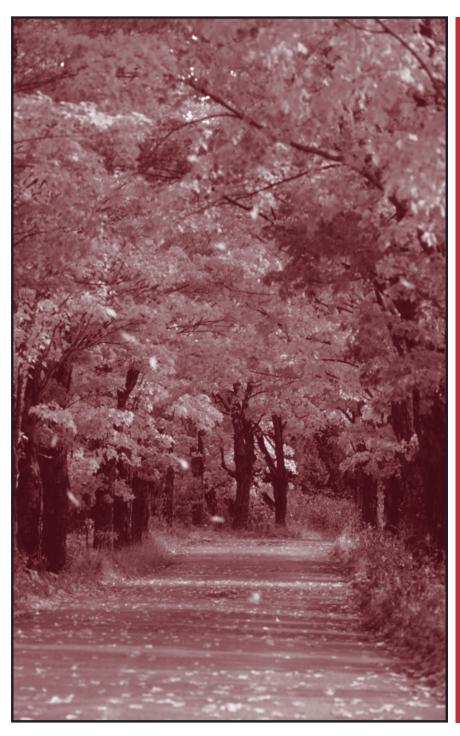
Health Law Journal

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A Message from the Section Chair

In my brief tenure as the Chair of the Health Law Section, the most challenging task assigned to me, at least so far, has been to add some words of wisdom to this *Journal*. Although I have made modest contributions to the *Journal* as its designated reporter on health-related legislation, that topic defines itself: because the Legislature generally provides sufficient



material for a column writer (let alone enough occasionally for a stand-up comic), piecing together a few paragraphs does not pose much of a problem. But instead of devoting much more time to staring at a blank screen, let me, as the Chair, begin by welcoming you to another spectacular issue of the *Health Law Journal* and to what we hope will be another very productive year for our Section.

Since this is my first column as Chair, I thought some introduction might be in order. Like many of you, my introduction to health law was largely accidental. Having attended law school at a time when the discipline had still not fully defined itself, I found myself gradually drawn to this field, perhaps as a result of being the son of a physician and nurse who showed insufficient scientific aptitude—or intestinal fortitude—to follow in my parents' footsteps. After a stint as an Assistant District Attorney, I began to become acquainted with health law issues—first, as an associate in a litigation department of an upstate law firm and, then, as the director of a volunteer legal services organization that addressed a host of health issues from the low-income consumer's point of view. My health law education reached the immersion phase when I served as an Assistant Counsel to the Governor in the early 1980s, where I had responsibility for legal and legislative issues in the health care and human services arena. (Robert Swidler, one of the editors of this Journal and a Past Chair of the Section, enjoyed the same educational experience.)

Not only was that my most intensive exposure to the then current issues in health law—ranging from health care reimbursement to involuntary commitment to "do not resuscitate orders" to medical malpractice reform—but it was my first exposure to some of the leading members of the healthcare bar. Barry Gold, whose premature death we mourned last year, was then the Chair of the Health Law Committee of the New York State Bar Association—years before Barry and others helped found this Section—and I used to look forward to the comments of the Committee on legislation pending before the Gover-

nor. I learned that the comments of the Committee could be depended upon to be legally astute and well-informed, without the same degree of special pleading or special interest that characterizes much of what policy-makers receive.

I take, therefore, special pride in being a part of this Section. We have not only been consistently one of the fastest growing sections of the Bar, we've been among the most productive: consistently high-quality CLE programs, topical and (especially this year) entertaining Annual Meeting sessions, a first-rate *Journal*, a sometimes overactive listserve and a recently published textbook that informs physicians what they need to know about New York health law. (What other Section provides its clients a product that might threaten its livelihood?)

I owe, of course, a special debt to Sal Russo, who has served this Section so well. His leadership resulted in the substantial growth in our Section, a geometric increase in CLE and other programs (including the initial planning of many programs that will occur during my tenure and for which I'll try to take all of the credit), a new law student writing competition (together with important steps toward strengthening the relationship of the Section with the region's law schools' health law programs), new efforts in providing direct input to the Legislature on health law matters and, perhaps above all, a renewed spirit of camaraderie and friendship among the members of the Section. He left large shoes to fill—which, as he might note, must be the only articles of his clothing that haven't substantially reduced in size over the past year.

The officers of the Section are already working on new ways to meet Section members' needs over the next year: we have some great programs planned, including a professional misconduct CLE program across the state and a reprise of a program on federal and state enforcement matters (involving federal and state prosecutors) this Fall; we hope to further strengthen and enhance the Section's legislative analysis and advocacy function; and we are interested in exploring new ways to enhance the spirit and collegiality of our Section through the planning of more social events that might bring us together for more than just the mandatory CLE credits.

I hope you will contact me if you have any suggestions on what we should be doing, particularly if that suggestion is accompanied by an offer to volunteer your efforts to accomplish it. I am very honored to serve as your Chair and I hope to work with and meet as many of you over the next year as possible as we continue to strengthen and grow the Health Law Section.

James W. Lytle

In the New York State Courts

By Leonard Rosenberg

Court Permits Mother to Withdraw Life Support from Her Child

In re AB, 2003 WL 21649677 (N.Y. Sup. Ct., May 16, 2003). In this case, the court held that state law permitted the parent of a three-yearold child to withdraw life support from the child, who was in a permanent vegetative state with no chance of recovery. AB was an apparently healthy three-year-old girl who lived with her mother. After having a seizure and collapsing, AB was rushed unconscious to Kings County Hospital, a part of the New York City Health and Hospitals Corporation (HHC), where she was diagnosed as being in a persistent vegetative state.

When AB's mother determined that it was in the best interest of her daughter to remove her from the mechanical ventilator, she sought a court order confirming her authority to direct the hospital to do so. The court appointed a guardian ad litem for AB and held a hearing on the issue. At the hearing, the mother, the child's treating physicians, and the guardian testified.

AB never regained consciousness. A series of neurological evaluations, electroencephalography and magnetic resonance imaging all confirmed that AB suffered a massive loss of brain functioning, did not respond to stimulation, required a feeding tube for nutrients, and a mechanical ventilator to breathe. The record also indicated that AB was permanently unconscious and totally unaware of the environment, not aware of sensation, and was without the ability to think or interact, with no chance of return to an awareness of, or interaction with, her environment.

The treating physicians and the guardian agreed with the mother's



request. The guardian testified that the mother's decision was not motivated by economics, there were never any alle-

gations of abuse or neglect of AB, and there was no evidence of disability-based discrimination. The father also supported the decision.

The court ultimately authorized the mother to direct AB's withdrawal from life support. In reaching its decision, the court reviewed applicable New York law. Initially, it noted that "[t]his case differs from the usual 'right to die' case in that typically family members seek court authorization to have life support systems terminated where the incompetent patient has earlier expressed his/her preference regarding such treatment." In contrast, AB is an infant who, "by definition, is incapable of making any determinations or formulating any preferences for treatment."

The court noted that, unlike a competent individual's common law right of self-determination, which "outweighs the rights of the patient's family, physicians, or other care providers to base a treatment decision on their individual interests or ethical imperatives," the law in New York is unsettled in cases in which a terminally ill patient has never been competent to express his or her wishes regarding medical treatment. Nonetheless, the court acknowledged that "where there is no compelling evidence of the incompetent's wishes, the court must determine whether withdrawal of life support will serve the patient's 'best interest.'" To determine best interest, "at a minimum, there

should be evidence that the burdens of prolonged life outweigh any physical pleasure, emotional enjoyment, or intellectual satisfaction that the patient may still be able to derive from life."

The court indicated that "[t]he highest courts in other jurisdictions have favored putting decisions such as the one which is before this Court in the hands of loving and caring parents of the infant, without the need for judicial intervention." Likewise, the court emphasized that "New York's law involving the right of a patient, or a surrogate, to decline medical treatment has evolved over the last decade." For example, "the Legislature [recently] enacted a new law which grants to guardians of individuals suffering from mental retardation the authority to withhold life-prolonging treatment."

Although the court recognized that the new law (known as the Health Care Decisions Act for Persons with Mental Retardation) specifically addresses guardians of individuals with mental retardation, it nonetheless stressed that "[i]t also reflects an evolving consensus in this State that the law must better allow health care practitioners, patients and their families to make decisions in the best interest of their children when faced with tragic circumstances."

The court further noted that "the scope of the authority conveyed on the guardian by the [new law] is similar to the authority sought by the mother here," and "the decision-making analysis employed by the mother . . . is similar to the 'best interest' standard articulated in [such new law]." The court also noted that it was uncontested by all of those involved in the case that the

mother was acting in the best interest of her daughter, that the "best interest" standard was consistent with guidelines proposed by the American Medical Association, and with traditional parental values and responsibilities. Thus, the court concluded that "[t]here can be no State interest great enough to compel AB to remain subjected to this extraordinary life-sustaining measure . . . [which] would merely prolong the death of a terminally ill child . . . while subjecting her to daily physical intrusions."

Court Holds That Confidentiality Provisions of a Settlement Agreement in a Malpractice Action Do Not Offend Public Policy

Speken v. Columbia Presbyterian Hospital Center, 759 N.Y.S.2d 47 (1st Dep't 2003). The Appellate Division for the First Department recently rejected a plaintiff's second attempt to vacate the confidentiality provisions of a settlement agreement in an underlying action for medical malpractice. The plaintiff had argued that the confidentiality provisions of the settlement agreement were void as against public policy.

Although the court affirmed denial of plaintiff's claim based on res judicata grounds, it noted, "[i]n any event, the settlement agreement, which prohibits plaintiffs from discussing or otherwise disseminating information about the malpractice action or their decedent's care and treatment at defendant hospital, does not offend the public policy against prior restraint of speech. . . ."

Appellate Court Holds That Tobacco Companies Are Not Liable for Unreimbursed Costs of Supplying Health Care to Consumers of Tobacco Products

A.O. Fox Memorial Hospital v. American Tobacco Company, Inc., 754 N.Y.S.2d 368 (2d Dep't 2003). Plaintiffs, consisting of approximately 170 New York non-profit hospitals

and a trade association, commenced an action against major tobacco companies and a public relations firm, "to recover the unreimbursed costs of supplying health care to unspecified consumers of tobacco products." Plaintiffs' primary assertion was that the defendants had "systematically conspired for at least half a century to fraudulently conceal the adverse health consequences of using tobacco to shift the health-related costs of smoking to the plaintiffs."

The Appellate Division for the Second Department affirmed the Supreme Court's decision dismissing the complaint for failure to state a cause of action. The court affirmed dismissal of the first 19 causes of action in the complaint on the ground that plaintiffs' allegation of economic injury was entirely derivative of the tobacco-related harm suffered by the individual patients, and therefore too remote to permit recovery.

The court held that plaintiffs' cause of action based on commonlaw subrogation was also properly dismissed "because the plaintiffs failed to identify the individual patients and their particular injuries and specify facts which, if proven, would establish liability."

Appellate Court Holds That Physician Has a Private Right of Action Under Public Health Law § 4406-d to Challenge Termination of HMO Contract

Foong v. Empire Blue Cross and Blue Shield, 2003 N.Y. Slip Op. 14567; 2003 WL 21234956 (1st Dep't 2003). The Appellate Division recently affirmed a lower court's ruling that section 4406-d of the New York Public Health Law permits physicians to seek judicial review of a health maintenance organization's (HMO) decision to terminate the physician from its network. Notwithstanding the HMO's assertion that section 4406-d merely requires an HMO to provide a physician with a

hearing prior to termination, the court concluded that the statute has the broader purpose of ensuring due process protection for health care providers.

In September 1993, Dr. Foong entered into an agreement with Empire Blue Cross and Blue Shield ("Empire") to become a participating managed care provider. In 1997, Empire amended the agreement to allow it to immediately terminate the provider "in the event of imminent harm to patient care, a determination of fraud or a final disciplinary action by the appropriate governmental authority that impairs Physician's ability to practice." Dr. Foong did not sign the amended Agreement.

The *Foong* litigation arose out of Empire's 13-month fraud investigation of Dr. Foong. Empire contended that it based its investigation on suspicions that Dr. Foong was over-utilizing some invasive gastroenterological procedures in his practice.

Eight months into the investigation, Dr. Foong complained to both the State Insurance and Health Departments about what he believed to be Empire's improper practices during the investigation. Dr. Foong alleged that Empire responded by falsely informing the Insurance Department that its dispute with Foong was currently "in litigation," which induced the Insurance Department to close its investigation.

Dr. Foong further alleged that notwithstanding a determination by the Review Committee of the New York County Medical Society that Dr. Foong's procedures were medically necessary and demonstrated sound medical practice, Empire summarily terminated him from its plan on the ground that he posed a threat of imminent harm to its members. One week later, Empire reported Dr. Foong's conduct to the Office of Professional Medical Conduct (OPMC).

Dr. Foong then sued Empire for breach of contract, violation of sec-

tion 4406-d of the Public Health Law, breach of the implied covenant of good faith and fair dealing, breach of fiduciary obligations, and bad faith reporting to OPMC in violation of section 230(11)(b) of the Public Health Law.

In response, Empire sought dismissal and/or summary judgment. With the exception of the claim for breach of fiduciary obligations (which it dismissed), the lower court denied Empire's motion. Empire appealed, but the Appellate Division, First Department, unanimously affirmed the lower court's decision.

Specifically, the lower court had sustained Dr. Foong's claim for breach of contract and noted that "whether Empire validly exercised the imminent harm exception to terminate Foong is clearly an issue of fact that cannot be resolved as a matter of law."

With respect to the section 4406d claim, the lower court noted that no court had previously addressed whether section 4406-d, which has no express private right of action, contains an implied private right of action. The court found that section 4406-d met the standards for an implied private right of action because: (1) Dr. Foong is one of the class for whose benefit the statute was enacted, (2) recognition of a private right of action would promote the legislative purpose of "provid[ing] due process protection for health care providers enlisted in HMOs," and (3) the creation of such a right is consistent with the legislative scheme.

Empire argued that "providing a private right of action . . . would . . . take the termination review out of the hands of the plan's appointed panel and place it in the hands of the Court." Empire also claimed that, because other provisions of Chapter 44 provide for Article 78 review, no private right of action could have been intended. The court disagreed.

Rather, it emphasized that Chapter 44 grants the opportunity to bring an Article 78 proceeding to HMOs, not health care providers. Moreover, it noted that "HMOs would have the right under Article 78 to challenge a governmental action regardless of whether it was mentioned in Section 4404(5)."

The Appellate Division's decision confirmed Dr. Foong's implied right of action under section 4406-d "against arbitrary termination of health care plan contracts," but also emphasized that Empire "remains free to terminate a provider without a hearing, although its grounds for doing so are subject to judicial review." In addition, the Appellate Division confirmed the lower court's conclusion that Dr. Foong has an implied private right of action under Public Health Law §230(11) with regard to whether Empire's report to the State Board of Professional Medical Conduct was in good faith.

Absolute Privilege Against Defamation Action Extended to Statements Made to a Court Evaluator in Guardianship Proceeding

55th Management Corp. v. Goldman, 2003 WL 1906744 (N.Y. Sup. Ct., April 9, 2003). In a matter of first impression, the New York Supreme Court (Justice Lebedeff) held that a defamation claim, based on out-of-court statements made to a court evaluator in the context of a guardianship proceeding commenced under Article 81 of the Mental Hygiene Law, was barred by the common law rule that a statement made in the course of judicial proceedings is absolutely privileged.

In 1999, a guardianship proceeding was commenced and a court evaluator appointed to investigate appointment of a guardian for an alleged incapacitated person (AIP). During the course of the court evaluator's investigation, a then 74-year-old tenant of the same building as

the AIP telephoned the court evaluator and made statements alleged by the AIP to be defamatory.

The court (Justice Lebedeff) considered the following three factors in determining whether an absolute privilege extended to the statements made to the court evaluator: "(1) whether the speaker's remarks were of a character permitting the assertion of the privilege; (2) whether addressing such remarks to a court evaluator is a statement made in the course of a judicial proceeding; and (3) whether the speaker has standing to claim the privilege."

As to the first factor, the court stated that, "[t]he well-settled test for a statement to which absolute privilege extends is that it is 'possibly pertinent' to the litigation which means it may possibly bear on the issues in litigation now or at some future time. . . ." The court found this factor satisfied because, if true, the information provided by the defendant "would have been highly relevant to the guardianship proceeding."

Regarding the second factor, the court noted that the primary concerns are society's interest in permitting individuals to assert their rights in legal proceedings without fear of liability to libel suits, and the greater harm suppression of the truth would have as compared to the rights of an individual against defamatory statements.

The court found that, "[t]his interest is directly implicated here for virtually no other civil proceedings more directly and simultaneously challenges personal, property and liberty interests than a guardianship proceeding." The court concluded, "[i]t takes no great astuteness to understand that the freedom to collect defamatory but pertinent information is necessary if a court evaluator is to perform a full investigation and report the evaluator's informed conclusions to the court."

The court thus held, given that the court evaluator serves as an investigative agent of the court and acts on behalf of the court and that no public policy mandates to the contrary, this court holds that a "statement made to a court evaluator is a communication properly subject to the absolute privilege." In this case, the court found that the defendant, as a potential witness, was protected by the privilege

Appellate Court Reverses Supreme Court in Upholding Physician's Challenge to Department of Health's Policy on Internet Publication of Disciplinary Proceeding Results

Anonymous v. Bureau of Professional Medical Conduct, ___ N.Y.S.2d ____, 2003 WL 22102750 (1st Dep't, Sept. 11, 2003). In 1999, the State Board for Professional Medical Conduct (BPMC), a disciplinary body under the Department of Health that handles complaints of medical misconduct, issued a statement of five charges of professional misconduct against a general practitioner stemming from "a social encounter [with a female] not involving the practice of medicine." The BPMC's Statement of Charges alleged that the physician treated a minor condition through a procedure that he was not certified to perform under state regulations, and had written a prescription for which he failed to maintain medical records.

After the physician denied the charges, BPMC conducted a hearing before a Hearing Committee ("Committee") in which four of the five charges were not sustained. As to these charges, the Committee discredited the complainant's testimony as "saturated" with exaggerations and inconsistencies, and in certain instances, defied logic. The fifth remaining charge, concerning the physician's failure to maintain a record in connection with the prescription, was sustained as a technical violation. The Committee found

that BPMC had failed to prove any serious form of misconduct, and that the alleged encounter did not involve the provision of medical care. On the sole sustained charge, the Committee desired to issue an administrative warning, but was directed by the Administrative Law Judge that the lowest legally permissible penalty in this case was a reprimand, which it issued.

Thereafter, BPMC published the entire Statement of Charges and its Determination and Order on its Web site following the final determination—including all factual allegations regarding the four charges that the Committee had not sustained. In response, the physician wrote two letters demanding that BPMC remove the information from the Web site and refrain from making it public. When BPMC did not remove the information, the physician filed an Article 78 proceeding against BPMC in the Supreme Court of New York County claiming that, because professional disciplinary proceedings are confidential, BPMC's publication violated Public Health Law (PHL) § 230 and impermissibly subjected his professional reputation to irreparable harm. Because the physician had alleged that BPMC's publication of the charges would harm the physician's professional reputation, the Supreme Court allowed the physician to proceed as an anonymous party in the ensuing litigation.

BPMC disagreed with the physician's arguments, and argued that its policy complies with the PHL. Specifically, it asserted that its "practice of releasing the disciplinary action taken is in accord with the underlying statutory intent and its policy serves to protect the public by disseminating information concerning unprofessional and dangerous physician conduct."

The Supreme Court rejected all of the physician's arguments, reasoning that confidentiality in disciplinary proceedings was designed to prohibit disclosure while the hearing was pending, not once it was complete. The Supreme Court ruled that nothing in the Public Health Law required the BPMC to change its publication policy. The physician appealed to the Appellate Division, First Department.

The Appellate Division reversed the Supreme Court, finding that "dissemination of unsustained charges after a confidential hearing advances no legitimate state interest." The appellate court reasoned that the policy of keeping disciplinary hearings confidential was grounded in a recognition of the irreparable harm that might befall a physician's reputation from unfounded charges. Whereas the Supreme Court had found nothing in PHL § 230 to prohibit publication, the Appellate Division held that nothing in the governing statute required BPMC to publish charges against a physician which are not sustained. The Appellate Division noted that the statue only required the Committee's findings to be publicized where a physician received a penalty of annulment, suspension, or revocation of license. In this case, the physician had merely received a reprimand. The Appellate Division reasoned that the procedural safeguards afforded at disciplinary hearings (i.e., the right to counsel, the right to cross-examine witnesses) were meaningless if dismissed charges were then *required* to be published. Additionally, the court observed, because other PHL provisions prohibit the Department of Health from publishing criminal "not guilty" verdicts in criminal trials and favorable verdicts or dismissals in civil actions against physicians, PHL § 230 must be read to keep favorable determinations in a medical disciplinary proceeding "insulate[d] from public access.'

The Appellate Division did not limit its opinion to pure statutory construction. Given the likelihood of harm to a physician's reputation resulting from publication of unsustained charges, the Appellate Divi-

sion found the BPMC's policy to be "utterly devoid of logic," and therefore arbitrary, capricious, and an abuse of discretion. The court opined that those reading about the unsustained charges would suspect that the physician had actually committed them, and effectively punish the physician for allegations that had never been proven. BPMC had complained that it would be difficult to redact its publication to remove information about the unsustained charges. The Appellate Division sharply disagreed, noting that redaction was not only readily accomplished and legally required, but also "the only decent and fair way to treat factually discredited accusations." Accordingly, the court directed the BPMC to withdraw all records of the four unsustained charges from public access.

Appellate Division Affirms Administrative Review Board's Revocation of Physician's License and Imposition of \$40,000 Fine

Prado v. Novello, 754 N.Y.S.2d 390 (3d Dep't, Jan. 2, 2003). The Appellate Division, Third Department, affirmed a decision by the Administrative Review Board for Professional Medical Conduct (ARB) that revoked a physician's license to practice medicine and imposed a \$40,000 fine. OPMC charged the physician, a plastic surgeon, with fraudulent practice, gross negligence, gross incompetence, and moral unfitness. These charges stemmed from the physician's failure to keep written records of treatment of ten of his patients over a 15-year period. A hearing committee sustained most of the charges against the petitioner, including fraud, negligence, and gross negligence. As a penalty, the Committee revoked the physician's license to practice medicine in New York.

OPMC sought ARB review of five findings that were favorable to the physician. The physician also sought review from the ARB, challenging the Committee's decision to revoke his license and its findings that he had engaged in fraudulent practice. The ARB affirmed the Committee's findings and the license revocation, and added a finding of moral unfitness. The ARB also imposed a \$40,000 fine. The physician appealed the ARB's decision to the Supreme Court, Appellate Division, Third Department.

