maintenance organizations (HMO) and the physicians who provide direct patient services on their behalf have sought to remove these claims to federal court and apply the ERISA preemption clause, § 514(a) and 29 U.S.C. § 1144(a).[3] Since employers typically supply health care benefits subject to ERISA guidelines, defendants have relied on the statutory language of ERISA in their defense.[4] This preemption clause states that ERISA "shall supersede any and all state laws insofar as they . . . relate to any employee benefit plan" covered under ERISA.[5] Once in federal court, the defendant physician and HMO could move to dismiss the claim on the basis that the ERISA preemption clause barred the plaintiff's action. Should the court sustain the motion and dismiss the claim, the plaintiff would be left with no avenue to pursue a remedy for either the alleged medical malpractice, breach of contract or breach of fiduciary duty. By its ruling in *Nealy*, the Court of Appeals has refused to apply an expansive definition of the preemption clause.

ERISA resulted from congressional concerns regarding mismanaged pension and employee welfare funds.[6] Its guidelines sought to impose a uniform, national standard regarding claim processing and disbursement of benefits.[7] Critical to achieving national uniformity among benefit plans, ERISA required a preemption provision that would enable its guidelines to supersede individual state laws that were in opposition. Therefore, pursuant to § 514(a) of ERISA, 29 U.S.C. § 1144(a), ERISA would preempt all state laws that "mandate employee benefit structures or their administration."[8]

In the case at bar, the Court of Appeals has clearly differentiated a benefit plan's administrative functions from the medical care provided. The Court held that ERISA preemption would apply only to such administrative procedures and not to claims for medical malpractice. This ruling was in accord with recent appellate division decisions.[9] By not permitting the ERISA "relate to" provision to preempt claims for medical malpractice, the Court of Appeals followed U.S. Supreme Court precedent in *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins*.[10] In this 1995 ruling in *Travelers*, the Supreme Court described ERISA's then-current statutory interpretation as "clearly expansive" and sought to narrow its application.[11] The Court in the instant case also sought to constrain the application of ERISA by allowing preemption only for administrative functions of the health plan and not for claims of malpractice—thereby adopting the Supreme Court's more constrained approach.[12]

Facts

In January, 1992, at age 37, the plaintiff's husband, Glenn Nealy, was diagnosed with coronary arteriosclerosis and a coronary artery lesion. He went on disability leave from his job. Dr. Stephen Green, a cardiologist, treated Mr. Nealy with coronary angioplasty in March 1992. His insurance carrier, Blue Cross/Massachusetts Mutual, covered the major portion of his health care expenses. This carrier had been selected by Mr. Nealy's employer to provide health insurance as an employee benefit.

Shortly after Mr. Nealy's angioplasty, his employer elected to change carriers for all the employees' medical benefits. The employer gave the employees a choice of three different HMOs and gave notice that, on April 1, 1992, coverage would switch to the new carrier. Mr. Nealy selected the United States Healthcare Versatile Plus HMO and paid his first monthly premium. The plan he selected permitted its members to see physicians who were non-participating.

On April 2, a day after coverage took effect, Mr. Nealy visited the office of the primary care physician he had selected, Dr. R. Yung. He had renewed chest pain and required follow-up care after the angioplasty. Because Mr. Nealy had not yet received a United States Healthcare identification number, he was refused an appointment. The following day, April 3, after speaking with a representative of the HMO who told Mr. Nealy that a copy of his enrollment form would suffice in lieu

of an identification number, he made a second visit to Dr. Yung. Again, Dr. Yung refused to see him because the enrollment form did not have Dr. Yung's correct physician number. Finally, on April 10, after Mr. Nealy received his identification card, Dr. Yung examined his new patient. Dr. Yung asked him to return three days later for follow-up laboratory tests. During one of these visits, Dr. Yung suggested that his patient see a cardiologist. Mr. Nealy asked to see the cardiologist who had performed the previous angioplasty, Dr. Green. Because Dr. Green was not a participating physician in the plan, Dr. Yung agreed to fill out the necessary paperwork and do what he could to arrange for Mr. Nealy to obtain an out-of-plan referral. It took Dr. Yung until April 20 to fill out this request and submit it for approval to the HMO.

On May 4, 1992, Mr. Nealy received a copy of the letter sent by United States Healthcare to Dr. Yung denying this referral because a participating cardiologist, Dr. C. Spivak, had an office in the area. Nealy agreed to see Dr. Spivak, but it was not until May 18 that he received the referral. Nealy made an appointment with Dr. Spivak for the following day, May 19. Mr. Nealy, however, never got to see Dr. Spivak. On May 18, he suffered a massive myocardial infarction and died.

Subsequently, Mrs. Nealy, wife of the deceased, brought an action alleging breach of contract, breach of fiduciary duty, wrongful death and negligence against Dr. Yung, Dr. Richard Bernstein (vice-president of United States Healthcare), and United States Healthcare. The plaintiff also brought a claim of medical malpractice against Drs. Yung and Bernstein. Pursuant to 28 U.S.C. §§ 1331 and 1441(a),(b) and (c), United States Healthcare and Dr. Bernstein successfully moved to remove the action to federal court on the grounds that the plaintiff's claim raised a federal question under ERISA.[13] Claims against these two defendants were dismissed on the basis of ERISA preemption.[14] Dr. Yung had not been served when the other two defendants successfully had their case removed to federal court. Thus, he did not take part in the removal motion. Rather, the federal court remanded the case against Dr. Yung to New York State Supreme Court. Dr. Yung unsuccessfully sought summary judgement arguing that ERISA preempted Mrs. Nealy's claim against him. The supreme court denied the motion, but the appellate division reversed the lower court, holding that ERISA, in fact, preempted the plaintiff's claims against Dr. Yung.

In so doing, the appellate division reasoned that "Dr. Yung's involvement in this matter was purely administrative, as a facilitator, rather than as an actual provider of medical care. As such he [was] protected against this lawsuit by the statutory preemption."[15] In its decision, the appellate division broadly applied the ERISA preemption clause and held that the actions against Dr. Yung for breach of contract and breach of fiduciary duty should be dismissed. Regarding the defendant's alleged medical malpractice, the appellate division held, "All of Dr. Yung's alleged malpractice l[ay] in his actions *in relation* to the decedent's United States Healthcare benefits."[16] (emphasis added). Given the language of the statutory preemption clause and applying it to the instant case, ERISA superseded the plaintiff's claim of medical malpractice because it related to her husband's healthcare benefits.[17] Accordingly, the appellate division dismissed the medical malpractice claim against Dr. Yung. Mrs. Nealy appealed this holding to the New York Court of Appeals.

The Court's Reasoning

The issue before the New York Court of Appeals was whether the ERISA preemption clause barred the plaintiff's actions against Dr. Yung for medical malpractice, breach of contract and breach of fiduciary duty. In deciding this issue, the Court had to consider: 1) the "relate to" statutory language in ERISA,[18] 2) the U.S. District Court's prior holding dismissing the plaintiff's action against United States Healthcare HMO and Dr. Bernstein[19] and 3) the U.S. Supreme Court's rejection of an expansive application of ERISA preemption in favor of the more constrained approach found in *Travelers*[20] and *DeBuono v. NYSA—ILA Medical and Clinical Services Fund*.[21]

In examining the statutory language in ERISA, the N.Y. Court of Appeals acknowledged that the "relate to" provision allowed for expansive application of preemption.[22] Citing *Travelers*, however, the Court of Appeals maintained that despite such "clearly expansive" language, the presumption was that Congress did not intend to supplant state law.[23] Federal law would not supersede a claim traditionally adjudicated in state court or involving a state law "unless that was the clear and manifest purpose of Congress."[24] In the instant case, the plaintiff's claims against Dr. Yung involved matters traditionally under state domain—medical malpractice, breach of duty and breach of fiduciary duty. On this basis, the Court of Appeals reasoned that the defendant bore the "considerable burden" of overcoming this presumption that Congress did not intend to preempt such claims.[25] Seeking to "surmount that formidable hurdle," the defendant had relied on the ERISA preemption clause. Because the plaintiff's claims "relate[d] to" Dr. Yung's duties on behalf of the United States Healthcare HMO, the defendant claimed that ERISA preemption was applicable.[26] More specifically, Dr. Yung alleged that his HMO-related activities were

all of an administrative nature.[27] Therefore, the defendant argued, he had overcome the presumption that Congress did not intend to preempt an action that typically fell under the domain of state regulation—in this case, medical malpractice.[28]

The Court of Appeals disagreed,[29] finding no basis on which ERISA could preempt the claims against Dr. Yung. In reaching its decision, the Court of Appeals examined this evolution in the Supreme Court's application of the "relate to" provision. It noted that in earlier decisions, the Supreme Court had adhered to a literal, expansive interpretation of "relate to," finding that a "law 'relates to' an employee benefit plan . . . if it has a connection with or reference to such a plan." [30] However, in the Court's 1995 decision in *Travelers*, Justice Souter expressed the Court's concern regarding the "clearly expansive" reach of ERISA preemption and wondered "whether the words of limitation ('insofar as they . . . relate') do much limiting."[31] Justice Souter concluded in *Travelers* that virtually each and every state law could be said to "relate to" an employee benefit plan, thereby making a "mere sham" of Congress' words of limitation.[32]

Justice Souter stressed it was necessary to go "beyond the unhelpful text and the . . . difficulty of defining its key term, and look instead to the objectives of the ERISA statute as a guide to the scope of the [S]tate law that Congress understood would survive.[33] In other words, an analysis based on the goals Congress intended in drafting ERISA would precede all decisions regarding preemption (i.e., the so-called, goal-based analysis).

The Court of Appeals also relied on the Supreme Court's ruling in *De Buono*,[34] which continued to apply constraints to the expansive application of the ERISA preemption clause.[35] Here, too, the Supreme Court used a goal-based analysis as its benchmark in deciding whether ERISA preempted the state statute or case law specific to *DeBuono*.[36] In the majority opinion, Justice Stevens concluded: "There is nothing in the operation of . . . that convinces us it is the type of [S]tate law that Congress intended ERISA to supercede."[37] Not only did Justice Stevens use this goal-based analysis to decide whether ERISA preemption should apply, he indicated the limitations of the "relate to" doctrine regarding " . . . one of 'myriad [S]tate laws' . . . that impose some burden on the administration of ERISA plans but nevertheless do not 'relate to' them within the meaning of the governing statute."[38] Thus, in *De Buono*, as well as in *Travelers*, the Supreme Court moved away from a literal interpretation of the "relate to" portion of the preemption clause. In its place, the Supreme Court examined ERISA's intended objectives, decided whether the relevant state statute or case law conflicted with these objectives and allowed preemption only if there was such conflict.

In the case at bar, the Court of Appeals adopted the Supreme Court's goal-based methodology, instead of the earlier, literal interpretation of "relate to," when it determined that Dr. Yung could not assert ERISA preemption against the plaintiff's claim of medical malpractice. Examining Congress' objectives in the ERISA legislation, it found that there was no evidence that Congress sought to preempt a plaintiff's claim of medical malpractice.[39] Furthermore, it ruled that there was nothing in the plaintiff's action that was even remotely in conflict with the goals of ERISA.[40] Dr. Yung implied that performing administrative tasks for the United States Healthcare HMO precluded him from functioning as a physician or from incurring the liability of a physician. The court rejected this contention, reasoning that even though Dr. Yung may have to refer to the administrative protocols of the HMO while delivering patient care or engage in administrative duties, that does not make him solely an administrator of the employee benefit plan; he was still directly involved in patient care. In the instant case, the plaintiff alleged that Dr. Yung "violated the duties and standard of care owed to his patient by improperly assessing the . . . extent of his condition and by failing to take reasonable steps to provide for his timely treatment by a specialist."[41] The court found that these were not the duties of an administrator, but, rather, those of a physician.

Analysis

There are significant ramifications of the decision made by the New York Court of Appeals. The growing influence and market share that health maintenance organizations have attained in New York state magnifies the importance of this decision. As exemplified in the case at bar, the HMO and the physicians providing patient care on behalf of the HMO could use the ERISA preemption clause as a shield against patient liability. Physicians who provided sub-standard care and HMOs that denied patients necessary healthcare resources could argue that the ERISA preemption clause protected them from state statutes and case law aimed at punishing and providing remedies for such conduct. Until the New York Court of Appeals pierced the protective veil enjoyed by HMOs and their physicians, people obtaining healthcare through an employer-sponsored HMO were left with no avenues to pursue redress in the state courts. Such matters would include actions for medical malpractice, breach of contract, and breach of fiduciary duty. The ERISA preemption clause, in essence, blocked the insured plaintiff's access to the state courts when actions that arose from the HMO's business activities required adjudication in those courts.

Until there was some constraint regarding the application of the preemption clause, there could be no way to impose accountability on the HMOs. In the case at bar, the Court of Appeals recognized that as healthcare benefits are managed more and more by HMOs, beneficiaries required the protections provided by state statutes and case law. If HMOs could overrule these protections with the preemption clause, healthcare consumers would be left defenseless. Quality healthcare in New York State required the Court of Appeals to adopt a less expansive interpretation of the ERISA preemption clause—thereby insuring the accountability of HMOs and the physicians working on their behalf.

Endnotes

1. *See Nealy v. United States Healthcare HMO*, No. 44, 1999 N.Y. Lexis 208, at 20 (N.Y.2d March 25, 1999).
2. *See id*. at 20.
3. *See* ERISA § 514(a), 29 U.S.C. § 1144(a).
4. *See Nealy, supra* note 1 at 21.
5. *See* ERISA, *supra* note 2.
6. *See id.* at 21.
7. *See id.* at 21.
8. *See New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.*, 514 U.S. 645, 646 (1995) (hereafter *Travelers*).
9. *See e.g. Blaine v. Community Health Plan*, 179 Misc. 2d 331 (1998); *Andujar v.Lenox Hill Hospital*, 226 A.D.2d 179 (1st Dep't 1996); *Tufino v. New York Hotel and Motel Trades Council*, 223 A.D.2d 245 (1st Dep't 1996).
10. *See Travelers, supra* note 12 at 645.
11. *See id*. at 655.
12. *See Nealy, supra* note 1 at 23.
13. *See Nealy v. United States Healthcare HMO*, 844 F. Supp. 966, 968 (SDNY 1994).
14. *See id*. at 968.
15. *See Nealy v. United States Healthcare HMO*, *supra*. note 16 at 144.
16. *See id*. at 144.
17. *See. id.* at 145.
18. *See* ERISA, *supra* note 3.
19. *See Nealy*, *supra* note 17 at 966.
20. *See Travelers, supra* note 12 at 645.
21. *See DeBuono v. NYSA-ILA Medical and Clinical Services Fund*, 520 U.S. 806 (1997) (hereafter *DeBuono*).
22. *See Nealy v. United States Healthcare HMO*, *supra* note 1 at 22.
23. *See Travelers, supra* note 12 at 654-655.
24. *See id*. at 654-655.
25. *See DeBuono, supra* note 22 at 807.
26. *See Nealy v. United States Healthcare HMO*, *supra* note 1 at 22.
27. *See id.* at 22.
28. *See id.* at 22.
29. *See Nealy v. United States Healthcare*, *supra* note 1 at 20.
30. *See Shaw v. Delta*, 463 U.S. 85 ,96 (1982).
31. *See Travelers, supra* note 11 at 655.
32. *See id*. at 655.
33. *See Travelers, supra* note 11 at 656.
34. *See DeBuono, supra* note 22 at 806.
35. *See id. at* 806.
36. *See id. at* 806.
37. *See id.* at 814.
38. *See id.* at 815.
39. *See Nealy v. United States Healthcare HMO*, *supra*, note 1 at 23.
40. *See id.* at 23.
41. *See id*. at 22-23.

Issues of Expert Testimony and Medical Malpractice in Childhood Lead Poisoning

By Therese Wittner

Childhood exposure to lead is potentially devastating and therefore adequate screening by health care providers on lead exposure and its effects is essential. This article explores the standard of care required of health care providers and the use of expert testimony in lead poisoning/failure to screen cases.