The Appellate Division affirmed the ARB's determination in all aspects. Initially, the court noted that the petitioner could not challenge aspects of the Committee's determination that he had not raised in his appeal to the ARB. Thus, petitioner's challenges to the Committee's findings of gross negligence and negligence, which were not raised by petitioner to the ARB, could not be reviewed by the court, and were affirmed. Additionally, the court disagreed with petitioner's claim that there was insufficient evidence in the record to sustain a determination of fraud as to certain patients. Petitioner argued that the Committee had failed to make a specific finding of an intent to mislead, but the court found sufficient evidence in the record demonstrating that petitioner had filed false reports with an intent to mislead. The court also affirmed the ARB's findings of moral unfitness due the petitioner's deliberate deceit and repeated false billing practices. Finally, the court held that the \$40,000 fine was not excessively disproportionate to the petitioner's offenses.

Appellate Division Decertifies Class in Action Challenging Hospitals' Photocopying Costs

Feder v. Staten Island Hospital, 304 A.D.2d 470, 758 N.Y.S.2d 314 (1st Dep't 2003). In what had previously been a class-action suit challenging the fees charged by several New York hospitals and copy centers for photocopying medical records, the Appellate Division reversed the grant of class certification. The suit alleges that defendants violated section 18(2)(e) the Public Health Law, which governs the permissible charges for reproducing patients' medical records. The statute at issue permits hospitals to impose "reasonable charges" based on "costs incurred," but not to exceed \$.75 per page. Plaintiffs alleged that defendants generally charged this statutory maximum, even though that figure did not represent the true copying costs, which were allegedly less than \$.75 per page.

The court noted that plaintiffs were required to present competent evidence satisfying several prerequisites for class certification as required by CPLR 901(a). Plaintiffs' evidence was found to be insufficient as to these prerequisites. First, plaintiffs' allegations that they, and thousands of others, had been overcharged for copies, were too conclusory to meet the legal standard for class certification, and did not rise to the level necessary for proof of common questions of law and fact, or that the plaintiffs' claims were typical of the class. Similarly, the court rejected as speculative plaintiffs' argument that defendants processed thousands of requests for medical records copying. Such an argument, the court ruled, was unsatisfactory proof for the necessary finding that the class was too numerous to allow joinder of all members. Because plaintiffs had failed to supply competent evidence of all the prerequisites for class certification, the court ruled that the class should be decertified. [Ed. Note: Garfunkel, Wild & Travis, P.C. represents several of the defendant hospitals in this suit].

Leonard Rosenberg is a partner of Garfunkel, Wild and Travis, P.C. The firm represents health care clients in New York and beyond.

In the New York State Legislature

By James W. Lytle

The 2003 legislative session will be remembered for an unusual bipartisan alliance between the Senate and the



Assembly on state fiscal issues—and for its inability to reach agreement on a host of other less budget-related health care issues. It is expected that the Legislature will be returning to address a number of these and non-health issues sometime during the balance of 2003. For now, here is a brief review of the principal issues on which agreement was reached, organized by the facility categories affected by the legislation:

Long-Term Care and Hospice

- Licensed Home Care Services Agency Reporting: This bill requires licensed home care services agencies to report to the Department of Health regarding the type of services they provide and their frequency and reimbursement. It also directs the Commissioner of Health to establish a cap on reimbursement for the agencies' administrative and general costs.
- Licensed Home Care Services
 Agency and Insurance Coverage:
 This bill made permanent provisions requiring insurers and
 HMOs to reimburse licensed
 home care services agencies for
 home health care services.
- Hospice Residence Pilot Program: This bill authorizes the
 Commissioner of Health to establish a hospice residence pilot program consisting of up to three residences serving between two and sixteen patients.

• Assisted Living Program Reimbursement: This bill requires that Medicaid reimbursement for certain free-standing assisted living programs include real property capital construction costs.

Hospitals

- Medical Malpractice: Both houses passed legislation to respond to the express invitation by the Court of Appeals in *Desiderio v*. Ochs, 2003 N.Y. LEXIS 432 (April 8, 2003) to remedy problems encountered in the application of the periodic payment statute that was enacted to address the malpractice crisis of the mid-1980s. The *Desiderio* case upheld a \$140 million medical malpractice judgment, applying the literal terms and procedures dictated by Article 50-A of the Civil Practice Law and Rules (CPLR), which requires that large malpractice verdicts be paid in periodic installments. The award reflected, in the views of the hospital industry, overcompensation to the plaintiff due to a provision in the statute that was interpreted to provide for double counting of inflation. While other changes were made to the CPLR provisions that allow for greater upfront payments to the plaintiff, the more significant changes in the manner in which awards are calculated is expected to stave off what might have been large increases in the costs of hospital and physician medical malpractice premiums.
- Emergency Contraception: This legislation requires hospitals that provide emergency treatment to rape survivors to provide information regarding emergency con-

- traception and to provide emergency contraception upon request, except when contraindicated. No hospital is required to provide emergency contraception to a patient who is pregnant.
- Federally-Aided Mortgage Loans on Health Care Facilities: This bill amends the New York State Medical Care Facilities Finance Agency Act to revise the definition of a "federally-aided mortgage loan" by deleting the requirement that each such loan be secured by a first mortgage lien on the real property of the project. Under the bill, any mortgage lien would suffice to secure a federally-aided mortgage loan. It further amends the Public Health Law to authorize the Commissioner of Health and the Dormitory Authority, as successor in interest to the Medical Care Facilities Finance Agency, to consent to the leasing of real property or other assets mortgaged or otherwise pledged to the agency.
- Rate Adjustment for New Stent: This bill allows the Commissioner of Health to establish "passthrough payments or other appropriate methodologies" through December 31, 2003 to provide reimbursement for the costs associated with the newly-approved drug eluding stent. In 2004, new diagnostic related groups (DRGs) will be incorporated into New York's payment system to accommodate the new stent.
- Exemption from Sharps Regulations for Dentists in Hospitals:
 This bill expands the exemption from sharps regulations to dentists who work in hospitals.

Diagnostic and Treatment Centers

- Hospital-Sponsored D&TC Indigent Care: The Legislature passed legislation that will permit the hospital-sponsored diagnostic and treatment centers (D&TCs) currently participating in the D&TC indigent care pool to shift into the hospital indigent care pool.
- Reimbursement for D&TCs
 Receiving PACS Rates: This bill
 allows D&TCs receiving products
 of ambulatory care services
 (PACS) rates that are higher than
 their rates under the new
 prospective payment system
 (PPS) to retain their PACS rates
 until the PPS rates reach the same
 level as the PACS rates.
- Reimbursement for Social Worker Visits at D&TCs for Individuals with Developmental Disabilities: This bill provides for Medicaid reimbursement for psychotherapy provided by social workers in D&TCs with a mission to serve individuals with developmental disabilities. This reimbursement for social worker visits applies only to those D&TCs whose base year cost report includes costs and threshold visits related to psychotherapy services provided by social workers.
- Unrestricted Access to Academic Dental Clinics Under Medicaid Managed Care: This bill allows Medicaid managed care beneficiaries to receive services from dental clinics affiliated with dental schools, even if the clinics do not participate in their managed care plan's network.
- Mandatory Clinical Breast Exam by Mammography Services
 Providers: This legislation requires mammography providers to determine when and if each patient has had a clinical breast examination and to alert health care providers if the

patient has not had a recent examination.

Insurance Issues

- COBRA Subsidy for Entertainment Workers and Dislocated Workers: This legislation provides for a state subsidy of up to 50 percent of the cost of COBRA coverage for entertainment workers and dislocated workers with income of up to 250 percent of the federal poverty level. A dislocated worker is a person whose employment has been terminated or who has received notice of termination as a result of a permanent closure or substantial layoff at a plant facility or enterprise. The program is funded with \$3 million from the HCRA tobacco pool and is effective as of April 1, 2004. Eligible workers may receive subsidies for COBRA coverage retroactive to July 1, 2003.
- Insurance Law Amendments to **Conform to Federal Trade Adjustment Assistance Reform** Act of 2002 (TAARA): This legislation prohibits health insurers from imposing pre-existing condition limitations on individuals and dependents who are eligible for a federal tax credit under the TAARA and who have three months of creditable coverage. It also directs the Superintendent of Insurance to notify the federal Centers for Medicare and Medicaid Services that New York's individual market policies and Healthy New York policies are qualified policies for purposes of the TAARA tax credit.
- Ban on Refusal to Issue Life or Disability Policies Based on a History of Cancer: This bill prohibits life and disability insurers from denying coverage solely because an individual has had any type of cancer, provided that the initial diagnosis of such disease occurred at least three years prior to application for insurance

- and that a physician has certified that the disease has not reoccurred in the applicant.
- Blood Glucose Monitor Mandate: This bill expands the existing blood glucose monitor mandate for the "legally blind" to benefit individuals who are "visually impaired."

Mental Hygiene

- Electroconvulsive Therapy Reporting: This legislation establishes reporting requirements for facilities that provide electroconvulsive therapy.
- Criminal Record Check on Employees of Article 16 Entities: This legislation requires providers of services to the developmentally disabled to secure criminal history information regarding new and prospective employees.
- Health Care Decisionmaking for Mentally Retarded Persons: This bill amends last year's surrogate decision-making legislation related to mentally retarded persons to permit corporate guardians to make health care decisions for mentally retarded persons.

* * *

The Legislature considered but did *not* reach agreement on the following significant health-related issues:

• Preferred Drug List (PDL): In his January budget presentation, the Governor indicated his intent to institute administratively a preferred drug list in the Medicaid program. In response, the Legislature included in its budget a provision blocking the implementation of a preferred drug list absent the enactment of authorizing legislation. The Legislature's budget, nevertheless, contemplated substantial savings attributable to the PDL. When the two houses of the Legislature sat

- down to draft the authorizing legislation, negotiations foundered over the question of exemptions from the PDL/prior authorization process and whether cost should be a criterion for selecting drugs for the PDL in the first instance. Legislators were under significant pressure from the pharmaceutical industry and consumer groups either to forestall the implementation of any PDL or to limit its impact on access to drugs. Because the enacted budget relies on significant savings associated with the PDL, it is likely that negotiations will resume, and some form of a PDL will ultimately be adopted.
- Assisted Living Regulation: The registration and regulation of assisted living facilities has been under consideration for at least three years. This year, the Assembly, Senate, and the Governor introduced similar bills that would provide consumer protections in, and regulatory oversight of, private-pay assisted living residences. Negotiations faltered, however, over the definition of "assisted living" and whether assisted living residences should be permitted to serve persons under age 55. Progress in resolving these issues was blocked when the Division of Budget suddenly revealed that the proposed legislation would cost the Medicaid program an additional \$50 million to \$100 million.
- Adult Home Reform: Despite the scandals uncovered in the adult home industry over the past several years, and the consensus that something must be done to improve conditions in adult homes, no agreement was reached on adult home reform. The Governor, Senate and Assembly released similar bills and publicly described the issue as a high priority. However, no agreement was reached.

- Mental Health Parity (also known as "Timothy's Law"): The Senate and Assembly introduced identical bills (with large numbers of co-sponsors) to require health insurers to provide mental health and chemical dependency benefits equivalent to physical health benefits. Mental health advocacy organizations mounted a grass roots and media campaign to press for the bill. In spite of their efforts and passage by the Assembly, no agreement was reached on the bill and no action was taken by the Senate.
- Family Health Care Decisions Act and Stem Cell Research Legislation: Two bills of great interest to the health care community, both involving sometimes difficult bioethical issues, failed to progress during the 2003 session. No agreement was reached on issues relating to health care decisionmaking for incapacitated New Yorkers who have not executed health care proxies, prolonging the struggles of families and health care providers who must contend with New York's restricting health care decisionmaking caselaw. Although the Assembly passed a bill that would ban cloning but authorize stem cell research in New York State, the Senate did not act on the bill, but proposed a study of the issue by the Task Force on Life and Law.

Compiled by James W. Lytle, managing partner of the Albany offices of Manatt, Phelps & Phillips, LLP. The firm, which is based in Manhattan, represents a wide array of health care and other regulated entities and devotes a substantial part of its practice to the representation of health care clients before the legislature and state regulatory bodies.

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In the New York State Agencies

By Francis J. Serbaroli

Health Department

HIV Testing

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend subpart 58-8 of title 10 N.Y.C.R.R. to revise clinical laboratory standards for human immunodeficiency virus (HIV) testing. *See* N.Y. Register, March 19, 2003.

Environmental Laboratory Standards

Notice of emergency rulemaking. The Department of Health repealed section 55-2.12 and added section 55-2.13 to part 55 of title 10 N.Y.C.R.R. in order to establish minimum standards for laboratory testing of biological and chemical agents of terrorism. Filing date: March 17, 2003. Effective date: March 17, 2003. See N.Y. Register, April 2, 2003.

Adult Day Health Care Regulations

Notice of emergency rulemaking. The Department of Health repealed parts 425-427 of title 10 N.Y.C.R.R. and added a new part 425 to title 10 N.Y.C.R.R to ensure that individuals receive adult day health care when appropriate and that providers are accountable for providing necessary and appropriate care. The proposed regulations provide for general requirements for operation, as well as specified minimum program and service components that must be available in adult health care programs. Filing date: March 21, 2003. Effective date: March 21, 2003. See N.Y. Register, April 9, 2003.



Smoking Cessation Products

Notice of emergency rulemaking. The Department of Health amended section 85.21 of title 10

N.Y.C.R.R. and section 505.3 of title 18 N.Y.C.R.R. in order to add over-the-counter smoking cessation products to the list of Medicaid-reimbursable over-the-counter products. Filing date: April 11, 2003. Effective date: April 11, 2003. See N.Y. Register, April 30, 2003.

Part-Time Clinics

Notice of emergency rulemaking. The Department of Health repealed section 703.6, amended section 710.1 and added a new section 703.6 to title 10 N.Y.C.R.R. to clarify and enhance the requirements that apply to part-time clinics and to require prior limited review of all part-time clinic sites. Filing date: April 25, 2003. Effective date: April 25, 2003. See N.Y. Register, May 14, 2003.

Smallpox Vaccine

Notice of emergency rulemaking. The Department of Health amended sections 2.1 and 2.2 of title 10 N.Y.C.R.R. to enable the Department of Health to monitor the adverse events among persons receiving smallpox vaccination, and request on a timely basis vaccinia immune globulin, used to treat adverse reactions to the vaccine, from the CDC. Filing date: April 29, 2003. *See* N.Y. Register May 14, 2003.

Newborn Screening

Notice of emergency rulemaking. The Department of Health amended section 69-1.2 of title 10 N.Y.C.R.R. to add three conditions (cystic fibrosis, medium-chain acyl-CoA dehydrogenase deficiency and congenital adrenal hyperplasia) to the current list of eight genetic/congenital disorders that comprise New York State's newborn screening panel. Filing date: May 5, 2003. Effective date: May 5, 2003. See N.Y. Register, May 21, 2003.

Treatment of Opiate Addiction

Notice of emergency rulemaking. The Department of Health added a new section 80.84 to title 10 N.Y.C.R.R. and amended section 80.86 of title 10 N.Y.C.R.R. to permit the treatment of opiate addiction in an office-based setting. Filing date: May 5, 2003. Effective date: May 5, 2003. See N.Y. Register, May 21, 2003.

Severe Acute Respiratory Syndrome (SARS)

Notice of emergency rulemaking. The Department of Health amended sections 2.1 and 2.5 of title 10 N.Y.C.R.R. to add SARS to the list of communicable diseases which providers are required to report to local and/or state health departments and require physicians to submit specimens for laboratory examination when they suspect a person is infected with SARS. Filing date: May 19, 2003. Effective date: May 19, 2003. See N.Y. Register, June 4, 2003.

Physician Profiling

Notice of emergency rulemaking. The Department of Health added part 1000 to title 10 N.Y.C.R.R. to implement the Patient Health Information and Quality Improvement Act of 2000. The Act requires the Department to collect information and create individual profiles on physicians that will be available for dissemination to the public. Information to be disseminated about the physicians includes criminal convictions and medical malpractice information. Filing date: June 3, 2003. Effective date: June 3, 2003. See N.Y. Register, June 18, 2003.

Insurance Department

Healthy NY Program

Notice of emergency rulemaking. The Department of Insurance added section 362-2.7 and amended sections 362-2.5, 362-3.2, 362-4.1, 362-4.2, 362-4.3, 362-5.1, 362-5.2 and 362-5.3 of title 11 N.Y.C.R.R. in order to reduce Healthy New York premium rates by adjusting the stop loss reimbursement corridors to (a) enable more uninsured businesses and individuals to afford health insurance; (b) lessen the current complexity in eligibility determination; (c) eliminate the copayment applied to wellchild visits; (d) create an additional benefit package which does not include prescription drugs to give

qualifying employers and individuals a choice of packages; (e) establish clear rules with respect to determining employment eligibility; (f) clarify employer contribution requirements for part-time workers; and (g) qualify Healthy NY as coverage eligible for a federal tax credit. Filing date: March 28, 2003. Effective date: March 28, 2003. See N.Y. Register April 16, 2003. The Department of Insurance also amended sections 362-2.3 and 362-4.3 of title 11 N.Y.C.R.R. in order to simplify the application process and clarify household income requirements for the Healthy NY Program. Filing date: May 14, 2003. Effective date: May 14, 2003. See N.Y. Register, June 4, 2003.

Partnership for Long-Term Care Program

Notice of adoption. The Department of Insurance amended section 39.3(b)(1) of title 11 N.Y.C.R.R. in order to increase the minimum daily benefit dollar amounts for nursing home and home care services under the Partnership for Long-Term Care Program in accordance with the program's requirements for an annual five percent inflation increase. Filing date: April 1, 2003. *See* N.Y. Register, April 16, 2003.

Physicians and Surgeons Insurance Merit Rating Plans

Notice of emergency rulemaking. The Department of Insurance amended part 152 of title 11 N.Y.C.R.R. in order to establish guidelines and requirements for medical malpractice merit rating plans and risk management plans. Filing date: May 16, 2003. Effective date: May 16, 2003. See N.Y. Register, June 4, 2003.

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 has served on the Executive Committee of the New York State Bar Association's Health Law Committee. He is the author of "The Corporate Practice of Medicine Prohibition in the Modern Era of Health Care" published by BNA as part of its Business and Health Portfolio Series.

The assistance of Ms. Denise Penn, a summer associate at Cadwalader, Wickersham & Taft LLP, and Ms. Vimala Varghese, an associate at Cadwalader, Wickersham & Taft LLP, in compiling this summary is gratefully acknowledged.



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In the Law Journals

By Dale L. Moore

Journal of Health Law, Volume 36, Number 1 (2003):

- James R. King & David S. Boyce, Revocation of Tax-Exempt Status, Excise Taxes, and Other Intermediate Sanctions Issues, Plus Income Taxes: How the Rules Have Changed After Caracci v. Commissioner.
- Frederic L. Ballard, Jr., *Tax-Exempt Bonds and Sponsored Research*.
- Susan Adler Channick, The Ongoing Debate Over Medicare: Understanding the Philosophical and Policy Divides.
- David L. Trueman, The Impact of the Recent Supreme Court Rulings in Pegram and Rush Prudential on State Regulation of Managed Care Organizations.
- Daniel Body, Federal Trade Commission v. Tenet: A Retrospective Review and Analysis.
- Joseph C. Mandarino, *Intermediate* Sanctions Flow Charts.

Practice Resource: Sample Business Associate Addendum.

The Journal of Legal Medicine, Volume 24, Number 1 (2003):

- Symposium
 - W. Eugene Basanta, Changing the Culture of Patient Safety and Medical Errors: A Symposium Introduction and Overview.
 - Paul Barach, The End of the Beginning: Lessons Learned from the Patient Safety Movement.

- Harold S. Kaplan, Benefiting from the "Gift of Failure": Essentials for an Event Reporting System.
- Edward A. Dauer, A Therapeutic Jurisprudence Perspective on Legal Responses to Medical Error.
- Marshall B. Kapp, Resident
 Safety and Medical Errors in
 Nursing Homes: Reporting and
 Disclosure in a Culture of
 Mutual Distrust.
- John Michael Ward, Online Pharmaceutical Regulation: An Avenue to a Safer World.
- Jonathan Weems, A Proposal for a Federal Genetic Privacy Act.
- Curt Richardson, Physician/Hospital Liability for Negligently Reporting Child Abuse.

New York Law School Law Review, Volume 46, Numbers 3 & 4, Part IV, Dealing with Mental Disability in Trust & Estate Law Practice:

- Michael L. Perlin, "Things Have Changed": Looking at Non-Institutional Mental Disability Law Through the Sanism Filter.
- Pamela R. Champine, A Sanist Will?
- Heather S. Ellis, "Strengthening the Things That Remain": The Sanist Will.

• Claire B. Steinberger, *Therapeutic Jurisprudence: The "Sanist" Factor—An Interdisciplinary Approach.*

In Other Journals:

- Diane Hoffmann & A. Tarzian, Achieving the Right Balance in Oversight of Physician Opioid Pre- scriptions for Pain: The Role of State Medical Boards, 31 Journal of Law, Medicine & Ethics 21 (2003).
- Irving Breitowitz, What's Wrong with Human Cloning?, Journal of Kennedy Institute of Ethics (Winter 2003).
- Deborah Hellman, Evidence, Belief, and Action: The Failure of Equipoise to Resolve the Ethical Tension in the Randomized Clinical Trial, 30 Journal of Law, Medicine & Ethics 375 (2002).
- Deborah Hellman, What Makes Genetic Discrimination Exceptional?, 29 American Journal of Law & Medicine 77 (2003).
- Karen Rothenberg & Diane Hoffman, Whose Duty Is It Anyway?:
 The Kennedy Kreiger Opinion and Its Implications for Public Health Research, 6 Journal of Health Care Law & Policy 109 (2002).

Compiled by Dale L. Moore, Associate Dean of Academic Affairs and Professor of Law, Albany Law School.

For Your Information

By Claudia O. Torrey

The following bullets highlight information of interest:

• On April 17, 2003, the Department of Health and Human Services (DHHS) issued an interim final rule (IFR) for the enforcement of civil money penalties (CMP) on covered entities (CE) that violate the non-privacy administrative simplification regulations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).1 The authority for administering and enforcing compliance with the privacy rule has been delegated to the Office for Civil Rights within DHHS.2 The IFR became effective on May 19, 2003 and will expire or sunset on September 16, 2003. Comments on the IFR were due by June 16, 2003.

HIPAA authorizes the Secretary of the DHHS to impose a CMP of not more than \$100 for each CE violation, and such CMPs may not exceed \$25,000 during a calendar year.3 The IFR includes some of the following substantive topics: limitations on the imposition of CMPs; settlement authority; administrative hearings; subpoenas; discovery; prehearing conferences; and judicial review. According to the IFR, the enforcement activities of CMS will be complaint driven; focus on voluntary compliance through technical assistance; and provide CEs with opportunities to demonstrate compliance or submit a corrective action plan.4

• Effective July 1, 2003, new duty standards for medical residents became the "law of the land." The standards were approved by the Accreditation Council for Graduate Medical Education. When the standards were initially being reviewed, this author

reported on these standards in a previous issue of this *Health Law Journal*.⁵

Among the provisions in the resident duty standards are: a limit of eighty hours per week averaged over a four-week period; one day in seven must be free from all educational and clinical responsibilities; there must be written policies and procedures distributed to residents and faculty; and frequent monitoring of resident duty hours is to be maintained by those entities that have a residency program.⁶

- On April 10, 2003, the Centers for Disease Control and Prevention (CDC) issued the first guidelines for school administrators and health officials concerning severe acute respiratory syndrome (SARS).⁷ To be classified as a case of SARS,8 a patient must have a fever of, or greater than, 100.4 degrees with symptoms peculiar to a dry cough.9 The CDC, along with blood banks and the Food and Drug Administration, is also in the process of drafting guidelines to temporarily defer blood donations from people who have recently traveled to Asian countries most affected by SARS.¹⁰
- A Model For The World—The New York City Department of Health and Mental Hygiene houses a cutting-edge computerized tracking system for safeguarding the public health. The system, known as the Syndromic Surveillance System (S³), is considered the most advanced, public health early warning system for disease outbreaks in the country. Supposedly, New York State officials are considering building a statewide system modeled on S³.