I. Background

A. Effects of Lead

Death and permanent brain damage occur in children with high lead levels. Moderate exposure damages the central nervous system, kidneys, and interferes with production of red blood cells. Diminished IQ, attention and behavior disorders, and diminished fine motor coordination are characteristic of mild lead exposure. Lead crosses the placental barrier causing stillbirths, miscarriages and developmental disabilities.[1]

B. Sources of Lead

Lead, a naturally occurring element and common industrial metal, has been used in production since 3000 B.C. Lead poisoning is implicated in the decay of the early Greek and Roman empires as it was used to transport water and store food and wine.[2] Lead generally enters the body through inhalation or ingestion. Today's common sources of lead are:

- decaying painted surfaces ingested by children in the form of paint chips and inhaled in the form of dust;
- leaded gasoline, airborne as the fuel is burned, deposited in the soil, then brought into the house in the form of dust, and ingested by young children in their normal, age-appropriate, hand-to-mouth behavior;
- drinking water from lead-soldered pipes and coolers; foods that are canned with lead solder, or absorbed by crops from lead-laden soil;
- folk medicine remedies, especially in the Mexican, Asian and Middle Eastern cultures;
- pottery glazes on ceramic ware used in food preparation and storage and
- a newly discovered source is porcelain bathtubs in which children bathe and drink the water.[3]

C. Political Positions with Social Effects

The legislature believes that elimination of childhood lead poisoning is important. Tough laws regulate the lead contents of manufactured products, the medical standard of care, and promote the inspection of property for deteriorating paint and other sources of lead poisoning. A serious environmental lead problem can be eliminated. The question is: what price for the health of our children? Awareness by parents, land owners and purchasers, about the risks of lead dust from deteriorating paint and remodeling of buildings, containment and/or abatement protects children. Antithetically, this awareness has caused commonplace discrimination against families with young children in Boston and New York City where the oldest housing stock in the country exists and the cost runs from about $3,500 to $8,000 per unit to redress lead hazards there.[4]

"The question is: what price for the health of our children?"

II. Interview

Interview with Christopher A. Kus, M.D., M.P.H., Pediatric Director of the Division of Family and Local Health, State of New York Department of Health.[5] Dr. Kus is also a specialist in Developmental Pediatrics.

Q. You have been called the expert on lead poisoning for the Department of Health.

A. Let's put that in perspective. What I do is implement public health programs based on the best available knowledge.

Q. Would you say that 'best knowledge' is the Standard of Care then?

A. Correct. The NYS Department of Health has developed a handbook as a result of collaboration with the American Academy of Pediatrics, District II; it was published in 1997. Most background information comes from the Centers for Disease Control (CDC), like *Preventing Lead Poisoning in Young Children: A Statement by the Centers for Disease Control*, Oct. 1991. The significance of this publica-

tion was the CDC revised the 1985 intervention level of 25mcg/dL downwards to 10mcg/dL because of 'new data indicating significant adverse effects . . . at lead levels previously thought safe'; announced its goal to reduce children's blood lead levels to below 10mcg/dL; and suggested communitywide interventions where many children have levels equal to, or greater than, 10mcg/dL. This was a huge departure from where we were at that time. It is a good publication for understanding interventions as related to blood lead levels (herein after, all blood lead levels are in mcg/dL micrograms per deciliter).

"If you look at a population with a higher lead level and compare to a population with a lower lead level, a decrease in IQ points is shown."

Q. What level sounds the first alarm?

A. We are concerned about levels of 10 and above. (Five and under is within the standard deviation of the test.) For children with a confirmed level greater than or equal to 20, evaluation includes a complete neurological and medical evaluation and an environmental assessment. We say that 10 to 20 is an elevated lead level, and that 20 and above is lead poisoning because that is when we take the bigger action. It is tough concept to explain to parents.

Q. Let's talk about action levels for children. A lead level of 20 will trigger an evaluation and inspection. How often will that occur?

A. That depends. We have a computerized system based on many factors which implements a time frame for follow-up inspection and testing. Specific case management recommendations are outlined in the Physician Handbook.

Q. As I understand it, blood lead levels between 10 and 20 are a real problem and call for educating parents about lead sources to prevent further exposure. Any level greater than 20 is considered 'poisoning' with testing of the home including abatement or containment of identified sources of lead. Neural damage and symptoms steadily increase as the lead level increases. Above 45, chelation therapy—a heavy duty treatment with corresponding side effects; to be avoided if possible—becomes a consideration. A blood lead level above 70 is a medical emergency requiring hospitalization, chelation therapy, and at least consultation with a Regional Lead Center.

A. That is correct except that chelation may be used in children with higher lead levels. Treatment recommendations are noted in the Physician Handbook. Children with venous blood lead levels greater than or equal to 45 should be chelated. Chelation may be considered in children with lower levels. Consultation with a Regional Lead Poisoning Prevention Resource Center is recommended. Our publication (the 1997 DOH Physician Handbook) has the most current recommendations, taking CDC information together with other background data, and presenting the standard of care for treatment of elevated blood lead levels. Since 1993, State law requires all children be tested for lead levels at ages one and two.

Q. Is there medically acceptable proof for the effects of low-level (10 to 20) lead exposure?

A. Yes. Multiple studies[6] taken together, after inconsistencies and confounding factors have been adjusted for, show a decrease in intelligence quotient (IQ) to a reasonable certainty (meaning the weight of the evidence is clearly supportive). These studies are similar to studies on alcohol and IQ. As the level of lead gets higher, you see decreases in IQ. We can't tell you that 10 is okay, but the significant findings are all at 10 and above.

Q. What are the effects shown in the studies on lower lead levels (10 to 20).

A. If you look at a population with a higher lead level and compare to a population with a lower lead level, a decrease in IQ points is shown. The applicability in individual cases is more difficult. You can say that a child's developmental problems are lead related or that other environmental factors are to blame. There are lots of possibilities.

Q. Are you suggesting that levels under 10 may affect young children?

A. That would be very hard to measure.

Q. If you were both a parent and an expert, what lead level would concern you?

A. You need to know what the community lead level is. When we had lead in gasoline, our baseline level across the board was about 7 or so. We would be brighter today if we hadn't lived with that. Now, the baseline is down to under 5. Presently, we are looking at the higher level areas and targeting our efforts in there. We can look at geographical areas since NYS has electronic reporting of all lead levels; few states that have that sort of reporting. For any

lead test done on a child in NY, I know what the community level is and how she compares.

Q. How does a physician go about determining that a particular child's problem is due to lead?

A. You look at the whole picture and do a differential diagnosis (a hierarchy of all possible medical conditions suggested by the symptoms, medical history, physical exam and tests) and make an educated decision on the most reasonable explanation, within a medical certainty. The higher levels of lead (over 20) are a marker of toxicity. The questions when you see a toxic level are: is this level on the way up or on the way down? Are there symptoms that go along with that lead level? If so, the association is stronger. You only know what the level is when the test is done—not before—which makes duration of exposure difficult to determine.

Q. How would you evaluate another expert's opinion?

A. Probably not according to the studies being used. The general feeling is there is enough clinical evidence for the range of possible symptoms related to lead. I would ask: Can I see associated symptoms? Is there a long history of this going untreated? The stronger case has a lead experience at high levels associated with the symptoms. The trouble is with the behavioral area. Lead problems can happen anywhere, although I must say that typically lead is a sign of poverty related to disrepair of old housing stock.

Q. What is the key to solving this problem?

A. The key is to remove lead from our environment as much as possible. Unleaded gasoline was a step in this direction. We now need to deal with our old housing stock—repair, contain, abate, etc. as appropriate. Screening children for lead allows us to target our primary prevention efforts. I always ask 'where's the money' because that's what it takes. But, universal screening is important. There is some debate in the medical community about universal screening and it is reasonably so if we are talking about screening every child in America.

Q. Isn't that why NYS has mandatory testing for one and two year olds?

A. It is because of our old housing stock, and we don't yet have enough data to determine a decision point where mandatory testing would be needless. The 1997 CDC publication for state and local public health officials stated criteria that could be used to say that an area doesn't need to be screened, based on a state plan. The quick sound-bite there was that universal screening was unnecessary. However, the DOH 1997 handbook came out right afterwards and reiterated to the NYS medical community that universal screening was still the law and reasonable due to our older housing, risk, and lack of data.