Because S³ focuses on syndromes and not diseases, it attempts to create insight into a disease at an early stage, before the disease itself becomes apparent. S³ costs approximately \$1 million a year, and analyzes some 50,000 pieces of information daily, including emergency room visits, 911 calls, and drugstore purchases. It is believed that S3 is much more useful in detecting outbreaks that are natural as opposed to manmade; however, the future ability of S3 to detect a bioterrorist attack is a work in progress.13

Endnotes

- Civil Money Penalties: Procedures for Investigations, Imposition of Penalties and Hearings, 68 Fed. Reg. 18895 (Apr. 17, 2003) (to be codified at 45 C.F.R. part 160).
- Id. at 18897. Enforcement responsibility for the non-privacy HIPAA rules has been delegated to the Centers for Medicare and Medicaid Services (CMS).
- 3. *Id.; see also* 42 U.S.C. 1320d-5.
- 4. Id.
- Claudia O. Torrey, Esq., For Your Information, NYSBA Health Law Journal, Summer/Fall 2002, at 18.
- 6. See http://www.acgme.org (June 23, 2003).
- 7. Lawrence K. Altman, Federal Agency Issues Guidelines on Handling Infected Students, N.Y. Times, Apr. 11, 2003, at A8.
- 8. *Id.; See also* http://www.cdc.gov (June 23, 2003).
- 9. Id.
- 10. *Id.*
- 11. Richard Pérez-Peña, An Early Warning System for Diseases in New York, N.Y. Times, Apr. 4, 2003, at A1.
- 12. Id.
- 13. Id.

Claudia O. Torrey, Esq. is a member of the American Health Lawyers Association, the American Bar Association, and a sustaining member of the New York State Bar Association.

Financing with the Dormitory Authority of the State of New York

By Jeffrey M. Pohl

The Dormitory Authority of the State of New York (DASNY) is New York State's principal health and education finance authority and is authorized to issue bonds on behalf on a variety of public and private entities. DASNY currently has approximately \$8.5 billion of bonds outstanding for health-related entities alone.

The general enabling legislation for DASNY is contained in Title 4 of Article 8 of the Public Authorities Law (the "Dormitory Authority Act"). In addition, upon the enactment of the Health Care Financing Consolidation Act in 1995, DASNY succeeded to the powers and duties of the New York State Medical Care Facilities Financing Agency² and the Facilities Development Corporation.³

DASNY is authorized to provide tax-exempt financing for the following private health-related entities:

- 1. Not-for-profit hospitals as defined in Article 28 of the Public Health Law.⁴
- 2. Nursing home companies incorporated under Article 28-A of the Public Health Law.⁵
- 3. Facilities for the aged (facilities occupied by persons age 60 or older and their spouses).6
- 4. Health maintenance organizations.⁷
- 5. Health care institutions specifically enumerated in the Dormitory Authority Act.

Financings undertaken for hospitals and nursing homes must either: (a) comply with the requirements of Articles 28-B and 28-A of the Public Health Law, respectively; or (b) be transactions for which mortgage insurance is obtained from the Federal Housing Administration. Also, DASNY guidelines require that facilities for the aged, which can include virtually any type of senior housing, have a "health care component" with the result that DASNY-financed projects are usually sponsored by health-care providers or their affiliates. To become an eligible borrower specifically enumerated in the DASNY Act, state legislation must be enacted to add the institution's legal name to the list of "dormitories" and "educational institutions" found in that statute.8

The Authority also makes loans to some private health-related entities through some of its public programs. For example, DASNY issues state-supported debt under its Mental Hygiene Services Facilities Improvement Program, some of the proceeds of which are loaned to voluntary providers under the supervision of an office in the Department of Mental Hygiene. DASNY also has issued bonds under its Municipal Health Facilities Improvement Program to provide financing for primary care centers in New York City. 10

DASNY also offers tax-exempt leasing programs to its clients (TELP). ¹¹ Hospitals and other not-for-profit clients utilize this program to finance necessary equipment on a tax-exempt basis. The program uses a simple lease-sublease structure with the financing being provided by an entity selected by the health-care institution.

Bonds issued by DASNY for the benefit of its clients are "special obligations" of DASNY; that is, they are payable solely from payments received from the borrower under a loan agreement between the borrower and DASNY and certain other security, such as a debt service reserve fund, that is pledged to the trustee for the benefit of bondholders. Interest on DASNY's bonds is usually exempt from federal and state taxes and, thus, the bonds must be issued in compliance with the applicable requirements of the Internal Revenue Code.

The financing guidelines adopted by DASNY's Board generally require that bonds issued by DASNY be secured by credit enhancement unless the bonds would garner a credit rating of at least A3/A- without credit enhancement. Credit enhancement can include: (a) a policy of municipal bond insurance; (b) an irrevocable direct pay letter of credit issued by a bank; (c) a mortgage insurance policy issued by the Federal Housing Administration; or (d) a credit facility issued by Fannie Mae. DASNY, however, will consider issuing unenhanced bonds for institutions below the A3/A-threshold in appropriate instances.

The loan agreement is a general obligation of the borrower that requires it to pay amounts necessary to pay debt service due on the bonds as well as certain other amounts payable to DASNY and the bond trustee. The institution's obligations under the loan agreement are typically secured by some or all of the following: (i) a lien on revenues of the institution; (ii) a mortgage on the revenue- producing facilities; or (iii) a guarantee of a third party. The loan agreement will also usually include financial covenants, such as a rate covenant, additional debt test, balance sheet tests or a pledge not

to encumber other assets of the borrower. The type of security and covenants required will vary according to the type and financial strength of the institution, as well as any requirements imposed by the provider of the credit enhancement.

DASNY's financing process involves two actions by the DASNY Board. First, the Board must adopt a Resolution to Proceed, authorizing DASNY staff to start working on the legal and other documents necessary to issue the bonds and to engage professionals, such as bond counsel, who will work on the transaction. At this stage, the DASNY Board is apprised of the purposes for which the bonds will be issued, the financial strength of the institution and the manner in which the financing is expected to be secured. Thereafter, when DASNY and the institution have completed certain additional steps, the Board will be asked to adopt the necessary bond resolutions and authorize the execution of other financing documents necessary to issue the bonds.

The proposed bond issuance must also be approved by the Public Authorities Control Board (PACB). ¹² This approval is usually obtained after adoption of the Resolution to Proceed. PACB is charged with reviewing the adequacy of the sources of repayment of the DASNY bonds.

Each project proposed to be financed by DASNY is also subject to review under the State Environmental Quality Review (SEQR) Act. The SEQR process must be completed prior to the adoption of the bond resolutions. Although DASNY frequently acts as lead agency for purposes of undertaking this review, the institution should consider having DASNY named as an involved agency if SEQR compliance is necessary to obtain other earlier approvals required for the project. Having DASNY named as an involved agency at an earlier point does not commit the institution to utilize DASNY, but may help streamline the process if DASNY is eventually asked to finance the project.

In addition to the above steps, both the institution and DASNY must undertake other actions. The institution and its consultants will generally be responsible for the following:

- Adoption of a Declaration of Official Intent— Resolution enacted by governing board of borrower declaring its intent to use tax-exempt financing to fund the project.
- Completion of Tax Questionnaire—Questions addressed to the borrower by bond counsel used in providing opinion as to tax exemption of the proposed borrowing.
- c. Adoption of Corporate Resolution—Resolution enacted by governing board of borrower author-

- izing the proposed borrowing and designating officers who may act on borrower's behalf.
- d. Preparation of the borrower's section of the Preliminary Official Statement (POS) that will be used to market the bonds—written description of the borrower, the project being financed, the borrower's operations and its financial performance.
- e. Accountant's Procedures Letters and Consents— Letters from borrower's accountants authorizing use of audited financial statements of borrower in POS and describing work done subsequent to completion of last audit up to four days before the sale of obligations.
- f. Opinion of Counsel for Borrower—Opinion must, among other things, address the authorization, execution, delivery and enforceability of the documents to be signed by the borrower and contain an opinion that the information in the POS and Official Statement provided by or about the borrower is true and correct and contains no false or misleading statements and that the borrower is a tax-exempt entity under the Internal Revenue Code.
- g. Real Property—Title and survey work necessary to provide DASNY with a mortgagee title insurance policy.

For its part, DASNY and its consultants assume responsibility for:

- a. Working with the institution to structure the financing and assisting in obtaining and negotiating the terms of a commitment by a credit enhancer, as well as preparing or reviewing all the financing documents.
- b. Ensuring compliance with SEQR and the public approval requirements of the Tax Equity and Fiscal Responsibility Act.
- c. Coordinating with the appropriate state regulatory agencies, particularly the Department of Health.
- d. Preparing the POS.
- e. Working with a lead underwriter, generally chosen by the institution, to market and sell the bonds. An institution can also choose to have the bonds marketed on a competitive basis and not through a predetermined underwriter.
- f. Executing and delivering documents necessary for the issuance of the bonds and delivery of bond proceeds.

Both DASNY and the institution have responsibility for ensuring that they have received a final commitment from the provider of credit enhancement (if any). This commitment will generally outline terms and conditions required by the issuer of the credit enhancement, including security and financial covenants.

DASNY generally charges two fees in connection with the issuance of bonds for its health care clients. The first fee, payable at closing, compensates DASNY for the work done to bring the deal to market. This fee, which is established before DASNY begins work on the transaction, is either \$100,000 or \$150,000, depending upon the complexity of the transaction. DASNY also charges an annual administrative fee (generally 5-8 basis points on principal amount of loan) to cover its annual costs associated with the bond issue. These expenses are incurred for such tasks as servicing the loan, investing funds held under the bond resolution and ensuring compliance with the rebate provisions of the Internal Revenue Code and the continuing disclosure requirements contained in Rule 15c2-12 adopted by the Securities and Exchange Commission.

The state also imposes certain fees in connection with bonds issued by DASNY and other conduit issuers for their health care clients.¹³ As with any other loan transaction, there are also other costs and disbursements that must be borne by the borrower.

Unlike other issuers of tax-exempt debt, DASNY's reputation in the market helps clients ensure that their obligations are marketed efficiently and in a cost-effective manner. In addition, DASNY is a full-service construction agency that provides its services to a wide variety of public and private clients, many of which are

involved in areas other than healthcare. DASNY welcomes the opportunity to meet with prospective clients to discuss how DASNY can help them meet their needs. More information about DASNY and its services can be found at its Web site (www.dasny.org), or by sending an e-mail request to DABONDS@dasny.org for more information about its financing and construction services.

Endnotes

- 1. Public Authorities Law §§ 1675-1694 (hereinafter "PAL").
- 2. Unconsol. Laws §§ 7411-7432.
- 3. Unconsol. Laws §§ 4401-4417.
- 4. Unconsol. Laws § 7413(6).
- 5. Unconsol. Laws § 7413(13).
- 6. PAL § 1676(6).
- 7. Unconsol. Laws § 7413(6).
- 8. PAL §§ 1676(2); 1680 (1). DASNY is also seeking the enactment of legislation that would expand the types of health care institutions to which DASNY can make loans without specific authorization for that institution (S.4330). If enacted, DASNY would be permitted to make loans to (among others): (a) any not-for-profit corporation under the jurisdiction or control of either the Department of Health or an office of the Department of Mental Hygiene; and (b) certain affiliates of hospitals that are members of obligated groups for which DASNY has previously issued bonds.
- 9. Unconsol. Laws § 7419-a.
- 10. Unconsol. Laws § 7419.
- 11. Unconsol. Laws § 7415-b; PAL § 1679-b.
- 12. PAL § 51.
- 13. PAL § 2976-a.

Jeffrey M. Pohl is General Counsel to the Dormitory Authority of the State of New York.

REQUEST FOR ARTICLES

If you have written an article and would like to have it published in the Health Law Journal please submit to:

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Civil Detention from Smallpox Preparedness to SARS Implementation

By Wilfredo Lopez

In the Fall of 2002 planning for a public health response to a bio-terrorist attack in New York City intensified, particularly in regard to the intentional release of smallpox. At the request of the federal Centers for Disease Control and Prevention (CDC), the New York City Department of Health and Mental Hygiene (DOHMH or the "Department") was preparing a plan for a smallpox vaccination program, which in fact was implemented in early 2003. In addition, DOHMH and the New York State Department of Health together issued guidelines to hospitals for the management of possible cases of smallpox. The guidelines called for hospitals to quickly evaluate individuals coming to an emergency department with a fever and a rash in order to determine if they presented a low, medium or high risk of smallpox disease. Suspected smallpox cases were to be immediately isolated; that is, separated from others so as to prevent the spread of disease. Also, the hospital was to call the Department. If upon consultation the Department deemed the case a high-risk situation, it would instruct the hospital to keep the individual in isolation, and dispatch a team to the hospital to investigate further. Internal discussions ensued about what to do when the Department ascertained that the physical plant and ventilation of the emergency room, combined with the length of time the suspect case lingered there and whether he or she was coughing or sneezing, presented a risk of exposure to the other individuals who were in contact with the suspect case before isolation. The worst-case scenario might require the detention of the contacts of the suspect case pending a definitive diagnosis involving laboratory confirmation that could take up to three days.

Another aspect of planning and preparing for a bioterrorist attack, indeed for a chemical or nuclear attack as well, is a review of the laws that are available to public health authorities to prevent, mitigate or respond to emergencies caused thereby. One such provision that has long been available in New York City is section 11.55 of the New York City Health Code (the "Health Code," 24 RCNY section 11.55). A review of the provision revealed that it authorized the Commissioner of Health, upon determining that a case, contact, or carrier, or a suspect case, contact, or carrier of communicable disease is endangering the health of others, to detain such a person in a hospital designated by the Board of Health. In applying the language of the section to the above-specified smallpox scenario, and considering modern day principles of due process, several problems emerged. One was that, because of the incubation period involved, the emergency room contacts of the suspect, but not yet confirmed, case of smallpox would not be endangering the health of others for at least a number of days. A court reading the words "is endangering" might say that the contact could not be detained pending confirmation. Another concern was that the contacts, since they were not yet sick or infectious, might not need to be detained in a hospital setting. A hotel or other facility might be more appropriate. Thirdly, convening the Board of Health in a clearly emergent situation in order to designate the detention facility would be problematic. And, section 11.55 did not set forth any due process protections for the detained individual.

"[One] aspect of planning and preparing for a bio-terrorist attack, indeed for a chemical or nuclear attack as well, is a review of the laws that are available to public health authorities to prevent, mitigate or respond to emergencies caused thereby."

When one stops to consider the catastrophic outcome that could occur if even one contact could not be located in the event that the suspect smallpox case were confirmed, it is obvious that the local health officer must have the ability to detain contacts. Accordingly, on March 20, 2003, the New York City Board of Health authorized the publication for public comment of an amendment to Health Code sections 11.01 and 11.55. In essence, the amendments would authorize the Health Commissioner, based on substantial evidence that a communicable disease could have catastrophic consequences, to detain individuals who may present a danger to others in an appropriate facility designated by the Commissioner. The proposal also included many due process protections such as an opportunity to be heard if the detention is for less than 72 hours and, if longer, a requirement to seek a court order within three business days of a request for release. Upon request, an attorney would be provided. A full discussion of the rationale for the proposal, as well as the complete text of the amendments, is available on DOHMH's Web page at http://www.nyc.gov/html/doh/pdf/public/ notice-adoption.pdf or on CDC's at http://www.phppo .cdc.gov/od/phlp/phlegalresponse.asp.

Contemporaneous with the Board of Health approval to publish for comment, the world's attention was captivated by a new emerging disease known as severe acute respiratory syndrome or SARS. The disease had devastated Beijing, Hong Kong, and Toronto, among other places, resulting in thousands of cases, hundreds of deaths, and many thousands of individuals being isolated or quarantined by compulsory measures. While a laboratory test for the presence of the corona virus, the agent thought to be the cause of SARS, was developed within weeks of the virus, the results of a test are not available for several weeks after submission of a specimen to a laboratory. Therefore, as in the smallpox scenario, the public health system was required to deal with probable or suspected, but not confirmed, cases of SARS. Indeed, the World Health Organization (WHO) and the CDC issued guidelines recommending that suspected cases of SARS be kept isolated for ten days after their symptoms had resolved. Since these individuals were no longer sick enough to require hospitalization, the recommended site of the isolation was the person's home.

"[M]odernizing public health laws without disturbing the principles that have historically been proven effective and necessary, such as isolation, quarantine, and civil detention, can be beneficial whether it be for bio-terrorism preparedness or in the context of new emerging diseases."

In New York City during April and May, the DOHMH, using the authority of the old but still existing section 11.55 as well as that of Health Code section 11.03(b), affording the Department broad authority to take whatever action is necessary to mitigate morbidity and mortality, found it necessary to issue two Commissioner's Orders detaining individuals in the hospital in which they were for the 10-day period. These situations involved two individuals meeting the WHO and CDC definitions of suspected cases of SARS, who were tourists with no adequate place to stay, and who presented a risk of flight. As was seen from the Toronto experience, where one "super spreader" of SARS returning from Asia caused a huge public health catastrophe, there is no margin for error in these situations. However, the Health Code provisions were implemented in a way that also provided the detainees with due process. In effect, the Commissioner's Orders included all of the due process protections that the proposed section 11.55 would require.

Interestingly, the Department also felt compelled to issue one home isolation order to an individual who did have an adequate place to stay, but did not fully accept his or her status as a suspect case. While violations of a Commissioner's Order can be prosecuted as a misdemeanor, the Department chose to forgo this option. Instead, the Order warned the recipient that a violation could result in the person's detention in a place other than the home. Compliance was monitored by several phone calls to the home each day.

This experience led the Department to consider how much due process was warranted in a situation where an individual is ordered to remain isolated at home, but where no physical means of restraint are implemented. That is, where no guards are posted outside of the home and no electronic bracelets are utilized, as they were in other parts of the world. Keeping in mind that due process is that process which is due under the circumstances, the Department determined that the subject of such a home isolation order should be afforded an opportunity to be heard, but that the full panoply of due process protections which are afforded to detainees, such as affirmatively seeking a court order and providing a lawyer, was not warranted. Indeed, the final proposal that was presented to the Board of Health for adoption made this distinction clear. On June 11, 2003, the Board adopted the amendments and they became effective on July 19, 2003.

The above illustrates how modernizing public health laws without disturbing the principles that have historically been proven effective and necessary, such as isolation, quarantine, and civil detention, can be beneficial whether it be for bio-terrorism preparedness or in the context of new emerging diseases. However, one should keep in mind that the authority provided to health officers under the New York State Public Health Law or the Health Code is necessary to have on a dayto-day basis. It allows the public health system to prevent dangerous situations from mushrooming into catastrophes necessitating gubernatorial or mayoral declarations of emergency pursuant to Article 2-B of the New York Executive Law. Such declarations would trigger an entirely different set of legal authorities that are not discussed here.

Wilfredo Lopez is the General Counsel for Health of the New York City Department of Health and Mental Hygiene. The views expressed herein are entirely his own and do not necessarily represent those of the Department or the City of New York.

A Legal Resource Guide for In-House Hospital Counsel

By Karen Illuzzi Gallinari and Sara Gonzalez

Introduction

Healthcare attorneys have the fortune of practicing in one of the most diversified areas of our profession. While most of us are passionate about healthcare, many of us are drawn to the field because we enjoy the variety of legal issues our clients present to us.

Few healthcare attorneys address more varied issues in a typical day than the average inhouse hospital counsel. A normal general counsel's day will involve knowledge or research on corporate law, environmental law, criminal law, employment law, health codes, whether there is sufficient, clear and convincing evidence to permit the removal of a respirator on a patient, and everything in between. Lucky for us, the volume of resources available providing relevant information on these issues is as numerous as the issues themselves. The in-house general counsel is also expected to be knowledgeable about these issues cold. We are called when the patient is on the operating table, the police have arrived on site to arrest a patient or, heaven forbid, an employee, etc., etc. Instant law is simply essential in most in-house counsel offices.

Despite the number of gray hairs many of us proudly display, none of us is foolish enough to profess to know every relevant statute, regulation, or case, nor how to put our finger on it most quickly in this age of endless computerized legal resources. Quite appropriately, we often rely on each other for certain details.

For us, who defend our choice not to memorize small details, noting that Einstein chose never to remember anything he could look up (allegedly including his own phone number), the In-house Counsel Committee of the Health Law Section has begun the following Health Law Resource Guide. This is intended to be a dynamic document which will be updated and available on our Health Law Section Web site at www.nysba.org/health. This first version does not contain everything each one of us finds essential or helpful. Readers are encouraged to submit suggestions and additions to assist us in making this a powerful tool for our field. Ultimately we hope to cross reference the resources listed by subject matter. In the meantime, we hope you will find this guide useful, particularly when your mentor, assistant or colleague had the nerve to step out of the office just when one of your many emergency calls arrives.

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Thanks also for assistance from Ameesha Patel, Summer Intern, and Robert Belfort, Esq., Partner Manatt, Phelps & Phillips, LLP.

NYSBA Health Law Section In-House Counsel Committee

Health Law Resource Guide

 Primary Resources—Many of the statutes and regulations that follow are available on-line. Web sites containing these statutes and regulations can be found in the secondary resource section of this guide.

A) Federal

- 1) Code of Federal Regulations
 - (a) Title 21 Food and Drugs
 - (b) Title 29 Labor
 - (c) Title 34 Education
 - (d) Title 40 Protection of Environment
 - (e) Title 42 Public Health
 - (f) Title 45 Public Welfare (HIPAA Statutes)
- 2) Department of Justice and Federal Trade Commission Antitrust Statements—can be viewed on the Internet at http://www.ftc .gov/ftc/antitrust.htm
- 3) United States Department of Justice Antitrust Division—can be viewed on the Internet at http://usdoj.gov/atr/index .html
- 4) OIG Advisory Opinions: http://oig.gov/fraud/advisoryopinions.html
 - There is also an area for Fraud Prevention and Detection: http://oig.gov/fraud/complianceguidance.html, and there is an available link to Corporate Responsibility and Corporate Compliance: a resource for Health Care Boards of Directors.