"Lead problems can happen anywhere, although I must say that typically lead is a sign of poverty related to disrepair of old housing stock."

Q. Are you aware if physicians are having medical malpractice problems due to a failure to screen children with lead poisoning?

A. I have not heard of such problems at this time. However, physicians who are not following the standard of care in this area may be at risk. Certainly if physicians are not screening one and two year olds, they are at risk for medical malpractice. Look at the CDC chart.[7] At blood lead levels of 10 there are developmental issues; fine cognitive function, decreased measured intelligence, learning problems and behavioral problems like ADD (Attention Deficit Disorder). As you go up the chart to the 20s there is anemia, and further nervous system involvement; then the red blood cell production is affected at 40. When I was doing my pediatric training in Detroit, children used to come in with levels in the 90's and have seizures and could die. We don't see those high blood levels so much today.

Q. Lead poisoning cases generally hinge on expert testimony. How would you evaluate an expert? How can an attorney tell if an expert knows what they are talking about?

A. Look at their training first. I would look for Developmental Pediatricians, Pediatric Neurologists, and some Hematologists. Always ask a physician if she treats children with lead poisoning on a regular basis. DOH has regional lead poisoning prevention resource centers with knowledgeable staff. When a child has a high lead level, and a physician is considering chelation therapy, or hospitalization, that physician in the field can call one of the centers.

Summary of Physician Requirements

According to the DOH handbook for physicians, NYS Public Health Law regulations §§ 67-1 and 67-3, require that physicians shall screen for lead in all one

and two year olds; inquire about lead screening whenever a child is treated as an emergency, or for non-primary care visits; give parents written proof of lead screening results; counsel parents on risk reduction and nutrition, and follow the standards for follow-up testing where a child has a lead level of 10 or greater; perform a complete exposure, nutritional, developmental and diagnostic evaluation on all children with lead levels of 20 or greater, and refer these children to the local or state health unit for environmental assessment and management and notify the local health unit, within 24 hours, of lead levels of 45 and above.[8]

"In New York, The Frye *standard requires that information from which an expert deduction is made be sufficiently established so to have gained general acceptance in the field to which it belongs."*

Conclusion

In New York, The *Frye* standard[9] requires that information from which an expert deduction is made be sufficiently established so to have gained general acceptance in the field to which it belongs. The interview with Dr. Kus establishes the state and medical community's general acceptance of studies showing the effects of low-level lead and that the appropriate standard of care in lead poisoning cases is the DOH Physician Handbook.[10] However, Dr. Kus points out that physicians generally are not relying on studies any longer since effects of low levels of lead are well settled by clinical experiential data. Since the applicability of the DOH Physician Handbook in individual cases may be difficult to determine, childhood lead poisoning screening cases are largely determined on the strength of expert testimony.

Endnotes

1. Case Studies in Environmental Medicine: Lead toxicity, Agency for Toxic Substances and Disease Registry of the U.S. Dept. of Health and Human Services, at: http://atsdr1.atsdr.cdc.gov:8080/cx.
2. John Harte [et al], Toxics A to Z: a guide to everyday pollution hazards, 333 (1991).
3. *Id.*; Preventing Lead Poisoning in Young Children. The Centers for Disease Control, U.S. Dept. of Health and Human Services. October 1991.
4. John Hechinger, *In the War Against Lead, Families Prove Casualties*, Wall St. J., Jan. 20, 1999.
5. Excerpts from Interview of May 26, 1999 at the New York St. Dept. of Health, Albany, NY.
6. U.S. Dept. of Health and Human Services, Centers for Disease Control, *Preventing Lead Poisoning in Young Children: A Statement by the Centers for Disease Control* 9 (Oct. 1991) provides a list of these studies.
7. *Id.* at 8.
8. New York St. Dep't of Health & American Academy of Pediatrics, District II, Physician's Handbook on Childhood Lead Poisoning Prevention 5 (1997).
9. *Frye v. US*, 54 App DC 46, 293 F 1013 (1923).
10. New York St. Dept. of Health & American Academy of Pediatrics, District II, Physician's Handbook on Childhood Lead Poisoning Prevention (1997).

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Committee Report

Parentage of Children Born as a Result of Assisted Reproduction Techniques: A Proposal to Amend N.Y. Domestic Relations Law § 73

Committee on Biotechnology and the Law, Health Law Section, NYS Bar Association

N.Y. Domestic Relations Law § 73 provides that a child born to a married woman by means of artificial insemination is the legitimate child of that woman and her husband, provided certain steps are followed.[1] This provision, based on the Uniform Parentage Act (UPA) and enacted by New York in 1974, removed uncertainty as to paternity in the most common applications of artificial insemination, and thereby vested in the resulting children support, inheritance and other rights.

However, neither § 73 nor any other statute lends similar certainty as to the parentage of children born as a result of other assisted reproductive techniques. Accordingly, when a woman bears a child with the assistance of a donated egg or embryo, there is at least the potential for a dispute regarding maternity. Indeed, in certain egg or embryo transfer circumstances, a court might well rule that the child has two legal mothers—a genetic mother and a birth mother.

Amending DRL 73 to cover egg and embryo donation would promote the interests of children born of assisted reproduction, intended parents and egg and embryo donors. In a report issued in 1998, the New York State Task Force on Life and the Law recommended that DRL 73 be amended to provide the certainty needed by children born of the practices as well as adults who participate as parents and donors.[2] The Task Force Report examined at length the ethical, legal and social issues posed by the amendment in reaching its conclusion. A decade ago, the Committee on Biotechnology made the same recommendation.[3]

The Amendment to DRL 73 proposed by the Health Law Section is consistent with the legal trend in states across the nation. As of 1998, at least five states had enacted laws to clarify parental status, rights and obligations in cases of egg and embryo donation consistent with recommendations set forth in this proposal, which is also consistent with the Uniform Status of Children of Assisted Conception Act.

But the task is more formidable than it might first appear. First, a DRL 73-type approach would indeed confirm the parental status of the woman who received the egg or embryo transfer—i.e., the "birth mother"—and her husband. But in some instances it is the other donors—the woman who provided the egg or the couple who provided the embryo—who are the intended parents. In such cases, the birth mother is intended to be only a gestational surrogate mother. Obviously, those situations raise more complex and controversial issues concerning parentage—issues not raised in the more common egg/embryo donation scenario.

Moreover, DRL 73-type approach would only clarify the parental status of married couples. An unmarried woman who receives an egg or embryo transfer may also have an interest in having her status as the sole lawful mother confirmed. But regularizing assisted reproduction for unmarried women raises its own set of moral and political controversies.

Finally, the language of DRL 73 is archaic and inadequate in several respects, even as applied to artificial insemination. It speaks of the "legitimacy" of children—a disfavored term because it signifies that other children somehow have less intrinsic worth. It calls for an "acknowledgment" by the parent and "certification" by the physician—requirements that arguably are tangential to and can obstruct the interest in ensuring the resulting child has legal parents. Yet the statute fails to require the donor's consent, and fails to explicitly provide that a consenting donor will not be deemed a parent for any purpose—a provision that would directly and significantly further the section's purpose.

After examining these issues, the committee arrived at two fundamental conclusions: First, we agree with the Task Force on Life and the Law that it is important to amend DRL 73 to lend certainty to parental status in the most common application of donor egg or embryo transfer, i.e., where a donated egg or embryo is implanted in a married woman who intends to parent this child with her husband, and the donor or donors did not intend to parent the child.

Second, the Committee concluded that amending DRL 73 to address a broader range of scenarios—e.g., unmarried women and gestational surrogacy—would raise legal, moral and political issues that may be too difficult to resolve at the current time. Accordingly, this proposal confirms the parentage of children born to married couples after egg or embryo transfer[4] and does not affect the law with respect to those other, less common, situations.

However, we also believe that it is important to confirm that those donors of semen, eggs or embryos who, at the time of donation, have no intent or expectation of being parents have a simple reliable means to end any legal basis for claiming to parental rights. The Task Force made this recommendation as well.[5] Accordingly, our proposal adapts language from the Uniform Parentage Act to accomplish that purpose.

Accordingly, we propose the following amendment to DRL § 73:

> **Sec. 73.** ~~Legitimacy.~~ **Parentage** of children born by artificial insemination **or other medically-assisted reproductive techniques.**
>
> **1.** Any child born to a married woman by means of artificial insemination **or other medically-assisted reproductive technique,** performed by persons duly authorized to practice medicine and with the consent in writing of the woman and her husband, shall be deemed the legitimate, natural child of the husband and his wife for all purposes.
>
> **2.** The aforesaid written consent shall be executed and acknowledged by both the husband and wife and the physician who performs the technique shall certify that he had rendered the service.
>
> **3. A person who consents, in writing, to the donation of semen, ova or an embryo for use in the impregnation of a married woman (other than the donor's wife) by means of artificial insemination or other medically-assisted reproductive technique, accomplished in accordance with paragraphs one and two of this section, shall be treated in law as if he or she were not the natural father or mother of a child thereby conceived.**
>
> **4. For the purpose of this section "other medically-assisted reproductive technique shall mean in vitro fertilization, embryo transfer, gamete intrafallopian transfer and such other assisted reproductive techniques as may be identified by the commissioner in regulation.**

The amended statute would provide a simple mechanism to ensure that a married couple who has a child with a donated egg or embryo are the legal parents of that child—and the donor or donors are not. However, in gestational surrogacy circumstances the parties could render the provision inapplicable by not signing the consents. Section 4 identifies the principle current assisted reproductive techniques, but provides for the possibility that others may be devised by empowering the commissioner to identify them in regulation.

The committee recommends the enactment of this proposal. It will confer legal certainty as to parentage in the most common and least controversial instances of assisted reproduction, without affecting the law with respect to the less common, more controversial applications of the new technique.

Endnotes

1. Sec. 73. Legitimacy of children born by artificial insemination or in vitro fertilization.

   > 1. Any child born to a married woman by means of artificial insemination performed by persons duly authorized to practice medicine and with the consent in writing of the woman and her husband, shall be deemed the legitimate, natural child of the husband and his wife for all purposes.
   >
   > 2. The aforesaid written consent shall be executed and acknowledged by both the husband and wife and the physician who performs the technique shall certify that he had rendered the service. 2, NYS Task Force on Life and the Law, Assisted Reproductive Technologies: Analysis and Recommendations for Public Policy (1998) at 351-352.

2. NYS Task Force on Life and the Law, Assisted Reproductive Technologies: Analysis and Recommendations for Public Policy (1998) at 351-352.

3. NYS Bar Association Special Committee on Biotechnology and the Law, Report on Gamete Donation and In Vitro Fertilization (May 1990).

4. The Biotechnology and Law Committee started on that path a decade ago and may have, as a result, lost the opportunity to help secure a valuable amendment to DRL 73. In 1990, the Committee proposed amending DRL 73 to provide, simply, that "Any child born to a married woman by means of artificial insemination or in vitro fertilization . . . shall be deemed the legitimate, natural child of the husband and his wife for all purposes." Report on Gamete Donation and In Vitro Fertilization (May 1990). But in 1992, the Committee revised its proposal to add a clause recognizing the birth mother as a lawful mother in all cases: "Any child born to a woman by means of artificial insemination or in vitro fertilization shall be deemed the child of that woman." The Legal Significance of Gestation in Assisted Reproduction (May 1992). In 1993, the NYSBA Executive Committee directed the Committee to propose a further amendment to recognize that a genetic mother must also be deemed a legal mother: "Any child born to a woman by means of artificial insemination or in vitro fertilization shall be deemed the child of that woman. Any child born by in vitro fertilization shall be deemed also the child of the woman who provided the ovum." Parents of Children Born Through Assisted Reproduction. (July 1993). On this, the Biotechnology and Law Committee's third foray into DRL 73, we have returned to our initial modest objective, and do not purport to address instances of gestational surrogacy.

5. Task Force, *supra* at 348.

Government Report

Recommendations on the Oversight of Human Subject Research Involving the Protected Classes

Report to the Commissioner of Health from the Advisory Work Group on Human Subject Research Involving the Protected Classes

Executive Summary

Human subject research involving individuals who lack decision making capacity presents significant challenges for public policy. The challenges stem from (1) the diversity among individuals who are or may be decisionally incapacitated, (2) the need to respect the present and former preferences of such persons, (3) the lack of consensus on the balance of risk and expected benefits deemed acceptable for research involving decisionally incapacitated persons, and (4) uncertainty as to the effectiveness of safeguards intended to protect decisionally incapacitated subjects who participate in research studies.[1]

Growing recognition by government, researchers and the public of these unresolved issues has led to increased attention and debate about the appropriateness of research involving persons who are unable to provide their own consent. These questions continue to gain academic, judicial and public attention.[2]

In New York, awareness of these issues was heightened by the December 1996 decision of the Appellate Division, First Department, in *T.D et al. v. New York State Office of Mental Health, et al.*[3] In response to this decision, the New York State Commissioner of Health, Barbara A. DeBuono, M.D., M.P.H., convened the Advisory Work Group on Human Subject Research Involving the Protected Classes ("Work Group") to make recommendations on the New York State Department of Health's oversight of human subject research involving minors, incompetent persons, mentally disabled persons and prisoners ("protected classes"), with a particular focus on more than minimal risk research involving individuals unable to provide informed consent.

The Work Group was charged with providing recommendations to the Department of Health on the interpretation and implementation of Public Health Law provisions governing human subject research. Specifically, the Commissioner requested advice on the policies and principles, the scope of oversight responsibilities, and the processes, standards and criteria the Commissioner should use in overseeing and deciding whether or not to approve non-federally funded research involving the protected classes.

Chaired by Herbert Pardes, M.D., Vice President for Health Sciences and dean of the Faculty of Medicine, College of Physicians and Surgeons, Columbia University, the 13-member Work Group included distinguished bioethicists, clinicians, researchers, attorneys, persons with governmental experience in overseeing research, a chairman of an institutional review board (lRB), and a family member of persons with mental disabilities.

The Work Group's deliberations between July 1997 and March 1998 were informed by a wide range of stakeholders, including researchers, IRB chairs, recipients of mental health services—including former participants in research, family members, hospitals, medical schools, professional associations and advocacy groups. Input was provided through written comments in response to an outreach letter and oral presentations made directly to the Work Group.

The Work Group maintained ongoing contact with the National Bioethics Advisory Commission and the Maryland Attorney General's Working Group on Human Subject Research Involving Decisionally Incapacitated Subjects. The Work Group used the third draft of the report of the Maryland Attorney General's Working Group as a framework to guide discussion on research involving adults who lack decisional capacity. Throughout its deliberations, the Work Group considered key policy issues related to research involving persons unable to provide informed consent as reflected in stakeholder comments, in the actual experience of Work Group members and as reported in the current research ethics literature.

In addressing the broad questions included in the charge, the Work Group focused on policy issues related to research involving persons who are cognitively impaired and who have been determined by a court to be incompetent or who lack decisional capacity to consent to research participation. Individuals in these groups are vulnerable and in need of special protections, because their capacity to understand information and their ability to make reasoned decisions about research participation are compromised.

The Work Group acknowledged that the current federal regulations governing human subject research, 45 C.F.R. part 46, do not have specific requirements related to research involving persons with mental disabilities, a population that includes individuals with mental illness, developmental disabilities, dementia and

other conditions associated with mental impairment. Instead, federal regulations allow IRBs to determine whether additional safeguards for mentally disabled subjects should be added to the basic provisions governing human experimentation. In the absence of specific requirements or regulations, investigators and IRBs lack adequate guidance on fulfilling this responsibility. As a result, there is little uniformity with regard to consent procedures, assessment of risks and potential benefits, and the role of proxy decision makers in research involving subjects whose mental functioning is compromised.[4]

In developing its recommendations, the Work Group relied on the ethical framework outlined in the Belmont Report. Issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research more than two decades ago, the Belmont Report identified three principles relevant to the ethics of research involving human subjects: respect for persons, beneficence and justice.[5]

The respect for persons principle embodies two major concepts: that individuals should be treated as "autonomous agents," and that "persons with diminished autonomy are entitled to protection. The recommendations in this report seek to respect the autonomy of individuals in the protected classes who have decisional capacity and, at the same time, provide protection for those individuals with diminished autonomy who lack full decisional capacity.