B) State

- 1) Official Compilation of Codes, Rules, and Regulations of the State of New York (N.Y.C.R.R.)
 - (a) Title 8 Education
 - (i) Unprofessional Conduct § 29
 - (b) Title 10 Health
 - (c) Title 14 Mental Hygiene

- (d) Title 18 Social Services
- McKinney's Consolidated Laws of New York Annotated
 - (a) Education Law
 - (b) Employer's Liability Law
 - (c) Mental Hygiene Law
 - (d) Not-For-Profit Corporation Law
 - (e) Public Health Law
 - (f) Social Services Law
 - (g) Insurance Law
 - (i) Articles 48 and 49 of NYS Insurance Law include the HMO and Utilization Review Statutes
- 3) Gould's New York Consolidated Laws Unannotated
 - (a) New York Family Law Handbook
 - (b) Penal Law and Criminal Procedure Law of the State of New York
- 4) New York State Department of Health Memoranda: www.health.state.ny.us (see #9 Web sites)
- 5) New York State Department of Environmental Conservation: www.dec.state.ny.us (regulations for hazardous waste, etc.)

C) City

- The Administrative Code and Charter of the City of New York
 - (a) Title 8 Civil Rights, Administrative Code of the City of New York §§ 8-101, 8-401–8-801
 - (i) Prevention of Interference with Reproductive Health Services §§ 8-801–8-804
 - (b) Title 17 Health, Administrative Code of the City of New York §§ 17-101–17-408
 - (i) Department of Health §§ 17-101–17-183
 - (ii) Medical Examiner §§ 17-201-17-206

- (iii) Licenses and Permits §§ 17-301–17-363
- (iv) Standards Governing the Performance of Sterilizations §§ 17-401–17-408
- (c) Title 21 Social Services, Administrative Code of the City of New York §§ 21-101–21-202
 - (i) Department of Social Services §§ 21-101–21-129
 - (ii) Department for the Aging §§ 21-201–21-202
- 2) Rules of the City of New York
 - (a) Title 24 Department of Health
 - (i) Method and Criteria for Approval of Clinical Laboratories for Training § 2-01–2-09
 - (ii) HIV/HTLV-III/LAV Antibody Testing §§ 3-01–3-10
 - (iii) Inhalation Therapy Service §§ 5-01–5-15, 5-21–5-25
 - (iv) Adjudicatory Hearings § 7-01–7-02
 - (b) New York City Health Code, Titles I-V
 - (c) Title 25 Department of Mental Health and Retardation § 1-01

D) Ethical Obligations

- 1) New York Code of Professional Responsibility
- 2) American Bar Association Model Rules of Professional Conduct
 - Most other states have adopted the ABA Model Rules.
- 3) New York State Public Officers Law
 - These laws are applied to individuals who are currently state officers and employees as well as former state officers and employees.
 - (a) Restrictions on the activities of current and former state officers and employees § 73
 - (b) Code of Ethics § 74

II) Secondary Resources

A) Government Web Sites

1) Centers for Disease Control: www.cdc.gov

- This Web site is beneficial for researching a specific disease.
- The site has links to an alphabetical listing of health topics, data and statistics, and access to publications, software and other products about diseases/injuries.
- No fee is charged for use of this site and users can subscribe to a FREE mailing list.
- Through the mailing list, the user may subscribe to specific newsletters (i.e., HIV/AIDS Conference & Training Updates, Minority Health Statistics).
- 2) Department of Justice and Federal Trade Commission Antitrust Statements—can be viewed on the Internet at http://www.ftc .gov/ftc/antitrust.htm
- 3) United States Department of Justice Antitrust Division—can be viewed on the Internet at http://usdoj.gov/atr/index .html
- 4) New York State Department of Health: www.health.state.ny.us
 - This site is very useful when looking for a specific statute. The text of a statute can be viewed by entering either the statute's title or section, or browsing the table of contents.
 - The user can also search for a wide variety of health care information.
 - This site includes the Public Health Forum, which contains the New York Codes, Rules, and Regulations (both Title 10 and Title 18) and New York State Public Health Law.
 - No membership fee is required for use of this Web site and no fee is charged for access.
- 5) New York City's Health and Mental Hygiene Web site (NY City Dept. of Health: www.nyc.gov/html/doh/home.html
 - This Web site is useful for looking up a specific topic that may be covered by a New York City statute, or that is directly related to New York City.

- This site is organized by Health Topics, Agency Information, and Publications.
- The user can access a number of publications including the NYC Department of Health and Mental Hygiene publications.
- The site provides free access to MEDLINE and other databases ("ageline"—psychological, social issues facing the aging, policy information exchange, center for disease control, Combined Health Information Database, etc.).
- Free access to periodicals, and Health Information Packets, etc. is also available.
- 6) New York Citizen's Access to State Government: www.state.ny.us/state_acc.html
 - Web site provides access to all state government agencies, including the Department of Health and the Department of Environmental Conservation.
 - This site provides free access to its resources.
- 7) Department of Health and Human Services: www.os.dhhs.gov
 - The Department of Health and Human Services site allows the user to search many databases and topics including:
 - Reference Collections (statistics, dictionaries, libraries);
 - Policies and Regulations (laws, policies, regulations);
 - Resource Locators (health care facilities, providers);
 - Disasters and Emergencies (bioterrorism, homeland security);
 - Diseases and Conditions (Mental Health, HIV/AIDS);
 - Families and Children (Medicaid, vaccines);
 - Aging (Medicare);
 - Specific Populations (men, women, disabled, etc.);

- Drug & Food Information (drugs, recalls); and
- Safety and Wellness (exercise, smoking, traveler's health).
- ° There is no charge for use of this site's services.
- 8) Code of Federal Regulations (CFR): www.access.gpo.gov
 - This Web site is a quick way to research the CFR under any title (Public Health is Title 42). You can enter a key word and/or section when in search field in order to view the document on your computer.
 - This Web site also sells CFR Titles.
 - There is no membership fee required for use of this Web site.
 - The documents can be printed from the site at no cost.
- 9) FirstGov: www.firstgov.gov
 - This site is easy to use for research of federal materials.
 - The site is organized primarily by topic (agencies, governmental agency contacts, references—laws and regulations).
 - It includes separate listings by branch of government (normally provides links to top-tier agencies, including health and safety).
 - The site also provides access to many legal and regulatory sources (federal laws, rules, regulations, judicial decisions, etc.).
 - There is no membership fee required for use of this Web site.
- 10) Centers for Medicare and Medicaid: http://cms.hhs.gov
 - This site provides access to information on Medicare, Medicaid,
 HIPAA, the State Children's Health
 Insurance Program (SCHIP), Clinical Laboratory Improvement
 Amendments (CLIA), Laws and
 Regulations, and state waivers.

- 11) OIG Advisory Opinions: http://oig.gov/fraud/advisoryopinions.html
 - This site provides access to the advisory opinions of the OIG.
 - Opinions may be requested through this site, and final rules of the Federal Register may be downloaded.
 - Compliance Guidelines may be viewed through this Web site as well
 - There is also an area for Fraud Prevention and Detection: http://oig.gov/fraud/complianceguidance.html, and there is an available link to Corporate Responsibility and Corporate Compliance: a resource for Health care Boards of Directors.

B) Association Web Sites

- 1) New York State Bar Association: www.nysba.org
 - This site has many resources for its members including access to free case law through LexisOne and Loislaw, free official approved forms and the ability to purchase other forms individually or in a form package, the NYSBA Journal, and State Bar News.
 - Non-members have access to a legal Web site directory, the Code of Professional Responsibility, the wEbrief newsletter, Multi-disciplinary Practice Rules, and Practice Management Products and Publications.
 - Membership fees vary:
 - Resident Attorneys— \$70.00–\$400.00 (depending on the year of admittance to the bar);
 - Non-resident Attorneys— \$70.00-\$200.00 (depending on the year of admittance to the bar);
 - Newly Admitted Attorneys— FREE (evidence of admission is required and must be presented in order for this to be processed); and

- ° Law Students/Graduated Law Students—\$10.00
- A waiver of the dues may be applied for by filling out the request form provided on the Web site.
- In addition to becoming a member of the New York State Bar Association, members may join any of the 23 available sections (Health Law, Corporate Law, etc.) at an additional cost.
 - Section membership prices vary, and the sections can be joined during the membership process, after one has obtained membership.
- 2) American Health Lawyers Association (AHLA): www.healthlawyers.org
 - Law-related materials, government agencies, health care and health law sites can be accessed through the AHLA Web site.
 - This Web site offers members access to publications, educational programs, news and news analysis, health law documents, press releases, and law related Web sites.
 - Non-members may gain access to a wide variety of resources including links to useful Web sites, news, and publications.
 - Listserve—Non-members have access to the AHLA Listserves. Listserves are free e-mail discussion groups that may be used to discuss different health law topics.
 - Ask Health Lawyers—Nonmembers may also access Health Law documents, which may be downloaded from the Internet for free or ordered in hard copy form from the AHLA (processing and paper fee will be charged).
 - Membership in the association is required in order to access specific materials (14 practice groups, online Health Law Digest, Health Lawyers News, discounts on publi-

- cations, and an on-line membership directory).
- Membership fees vary:
 - Attorneys—\$150.00 to \$315.00 (depending on years since admission to the Bar)
 - Government Attorneys or Academics—\$150.00
 - ° Health Professionals—\$315.00
 - ° Law Students—\$20.00
- Membership is purely individual and will therefore not be affected by change in employment.
- A \$35.00 annual fee is charged for membership in a practice group.
 - In-House Counsel and Fraud and Abuse are two of the many practice groups available.
- 3) National Health Law Program (NEHLP): www.healthlaw.org
 - This is an invaluable Web site maintained by a national public interest law firm that seeks to improve health care for uninsured or underinsured low-income people.
 - This site contains many helpful links including links to the Federal Register, federal agencies, various organizations, children's health, reproductive health, public accountability, state and regional projects, immigrant health, managed care, and state health information.
 - There is no charge for using this site, but there are fees for purchasing NHLP publications (i.e., Advocates Guide to Medicaid) and executive summaries through this Web site.
- 4) Greater New York Hospital Association: www.gnyha.org
 - The site lists GNYHA member hospitals and providers as well as links to health care agencies, the Emergency Preparedness Resource Center, press releases, public testimony,

- publications, and the Center for Continuing Care.
- This site links many articles discussing current issues affecting hospitals, such as congressional cuts to teaching hospitals, and the impact of "9/11" on the New York hospital system.
- This site contains links to information about smallpox and a mental health services at member hospitals.
- Members can also access a HIPAA resource area.
- 5) The Judge David L. Bazelon Center for Mental Health Law: www.bazelon.org
 - The Bazelon Center is known as the nation's leading legal advocate for the rights of people with mental illness and disabilities.
 - The Center's attorneys provide technical support for and cocounsel selected lawsuits with private lawyers and legal service programs, ACLU chapters, and state protection and advocacy systems.
 - The site provides links to news and information regarding certain mental health issues.
 - The center publishes handbooks, manuals, issue papers and reports which may be purchased through their Web site.
- 6) National Alliance for the Mentally Ill: www.nami.org; www.naminys.org
 - The National Alliance for the Mentally Ill (NAMI) is a nonprofit, grassroots, self-help, support and advocacy organization for people who suffer from mental illness and their families.
 - NAMI-NYS (www.naminys.irg) is New York State-specific and has 5,000 members and 58 affiliate local organizations across the state of New York.
 - The organization works on the national, state, and local levels to

- provide education about mental illness, support increased funding for research, and advocates for adequate health insurance, etc.
- This Web site is an invaluable tool for attorneys who are confronted with issues involving mental illness and contains a wealth of information relating to mental illness.
- Members can research policy issues and regulations that affect the mentally ill.
- Membership in the organization is available and can be obtained through one state and/or local NAMI office (membership in NAMI-NYS is \$25.00-\$500.00).
- 7) American Bar Association: www.abanet.org
 - This site provides access to a number of legal resources including list serves, Weekly Briefing of legal issues and the online ABA Journal.
 - Members receive a monthly publication from the Association and have access to ABA publications.
 - Membership fees vary based upon how long one has been admitted to the bar:
 - FREE for those admitted less than one year up to \$295.00 (reduced dues are available for judges and lawyers in public service).
 - There are twenty-three (23) sections that a member may join at an additional cost. This cost ranges from \$30.00 to \$50.00 (Health Law Section fee is \$40.00).
 - There are 4 divisions that may be joined (membership fee ranges from FREE—young lawyers division—to \$40.00).
 - There are also forums available that may be joined (prerequisite to joining a forum is the membership in at least one section or division):
 - Cost for membership in an ABA Forum ranges from \$30.00 to \$50.00.

- The American Bar Association also offers a special joint rate offer (a single fee will cover the rates for Government and Public Sector Lawyers Division and any one of the nine (9) listed areas of law (including Health Law).
- The ABA has an affordable dues program in which those attorneys who are experiencing financial hardship will be able to receive a discount on their dues.
- There are also a few sections that offer an additional financial hardship discount.
- 8) Joint Commission on Accreditation of Healthcare Organizations (JCAHO): www.jcaho.org
 - This Web site provides access to the comprehensive accreditation manual for hospitals.
 - This site also provides up-to-date news relevant to hospitals and hospital administrators.

C) Other Web Sites

- HEALTH HIPPO: http://hippo.findlaw.com/hippohome .html
 - This site is a collection of policy and regulatory information related to a wide variety of health care issues.
 - The site provides links to many topics facing health law professionals:
 - Advance Directives, Antitrust, Vaccines, FDA, Fraud & Abuse, Quality Assurance, Public Health, Research Integrity & Bioethics, etc.
 - Within each topic are links to the relevant statutes, rules/regulations, legislation, cases and reports.
 - No membership fee is required for use of this Web site and no fee is charged for access.
- 2) The Health Law Resource: www.netreach.net/~wmanning/

- This site contains links to health and technology pages as well as government pages.
- This Web site also contains links to topics such as:
 - Fraud & Abuse,
 - Mergers & Acquisitions,
 - ° Bioethics/Patients, and
 - ° Medicare/Medicaid.
- The site provides links to the CFR and STARK II Regulations.
- The site also provides related government and law links:
 - Government Sites, Statutes, and Cases,
 - Law Firms, University
 Resources & Other Indexes,
 - ° On-line Legal Publications,
 - Related Technology and Medical Links, and
 - ° Non-legal Links.
- No membership fee is required for use of this Web site and no fee is charged for access.
- 3) Saint Louis University School of Law— The Center for Health Law Studies: http://law.slu.edu/healthlaw/research/ links/index.html
 - This site contains many health law links and users can search by Topic, Agencies and Institutions, Journals and Publications, and HIPAA and Health Privacy.
 - Users can also link to Portals, Indexes, and Search Engines and free Legal Information Institute case law and statutory searches.
 - No membership fee is required for use of this Web site and no fee is charged for access.
- 4) The Center for Regulatory Effectiveness (CRE): www.thecre.com

- Although this site will require some time for navigation and searching before getting to what you are looking for, it is very helpful.
- This site provides links to federal government Web sites, the Federal Register, federal regulations under development by a particular agency, and allows the public to comment on the effectiveness of certain regulations. The interested public is urged to take an active role in public policy debates on the issues contained in the CRE site.
 - Where possible, agency contacts will be identified and opportunities for public comment in the Federal Register or elsewhere will be noted.
- This site provides direct links to agencies (DHHS) and to the Fed-Law Web site (federal laws and regulations, the U.S. Code).
 - Federal Statutes are searched for using an alphabetical Topical and Title Index.
- Use of the CRE is free and there is no fee charged for any research done.
- 5) WashLaw Web: www.washlaw.edu
 - This site allows the user to search for a specific topic in numerous ways, including:
 - By state, by circuit, in law journals, etc.
 - This site also provides a link to a list of legal search engines, and can be searched in its entirety by keyword.
 - No fee is charged for use of this site.
- 6) LexisNexis—Lexis One: www.lexisone.com
 - This Web site is one way that firms on a limited budget may have access to the LexisNexis research system.

- The site has links to find other legal Web sites, access public records of states, access cases, legal forms, state resources, and Shepards®.
 - Access to Shepards® is quoted at \$30.00 per day.
- A fee is charged for use of this site.
 - Firms can pay as they go, or subscribe to LexisNexisTM by the day, week, or month.

7) Find Law: www.findlaw.com

- This site is a part of WestLaw®, and allows the user to search its database by topic, but also provides the opportunity for a general search.
- There are research links, state law links, federal law links, government resources, legal news and legal subjects.
- For a fee, an attorney and/or firm may purchase specific services such as West WorkspaceTM, and West Legal DirectoryTM.
 - To find out specific fees, the site provides contact numbers to reach a representative.

8) LexisNexisTM: www.lexisnexis.com

- This legal web service provider allows a user to use a large amount of resources.
- Like WestLaw®, the user can search either by topic, area of law, date, and jurisdiction.
- Also, similar to Westlaw®, a user would have to be a member in order to use this service.
- Many services are provided and each requires payment of a fee for use (Shepard'sTM, SmartLinksTM, Corporate AffiliationsTM, etc.).
- There are many price plans and packages available and information on the available plans and packages can be received by contacting a representative.

9) WestLaw®: www.westlaw.com

- This site provides attorneys with a vast amount of legal information, including law journals and law reviews, case law and opinions, and state and federal law.
- Legal material may be researched by area of law, jurisdiction, and topic, as well as by date.
- Queries are sorted by relevance and are also organized by a color category that explains how relevant the law is.
- One must be a member to access WestLaw®, and fees range depending on both the firm size, and the required services. For an inquiry into the pricing options, a representative may be contacted.
 - There are hourly packages, and credit card use is available as well.
- 10) American Law Sources Online (ALSO): www.lawsource.com/also
 - This site covers North America (USA, Canada. and Mexico) and provides a comprehensive collection of links to FREE resources on the Internet and is organized by jurisdiction.
 - For each jurisdiction, sites are provided to sources of primary law, commentary to that law, and practice aids (official forms and court information).

11) Internet Public Library: www.ipl.org

- This site is maintained and sponsored by the School of Information of the University of Michigan.
- The site is useful for searching a specific topic or for searching all related issues under a specific heading/topic.
 - o The library's Subject Collections area has links to "Health & Medical Sciences", and "Law, Government and Political Science" as well.

- No fee is charged for any research done.
- 12) Legal Information Institute (LII): www.law.cornell.edu
 - This site offers a wide variety of resources including:
 - Law by source or jurisdiction;
 - Constitutions and Codes:
 - UCC, CFR, U.S. Code, Federal Rules of Civil Procedure, Federal Rules of Criminal Procedure, Federal Rules of Evidence; and
 - ° Court opinions.
 - No fee is charged for use of this site.
- 13) The Virtual Chase: www.virtualchase.com
 - This Web site contains a legal research guide and is sponsored by Ballard, Spahr, Andrews & Ingersoll, LLP.
 - The user can search or browse the collection of annotated resources for legal research (i.e., Health Law, Elder Law) and factual research (i.e., Medicine and Health).
 - Also listed on this Web site are federal agencies and Health Law related organizations:
 - Dept. of Health and Human Services, FDA, Office of the Inspector General;
 - Government Databases:
 JCAHO, American Health
 Lawyers Association, American
 Medical Association, Center for
 Disease Control;
 - Government-based Topical Web Sites: Medicaid Fraud Statutes, State HIPAA Laws, State Medicaid Policy Search; and
 - Other Useful Databases: AMA
 On-line Doctor Finder, The
 American Hospital Directory,
 Preventable Tragedies, etc.
 - No fee is charged for use of this site.

- 14) Hieros Gamos: www.hg.org
 - This index is international in scope and is organized under an index of topic and scope.
 - This site contains links to international sites, commentary, cases, statutes, publications, etc.
 - This Web site also provides access to legal Web sites, legal associations, and bar associations.
 - Also provided are links to United States law (Constitutional-Judicial, Legislative, and Executive, Federal, and State).
 - Use of this site and access to materials is free.
- 15) New York Lawyer: www.nylawyer.com
 - This site has a link to "The Best Legal Web Sites" which are organized into different categories including:
 - Crawlers & Metasearchers, Government Sites, People Finders, LawCrawler & Legal Indexes, Legal "Destinations" and Search Tools, Virtual Reference Libraries, Public Records, and Converters and Calculators.
 - These sites are also labeled as general sites that are related to law, loosely related to law, or not even remotely related to law.
 - No fee is charged for use of this site
- 16) LawCrawler: http://lawcrawler.lp.find-law.com
 - This site is known as a metasearcher (it will send the query to multiple search engines simultaneously) and is sponsored by Findlaw, an extension of Westlaw®.
 - o This search engine will only search sites, known to contain legal information, that are governmental and commercial domains (".gov" or ".com").

- Allows user to look up state and federal case law as well as statutes and regulations.
- This site allows the user to limit the search to particular sites and databases such as government sites, state sites, law reviews, and Supreme Court opinions.
- Use of this site is free.
- 17) Legal Ethics: www.legalethics.com
 - This Web site provides users a way to research legal categories and then topics within that category (i.e., Laws/Local codes).
 - This site also publishes legal ethics opinions and recent ethics cases.
 - No fee is charged for use of this site
- 18) E-Clips: www.eg3.com/eCLIPS/newsletter.htm
 - This Web site allows individuals to sign up for free newsletters to be delivered to their e-mail addresses.
 - These newsletters are organized by industry.
- 19) The Advisory Board: www.advisoryboard-company.com
 - The advisory board is a membership of many of the country's progressive health systems and medical centers.
 - The board publishes a daily and weekly news service.
 - The board researches the best (and worst) demonstrated practices, helping member institutions benefit from one another's learning curves.
 - For an annual fee, members have access to research results, executive education, and the news services.

III) Other Secondary Resources

- A) Loose-leaf Services
 - 1) Bureau of National Affairs (BNA)
 - 2) Commerce Clearing House (CCH)

- Fraud and Abuse
- B) Health Care Clippings Services
 - 1) E-Clips: (see # 29 above)
 - 2) The Advisory Board: www.advisoryboard-company.com (see # 30 above)

C) Texts

- 1) Employment Litigation in New York
 - Kenneth W. Taber
 - West Group/Thomson Company 1996
- 2) Health Care Fraud: Criminal, Civil and Administrative Law
 - Pamela H. Bucy
 - Law Journal Seminars-Press 1996
- 3) Health Care Law: A Practical Guide
 - Scott Becker
 - Matthew Bender 2002
- 4) Hospital Liability
 - James Walker Smith
 - Law Journal Press 2000
- 5) Healthcare Association of New York: Managed Care Credentialing Manual
- 6) New York State Bar Association: Legal Manual for New York Physicians

D) Guidelines

- HIV/AIDS Testing, Confidentiality & Discrimination—What You Need to Know About New York Law
 - Legal Action Center of the City of New York 2001 (www.lac.org)
- 2) New York Health Law (Seventh Edition)— A Guide for Health Care Providers
 - Barry A. Gold, J.D., LL.M.
 - Fort Orange Press 2002
- The End of Life: Guidelines for Health Professionals Concerning Death Certificates, Autopsies and Organ & Tissue Donations
 - Sixth Edition 1994 (currently searching for a more recent edition)
 - The New York Academy of Medicine

- 4) When Others Must Choose: Deciding for Patients Without Capacity
 - The New York State Task Force on Life and Law 1992
- E) **Newsletters**—Many law firms with a health law practice section and trade associations put out periodic newsletters.