Promoting human well-being is at the heart of the beneficence principle: The principle of beneficence creates an obligation in the research context "to maximize possible benefits and minimize possible harms," and to ensure that "research risks [are] reasonable in relation to the anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result." The Belmont Report applies the beneficence principle to research involving children, noting that effective ways of treating childhood diseases and fostering healthy development are benefits that can justify research even when individual research subjects are not direct beneficiaries. These same considerations apply to research involving adults with mental disabilities who lack the capacity to consent to research participation on their own behalf. The Work Group acknowledged the ethical problem posed by research that presents more than minimal risk without immediate prospect of direct benefit to subjects, but determined that to preclude such research would rule out research promising great benefit to others in the future. The Work Group determined that, as long as safeguards are in place to protect individual subjects from serious harm, certain studies in this category may be ethically acceptable.

The concept of justice addressed in the Belmont Report is that of "fairness in distribution" of both the burdens and benefits of research. The class of persons that share the burdens of research risks should receive an appropriate benefit, and the class primarily intended to benefit from the research should share a fair proportion of the risks and burdens. As a matter of social justice, some classes of potential research participants may be involved as research subjects only after certain conditions for research participation are satisfied. Yet to deny any one group access to research would foreclose the potential benefits such research may provide to them or to others like them in the future.

Consistent with these principles, the Work Group offers the following recommendations regarding the Commissioner of Health's oversight of human subject research involving the protected classes.

Recommendations

1. The Department of Health's implementation of its human subject research oversight responsibilities pursuant to article 24-A of the Public Health Law should be consistent with the policies and principles articulated by the New York State Legislature in Public Health Law § 2440, and guided by the three ethical principles identified in the Belmont Report: respect for persons, beneficence and justice.

2. The Commissioner of Health should oversee all risk-benefit categories of non-federally funded human subject research involving the following protected classes of persons: persons determined by a court to be incompetent, other adults who lack decisional capacity to consent to research, capable adults whose condition creates a reasonable likelihood of decisional impairment during the course of a research study and minors.

3. The Commissioner of Health should develop and promulgate regulations to govern non-federally funded research involving these protected classes of persons.

4. The Commissioner of Health should rely on existing IRBs to provide the front-line review and approval of non-federally funded research involving these protected classes of persons in accordance with state-promulgated regulations.

   (a) The Department of Health should provide guidance, documents, training and technical assistance to IRBs on a routine basis to enable them to perform their role effectively.

   (b) The Department of Health should establish and maintain a statewide registry of IRBs

and IRB-approved research involving these protected classes of persons.

5. The Commissioner of Health should review all IRB-approved non-federally funded research involving these protected classes of persons and determine whether or not to approve the conduct of such research.

   (a) The Commissioner should consider using an expedited review process to review some research.

   (b) The Commissioner should implement a full review process, involving clinical consultants with appropriate expertise, to review research determined by an IRB to present no prospect of direct benefit and a minor increase over minimal risk and all research determined to present more than a minor increase over minimal risk.

   (c) The Commissioner's review of research involving these protected classes of persons should be timely. Expedited reviews should be completed within seven to 14 days and full reviews should be completed within 30 to 35 days.

6. The Commissioner of Health should work in partnership with IRBs and the federal Department of Health and Human Services Office for Protection from Research Risks to ensure, to the degree possible, uniform standards for human subject research involving these protected classes of persons.

7. Procedures, standards and criteria for research involving adults who lack decisional capacity to consent to research and capable adults whose condition creates a reasonable likelihood of decisional impairment during the course of a research study should be established in state-promulgated regulations. These regulations should be consistent with those proposed in Appendix D and should address:

- responsibilities of investigators,
- responsibilities of IRBs,
- requirements for informed consent and subject assent,
- procedures for determining capacity of prospective research subjects,
- authorization of health care agents, research agents, and surrogates (family members and close friends) to consent to research on behalf of adults lacking decisional capacity under specified circumstances,
- use of research advance directives,
- requirements for monitoring during research and other special safeguards to protect the rights and well-being of research participants and
- reporting requirements, including the establishment of a statewide registry of IRBs and IRB-approved research.

In carrying out its oversight of human subject research, the Department of Health must promote research while safeguarding the legal and constitutional rights of all individual research participants, with special attention to those most in need of protection. Such actions will contribute to New York's long legacy of leadership in biomedical and behavioral research, the continued advancement of scientific knowledge and the improvement of the health of all New Yorkers, while safeguarding the human rights and welfare of individuals who participate in research.

Endnotes

1. Dresser, Rebecca J.D.; *Research Involving Persons with Mental Disabilities: A Review of Policy Issues and Proposals; Contract Paper for the National Bioethics Advisory Commission*, p.1 (unpublished paper).
2. DeRenzo, Evan G.; *Decisionally Impaired Persons in Research: Refining the Proposed Refinements*; Journal of Law, Medicine and Ethics, 1997, 25: p.1 39.
3. *T.D. et al. v New York State Office of Mental Health et al.*, 228 A.D.2d 95 (1st Dept. 1996). This lawsuit, brought by several psychiatric patients and advocacy organizations, challenged regulations promulgated by the New York State Office of Mental Health (OMH) governing research at all OMH-licensed or operated facilities. The Appellate Division's decision held that Public Health Law article 24-A vested the Commissioner of Health with the exclusive authority to promulgate human subject research regulations Thus, the Court ruled that the OMH human subject research regulations were invalid because OMH lacked the statutory authority to promulgate them. The Court also held that Public Health Law Article 24-A required researchers to obtain the consent of the Commissioner of Health for non-federally funded, more than minimal risk research involving incapable adults or minors. In addition, the Court found that, with respect to non-federally funded, more than minimal risk research with no prospect of direct benefit involving incapable adults or minors, the OMH regulations violated certain constitutional and legal requirements The New York Court of Appeals subsequently ruled that this aspect of the Appellate Division's decision was an inappropriate advisory opinion.
4. Dresser, Rebecca J.D.; *Research involving Persons with Mental Disabilities: A Review of Policy Issues and Proposals; Contract Paper for the National Bioethics Advisory Commission*, pp.2-9.
5. National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research; *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979).

This is an excerpt from the Advisory Work Group's Report. The full report, the regulations proposed by the Work Group, are available from DOH's Office of Public Affairs, 518-474-7354.

	1. WHO CAN AUTHORIZE PARTICIPATION OF DECISIONALLY INCAPACITATED PERSONS IN EACH RISK/BENEFIT CATEGORY OF RESEARCH?		
	MINIMAL RISK	**MINOR INCREASE OVER MINIMAL RISK**	**MORE THAN A MINOR INCREASE OVER MINIMAL RISK**
PROSPECT OF DIRECT BENEFIT RESEARCH	• Judge through a court order. • Court-appointed guardian. • Health care agent authorized through a health care proxy. • Research agent specifically authorized through a research advance directive to grant permission for participation in prospect of direct benefit research. • Surrogate (family member or close friend) as defined in regulation.	• Judge through a court order. • Court-appointed guardian. • Health care agent authorized through a health care proxy. • Research agent specifically authorized through a research advance directive to grant permission for participation in minor increase over minimal risk/prospect of direct benefit research. • Surrogate (family member or close friend) as defined in regulation.	• Judge through a court order. • Court-appointed guardian. • Health care agent authorized through a health care proxy. • Research agent specifically authorized through a research advance directive to grant permission for participation in more than a minor increase over minimal risk/prospect of direct benefit research. • Surrogate (family member or close friend) as defined in regulation.
NO PROSPECT OF DIRECT BENEFIT RESEARCH	• Judge through a court order. • Court-appointed guardian specifically authorized to grant permission for participation in minimal risk/no-prospect of direct benefit research.. • Research agent specifically authorized through a research advance directive to grant permission for participation in minimal risk/no-prospect of direct benefit research. • Surrogate (family member or close friend) as defined in regulation.	• Judge through a court order. • Court-appointed guardian specifically authorized to grant permission for participation in minor increase over minimal risk/no-prospect of direct benefit research. • Research agent specifically authorized through a research advance directive to grant permission for participation in minor increase over minimal risk/no-prospect of direct benefit research. • Surrogate (family member or close friend) as defined in regulation.	• Research agent specifically authorized through a research advance directive to grant permission for participation in more than a minor increase over minimal risk/no-prospect of direct benefit research.