Law Firm Newsletters

- 1) Garfunkel, Wild, & Travis, PC
- 2) Cadwalader, Wickersham, & Taft LLP
- 3) Epstein, Becker & Green, PC
- 4) Reed Smith
- 5) Ropes & Gray LLP
- 6) Proskauer Rose LLP
- 7) McDermott, Will & Emery
- 8) Manatt, Phelps & Phillips, LLP

Trade Association Newsletter

1) American Health Lawyers Association

F) Other Practice Aids

- New York State Bar Association Health Law Section, Legal Manual for New York Physicians—BRAND NEW Comprehensive Reference
- 2) Frequently Asked Questions Manual
- 3) Epstein, Becker & Green–Employment Law Glossy Tri-fold

(IV) Trade Associations

A) Legal

- 1) New York State Bar Association (NYSBA)
- 2) American Bar Association (ABA)

- 3) American Health Lawyers Association (AHLA)
- 4) New York City Bar Association—Health Law, Bioethics, and Insurance Committees

B) Hospital

- 1) Greater New York Hospital Association (GNYHA)
- 2) Healthcare Association of New York State (HANYS)
- 3) The Mental Health Association in New York State (MHANYS)

C) Providers

- 1) Medical Society of the State of New York
- 2) American Society of Clinical Oncologists (ASCO)

V) Patient Support and Advocacy Groups

Many of the following patient support and advocacy groups are valuable resources for patients with insurance, financial and other problems related to their illness. Many also have legislative experts and healthcare attorneys assisting their patient support and lobbying efforts.

- A) Patient Advocate Foundation and The National Patient Advocate Foundation
- B) New York Legal Assistance Group (NYLAG) Health Law Section
- C) American Cancer Society
- D) Cancer Care
- E) SHARE
- F) Gilda's Club
- G) Leukemia & Lymphoma Society

EPA Region 2 Launches Hospital Enforcement and Compliance Initiative

By Jean H. McCreary

Many hospital CEOs' first New Year's gift was opening the U.S. Environmental Protection Agency's December 27, 2002 letter informing them that EPA planned to conduct extensive regulatory compliance inspections targeted at hospitals during 2003. (See attachment.) Inspectors will look for violations of any of a broad range of federal environmental regulations, including those implementing the Resource Conservation and Recovery Act (RCRA),¹ the Clean Air Act,² the Clean Water Act,³ the Emergency Planning and Community Right to Know Act,⁴ the Federal Insecticide, Fungicide and Rodenticide Act⁵ and the Toxic Substances Control Act.⁶ Violators will be subject to potentially substantial monetary damages and fines, and in some cases criminal penalties.

In the same letter, the EPA offered to reduce or eliminate the "gravity-based component" of penalties for violations detected (i.e., the part of the penalty that is unrelated to the violator's economic benefit from noncompliance) for hospitals that sign an agreement to perform a comprehensive compliance audit and report any violations detected during the process. Those that sign the audit agreement are given "low priority" status for regulatory inspections. Those that do not sign face the prospect of multi-media inspections (i.e., air, water, waste, etc.) and no penalty mitigation.

The letter went to over 500 hospitals in EPA Region 2 (New York, New Jersey and Puerto Rico). The initiative is aimed at hospitals (i) because hospitals produce a wide variety of hazardous wastes (including chemotherapy and antineoplastic chemicals, solvents, photographic chemicals, radionucleides, lead and mercury) and over 2 million tons of waste annually (greater than 1% of the total municipal solid waste produced in the U.S.) and (ii) because EPA perceives the compliance rate as low.

The initiative is modeled on the enforcement program that has been in place since 2000 against colleges and universities. In that program nearly 50 of the approximately 350 institutions that received the letter took advantage of penalty mitigation provisions under EPA's audit policy (65 Fed. Reg. 19618-19627, April 11, 2000) resulting in the waiver of over \$2.5 million in potential penalties. Nearly a dozen institutions, including the major New York public colleges, SUNY and CUNY, signed the audit agreement and more are in the works. About ten regulatory inspections have been con-

ducted at non-participating institutions with virtually all resulting in the imposition of penalties, some quite substantial.

During 2003, EPA has embarked on a compliance assistance program that has included over a dozen seminars to hospital environmental managers and the posting of substantial compliance materials on EPA's Web site devoted to the initiative: www.epa.gov/region02/healthcare. There are links to various health-related waste minimization initiatives, as well as to EPA's model audit agreement as well as environmental compliance requirements and audit protocols for all major EPA regulatory programs. Forthcoming on the Web site will be the audit protocols used by Rutgers and SUNY in performing their audits, including at associated medical facilities.

At the close of the compliance assistance program, EPA will begin to launch its inspection program for facilities that have not signed the audit agreement. Even without executing an EPA agreement, some penalty mitigation may be available. If violations are detected during a self-audit, under EPA's audit policy they must be reported to EPA within 21 days of detection and corrected within 60 days. Up to 100% mitigation of the gravity-based component of penalties is contingent upon demonstrating that the facility has met the nine conditions set forth in the policy (see side box on p. 56), although EPA's policy cautions that it is guidance only, does not bind EPA and does not create enforceable rights. No penalty mitigation is offered for the "economic benefit" component of the penalty (the avoided cost of compliance) in order to ensure that through this program EPA does not place non-complying parties in an advantageous position over parties who have incurred the costs of compliance all along. However, during the college and university initiative, EPA did not impose economic benefit penalties on any participating facility as these were viewed as de minimis.

Some of the issues for hospital counsel to consider in advising their clients regarding the decision to enter into the audit agreement program are as follows:

NYSDEC, which has delegated enforcement authority for many of the programs covered by the EPA initiative (such as RCRA, State Pollutant Discharge Elimination System (SPDES), stormwater, discharges to Publicly Owned Treatment Works (POTWs), air

permits, tanks, etc.) is not a signatory to the agreement and thus has not *formally* agreed to either low priority inspection status or to waiver of penalties.

- Findings disclosed to EPA are available to NYSDEC as well as potential citizen suit plaintiffs.
- There is no pre-disclosure method of confirming that the nine conditions have been met before the disclosures are made.
- The penalty mitigation, and promise of no criminal referrals, is not available to individuals—only to entities, creating a risk of additional enforcement if disclosed violations are sufficiently serious to trigger criminal enforcement against individuals.
- If violations are detected, EPA may require corrective action to be conducted under a compliance schedule embodied in an administrative consent order, and if the extent of non-compliance suggests management system issues, EPA may require implementation of an environmental management system similar to ISO 14000.

Experience with the colleges and universities enforcement initiative suggests that EPA is determined to make the audit policy and audit agreement process an attractive option for many facilities. However, the timing of the initiative is a challenge in New York as nearly all hospitals in this state are non-profit or public institutions with scarce resources, and nearly all hospitals in this state are struggling from multiple pressures, including Medicare and Medicaid cuts, a highly competitive economic environment, and compliance threats and costs from governmental initiatives such as Medicare fraud and abuse enforcement, HIPAA, and other programs that are competing for internal resources.

Endnotes

- 1. 40 C.F.R. parts 240-282.
- 2. 40 C.F.R. parts 50-99.
- 3. 40 C.F.R. parts 100-136, 140, 230-233, 401-471 and 501-503.
- 4. 40 C.F.R. parts 392, 355, 370 and 372.
- 5. 40 C.F.R. parts 150-189.
- 6. 40 C.F.R. parts 700-799.

Jean H. McCreary, Esq., chairs the environmental practice group of Nixon Peabody LLP, which has a 30-member energy and environment group (which includes in-house environmental technical professionals) and a 25-member health services practice group. She is also a Certified Professional Environmental Auditor.

Summary of EPA Audit Policy Conditions

AUDIT: The violation must be discovered through either (a) an environmental audit or (b) a compliance management system. An audit must be systematic, and the facility must reflect due diligence in "preventing, detecting and correcting" violations.

VOLUNTARY and INDEPENDENT: The violation must be discovered voluntarily, and not through permit-mandated monitoring or a consent order, and independent of any notice of an impending inspection or citizen complaint.

DISCLOSURE: Violations must be disclosed in writing to EPA within 21 calendar days of discovery, which means when "any officer, director, employee or agent of the facility has an objectively reasonable basis for believing that a violation has, or may have, occurred."

CORRECTIVE ACTION: The facility must certify it corrected violations and remediated any environmental harm within 60 days of discovery or as expeditiously as possible.

PREVENTION: The facility must take steps to prevent recurrence of the violation.

NON-HABITUAL VIOLATOR: The facility cannot have had the same or a closely related violation in the past three years, or a pattern of similar violations at any facility of a common parent in the past five years.

EXCLUDED: Policy benefits are not available for violations that result in serious harm to the environment or imminent and substantial public endangerments or that violate consent orders.

COOPERATION: Cooperation with EPA to supply the "information it needs" to assess the policy criteria.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 2 290 BROADWAY NEW YORK, NY 10007-1866

DEC 2 7 2002

To Whom It May Concern:

Re: Hospital Environmental Compliance Initiative and Voluntary Discovery/Disclosure of Potential Environmental Violations

I am writing this letter to urge you to take advantage of EPA's Audit Policy.

In many instances, unilateral EPA action can be avoided by voluntary compliance through the utilization of EPA's Audit Policy "Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations, Notice, 65 F.R. 19618, April 11, 2000." The Audit Policy has several important goals including promoting greater compliance with federal laws and regulations which protect human health and the environment through self-policing, discovery, disclosure, correction and prevention. If certain criteria are met, reductions in gravity-based penalties of up to 100%, resulting from EPA enforcement of violations discovered and disclosed by your institution under the Audit Policy, are possible. A copy of the Audit Policy is enclosed. The Audit Policy, along with some interpretive guidance, is also available on the Internet at http://www.epa.gov/region02/capp/cip/.

The U. S. Environmental Protection Agency (EPA) Region 2 is planning to conduct inspections of hospitals within our region (New York, New Jersey, Puerto Rico, and the U.S. Virgin Islands) during the coming year to determine compliance with environmental regulations, including but not limited to, regulations under the Resource Conservation and Recovery Act, the Clean Air Act, and the Clean Water Act.

I urge you to take advantage of the Audit Policy to identify any violations and to voluntarily correct them prior to our planned inspections. If violations are discovered during an EPA inspection of your facility that was planned prior to your self-disclosing them, penalty reductions that might be possible through the Audit Policy will not apply.

Any voluntary compliance evaluations undertaken by your institution in response to this letter should focus on compliance with all federal environmental regulations, particularly those dealing with hazardous waste regulations, underground and above ground storage tanks, water discharges and air emissions. To help you in this endeavor, I have enclosed a list of environmental regulations that may apply to your hospital and a list of some of the common violations found in the healthcare sector. There may be other environmental regulations that apply depending on the activities at your facility.

To assist you in understanding some of the most significant federal environmental regulations, and to provide you with facts about the Audit Policy, the usefulness of environmental management systems and what efforts hospitals can undertake to minimize pollution, we are offering a number of conferences, the next of which will be with Long Island Jewish Hospital at the Zucker (formerly Hillside) Memorial Hospital facility on January 21, 2003, followed by another at Beth Israel Medical Center in Manhattan on February 26, 2003. Information about the location, registration and agenda will be forthcoming in the mail, and on the Region 2 website at http://www.epa.gov/region02/capp/healthcare/.

If you have questions or need more information regarding this compliance initiative, please see the following website, http://www.epa.gov/region02/capp/cip/ or you may call Diane Buxbaum, Hospital Compliance Coordinator at (212) 637-3919. For questions regarding the Audit Policy, please contact John Gorman, Audit Policy Coordinator, at (212) 637-4008. Enclosed is a fact sheet with useful websites, documents and other resources.

EPA is planning to offer additional conferences in 2003 to expand the level of awareness of environmental and pollution prevention issues in the hospital sector. If your facility is willing to host such a conference, with EPA providing the speakers and training materials, please contact Diane Buxbaum of my staff at (212) 637-3919.

Sincerely yours,

Richard L. Caspe, P.E., Director

Division of Enforcement and Compliance Assistance

Enclosures

cc:

James H. Ferreira, Esq., Deputy Commissioner and General Counsel New York State Department of Environmental Conservation

Lisa Jackson, Assistant Commissioner, Compliance and Enforcement New Jersey Department of Environmental Protection

Zoraida Samo, Esq., Director, Legal Division Puerto Rico Environmental Quality Board

Hollis L. Griffin, Director, Division of Environmental Protection U.S. Virgin Islands Department of Planning and Natural Resources

Emerging Ethical Issues in the Provision of Healthcare

By Claudia O. Torrey

I. Topic Summary

This article will provide a historical overview of professional and medical ethics and will explore the impact of technology on the interface of law and medicine. Because of the intersections of law, medicine, science, and technology, today's medical professional must constantly balance legal liability risks with ethical principles and concerns.

Advancements in technology have left the law and ethics trying to keep up; to wit, the "tension of progress." Examples of this tension can be found in the areas of informed consent, health information privacy and confidentiality, medical errors, and genomics.

II. Historical Overview of Professional and Medical Ethics

Ethics is the branch of philosophy that attempts to address questions of right and wrong using reason. Ergo, ethical reasoning can be characterized as a process that never ends. The short historical overview presented here forms the basis for a discussion of the areas of ethical tension presented in modern times.

The period between pre-1500 to the 1700s is often considered the period of ancient ethics. Before 1500, the theories and ideas of numerous philosophers of both Eastern culture (i.e., Confucius, Mencius, and Hsün-tzu) and Western culture (i.e., Pythagoras, Ovid, and Porphyry) abounded. To be sure, Greece is considered the birthplace of ancient ethics or Western philosophical ethics.

An important catalyst of moral, philosophical, and ethical thought came from a Greek group of thinkers known as Sophists. The term was used in the fifth century to refer to a class of professional teachers of rhetoric and argument³ whose beliefs, some say, espoused "winning at any cost" because society values success. One of the more famous Sophists, Protagoras, is credited with the statement "man is the measure of all things." Thus, the moral, the upright, the good were to be followed only if doing so satisfied one's interest or concept of "success." Is it any wonder that other Greek philosophers and learned individuals sought to challenge the negative, corruptive foundations of the Sophists' belief system?

Perhaps in defiance of Sophistry, shortly after Protagoras, a Greek physician named Hippocrates came to be known as the founder of the concepts we now call medical ethics. Born in 460 B.C. in the Greek city of Cos,

Hippocrates' greatest legacy is the charter of medical conduct embodied in the Hippocratic Oath.⁴ The oath is viewed as an ethical ideal that has guided the practice of medicine throughout the world for more than 2,000 years.⁵

Hippocrates, along with Avicenna, an Arab physician and philosopher born in 980 and author of the *Canon of Medicine*, and Maimonides, a Jewish physician and philosopher born in 1135 and author of the *Aphorisms of Medicine*, promulgated solemn recommendations for physicians: to respect their patients; to do no harm to their patients; and to maintain their patients' confidentiality.⁶ Thus, it can be said that "[t]hese traditional human values, personal and common, . . . contribute to a bioethics which regulates biotechnologies and new therapies, and not as some people fear, a bioethics stemming from and dependent upon biotechnologies."⁷

Ethical theorists have tended to follow three main Greek philosophers: Aristotle, who was a student of Plato; Plato, who was a student of Socrates; and Socrates. Their main tenet portrayed ethics as the good life—that is, those virtues and characteristics that made life worth living (i.e., inner happiness, honor, integrity, a handshake). Aristotle is often called the father of ethics because he opined that good judgment was the most important ethos one could embody. That is, the ability to reason well is to live well the good life.

As time moved on, through the medieval and renaissance periods, there were those who gleaned their sense of ethics from the Bible—the Old Testament with its emphasis on the divine law of the Scriptures, and adherence to the express dictates of God's law; or the New Testament with its emphasis on Jesus as the Son of God, and less adherence to the express dictates of the Scriptures. History gave us the rise and fall of the Scholastics, and history also gave us Niccolò Machiavelli. Machiavelli, an Italian, deliberately snubbed lofty moral and ethical beliefs. Like the Sophists, he believed one was to achieve goals with power and by any means necessary. There was no room for such niceties as ethical behavior.

In 1513, Machiavelli's *Il Principe* (The Prince) was published.⁸ His advice to rulers: "It is necessary for a prince, who wishes to maintain himself, to learn how not to be good, and to use this knowledge and not use it, according to the necessities of the case." Thus, Machiavelli's name became synonymous with political cynicism and deviousness. 10

The concept of modern ethics started to develop around 1500.¹¹ While ancient ethics did not try to provide rules or guidelines for making difficult choices, modern ethics attempts to sort out the good, the bad, and the ugly of one's choices. Modern ethics seeks "to help one decide which reasons are important or fundamental, and which are less important or not valid at all." With the Machiavellian ethos essentially reviving the Sophists' view, one can see why society sought to develop an ethics that celebrated the deontological approach to ethical decisions.

As the modern ethos was developing, American institutions of higher education were also growing. ¹³ Academia aligns itself professionally with law and medicine. Although early American colleges consciously modeled themselves on English institutions in many ways, they were governed from the beginning by outside boards of non-academics. ¹⁴ Medicine, law, and academia are seen as having an unwritten social compact or social contract with society. ¹⁵

In Latin, the word profession means "bound by oath." Society and members of a profession form an unwritten social compact whereby the members of a profession agree to restrain self-interest, promote ideals of public service, and maintain high standards of performance. In return, society allows the profession substantial autonomy to regulate itself through peer review.¹⁶ The ethics of each profession are descriptive of the professions' duties under the social compact. ¹⁷ In order to maintain its autonomy, a profession must develop clear principles of professional conduct and hold its members accountable for implementing the principles.18 Thus, "... a profession includes firefighting, plumbing, management, and medicine insofar as the professional performs a particular line of work to make a living and is committed to a set of standards."19

Aristotle may be considered the father of ethics, but it is Immanuel Kant, an eighteenth century German philosopher, who formulated the principles now accepted for the ethos.²⁰ Kant's work represents the seminal cornerstone of modern ethics—consistency and man's ability to reason; that is, you apply the same standard to others that you apply to yourself.21 According to Kant, man's rational thought leads to universal principles to be respected as laws of nature, inciting a deontological approach that accords with most religious moralities and codes of conduct of health organizations.²² The essential distinction between people and things, which has extended to the unconditional condemnation of all forms of slavery, all forms of torture, and the respect of the embryo as a potential human being, all bear the mark of Kant.²³

In 1794 Thomas Percival proposed a code of ethics for physicians. He recognized the need for a detailed,

written code, especially for large entities. In 1803, Percival adopted the terms "professional ethics" and "medical ethics." In 1847, the American Medical Association (AMA) became the first national professional society to adopt a "Percivalaen" code of ethics. The code mandated that physicians keep a patient's confidences, unless imperatively required to do otherwise. True to the period of ancient ethics, the Percivalaen code did not give clear guidance concerning when a disclosure was imperative.²⁴

A discussion of medical ethics is incomplete without mention of the evolution in the protection of human research subjects. Regulation in this area has followed a long and checkered history of research abuses.²⁵ Some ethicists have described this history as progress propelled by scandal.²⁶

The "lid on the scandal" first came off in 1947 when the Nazi Doctors Trial shed light on the numerous atrocities to human beings during World War II.²⁷ The trial, held in Nuremberg, Germany, concluded with ten principles for conducting research on human subjects.²⁸ These principles included the statement that "the voluntary consent of the human subject is absolutely essential."²⁹ As this area of medical ethics evolved in the United States, 1962 saw Food, Drug, and Cosmetic Act amendments mandating that experimental drugs could be used only if physicians obtained informed consent.³⁰

The next major advancement in this area came in 1964 when the World Medical Association, an arm of the United Nations, adopted the Declaration of Helsinki (Declaration).31 The Declaration provided guidelines for physicians conducting medical research on human subjects.³² A new Declaration, approved in October 2000, created new international standards to tighten rules for clinical research.³³ In 1966, the federal Public Health Service Act required peer review of all research that presented potential risk to human beings,34 and in 1974, as a result of a 1972 newspaper story on the federal Tuskegee Syphilis Study, the National Research Act was enacted.35 It gave institutional review boards (IRBs), not principal investigators, the responsibility of weighing risks and benefits to potential human research, and also established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission).³⁶

The Belmont Report of 1979, a product of the National Commission, etched its place in history by laying out the basic ethical principles for guiding human subject research: respect for persons or personal autonomy, from which the doctrine of informed consent flows; beneficence; and justice.³⁷ New York State's own human subject research statute seeks to honor these three ethical principles.³⁸ History has taught us to plan and think

ahead. We, as a society, can definitely learn from the fumbles and recoveries of the medical research arena.

III. Informed Consent

The "tension of progress" is a constant theme underlying many of today's ethical dilemmas. While medical and technological advancements demand that the ethics of the advancement be a central component, one is constantly amazed by the penumbral position of most ethical issues. Trust, like respect, must be earned. Trust hinges on a concrete affirmation of trustworthiness.³⁹

The doctrine of informed consent flows from the historical, ethical principle of respect for the personal autonomy of the patient/human subject by the physician/researcher. Perhaps the tension of progress is best crystallized by Dr. Daniel D. Federman, Senior Dean for Alumni Relations and Clinical Teaching at Harvard University:

Protecting research participants looms especially large in clinical research, where the risks are often the highest, professional roles are conflicted, and ethical lapses have been most salient. The physician doing research is wittingly cast in two different and often conflicting roles. Above all else, he or she is a doctor, sworn first to do no harm and always to act in the best interest of the patient. As investigator, however, the same person trained to randomize his or her patient's participation to an at least 50 percent likelihood of no benefit and, indeed, to treat all research participants with a neutral regard that puts the sought-after truth ahead of the research participant's immediate interest. As if this dual identity of dedicated physician and disinterested inquirer were not enough of a weight to sustain, the physician researcher has two burdens of (self) interest. One of these, familiar now for more than half a century, is the linkage of research and publication to academic promotion and professional advancement. The other, newer pressure, is that of obtaining additional income from sources that have a huge interest in a positive outcome of the research. Many and perhaps most clinical trials are now supported by pharmaceutical and biotechnology companies. Honoraria, speaker fees, paid travel, and further research support may all be available to

the bearer of positive tidings. These emoluments, though, are dwarfed by the potential of equity participation in the sponsoring company by the investigator.

To be sure, a sobering reality.

We can thank the federal government for this sobering reality. In 1980, the Bayh-Dole Act increased the commercialized sponsorship of research.⁴⁰ Prior to Bayh-Dole, the rights or claims to any discovery growing out of federally funded research remained in the public domain for the use of its citizens;⁴¹ post Bayh-Dole, researchers, and/or their host institutions, can patent discoveries and create spin-off companies that license the patents to private industry.⁴²

The Common Rule,⁴³ promulgated by the federal government, seeks to standardize human subjects regulations across agencies and departments.⁴⁴ The quest to balance the research subject's autonomy and ethical right to full and informed content, against the researcher/institutional need to produce results and keep the research funded, often creates warring opposites. Clearly, the right of informed consent necessarily yields a right of "informed refusal." The logical corollary of the doctrine of informed consent is that the patient generally has the right not to consent, that is, the right to refuse treatment.⁴⁵ This would apply whether the relationship is doctor/patient or researcher/human research subject.⁴⁶

Collegial Discussion Issues

- 1. Should a physician/researcher disclose, in writing, to the patient/human subject the financial interest s/he has in a particular product?
- 2. Should liability insurance, similar to directors' and officers' insurance for corporate board members, be given to IRB members?
- 3. Is the "right to know" synonymous with the concept of informed consent?

IV. Health Information Privacy and Confidentiality

The ancient Greeks, including Hippocrates, never imagined a computer-advanced society whose reach would allow access to individual health information, thereby creating new privacy issues. Some may argue that the privacy of one's health information is becoming more and more elusive; a cogent argument, however, could be made for the proposition that the root of most ethical problems in this area concern the confidentiality of health information—specifically, the management or re-release of one's private health information to third parties. Of course, codes of medical ethics or a civil

action for tort damages can put the teeth into enforcement of a physician's ethical duty of confidentiality.⁴⁷

The new health information privacy rule ⁴⁸ under the Health Insurance Portability and Accountability Act (HIPAA) was born out of a recognition by the federal government of the need to have a national standard for the protection of health information. The paper medical record, as we have known it, is quickly eroding. The electronic medical record is becoming the norm for the twenty-first century. As we become a more computer reliant society, the HIPAA privacy rule really seeks to address issues of health information confidentiality.

One healthcare forecaster predicts that the perceived resistance of the medical community to the use and adoption of technology, as well as the political problems associated with protecting the confidentiality of patient records, will pose hurdles to the accepted integration of the Internet into medical practice. ⁴⁹ The legal liability risks, along with the loss of community goodwill associated with the mishandling of computerized health information, create a chilling effect. Thus, the confidentiality, and privacy, of computerized health information needs to be the result of an ethically motivated, technological design choice. ⁵⁰ In effect, the ethically motivated design choice becomes the healthcare provider's brand. ⁵¹

Collegial Discussion Issues

- If a healthcare provider uses a computerized medical decision support system to assist in making clinical decisions, should failure to use such a system be considered unethical or grounds for malpractice?
- 2. Is the physician-patient privilege breached if, without the patient's knowledge, the primary care provider consults on-line with an out-ofstate colleague about the patient's health information?
- 3. Should the above scenario be viewed as an informed consultation between colleagues?

V. Medical Errors

The foundational points of the 1979 Belmont Report can be used in any medical ethic arena. The concepts of patient autonomy, beneficence, and justice set a gold standard! Bolstering that point, a recent survey conducted by the Healthcare Information and Management Systems Society reveals that enhancing patient safety and upgrading information technology (IT) security systems are the top IT priorities for healthcare providers.⁵²

If we do not learn from our mistakes we are doomed to repeat them. Yet the fear of liability or punishment has not necessarily decreased medical error. The potential "costs" of unaddressed medical errors are great—lost patient trust, lawsuits, and high malpractice rates that serve to undermine the healthcare delivery system.

The main mission of the National Quality Forum (NQF),⁵³ a public-private collaborative started in 1999, is to increase the provision of high quality healthcare. One way the NQF seeks to achieve this goal is by pursuing a strategy of standardizing the means by which healthcare quality is measured and reported.⁵⁴ The NQF considers improving patient safety an ethical imperative for healthcare providers, individually and collectively, and error prevention and safety promotion to be the job of everyone who works in healthcare.⁵⁵

Collegial Discussion Issues

- 1. Should non-punitive medical error reporting be mandated in all healthcare settings?
- 2. Has the ethos of patient autonomy, beneficence, and justice been breached if a physician does not follow a standard of care outlined in a clinical or practice guideline?
- 3. Is Sophistry alive and well in the healthcare community regarding medical errors?

VI. Genomics

The study of man's genetic code is called genomics. The National Human Genome Research Institute⁵⁶ (Genome Project) completed its distillation of our human genetic sequence in 2000. Therapeutic interventions that might be used for the discovery of, or avoidance of, a disease are known as the study of pharmacogenomics.

The legal and ethical issues involved in the Genome Project are so voluminous that one author has called for "taking ethics seriously."⁵⁷ Clearly, the protection from employment and insurance discrimination come to mind immediately. In fact, Congress may act on this issue during the 2003 session.⁵⁸ New York State covers informed consent of genetic testing, but more needs to be done regarding genetic testing/screening and employment.⁵⁹

Genomics may soon be eclipsed by proteomics—the collective body of proteins made by a person's cells and tissues.⁶⁰ The proteome is considered much more complicated than the genome because, among other things, proteins have a diverse three-dimensional structure and are hard to match with other proteins.⁶¹ Thus, whoever

can successfully penetrate proteomics research will probably have a lucrative relationship with the pharmaceutical industry.⁶² Since

the same gene can make a range of proteins, claims based on the proteins themselves could be more valuable and offer a way to get around patents on the DNA sequences held by competitors. If so, the courts could be one more arena where genes will have to move over in favor of proteins.⁶³

Collegial Discussion Issues

- If a patient consents to genetic testing but does not want to know the results, does the physician have a duty to warn the patient's family members if the test results show a strong familial disposition for a serious disease?
- 2. Should an insurance company be allowed to demand genetic testing for rate purposes, and not for determining coverage?
- 3. If genomics and proteomics provide the source for disease cures, can unethical behavior ever be justified as ethical behavior for the betterment of society? Does the end justify the means?

VII. Conclusion

The tension of progress is necessarily created by the intersection of law, medicine, science, and technology. If ethical reasoning is a process that never ends, then technological advancements will challenge the twenty-first century to effectively, efficiently, and ethically integrate the advancing IT with the delivery of health services.⁶⁴

The ancient Greeks held to the ethos that one's honesty, integrity, and prudence were paramount. Modernday ethicists contend that we are constantly balancing the tenets of the ancient ethos and the legal rights of patients. Arguably, ethics goes beyond "rights." A right is respected when it is followed, regardless of the profession. Medically speaking, ethics requires a physician to be good, honest, and disinterested, in the broadest sense of the word, which is something no right can guarantee. Thus, the more statutes, regulations, and court cases decide ethical issues, the narrower the scope of ethical decision-making by healthcare providers.

The social compact or contract that medicine has with society has rich historical roots. Professionalism is the basis of medicine's contract with society, and trust is an essential component of the contract.⁶⁷ Keeping the social contract in mind, a group known as the Medical Professionalism Project (MP²) published a global charter on medical professionalism in the new millennium.⁶⁸ Sponsored by the American Board of Internal

Medicine, the American College of Physicians—American Society of Internal Medicine, and the European Federation of Internal Medicine, the MP² charter calls for a new dedication by physicians to the principles of patient welfare, patient autonomy and social justice.⁶⁹ The charter is intended to be applicable to different political systems and different cultures.⁷⁰

Quoting Jo Ann Barefoot, Managing Director of KPMG Consulting, "[t]here's no question that technology and its ability to keep track of . . . data, is putting people into terrain where they don't know what the ethics are. . . . I'd say the law is about ten years behind the technology, and we're going to be dealing with this for a long time." Ethics in the provision of healthcare, as well as ethics in any other profession, demands that we search for the God in our work, and not make our work into a god.

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Hi-ethics: <<http://www.hi-ethics.org>>

Mds proteomics: <<www.mdsproteomics.com>>

Medical Professionalism Project: << www.professionalism.org>>

Public Responsibility in Medicine and Research: <<http://www.primr.org>>

The Applied Research Ethics National Association: <http://www.ARENA.org>

The Center for Bioethics: <<www.uphs.upenn.edu>>

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Eichner and **O'Connor** Revisited: Neither Clear Nor Convincing

By Mark Joy, M.D., J.D.

The process of dying in New York State sometimes can be difficult, perhaps more so than anywhere else. The source of the difficulty can be easily identified, although not easily explained: several decisions made by the Court of Appeals, the state's highest court, have created an impediment that often overrides all other considerations in end-of-life care. The legal standard arising from those decisions that affects how we confront the issue of not providing life-sustaining medical care is, at best, confusing and ambiguous and even can seem to contradict logic and common sense.

No decision made by a physician in the practice of medicine carries with it more serious consequences than that of withholding or withdrawing life-sustaining medical treatments. Much effort is devoted to avoiding, or at least delaying, death, but often the moment is reached in a person's declining life when death's ineluctability is realized. We then can no longer embrace hope that we will prevail in maintaining life. When that moment arrives, the focus falls exclusively on providing comfort, for the person and for the loved ones. Implicit in that comfort is the need to avoid prolonging death, because we might be extending agony. To that end there is a necessity in removing expeditiously all treatments that do not bring comfort.

Often barriers exist that prevent us from taking away whatever does not provide a clear benefit, because the determination that a particular treatment is futile can be difficult. Reasonable people may differ. Physicians may not agree among themselves; relatives may not think as one; the physician and the family members may not reach the same conclusion; medical ethicists may not achieve unity of thought. But there are also many instances when everyone involved agrees that continuing certain interventions will not help the dying person in any way and rather may prolong his or her suffering. When that point is reached, it is best to move quickly to bring about life's finality.

In those situations when physicians and family members of the patient are in agreement that removal of life-sustaining medical treatment is appropriate, the law in New York nonetheless may prevent them from doing so. The decisions of the Court of Appeals that gave us the legal standard for determining whether we may withhold or withdraw life-sustaining measures, while intended to serve the interests of patients, at times can be a barrier to doing what all agree is best for a particular patient. What was intended by the judges

on the Court to clarify and provide uniformity rather has been much the cause of the uncertain and sometimes harmful state in which we currently function.

Life-Sustaining Medical Care and the Case of Karen Ann Quinlan

The medical, legal, and ethical problems that arise when we confront the issues of withholding and withdrawing life-sustaining medical treatments are largely the products of modern, technology-based medicine. It was not until the second half of the last century that medical science developed the capability of effectively extending life through such means as ventilators, dialysis, and critical care units. Lives have been saved from conditions that in earlier times would have caused a quick and certain death.

The news media often extol the wondrous benefits and capabilities of medical technology. Far less often do we hear of its less fortunate results. The first time the issue of those sad outcomes entered the awareness of the general public on a large scale was in the case of Karen Ann Quinlan, in 1976. After an unfortunate experience with recreational drugs, Ms. Quinlan was left in a persistent vegetative state and was dependent on a ventilator and a feeding tube to sustain her life. After she spent a year in that condition, her parents requested that her ventilator be removed so that she would be, in the words of her parents, "allowed to die." The New Jersey Supreme Court held that the parents had the right to withhold or withdraw life-sustaining medical treatment from an incompetent family member, and it was the first high court of a state to find that right.

In the 25 years since the *Quinlan* case, numerous court decisions, including one by the United States Supreme Court, have upheld the right to withhold or withdraw life-sustaining treatments from incompetent patients. That right, of course, is not absolute. Legal standards vary among different states, but central to all is the concept that there is no need to continue providing medical care that is of no benefit.

The Enigma of Medical Futility

The ideal of not administering medical treatments that do not help the patient may seem simple and obvious. Putting that principle into practice can be exceedingly complex and a source of contention. The issue becomes focused on the question of whether or not a particular medical intervention is therapeutically futile. Attempts have been made, by physicians and by ethicists, to define medical futility, but finding a definition that most people agree upon has proven to be elusive. To a large extent the difficulty arises from the several ways in which benefit in medical care can be manifested. Is it curing of disease, relieving pain, slowing the growth of a cancer, maintaining function of vital organs, providing a little more time for a dying patient to spend with her family? In a given case, the answer may be more than one of those simultaneously, and physicians may disagree about whether a putative benefit is a true benefit.

If a particular treatment is deemed to be of no benefit, then of course it should be withdrawn, but in New York that is not always a simple matter. Sometimes it is impossible to take it away. Even when the physicians and the family members of an incompetent patient agree that the care is futile, the law in New York sometimes prohibits its removal. As a result, persons are maintained on ventilators and other medical interventions for months or years even when all concerned, especially the loved ones and the health care givers, believe the efforts are in vain.

New York Law After *Quinlan*—The *Eichner* and *Storar* Cases

After the Quinlan case, the New York Court of Appeals first confronted the issue of withdrawing lifesustaining medical care in two companion cases that were decided in 1981. One was the Eichner² case, which involved Brother Joseph Fox, a member of the Society of Mary. In 1970, Brother Fox retired and went to live at Chaminade High School in Mineola. There he lived with other members of the religious order on the school staff, where he performed limited duties. In 1979, at the age of 83, he developed a hernia. Surgery was recommended, to which Brother Fox agreed. During the operation, Brother Fox experienced a cardiac arrest and was resuscitated. During the event, he suffered a critical lack of oxygen to the brain, resulting in permanent damage that left him in a persistent vegetative state. He was placed on a ventilator because of respiratory failure. Several physicians concluded that Brother Fox had little or no chance of meaningful recovery.

Father Philip Eichner was the president of Chaminade and the director of the Society of Mary. When he learned of Brother Fox's prognosis, he asked that the ventilator be removed so that Brother Fox would be permitted to die. The hospital refused to do so without a court order. Father Eichner then applied, within the authority of the Mental Health Law, to be appointed committee of the person and the property of Brother

Fox so that he could authorize removal of the ventilator. Father Eichner's application was supported by Brother Fox's nieces and nephews, who were his only surviving relatives.

At the hearing for Father Eichner's application, evidence was presented to show that in the past Brother Fox on two occasions had expressed his desire not to be kept alive by extraordinary means if there was no chance of meaningful recovery. One statement was made during a formal discussion of Catholic principles and extraordinary medical care after the Quinlan case. The other statement was made a few months before his unfortunate event. The judge concluded that Brother Fox had a common law right to decline treatment and that his prior statements regarding care when there was a poor chance of recovery were sufficient to justify taking him off the ventilator. The appellate court affirmed that decision, finding both common law and constitutional bases for its decision. The case was then heard by the Court of Appeals.

The companion case decided with Eichner involved that of John Storar.³ Mr. Storar was a 52-year-old man with severe mental retardation, with his cognitive function assessed to be approximately that of an 18-monthold child. Since the age of 5 he had been a resident at a state home. His mother was his closest relative and visited him almost daily. In 1979, he was diagnosed as having bladder cancer. His mother was appointed his legal guardian, and she gave her consent for him to receive radiation therapy. In March of 1980 he again developed blood in his urine. Attempts to stop the bleeding were not successful, and in May his mother agreed to have him transfused, after initially refusing her assent to that procedure. He required intermittent transfusions, but on June 19 she asked to have them stopped. The director of the facility where he resided initiated a proceeding, pursuant to the Mental Hygiene Law, asking to have the transfusions continued. Mrs. Storar petitioned to terminate the transfusions. At a subsequent hearing, it was not contested that Mr. Storar had advanced, metastatic cancer, and his remaining life was estimated to be of no more than about six months duration. He required two units of blood every one to two weeks. The staff at his facility reported that Mr. Storar seemed to improve in terms of his overall wellbeing after the transfusions, but he did not tolerate the procedures well and required sedation prior to each. Mrs. Storar's motivation in stopping the transfusions was to make her son comfortable, because of his obvious dislike of them. Both the trial and the appellate courts ruled that the transfusions could be stopped, finding that his mother was the appropriate person to decide about his medical care and that her desire to have his suffering end was reasonable.

In its *Eichner* decision, the Court of Appeals quoted the famous statement by Judge Cardozo, from the *Schloendorff* case in 1914, that every person "... of adult years and sound mind has a right to determine what should be done with his own body...," and found that Father Eichner could have Brother Fox removed from the ventilator based on common law principles. The Court also found that it was permissible for Father Eichner to make a decision on behalf of Brother Fox once the latter became incompetent.

Of particular significance in its decision, the Court agreed with the lower courts that the standard of proof for determining what the wishes were of a patient before he became incompetent requires a showing of those wishes by "clear and convincing" evidence, the highest standard typically used in civil law. The holding in *Eichner* was specifically directed to the termination of "life sustaining procedures when there is no hope of recovery."

The Court gave examples of how the clear and convincing standard was met in *Eichner*. Brother Fox had "carefully reflected on the subject"; he had made "solemn pronouncements and not casual remarks made at some social gathering, nor can it be said that he was too young to realize or feel the consequences of his statements." It was a "persistent commitment [as] evidenced by the fact that he reiterated the decision but two months before his final hospitalization."

In the case of John Storar, the Court of Appeals faced a different set of facts. He was never competent to make medical decisions. "Mentally John Storar was an infant . . . " The Court thus viewed the situation in the same context as others where a parent must make decisions on behalf of a minor child. In New York, the courts have invoked the parens patriae interest of the state in protecting the life and health of the child, an interest that takes precedence over rights of the parent, even when a constitutionally-protected right, such as that of religious practices, is at issue. States have allowed medical treatment of children of Christian Scientists and blood transfusions in Jehovah's Witnesses over the objections of the parents. John Storar never had the capacity to comprehend the implications of accepting or refusing medical tests or treatments; he was never able to make any "solemn pronouncements" or form any "persistent commitments" to any particular course of action. While manifesting a sensitivity to the delicacy of the circumstances and of the mother's agony, the court could not "... permit a parent to deny a child all treatment for a condition which threatens his life." In a partial dissent, one of the judges, with great prescience, expressed his discomfort with the position in which the Court was placed. Cases involving medical decisions are ones "... which the judicial system is

unsuited and ill-equipped to solve and which should not usually be made the subject of judicial attention." The amount of time it normally takes for a case to wend its way through the maze of proceedings

... will almost always be unacceptable and makes recourse to judicial proceedings impractical. The methodology and the techniques for our classic adversary system are not best suited to the resolution of the issues presented. The courts can claim no particular competence to reach the difficult ultimate decision, depending as it necessarily must not only on medical data, but on theological tenets and perceptions of human values which defy classification and calibration.

The judge then held that he would "... explicitly affirm the authority of our courts . . . to grant authorization for withholding or withdrawal of extraordinary life support medical procedures," even when there has been no prior statement of the patient's wishes. Again displaying great prescience, the judge lamented that the Court could not reach a consensus and set proper standards to provide guidance for lower courts and, more importantly, to hospitals and physicians when issues arise involving the withdrawal and withholding of lifesustaining medical care. He was able to foresee the confusion and ambiguity we since have faced when the issue of the futility of medical care arises in persons with terminal conditions or when there is miniscule hope of meaningful recovery after severe neurological injury.

The Delio Case

The next case in New York in which the issue was raised regarding the withdrawal of life-sustaining medical treatment was the Delio⁴ case, decided in 1987. Mr. Delio was in a persistent vegetative state as a result of anoxic brain damage he suffered during a routine surgical procedure, but his condition was not terminal. When he was competent, Mr. Delio, an exercise physiologist who worked in a hospital, repeatedly expressed in strong, clear terms his desire not to be kept alive if there was little or no chance of meaningful recovery. The Appellate Division found that his statements satisfied the criterion of clear and convincing evidence, and it allowed the removal of tube feedings and intravenous hydration. The Appellate Division's holding is of importance for several reasons. Mr. Delio did not suffer from a terminal disease as did John Storar. He was young, unlike Brother Fox, and possibly could have been maintained in a persistent vegetative state for many years. The Delio case also established that artificial nutrition and hydration are to be viewed like any other medical intervention and could be withdrawn if the evidence of the patient's prior wishes satisfies the clear and convincing standard.

The O'Connor Case

The Court of Appeals next confronted the issue of life-sustaining medical treatment in the O'Connor⁵ case, decided in 1988. After Eichner and Delio, the O'Connor decision did not establish any new evidentiary standard or legal principle, although it is often mentioned as the case from which we draw the standard for withholding and withdrawing life-sustaining care. With O'Connor, the Court took the clear and convincing standard it employed in Eichner, where it allowed the withdrawal of a ventilator from an incompetent patient (who was in a "vegetative coma"), and applied it to the withholding of tube feedings and the withdrawal of intravenous hydration from a woman with severe dementia. The facts in O'Connor somewhat resembled those in Delio. In each the medical issue involved the administration of nutrition and hydration via tubes. Both Delio and O'Connor suffered permanent cognitive dysfunction, although Delio could not respond to the promptings of persons around him while O'Connor had some limited ability to respond, such as by following some simple commands and responding verbally at times to questions. Neither had what would be considered by many observers to be a "terminal" condition, such as advanced, untreatable cancer. Although many experts put advanced dementia in that category, the Court of Appeals did not seem to view it as such. What was new for the Court in O'Connor was the issue of the withholding of artificial nutrition and hydration, since the Delio case did not go higher in the appeals process than to the Appellate Court.

Mary O'Connor was in her late 70's. She had severe dementia after having had several strokes. In 1988 she was placed in a long-term geriatric facility. In June of that year, she was admitted to Westchester County Medical Center because of dehydration and probable pneumonia. She responded to treatment with intravenous fluids and antibiotics and became, according to the Court, "alert, able to follow simple commands and respond verbally to simple questions." Because her dementia had left her with little or no ability to swallow foods, Mrs. O'Connor's attending physician determined that a nasogastric tube should be inserted to provide proper nourishment. Her daughters objected, and the hospital sought judicial authorization to place the tube against their wishes. The daughters submitted affidavits stating that placement of the tube "was against their mother's expressed wishes because before becoming incompetent, she had repeatedly stated that she did not want her life prolonged by artificial means if she was

unable to care for herself." They also sought to have the intravenous fluids stopped.

Judge Wachtler, who wrote the majority opinion and who also wrote the *Eichner* and *Storar* decisions, seemed in *O'Connor* to have been influenced very strongly by the particular characteristics of Mrs. O'Connor's condition. Although her cognitive ability was impaired, with little chance of substantial recovery,

... she was not in a coma or vegetative state. She was conscious, and capable of responding to simple questions or requests sometimes by squeezing the questioner's hand and sometimes verbally. She was also able to respond to noxious stimuli, such as a needle prick, and in fact was sensitive to 'even minimal discomfort', although she was not experiencing pain in her present condition. When asked how she felt she usually responded "fine," "all right," or "OK"... during the latest examination conducted that morning, in response to the doctor's request she had attempted to sit up and had been able to roll over on her side so that he could examine her lungs.

Judge Wachtler further noted that if the feeding tube was not to be placed and intravenous fluids were not given,

... she would die of thirst and starvation within 7 to 10 days. The doctor stated that death from starvation and especially thirst was a painful way to die and that Mrs. O'Connor would, therefore, experience extreme, intense discomfort since she is conscious, alert, capable of feeling pain, and sensitive to even mild discomfort.

The Court seemed also to be impressed by some improvement Mrs. O'Connor had shown and by her ability to respond, in a limited manner, to other people.

... she was generally able to respond to simple commands, such as a request to move her arm or foot. [The neurologist] also noted that she was able to state her name, seemed to be aware of where she was, and responded to questions about 50 to 60 percent of the time, although her speech was slow and halting and her responses were not always appropriate. Most significantly, she was able to converse in short sentences of two or three words which, he noted, she had

not been able to do since her admission to the hospital.