	2. LEGALLY AUTHORIZED REPRESENTATIVES CRITERIA FOR CONSENT IN PRIORITY ORDER		
	MINIMAL RISK	**MINOR INCREASE OVER MINIMAL RISK**	**MORE THAN A MINOR INCREASE OVER MINIMAL RISK**
PROSPECT OF DIRECT BENEFIT RESEARCH	**Research Agent** • research is consistent with instructions in research advance directive. **Health Care Agent** • research is consistent with instructions in health care proxy; or • is in accordance with individual's reasonably known wishes; or • is in accordance with the individual's best interest. **Surrogate** • only in the absence of a health care agent and a research agent when research is in accordance with individual's reasonably known wishes; or • is in accordance with the individual's best interest.	**Research Agent** • research is consistent with instructions in research advance directive. **Health Care Agent** • research is consistent with instructions in health care proxy; or • is in accordance with individual's reasonably known wishes; or • is in accordance with the individual's best interest. **Surrogate** • only in the absence of a health care agent and a research agent when research is in accordance with individual's reasonably known wishes; or • is in accordance with the individual's best interest.	**Research Agent** • research is consistent with instructions in research advance directive. **Health Care Agent** • research is consistent with instructions in health care proxy; or • is in accordance with individual's reasonably known wishes; or • is in accordance with the individual's best interest. **Surrogate** • only in the absence of a health care agent and a research agent when research is in accordance with individual's reasonably known wishes; or • is in accordance with the individual's best interest.
NO PROSPECT OF DIRECT BENEFIT RESEARCH	**Research Agent** • research is consistent with instructions in research advance directive. **Surrogate** • only in the absence of a research agent when research is in accordance with individual's reasonably known wishes.	**Research Agent** • research is consistent with instructions in research advance directive. **Surrogate** • only in the absence of a research agent when research is in accordance with individual's reasonably known wishes.	**Research Agent** • research is consistent with instructions in research advance directive.

News from the Health Law Section

Committee on Securing Health Care for the Uninsured Formed

At a June meeting, the Executive Committee approved the formation of a new committee: the Committee on Securing Health Care for the Uninsured. Peter Millock of Nixon Peabody will chair the committee. Mr. Millock is the former general counsel to the NYS Department of Health.

The committee's statement of purpose is as follows:

Some three million New Yorkers lack health insurance, and that number is growing. The need to find sound and practical measures to secure care for the uninsured—measures that balance public and private responsibility—is arguably the most pressing policy issue in health care.

The Committee on Securing Health Care for the Uninsured was formed in the belief that the health care bar can provide significant support for the effort to address this problem, without being drawn into political or ideological battles. Accordingly, the Committee's purpose will include:

- *To identify the principal federal and state initiatives to secure health care coverage for the uninsured New Yorkers.*
- *To bring those proposals to the attention of the Section.*
- *To analyze legal issues raised by such proposals.*
- *To organize balanced professional and public education programs regarding such proposals.*
- *To comment on the impact of current and proposed laws and regulations on the uninsured.*
- *To examine ways for health care attorneys to help address the problem of access to health care.*

Significantly, the committee's purpose does not include developing an affirmative proposal to secure health care for the uninsured; or adopting a position supporting or opposing any particular proposal to secure health care for the uninsured.

Section members are invited to join the committee. To join, contact NYSBA staff member Kathy Plog by calling 518-487-5681, or e-mail her at kplog@nysba.org.

Preliminary Results of Health Law Section Survey

Over two hundred members of the Health Law Section responded to a recent survey that was designed to gauge the wishes and interests of members. Among the results:

- The benefits and services that members considered most important were "Accessing information specific to your area of practice" (80.4%) and "Keeping you current on legislation and regulations affecting your areas of practice." (respondents gave two top choices).
- The most important factors in deciding whether to attend a meeting or event were "program subject/topic" (58.8%) and "geographic location" (37.7%). Some also filled in "cost of program."
- The main reason members did not serve on committees were "lack of time (39.2%) and "meeting location not convenient." (19.1%). Several filled in that they had not received information about meetings.
- 53.7% of members expressed an interest in participating in meetings by videoconferencing.
- Upstate NY and Greater NYC are evenly represented (45.5% each).

In response to a request for suggestions, members suggested:

- do more to facilitate participation by members from western and central NYS
- set up an e-mail discussion listserve.
- issue a membership directory
- vary meeting locations
- update the website with meeting information

The great majority of members said they planed to continue their membership (84.7%). Only 1% said they would not. Others said "don't know."

The Section's Executive Committee has reviewed these results and is promoting many of the changes members recommended.

Members who have not yet responded but wish to do so can find the survey form on the Section's website—www.nysba.org/sections/health.

Recent Program on Provider Transactions Sets Attendance Record

"Transactions Among Health Care Providers" a program cosponsored by the Health Law Section with NYSBA's CLE department, was attended by about 350 persons. The attendance set a record for a Health Law Section-CLE program.

The program, chaired by Robert Wild of Garfunkle, Wild & Travis, included sessions on antitrust, federal and state regulatory issues, tax and financing considerations and health care provider transactions.

The program materials, including an audio tape, are available from the NYSBA. Call 1-800-582-2452 or 518-463-3724.

Meet Your New Elected Officers

The Section officers elected to serve from June 1999 until June 2000 are as follows:

Chair-Robert N. Swidler. Mr. Swidler is Corporate Counsel at Northeast Health, a system of hospitals, primary care centers, nursing homes, home care and residences in the Capital District.

1st Vice-Chair/Committees. Tracy E. Miller - Ms. Miller is Clinical Associate Professor in the Department of Health Policy at Mt. Sinai School of Medicine in NYC. She is also Director of the United Hospital Fund project to establish the national Forum for Quality Measurement and Reporting.

2d Vice Chair/Professional Education - Robert Abrams. Robert Abrams practices health and elder law in The Law Offices of Robert Abrams, P.C., Lake Success, NY.

Secretary - Linda J. Nenni. Ms. Nenni is the General Counsel of Kaleida Health, the Buffalo-based health system.

Treasurer - Salvatore J. Russo. Mr. Russo is Assistant Counsel to the NYC Health and Hospital Corporation.

Fraud, Abuse and Compliance Committee Created

Committee may also address tax-exemption compliance

From the Baptist Medical Center convictions through the OIG Special Advisory Bulletin on gainsharing, the developments in the specialty of fraud, abuse and compliance law are fast-moving and far-reaching.

Accordingly, at its June meeting, the Health Law Section Executive Committee established a committee on Fraud, Abuse and Compliance. The committee will be chaired by Jim Horwitz, who is General Counsel to Glens Falls Hospital.

The committee's initial purpose is envisioned to be both educational and practical. The committee will provide to the Health Law Section summaries and analysis of critical decisions and developments and recommend compliance policies, procedures, tools and guidelines.

Since the Fraud, Abuse and Compliance Committee is a new committee, a special opportunity exists for the initial membership to define itself and the committee's direction. Interested members can sign up by calling Kathy Plog at 518-487-5681. For more information, call Jim Horwitz at 518-761-5208.

Section Creates Special Committee on Medical Information

At its June Executive Committee meeting, the Section created a Special Committee on Medical Information. Anne Maltz, an attorney with Stroock, Stroock & Lavan, was appointed chair of the new committee.

The Special committee will continue the work of the Health Law Section's former Work Group on Health Information and Privacy. That Work Group analyzed and issued comments on HHS' recommendations on protecting medical information, issued pursuant to § 264 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

HIPAA required Congress to pass a comprehensive law to protect the privacy of patient health information by August 21, 1999. If it fails to do so, the same law directs HHS to issue regulations by February 2000.

The committee will examine the changes in federal law and the impact of those changes on New York State's privacy and confidentiality laws. It will also provide information to the bar on this important subject which is relevant to all health care consumers and health care attorneys.

Persons interested in joining the committee should contact Anne Maltz at 212-806-6673, or NYSBA staff person Kathy Plog at 518-487-5681.