The Court then addressed Mary O'Connor's statements made in the past in an effort to discern her wishes. One acquaintance testified about a conversation he had had with her when his father was dying of cancer. Mrs. O'Connor responded by stating, "I would never want to be a burden to anyone and I would never want to lose my dignity before I passed away." She had indicated her feelings "that nature should take its course and not use further artificial means." The friend testified that they had had several conversations on the topic:

... Mrs. O'Connor variously stated that it is "monstrous" to keep someone alive by using "machinery, things like that" when they are "not going to get better"; that she would never want to be in the same situation as her husband [who died of brain cancer] ... and that people who are "suffering very badly" should be allowed to die.

Mary O'Connor's daughters also testified about their mother's statements in the past. One discussion had taken place in 1967, after her husband had been hospitalized for cancer. "At that time Mrs. O'Connor said that she never wanted to be in a similar situation and that she would not want to go on living if she could not 'take care of herself and make her own decisions.'" Another discussion followed her stepmother's death from cancer and Mary O'Connor's hospitalization for a heart attack.

My mother said that she was very glad to be home, very glad to be out of the hospital and hope[d] she would never have to be back in one again and would never want any sort of intervention any sort of life support systems to maintain or prolong her life.

Another daughter provided similar testimony, but the Court characterized Mrs. O'Connor's statements as being "less solemn": "It was brought up when we were together, at times when in conversations you start something, you know, maybe the news was on and maybe that was the topic that was brought up and that's how it came about."

The Court made a point of noting that none of the witnesses had ever spoken to Mary O'Connor specifically about nutrition and hydration administered by medical means. None had ever heard her state that "she would adhere to her view and decline medical treatment 'by artificial means' if that would produce a painful death."

The Court examined Mary O'Connor's statements under the clear and convincing evidence standard of *Eichner*. To contrast the facts in *O'Connor* with those of Brother Fox, whose views the Court found to be "so clear," Judge Wachtler noted that he "was a member of a religious order who had conscientiously discussed his moral and personal views concerning the use of a respirator on persons in a vegetative state." He quoted his writings from the *Eichner* decision to show the basis of the Court's conclusion in that case:

"[That] he carefully reflected on the subject [was] supported by his religious beliefs and [was] not inconsistent with his life of unselfish religious devotion . . . [he made] solemn pronouncements and not casual remarks made at some social gathering, nor c[ould] it be said that he was too young to realize or feel the consequences of his statement."

In contrast to Brother Fox, Mary O'Connor's statements, even though made more than once over the course of several years, were merely "immediate reactions to the unsettling experience of seeing or hearing of another's unnecessarily prolonged death. Her comments . . . are, in fact, no different than those that many of us might make after witnessing an agonizing death." Her fears of being a burden to others were expressed in comments that "older people frequently, almost invariably make."

Mary O'Connor's condition and prognosis at the time of the legal dispute were crucial in determining how the Court decided:

Mrs. O'Connor does not have a terminal illness, except in the sense that she is aged and infirm. Neither is she in a coma or vegetative state. She is awake and conscious; she can feel pain, responds to simple commands, can carry on limited conversations, and is not experiencing any pain. She is simply an elderly person who as a result of several strokes suffers certain disabilities, including an inability to feed herself or eat in a normal manner . . . no one contends, and it should not be assumed, that she contemplated declining medical assistance when her prognosis was uncertain. Here both medical experts agreed that she will never regain sufficient mental ability to care for herself, but it is not clear from the record that the loss of her gag reflex is permanent and that she will never be able to obtain food and drink without medical assistance.

Judge Hancock wrote a concurring opinion, in which he agreed that Mary O'Connor's statements were "too general and imprecise" to satisfy the clear and convincing evidence standard. For him also, her condition at the time of the dispute was crucial: "The patient is neither terminal, comatose nor vegetative; she is awake, responsive and experiencing no pain; and the prescribed procedure is relatively simple and routine."

Judge Hancock's opinion is most noteworthy because of the great insight he showed concerning the difficulty of applying the Court's standard in particular cases

But there are, I believe, several reasons why the present New York rule—requiring a factual finding of the patient's actual intent and precluding the exercise of judgment in her best interests and on her behalf by her physician and family, a court or guardian—is unrealistic, often unfair or inhumane and, if applied literally, totally unworkable.

As he so very well described, the rule in New York requires, under the most strict evidentiary standard commonly used in civil law, "proof of a fact which is inherently unknowable: what the incompetent patient would actually have intended at the time of the impending life support decision." But more than intent is demanded, as Hancock noted. The rule requires that the "actual desire" of the incompetent patient be discerned regarding the particular treatment. Unless the patient made explicit statements in the past that specifically address her medical condition when questions arise about the benefit of life-sustaining care, then the care cannot be withdrawn absent the existence of someone who has been given legal authority to make health care decisions for the patient.

As Hancock interpreted *Storar*, without clear, specific statements by the patient when she was competent, life-sustaining medical care cannot be withheld or withdrawn even if the patient is in a permanent coma, or she is in a terminal condition in the absence of a coma or a vegetative state: "... life sustaining procedures must, apparently, be undertaken and continued."

Judge Simons dissented in *O'Connor* and was joined in his decision by Judge Alexander. For them, Mary O'Connor's prior statements were sufficient to meet New York's clear and convincing evidence standard. Simons reviewed the facts and testimony from the trial record and took a less optimistic view of her condition and prognosis than did the majority. "While she may not be terminally ill in the sense that death is imminent, she is dying because she has suffered severe injuries to her brain and body which, if nature takes its course,

will result in death. Full medical intervention . . . will only maintain her in a rudimentary state of existence."

As for Mary O'Connor's statements in the past, he agreed with the determinations of both the trial and the appellate courts that they were sufficient to allow withholding of tube feedings, even under the stringent standards of New York law.

The clearest statement of Mrs. O'Connor's wishes was made after her own hospitalization for congestive heart failure. She told her daughter that she "was very glad to be out of the hospital and hope[d] she would never have to go back in one again and would never want any sort of intervention, any sort of life support systems to maintain or prolong her life."

Judge Simons noted that Mary O'Connor's statements were not "casual remarks" and emphasized that she had worked more than 20 years in a hospital and was quite familiar with the various burdens and benefits of life-sustaining treatments. She had also carefully considered what life would mean to her if she were to become dependent on others.

There can be no doubt she was aware of the gravity of the problem she was addressing and the significance of her statements, or that those hearing her understood her intentions. She clearly stated the values important to her, a life that does not burden others and its termination with dignity, and what she believed her best interests required in the case of severe, debilitating illness. She found "monstrous" the imposition of artificial means to maintain her under circumstances when natural conditions would end her life, and she objected to the use of "any" and "all" life support systems on her behalf.

Judge Simons also found fault with the majority's finding that Mrs. O'Connor's statements in the past did not address specifically her condition and the proposed medical treatments at the time of the dispute. For him, the standard required in their decision would seldom be met, even if a patient took the time to express her wishes in writing. The majority was asking for a degree of foresight beyond the capability of common human experience. That physicians and other experts have not been able to agree on what constitutes "ordinary" versus "extraordinary" care compounded the problem, according to Simons. Ultimately, he found the majority's standard both unwise and "all but useless"; it would prevent the patient's wishes from being carried

out in all but a few instances because physicians would rarely feel assured that the patient's declarations met the rigid standard established by the Court. Thus, the principle of patient self-determination, which now is an essential element of medical care and medical ethics as a result of a long evolution, has been weakened by the Court of Appeals decision in *O'Connor*. Judge Simons highlighted the irony that his colleagues, "the persons least qualified by training, experience or affinity to reject the patient's instructions," in applying their own substituted judgment, "over[rode] Mrs. O'Connor's wishes, negated her long held values on life and death, and imposed on her and her family their ideas of what her best interests require."

The Illusion of a Clear and Convincing Standard

Courts in New York have cited *Eichner*, *Storar*, and *O'Connor* in subsequent cases in which disputes over the withdrawal of life-sustaining medical care have arisen, with varying results. One example is the *Delio* case. In other cases, courts have found that patients' prior statements did not meet the requisite clear and convincing evidence standard to discontinue treatments. One case found that the standard was met based on one statement the patient had made 10 years earlier while watching a television account of the Sunny von Bulow case.

One studies these cases with the hope that a common, objective, unifying theme can be discerned to explain and make clear how and why the judges made the decisions they did. In *Eichner* and *O'Connor*, the Court of Appeals majorities may have felt they were providing such a standard. With the best of intentions and as well as they could given their experience, what the judges created fell far short of producing a clear, objective standard.

The Court of Appeals took as its legal foundation, in both *Eichner* and *O'Connor*, the principle that became established in American jurisprudence in the Schloendorff case, that a person has the right to determine in matters of health what shall be done to his or her body. That right always has to be judged and balanced against the state's interest in protecting life. Because the issue involved the critical question of withdrawing or withholding life-sustaining medical care, the majority chose to follow the standard adopted by the lower courts of requiring "clear and convincing" evidence of the patient's wishes. That standard is a demanding one used in civil law, above that of the more common "preponderance of the evidence" requirement. The preponderance standard is generally accepted as denoting anything above a 50% likelihood of a particular fact being true. The Court chose a middle ground between a preponderance of the evidence and the highest evidentiary

level, used in criminal law, the well-known "beyond a reasonable doubt."

The Court explained that the clear and convincing standard is used in civil law where important rights and issues are involved, and no one could reasonably argue that withdrawal of ventilators and feeding tubes is not an important matter. In the majority opinion, Judge Wachtler attempted to provide guidance in assessing whether or not the proper standard of evidence is satisfied. For Brother Fox, it was noted that he had "carefully reflected on the subject," that he had expressed his views, and those views were "supported by his religious beliefs." Everything was underscored by his life "of unselfish religious devotion." His comments were "solemn pronouncements and not casual remarks"; he was old and mature enough to understand their implications. That he had a "persistent commitment" was manifested by his reiteration of his beliefs two months before his hospitalization. To the majority, the evidence "clearly and convincingly show[ed] that Brother Fox did not want to be maintained in a vegetative coma by use of a respirator."

In O'Connor, Judge Wachtler again wrote for the majority and again attempted to provide guidance for determining if the clear and convincing standard can be met. One must find that there was "a firm and settled commitment to the termination of life supports under the circumstances like those presented . . . [and] the strength of the individual's beliefs and the durability of the individual's commitment to those beliefs makes a recent change of heart unlikely." The assessment should take into account the "persistence" and "seriousness" of the patient's statements and any inferences "that may be drawn from the surrounding circumstances." A writing would provide the strongest evidence, but the Court recognized that requiring it in all cases would be unrealistic.

After providing what it felt was guidance about what to look for when assessing a patient's prior statements, the Court indicated that it is not enough to examine the statements and the contexts in which they were made. It is also necessary to compare the types of "infirmities" and the procedures the person was contemplating at the time of her statements with her medical condition now. In addition, the Court said that the circumstances in which the statements were made need to be considered. For Mary O'Connor, it was important to the Court that her prior comments were generally made in response to persons with terminal illnesses, especially cancer. According to the Court, she had no terminal condition. The majority also emphasized that she was not in a coma or vegetative state but was awake and conscious. The prognosis for her inability to swallow was uncertain, according to the Court, and it was not clear that she would never regain that function.

In spite of the Court of Appeals efforts, attaining a consensus of what constitutes clear and convincing evidence of a patient's wishes in particular cases has proven to be elusive, and the *O'Connor* case perfectly illustrates why. With the same facts presented at all levels, the trial judge, a majority in the Appellate Division, and two of seven judges on the Court of Appeals found that Mary O'Connor's statements met the clear and convincing standard. If two judges in the majority had voted differently, the request by her daughters would have been honored. Of all the judges who reviewed the facts, close to 50% felt her statements met the stringent standard and close to 50% felt they did not.

In contrast to the majority, Judge Simons found that Mary O'Connor's statements "abundantly supported" a finding that the evidence was clear and convincing; she had "consistently expressed" her views about life support. He correctly noted that the majority did not find that the lower courts had used the wrong standard in evaluating the evidence before them. What the majority found insufficient was the specificity of her comments. They demanded that the patient demonstrated a "firm and settled commitment" to withdrawing life-sustaining treatments "under the circumstances presented"; "the infirmities she was concerned with and the procedures she eschewed are qualitatively different than those now presented."

Simons characterized the majority opinion as "unworkable and unwise," because it required an ability to predict the future of which we are not capable. The majority provided no test of how qualitative differences or similarities are to be judged, and he was doubtful that physicians would be able to employ the majority's "qualitative" standard. Experience has proven him correct. Anyone who has served as a hospital ethics consultant has encountered patients who took the time to write very detailed living wills, who subsequently lost decisional capacity, and who ended up in clinical scenarios that were not directly addressed in their prior writings.

It could be argued that the qualitative similarity the Court sought in *O'Connor* between her prior statements and her subsequent condition was not present in the *Eichner* case, yet the Court found that Brother Fox's statements met the clear and convincing standard. The only quote it provided from Brother Fox was that he would not want any "extraordinary business." They noted that he first expressed his views during a discussion organized by his church in response to the Karen Quinlan case, and several months before his last hospitalization he again said that he would not want his life extended by extraordinary means if his condition was hopeless. However, the record does not show any more

specificity in Brother Fox's statements than in Mary O'Connor's. The O'Connor opinion documents several discussions, recounted by three witnesses, showing that she did not want to be kept alive by "machinery" if she was "not going to get better." Yet the Court downplayed the importance of her statements because she never had specifically discussed "providing food or water with medical assistance," nor had she stated that she would want to decline tube feedings if it would result in a "painful death." However, it must be emphasized that Brother Fox never specifically addressed ventilators.

After studying the majority and dissenting opinions in Eichner and O'Connor, and considering that of the various judges who assessed the facts in O'Connor the number who felt the clear and convincing standard was met was nearly the same as the number who felt it was not, it is difficult to conclude that the standard has any real meaning in the context of assessing an incompetent patient's wishes. As an evidentiary rule for use in court, the standard of clear and convincing evidence serves a useful function, and it is commonly applied in various contexts by courts from the United States Supreme Court down to trial courts in the states. However, as a tool for making health care decisions it presents difficulties. It sometimes leads to care being continued when it is clearly not in the patient's best interest; it at times causes undue suffering in family members; and there is no evidence that it prevents alleged abuses by physicians who might be accused of terminating care prematurely. While it was meant to induce physicians to err on the side of preserving life, in many instances it merely prolongs the process of dying.

A Standard with No Firm Foundation

There are two fatal flaws in the standard demanded by the Court of Appeals. One was revealed by Judge Simons in his O'Connor dissent: the concept of specificity demanded by the majority. Judge Wachtler no doubt had a sense of the problem, because he felt compelled to point out that a person's prior statements need not specify "a precise condition and a particular treatment." But in making the threshold question to be whether or not there is a "qualitative" difference between those earlier statements and the subsequent circumstances he imposed a test that is, as Judge Simons stated, "unworkable." There is no objective way to assess whether that qualitative difference is present or not, and each person reviewing the facts will form his or her subjective impression. The O'Connor case itself serves as a fitting example of that, as the judges' various interpretations of the facts show. Nor do the suggestions in the opinion of how one might assess the qualitative similarities or differences offer any help. How, for example, do Brother Fox's statements on two occasions in Eichner, in which he said he wanted no "extraordinary business,"

show more of a "firm and settled commitment" than do Mary O'Connor's several declarations of her wishes?

The other flaw in the standard set is that the Court failed to explicitly acknowledge the actual process by which it arrived at the conclusions that Brother Fox could have his ventilator turned off and that Mary O'Connor must have her feeding tube placed. The Court purported to show that the essential question was how closely a patient's prior statements about declining medical treatment comported with his or her present condition and the medical intervention at issue. That is, to what degree did she anticipate in the past the set of circumstances in which she is later placed? But a careful reading of Eichner and O'Connor shows that the analysis actually used by the Court in each was the same we all employ, consciously or not, virtually every time we encounter the question of withholding or withdrawing life-sustaining medical care. That analysis compels us to confront the issue of what can be done that is best for the patient, with consideration given to all relevant factors. The answer is found by doing what the Court did with Brother Fox and Mary O'Connor: we look at the patient's medical condition, his prognosis, his prior declarations, if any, about medical care, and the thoughts and feelings of those who are closest to the patient. A subjective impression is formed about what would be the best course. Even when a patient has left detailed directions, we still must place those statements in the present context and try to make the best decision based upon the combination of the statements and her condition and her prognosis.

In Eichner, Judge Wachtler made note of the fact that the 83-year-old Brother Fox was in a persistent vegetative state, and it was uncontested that he had no reasonable chance of recovery. Certain personal characteristics of Brother Fox and the context of his statements made a significant impression on the judge. He mentioned Brother Fox's religious views and "his life of unselfish religious devotion." His statements were made in the context of a conference organized by his religious order and thus were felt to be "solemn" and not "casual remarks." It helped too that he was found to be in a condition "identical" to that of Karen Quinlan, whose case prompted the conference at which his statement was made. Except for the absence of a detailed writing memorializing his wishes, Brother Fox's case seemed to provide the Court with the perfect set of circumstances to conclude that the ventilator could be withdrawn. However, as noted above, Brother Fox never made any comments about specific treatments, including ventilators.

Mary O'Connor's condition presented more ambiguity. She had severe dementia that was only going to worsen, but she was awake and could respond in a limited manner to other people. Experts differed about

whether withholding food and water would cause a painful death. It was not certain also that her ability to swallow would not return in the near future. Her prior statements were, according to the majority, merely "immediate reactions to the unsettling experience" of another's death. They were "no different than those that many of us might make after witnessing an agonizing death." Her comments about not wanting to be a burden to others were the kind that "older people frequently, almost invariably make."

Mary O'Connor's statements could not provide the majority with "unequivocal proof" that she would not want the feeding tube, because she did not sufficiently predict what her condition and the proposed life-sustaining treatment would be. Her statements were made in response to people dying from cancer, which she did not have. She did not state that she would not want treatments if her prognosis were "uncertain." The majority members could not appreciate that her diagnosis of severe dementia meant that she had a sure prognosis of further decline of her cognitive function, but Judge Simons, in his dissent, recognized that Mary O'Connor was dying, even though death was not imminent.

The majority tried to adhere to the principle that "the inquiry must always be narrowed to the patient's expressed intent," but the judges failed to recognize the degree to which the respective conditions and prognoses of Brother Fox and Mary O'Connor had a profound influence on their reactions to each case. Brother Fox was not awake, it was very unlikely that he ever would regain consciousness, and he would always be dependent on the ventilator. Mary O'Connor was awake, could follow simple commands, could at times respond verbally in a simplistic manner, and the experts could not state with certainty that her ability to swallow would not return. They also believed that to deny her food and water would cause her pain. In responding to these two different sets of circumstances, the judges responded in a very basic, emotional, human manner. Everyone with experience with these kinds of cases knows it is far easier to stop treatment in a person who is not awake than in one who can talk, look back into our eyes, and show some vestige of a soul still able to respond to the world around her. It is quite possible that, in opposition to the ideal way in which we imagine jurisprudence functions, the judges reached a conclusion in each case mainly based upon the patient's level of cognitive function in regard to the benefit of life-sustaining treatment and then interpreted the prior statements and their contexts to buttress and explain their conclusions.

One theme that comes across strongly, sometimes explicitly, in the opinions is the judges' frustration at being placed in the position of making medical deci-

sions. Judge Jones, in his dissent in *Storar*, the companion case of *Eichner*, explained clearly how courts are "unsuited and ill-equipped" to deal with decisions about the appropriateness of medical care. He also felt that the Court failed to provide "more constructive direction" for courts, hospitals, and physicians regarding procedural matters when they face these issues. Judge Jones made note of New York's failure to address the issue in the legislature, and Judges Hancock and Simons in *O'Connor* seemed to express frustration with the law as it was established in *Eichner*.

The Need to Eliminate the Standard

The standard of clear and convincing evidence for withholding and withdrawing life-sustaining medical treatment needs to be abandoned in New York, for many reasons. The most compelling one is that it is, as Judge Simons described, unworkable. As useful as it is in a court of law, the standard of clear and convincing evidence does not fit in the practice of medicine. As much as the judges in the majorities in *Eichner* and *O'Connor* may have hoped to create an objective, systematic standard, the multifarious nature of human existence and the technologic complexity of modern medicine together defeat their noble attempt. What they envisioned as a workable standard does not and cannot exist in any consistent, practical manner.

As was noted, the *O'Connor* case itself is an ideal example of the false foundation upon which the clear and convincing standard is built. All the judges who confronted it, from the trial court up to the Court of Appeals, were looking at the same set of facts and applied the same standard from *Eichner*. Almost as many found the standard was met as did those who found it was not. If such disparity existed among the learned and wise members of the courts, viewing the matter from their distant, emotionally-detached perspective, how are the loved ones and physicians at the bedside of a seriously ill person supposed to be able to determine that his prior statements satisfy the Court's formula? What if the person never discussed life-sustaining medical care?

Judge Wachtler, who wrote both the *Eichner* and the *O'Connor* decisions, inadvertently provided an example of the difficulty of finding a systematic approach to applying the very standard he authored. In an interview in the *New York Times* in 1992 about the law in New York, he stated that the clear and convincing standard was never meant to be applied to a person in a coma. However, Brother Fox, for all practical purposes, was in a coma, and the clear and convincing standard was first applied to his case. Furthermore, nothing in either *Eichner* or *O'Connor* indicates that a person in a coma is not to be judged by the rigorous standard created by the Court.

For evidence of the impracticality of the clear and convincing standard, one need look no further than the local hospital to see how it is applied. Many physicians and hospital lawyers, knowing that some manifestation of the patient's wishes must be found, will accept almost anything as an indication of what the patient would have wanted. In cases where everyone agrees that further medical care is futile, it sometimes happens that the only known relative is contacted, who may not have spoken to the patient for many years. If the relative gives any indication that the patient once spoke about not wanting to be kept alive "by machines," then that is taken as sufficient evidence to withdraw care, even if the statement was made only once, in casual conversation. The case in which the patient had made one statement while watching a television show about Sunny Von Bulow 10 years earlier presented a similar situation. The judge, citing Eichner, Storar, and O'Connor, found the clear and convincing standard to be met. Did that one statement while watching television manifest a "firm and settled commitment" against life-sustaining medical care? At the other extreme, some institutions have interpreted the New York standard as requiring written documents, in some cases even notarized ones, even though the Court of Appeals explicitly stated that such writings are not needed.

Another indication of the great gulf between what the Court of Appeals felt it was creating and what actually occurs in medical practice is found in O'Connor. At issue there was whether or not a feeding tube should be inserted, and the Court specifically stated that the clear and convincing standard applies to both withdrawing and withholding of medical therapies. Even though various courts and most medical ethicists do not distinguish between withdrawing and withholding care, in the daily practice of medicine they are virtually always viewed differently. Emotionally it is much more difficult to take away treatment that has already been instated, and some physicians and health care attorneys commonly apply the clear and convincing standard only to those situations, and not to the withholding of care, despite the explicit holding in O'Connor.