NYS DOH Seeks Health Law Section's Advice

Last January, while giving the luncheon address at the Section's Annual Meeting, DOH's General Counsel Hank Greenberg urged the Health Law Section to become more active in reviewing and commenting on Public Health Law provisions and DOH regulations. In recent conversations with various Executive Committee members, he reiterated that invitation.

"The Health Law Section can be an enormously valuable force for improving health policy in this state," he said. "We need your advice. When your diverse and experienced membership forges a consensus on a statutory or regulatory recommendation, it carries great weight with us, far more weight than the views of special interest groups."

The Section and DOH are also looking for other ways to work more closely together. For example, this *Journal* will be used as a vehicle to disseminate DOH reports—such as the report in this issue by a DOH-sponsored Advisory Group on Human Subject Research.

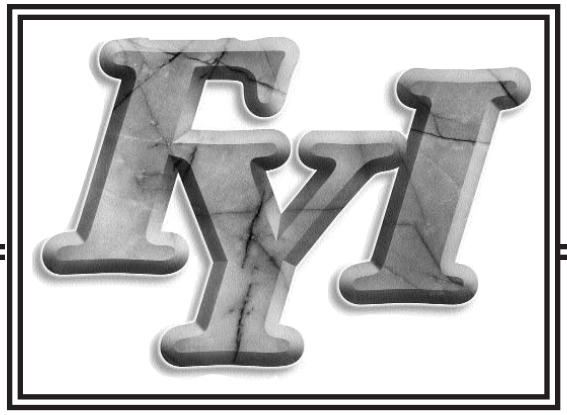
Committee Meeting Travel Fund Planned

At its June meeting, the Health Law Section decided to establish a travel fund to help subsidize the costs members incur in traveling from one city to another to attend a committee meeting.

The fund reflects the Section's determination to overcome the problem of distance and to attract membership participation from throughout the state.

While details regarding the fund are being worked out, it is expected to work as follows: The Section will make an amount available each quarter. Members who take a plane or train for over 100 miles solely to attend a Health Law Section committee meeting will be invited to forward their receipt for such travel to the NYSBA. Each quarter, the fund amount will be divided among the claimaints in proportion to their expenses.

The rules and requirements of the fund will be sent to members when finalized. Meanwhile, members who travel by train or plane to a committee meeting should save their receipts.



FYI is a new column that offers Section members a way to keep up on the comings and goings of their colleagues and upcoming events of interest. Has there been a change in your practice? Any recent or forthcoming articles or lecture presentations? Won any awards recently? Please send submissions to Professor Barbara Atwell or Professor Audrey Rogers, Pace University School of Law, 78 North Broadway, White Plains, NY 10603.

Barry A. Gold has been elected to a three-year term on the National Board of Directors of the Myasthenia Gravis Foundation of America. He is a health lawyer and a partner in the Albany firm of Thuillez, Ford, Gold & Johnson, LLP, and an adjunct associate professor at Albany Medical College. Barry was the founding Chair of the Health Law Section of the New York State Bar Association and author of *New York Health Law.*

This fall, the **Pace Health Law and Policy Program** is offering practicing lawyers in the tri-state area the opportunity to take courses in real-time, sharing a "virtual classroom" with students on the White Plains campus via Pace's Distance Learning Centers in Manhattan and Pleasantville. Food and Drug Law, taught by Adjunct Professor Joseph McAuliffe, former vice president and general counsel of American Cyanamid, is offered on Monday nights. Introduction to Health Law is taught by Professor Barbara Atwell on Monday and Wednesday evenings. In the Spring 2000 semester, Pace plans to offer Public Health Law and Antitrust Law via distance learning. For further information about the Health Law and Policy Program distance learning courses, please contact Professor Linda Fentiman, at 914/422-4422, or her assistant, Mrs. Kathleen Lambert, at 914/422-4223.

Welcome New Members:

Shraga D. Aranoff
Carl R. Aron
Betty L. Atlas
Barbara A. Bablens
Amy S. Barash
Melinda Aikins Bass
Kelley Ann Bieber
Igor Bilewich
Jacqueline A. Blackley
Fern H. Block
Andrew E. Blustein
Coreen A. Bromfield
Michael David Brophy
Deborah A. Brown
Elizabeth Anne Burns
Maureen Callinan
Dale B. Campbell
Susan O. Cassidy
Jeffrey D. Chansler
Charles B. Ciago
Jennifer M. Coffey
Frederick B. Cohen
Joshua Cohen
Doreen A. Cronin
Jennifer D'Afflitto
Thomas S. D'Antonio
Elizabeth M. D'Elia
Delinda C. Dacoscos
Armand P. Damato
Herbert Dicker
Edward D. Eckaus
James H. Erceg
Francine E. Fainelli
Paul Gerard Ferrara
Barbara Fifield-Guzman
James S. Frank
Glenn F. Gakovic
Patricia Garofalo
Amanda E. Gerhardt
Marshall J. Gluck
Richard Shalem Goodman
Stephen J. Grifferty
James A. Griffin
Noreen DeWire Grimmick
Dennis J. Gruttadaro
Howard G. Halee
Amanda L. Hart
Khalid Hassan
Catherine M. Hedgeman
Patricia A Herring
Bryan D. Hetherington
Dana W. Hiscock
Cheryl P. Hogan
Evelyn Huang
Robert George Iadicicco
Ilene H. Iannuzo
Joseph I. Jancko
Laurance Jerrold
Lee J. Johnson
Sally A. Johnston
Karen J. Kachik
Stacy L. Klein
Kristin E. Koehler
Darin Kossin
Lori K. Ladhani
Monica Lamb
Kristin L. Lewis
Deirdre A. Long
Megan M. Lorentz
Megan M. Malone
Jeremiah F. Manning
Lori Ann Marano
Lewis W. Marshall
Gina M. Martin
William M. McGoldrick
Steven I. Milligram
Robert Francis Mogavero
Patricia Mooney
John R. Murphy
Sheila J. Namm
Francis J. Offermann
Joyce R. Parker
James E. Patrick
Ann Phillips
Ilena I. Pimentel
Luke M. Pittoni
Alan Podhaizer
Sara B. Potter
Susan Richter
James T. Rochford
Nancy J. Rudolph
Carol Santangelo
Craig A. Schaum
Dana Jill Scher
David Schlang
Ralph Scola
Barbara A. Sherk
Anuwinder Kaur Singh
Naomi Sinnreich
Bruce G. Soden
William S. Spiegel
Walter C. Squire
Tamara Stack
Paul Svenson
Kenneth A. Votre
Ruthanne Wannop
Cheryl A. Wasserman
Harvey Weinberg
Michael Gary Weisberg
Mary Anne Wirth
Elizabeth A. Wolford
Doug J. Yoon

Section Committees and Chairs

The Health Law Section encourages members to participate in its programs and to volunteer to serve on the Committees listed below. Please contact the Section Officers (listed on the back page) or Committee Chairs for further information about these Committees.

Biotechnology and the Law
James W. Lytle (Chair)
Kalkines Arky, et al.
121 State Street, 3rd Floor
Albany, NY 12207
(518) 432-5990
Fax (518) 432-5996
e-mail: jlytle@kazb.com

Consumer/Patient Rights
Jeffrey S. Gold (Co-Chair)
Office of the Attorney General
Health Care Bureau
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Guardianship Practice in New York State

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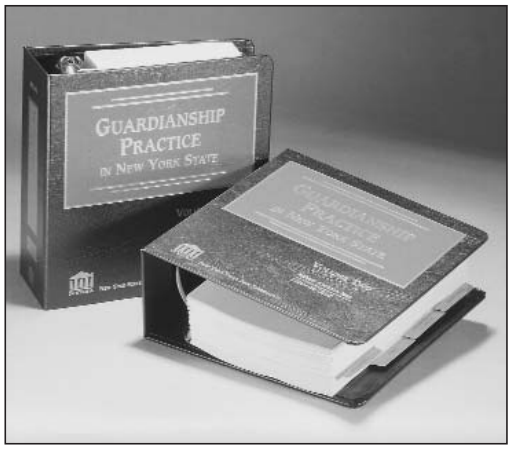

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