Some will argue that we need the higher standard of clear and convincing evidence because we are using it in situations where we literally are deciding if someone shall live or shall die. Will some physicians, particularly in an age of concern about health care costs and managed care, find it easy to remove feeding tubes and ventilators without giving proper consideration to the patient's condition, prognosis, and prior declarations of her wishes, if any? The answer is most likely no. Physicians do not make these decisions in a vacuum. Not only is more than one physician typically involved in these matters, so too are other health care workers. A physician acting without proper regard for what is best

for the patient is usually dealing with family members of the patient, but more importantly he or she is being observed by other physicians, nurses, social workers, patient care personnel, and any of them potentially can report any wrongdoing to the institution's ethics committee, medical board, the state Department of Health, the Office of Professional Medical Conduct, the local district attorney, or a personal injury lawyer.

As further proof that the clear and convincing standard is not vital to prevent the capricious termination of vulnerable lives, we only need consider what is happening outside of New York. The majority of states do not require the clear and convincing standard. Certainly, if the stricter standard were essential to keep physicians from ending lives prematurely, without due consideration, we would be barraged with reports of abuses from those other states. Their absence speaks volumes.

To those who argue that the higher standard is necessary to "preserve" life, we can ask, where is the evidence that it accomplishes that goal? There is ample anecdotal evidence that it often prolongs the dying process and creates needless suffering, the latter occurring both in patients and in their loved ones. With a visit to any medical intensive care unit one is likely to find a person who is comatose or in a persistent vegetative state, who in the opinion of all observers has no meaningful chance of recovery, and who nonetheless is being kept alive because she never made any advance directives, never executed a health care proxy, and never declared her wishes about ventilators or feeding tubes.

In an ideal world, everyone would appoint a health care agent to make decisions when one loses the capacity to decide, would describe his preferences in a living will, and would discuss those preferences with loved ones and friends. In our world, people often do none of those things, and we then face the quandaries presented in *Eichner* and *O'Connor*.

A Reasonable Solution Languishing in Albany

As several of the judges in *Eichner* and *O'Connor* lamented the state of the law in New York regarding non-beneficial life-sustaining medical care, so too have others. In a case in Albany in 1996, *In re Matthews*,⁶ the judge felt "regrettably constrained" to authorize placement of a feeding tube. The patient was 27 years old, was born with severe cerebral palsy, and never was able to speak. He had spastic quadriplegia and developed a non-treatable swallowing disorder, causing his weight to decline to 42 pounds. His parents refused to give consent for placement of a feeding tube. The judge felt the views of the parents should be given "great deference": "They have consistently demonstrated during

Scott's lifetime their overwhelming dedication to Scott's best interests, extending every effort to minimize his pain and maximize his quality of life and dignity." The judge expressed his dissatisfaction in his decision:

The absence of relief in New York under such circumstances undoubtedly inflicts needless suffering on many of our citizens, and simple decency requires that a remedy be found . . . [the law in New York] has left us with a legacy of mandatory life support, regardless of the circumstances, for all parties unfortunate enough to have failed to express contrary intent and for all parties who, by dint of circumstances beyond their control, have no capacity to form an opinion on the issue . . . a person in Scott's circumstances has been denied the right to have his treatment determined by the very people who are best suited to make that determination . . . I would prefer that we provide relief by broadening our limited rules and joining the majority of American jurisdictions that recognize some form of substitute judgment.

For those who feel in sympathy with the sentiments expressed by the judge regarding Scott Matthews and who wonder what can be done to change the current state of affairs, a remedy has been proposed and has languished in Albany for over ten years. The Family Health Care Decisions Act, formerly known as the Surrogate Decision Act, was drafted to put in place a formal mechanism to appoint decision makers for those persons who never executed an advance directive. It also eliminates the confusion and ambiguity of the clear and convincing evidence standard. Instead, it requires the surrogate to take into consideration any previouslyexpressed wishes of the patient; religious or moral views, if known; relevant diagnoses; and the prognosis. By weighing all those factors, which reflects the method we employ when end-of-life decisions arise, the surrogate then makes a decision that serves the patient's interests to the fullest extent determinable. Multiple levels of due process protections are built into the mechanism, such that no one could be withdrawn legally from life-sustaining treatment based on the knowledge and judgment of only one person. In many respects, the proposed legislation effectively and adequately remedies the faults created by Eichner, Storar, and O'Connor.

So why has the legislation been languishing? The answer lies in the arcane political process in Albany and the pressure brought by a few vocal and influential groups. Those special interest groups have prevented

the legislation from moving beyond the committee stage. The work of many knowledgeable and thoughtful persons in writing the proposed legislation, with strong bases in medicine, law, and medical ethics, in essence has been held hostage by those moral opinions.

An example illustrates the harm the can result from the situation in which we now find ourselves in New York because of misguided court decisions and the vagaries of the legislative process. John Kelly was an 87-year-old man who was admitted to the hospital because of a declining mental status. He was diagnosed with dementia and was found to have pneumonia, for which he received antibiotics. A treatable source of the dementia could not be found. His lung function declined, and he was placed on a ventilator. Despite treatment of the pneumonia, Mr. Kelly could not tolerate removal of the ventilator, and he had to undergo a tracheostomy. His wife consented to the tracheostomy and to the placement of a feeding tube. Over the next several months he had several more episodes of pneumonia that were treated successfully, but he could not be weaned from the ventilator. His mental status showed a progressive decline, and after being in the hospital for nine months he remained dependent on the ventilator. He was not awake and could not follow verbal commands.

Mr. Kelly's wife visited him daily. They had been married over 60 years. She was very distressed as a result of her husband's deteriorating health, and she reached a point where she wanted him removed from the ventilator. A member of the hospital ethics committee met with her. It was found that Mr. Kelly never executed an advance directive. Ms. Kelly could not recall any conversations in which her husband expressed his feelings about life-sustaining medical care, nor could any other family member. After discussion with the hospital attorney, it was determined that Mr. Kelly could not be removed from the ventilator because the legal standard for removal of life-sustaining medical care in New York had not been met. To the further distress of Ms. Kelly, her husband eventually was transferred to a nursing home, still attached to the ventilator and not able to respond to his surroundings.

As a result of the law in New York, John Kelly's death was needlessly prolonged and his wife's anguish extended, and there are many similar cases. Ms. Kelly, who lived with her husband for 60 years and who was most affected by his prolonged process of dying, was prevented from enacting a decision that she felt was best for him and what he would have wanted. The power to act upon that decision was been taken from her by the New York State Court of Appeals and by

those who have caused the Family Health Care Decisions Act to undergo a slow, legislative death.

Conclusions

Stopping a medical treatment that is sustaining life is always difficult, for reasons that are all too obvious. For many physicians, it represents a defeat, the ultimate affront to what the culture of medicine in our time has trained them to do. Yet sometimes the only humane thing to do is to stop. When that time arrives, the decision should be made by the medical professionals involved and the loved ones of the patient, after carefully examining the patient's condition, prognosis, treatment options, and any expressions he or she may have made when competent about care that sustains life. Everyone should be educated about and encouraged to make advance directives, especially a health care proxy, but we can never expect that such will be done in every case.

For the many persons who cannot or will not plan in advance, the Family Health Care Decisions Act needs to be put into effect. Its scope is broad, addressing even those situations when a person loses capacity to make decisions and has no loved ones or friends to do so for her. New York should not have legal barriers to the reasonable and humanistic practice of medicine when death is foreseeable and near. The irrationality and confusion in which we currently function need not continue. The anomaly of New York law concerning life-sustaining medical care, compared to nearly every other jurisdiction in the United States, must be abolished. Where reside the authority and courage to accomplish that?

Endnotes

- In re Karen Quinlan, 70 N.J. 10, 355 A.2d 647 (N.J. 1976).
- In re Eichner, 102 Misc. 2d 184, 423 N.Y.S.2d 580 (Sup. Ct., Nassau Co. 1979).
- In re Storar, 52 N.Y.2d 363, 438 N.Y.S.2d 266, cert. denied, 454 U.S. 858 (1981).
- Delio v. Westchester County Med. Ctr., 129 A.D.2d 1, 516 N.Y.S.2d 886 (2d Dep't 1987).
- In re Westchester County Med. Ctr. (O'Connor), 72 N.Y.2d 517, 534 N.Y.S.2d 886 (1988).
- In re Scott Matthews, 225 A.D.2d 142, 650 N.Y.S.2d 373 (3d Dep't 1996).

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Court Clarifies Law Regarding Parents' Right to Decide on Withdrawing Life Support for Minors

By Salvatore J. Russo

Absent extraordinary circumstances such as incapacity, conflict of interest, or disagreement between parents, a parent of a minor child with an established diagnosis of persistent vegetative state should have the right to decide whether to terminate life support in the best interests of the child, without the necessity of judicial intervention.¹

In a thoughtful and compassionate 25-page written opinion, New York State Supreme Court Justice Doris Ling-Cohan clarified an area of law that has appeared somewhat murky since the decision in the *Storar* case.² In its decision the court was presented with the novel issue of whether a parent may "exercise her discretion, which is wholly supported by the other parent and the child's treating physicians, to withhold life support to her minor child who has been diagnosed to be in a persistent vegetative state with no chance of recovery."³ This question has not specifically been addressed by the legislature or any court in this state in the 22 years since *Storar*.

This case involved AB, a 3½-year-old female with no significant prior medical history, who resided with her mother, CD, in Brooklyn, New York. On December 31, 2002, AB had a seizure, collapsed and was rushed unconscious to Kings County Hospital Center (the "Hospital"), a New York City Health and Hospitals Corporation facility. At the time of the hearing, AB remained comatose and was diagnosed to be in a persistent vegetative state, with no reasonable medical basis for a reversal of this condition. AB was unresponsive to any verbal or physical stimuli, and had no spontaneous movements. AB was ventilator-dependent and required extreme medical intervention for all her activities of daily living. The mother expressed the wish that, in the absence of any reasonable hope of brain function recovery, as well as the complete dependence on mechanical ventilation and other artificial measures to maintain most normal bodily functions, she did not want AB's health care providers to continue life-supportive measures. AB's caregivers expressed no disagreement with this request. The natural father confirmed his willingness to defer to CD's wishes. The Hospital's Ethics Committee also supported CD's wish to remove her daughter from life support. However, given the legal uncertainty as to parental authority in these circumstances cast by the shadow of Storar, the

Hospital was unable to honor the parent's decision without a court order.

In a non-adversarial proceeding, the parent and the Hospital sought judicial intervention to clarify the scope of parental authority under these particular medical circumstances. A closed hearing was held by the court on two separate dates. During the hearing, the court appointed a guardian ad litem for AB. The court heard the testimony of CD; Dr. Gilbert M. Goldman, AB's treating physician; and the guardian ad litem. The court reviewed AB's medical records, the report of the guardian ad litem, and briefs submitted by the parties. In addition, the court reviewed the supporting affirmations from Drs. Alan Fleischman and John Lantos, experts in pediatric medicine and bioethics, as well as ethicist-lawyer, Professor Nancy N. Dubler. The court also received an affidavit from AB's father, who is separated from CD, which supported CD's decision. The father's support for CD's decision was also confirmed by the guardian ad litem, although he declined to appear before the court.

"In a thoughtful and compassionate 25page written opinion [In re AB], New York State Supreme Court Justice Doris Ling-Cohan clarified an area of law that has appeared somewhat murky since the decision in the Storar case."

At the conclusion of the hearing, the court determined that CD had proven, by clear and convincing evidence, that it was in the best interest of her child to remove mechanical ventilation. In making its determination, the court employed the best interest standard, weighing whether the burdens of prolonged life outweighed any physical pleasure, emotional enjoyment, or intellectual satisfaction that AB may still have been able to enjoy. In addition, the court considered the factors listed in Surrogate Court Procedure Act 1750-b4 and the considerations listed in the American Medical Association Report issued in 1992.⁵ The court's written decision also reviewed the law in other jurisdictions. The court distinguished the applicability of *Storar* to the instant matter, finding that, unlike in Storar, where the treatment recommended by the physicians was refused by his mother, here all the treating physicians, the Hospital, AB's parents and family, and the guardian *ad litem*, all concurred that the continued maintenance of the ventilator was not in AB's best interests. Also, unlike the facts in *Storar*, where transfusing John Storar did not involve excessive pain, although he disliked it, and without it, his mental and physical abilities would not be maintained at the same level, AB's medical interventions were more invasive and pervasive, and AB received "absolutely no benefit" from their imposition.⁶ Finally, the Court of Appeals was careful to state in its opinion that its role is limited to resolving the issues raised by facts presented in particular cases, and that any guidance the court provides is necessarily limited to those parameters.

Accordingly, the court granted CD's petition to consent to the removal of the mechanical ventilator for AB, ordering that the Hospital honor the mother's request and that the records of the proceedings be sealed except for the written decision, and the names and contact information of the parties' attorneys.

Although this decision emanates from a state Supreme Court, is not likely to result in an appellate review, and is limited to the specific facts of the case, it is likely that this well-reasoned opinion may serve as a guide to patients and facilities confronting similar situations, which have heretofore not had the benefit of any judicial guidance on this issue in the past 22 years.

Endnotes

- In re AB, a minor child, By Her Mother CD, 2003 N.Y. Lexis 878, May 16, 2003 (Sup. Ct., N.Y. Co. (Ling-Cohan, J.)), Index No. 401184/03, hereinafter referred to as In re AB.
- 2. In re Storar, 52 N.Y.2d 363 (1981). In Storar the mother of a 52-year-old mentally retarded adult with terminal bladder cancer sought to discontinue blood transfusions which her son found disagreeable and resisted, but were nevertheless sustaining his life. Mr. Storar's life expectancy due to his illness was three to six months. The Court denied the mother's petition due to the fact that Mr. Storar never had capacity to have wishes regarding such matters and the state's parens patriae interest in protecting the health and welfare of minors and incompetents.
- 3. *In re AB*, p. 1.
- 4. Effective March 16, 2003 the Health Care Decisions Act for Persons with Mental Retardation amended Article 17-A of the Surrogate's Court Procedure Act to permit guardians of individuals suffering from mental retardation to withhold life-prolonging treatment, under certain specific circumstances. While the court noted that the instant case was not covered by the statute, the analytical process established by this act for surrogate decision-making was an appropriate framework for review of this matter. The court also noted that based upon medical testimony, AB's mental condition was far more severe than that of a person with mental retardation. AB totally lacked the ability to interact with

- her environment, unlike someone who is mentally retarded.
- American Medical Association, Council on Ethical and Judicial Affairs, Op. 2:215, Treatment Decision for Seriously Ill Newborns, June 1992. Although expressly applicable to newborns, these guidelines also provide a framework for ethical analysis of treatment decisions in this case.
- 6. *In re AB*, p.5.

Mr. Russo is Deputy Counsel for Medical-Legal and Mental Health Affairs within the Office of Legal Affairs (OLA) of the New York City Health and Hospitals Corporation (HHC), and he also is the immediate past Chair of the Health Law Section of the New York State Bar Association. The opinions expressed in this article are his own, and do not necessarily reflect the opinions or policies of HHC.

The author expresses his condolences to the family of AB, as well as his respect for their courage in bringing this matter before the court. Additionally, he wishes to acknowledge his colleagues who represented AB's mother, CD, Elisabeth R. Benjamin and Samuel Davol of the Legal Aid Society of New York City, as well as his colleagues representing HHC, Stacey B. Mondschein of HHC OLA and Kenneth R. Larywon and Michael Zhu of Martin Clearwater and Bell, L.L.P. The author also wishes to recognize the invaluable work on this matter provided by Wayne McNulty, Assistant to HHC Counsel. Additionally, he wishes to recognize the steadfast leadership and support which the following HHC senior executives provided in the resolution of this matter: Dr. Benjamin Chu, HHC President; Dr. Van H. Dunn, HHC Senior Vice President of Medical and Professional Affairs; and Alan D. Aviles, Esq., HHC Senior Vice President and General Counsel. Without their involvement this matter would not have achieved a court determination.

The author also wants to thank Dr. Goldman and the staff at Kings County Hospital Center for providing compassionate care to AB and her family, as well as their cooperation in pursuing this matter. Additionally, he would like to acknowledge the generous gift of time and effort by Nancy N. Dubler, and Drs. John Lantos and Alan R. Fleischman, the uncompensated experts in pediatric medicine and ethics. The author would also wish to acknowledge the prompt, thorough and compassionate way in which the court-appointed guardian ad litem discharged her responsibilities. Lastly, the author would like to recognize the dignified, sensitive, considerate and compassionate manner in which Justice Ling-Cohan conducted the proceedings.

Reports and Other Materials

IN THE MATTER OF AB, 23664 (2003)

IN THE MATTER OF AB, A MINOR CHILD, BY HER MOTHER CD, Petitioner.

23664

SUPREME COURT OF THE STATE OF NEW YORK, COUNTY OF NEW YORK

May 16, 2003.

Legal Aid Society, New York City (Elisabeth Ryden Benjamin and Samuel Davol of counsel), for petitioner.

Martin Clearwater & Bell, LLP, New York City (Kenneth R. Larywon, Michael Zhu, Salvatore Russo and Stacey B. Mondschein of counsel), for New York City Health & Hospitals Corporation.

DECISION AND ORDER

Doris Ling-Cohan, JSC.

To have your minor child die is every parent's worst nightmare. To have to make the decision to terminate your own child's existence is beyond most people's comprehension. However, notwithstanding this, most parents are capable of making a considered decision in their grief, for the best interest of their child, with the help of the child's medical providers.¹

This tragic case presents a novel issue which has not been specifically addressed by the Legislature or the Courts of this State: May a parent exercise her discretion, which is wholly supported by the other parent and the child's treating physicians, to withhold life support to her minor child who has been diagnosed to be in a persistent vegetative state with no chance of recovery?²

AB is a three and half year old child who resides with her mother CD in Brooklyn, New York.³ As a healthy child, AB was rambunctious, happy and loving. Sadly, on December 31, 2002, AB had a seizure, collapsed and was rushed unconscious to New York City Health and Hospitals Corporation's Kings County Hospital ("HHC"). AB does not respond to any stimulation and is unable to feel joy or any other emotion; she cannot smile or respond to her mother; she cannot play, eat or speak. In short, AB requires extreme medical intervention for all of her activities of daily living, including a mechanical respirator to breathe. To this day, AB remains unconscious in King's County Pediatric Intensive Care Unit, having been diagnosed to be in a persistent vegetative state ("PVS").

After much reflection and consultation, AB's mother now asks this Court to rule that she has the authority

to remove AB from the mechanical respirator. After many discussions, with the advice of AB's medical providers, and upon deep consideration, CD believes that it is in the best interest of her child to remove her from the mechanical respirator so that she can die in peace. HHC's policies, however, do not permit hospital staff to withdraw or withhold care—such as a mechanical respirator—in cases such as this. Absent intervention by this Court, AB is likely to languish in a persistent vegetative state.

I. Hearing

The Court appointed a guardian *ad litem* for AB and held a hearing in which the mother CD, Dr. Gilbert M. Goldman and the guardian testified. In addition, on consent of HHC, the affirmations of Dr. John Lantos, Dr. Alan R. Fleischman, Professor Nancy Dubler and Dr. Goldman were made a part of the record. HHC consented to the jurisdiction of this Court and participated in the hearing. The record reflects the following and constitutes the Court's finding of facts.

AB, a three and a half year old child, lives with her mother, CD, who is employed as a home care attendant. On New Year's Eve 2002, AB experienced shortness of breath and collapsed, apparently undergoing a seizure.

AB was rushed in an ambulance to Kings County Hospital Emergency Room where she was immediately treated with a tracheal intubation and placed on a mechanical ventilator. AB was sedated and transferred to the Pediatric Intensive Care Unit where she was evaluated by a pediatric cardiologist. The cardiologist deter-

mined that AB had a cardiac arrhythmia. AB never regained consciousness.

HHC's physicians have performed a series of neurological evaluations, Electroencephalography and Magnetic Resonance Imaging, which all confirm that AB suffered a massive loss of brain functioning. AB does not respond to stimulation. She can only breathe when she is attached to a mechanical ventilator. She is provided nourishment through a feeding tube inserted into her stomach.

HHC's physicians and neurologists have made a definitive diagnosis that AB is in a persistent vegetative state. Dr. Goldman defined persistent vegetative state as being in permanent unconsciousness where the patient is totally unaware of the environment, without awareness of sensation and the ability to think or interact.

Dr. Alan Fleischman, an independent pediatrician, has confirmed HHC's diagnosis. AB's treating physicians, Dr. Goldman and Dr. Fleischman, as well as Dr. John Lantos, an expert in pediatrics and bioethics, all concur that the chance of AB's return to an awareness of, or interaction with her environment, is virtually impossible.

Dr. Lantos, Section Chief for General Pediatrics and Associate Director for the Center for Clinical Medical Ethics at the University of Chicago, reviewed AB's case and medical records. From this review, he has determined that AB should be removed from the mechanical ventilator because: (1) she has no quality of life to speak of in that she cannot experience joy or perform any activities of daily living on her own; and (2) her parents believe that it would be in her best interest.

Dr. Goldman, AB's treating physician, opines not only that AB is in a persistent vegetative state, but that there is no possibility of recovery, and that consistent with the American Medical Association's guidelines concerning treatment decisions for seriously ill newborns (which he considers applicable in this context), CD is making an informed decision about the removal of the mechanical ventilator in AB's best interest. Because of AB's unique condition, Dr. Goldman also feels that such a decision is not only informed, but correct. According to Dr. Goldman, AB's condition is extremely severe and rare. He stated that, typically, children who are in a persistent vegetative state are able to breathe without the assistance of a mechanical ventilator; however, this case presents the particularly devastating and rare combination of co-morbidities in which the child is permanently unconscious and unable to breathe on her own. Dr. Goldman concludes that it is medically and ethically appropriate at this point to observe the mother's wishes and remove the ventilator given that it is merely postponing AB's eventual death.

CD is a loving mother who visits AB every day in the hospital. Her daughter cannot respond or speak when CD speaks or touches her. CD believes that there is nothing peaceful about her daughter's condition. CD's grief is so severe that she is unable to sleep at night and cannot return to the home she once shared with her daughter. She has been unable to work as a home care attendant since her child has entered the hospital. The mother, and her close knit family, feel paralyzed. They cannot grieve the loss of AB because she is not medically dead; yet, she is not fully alive. One of CD's sisters arrived from Canada immediately after AB's seizure and cannot go home until she feels that there has been some closure. CD testified that her decision to remove the mechanical ventilator was a hard decision to make; however, she believes that it is in the best interest of her daughter in that it would allow her daughter to be at peace.

The father of AB, who is separated from the mother, supports the mother's decision as indicated by his affidavit and as confirmed by the guardian *ad litem*. Further, he has been notified of this proceeding, but has chosen not to appear.

The guardian *ad litem* testified that she was impressed by the warm and respectful relationship that the medical and nursing staff had with the mother and that CD is making a "conscientious, fully informed decision". The guardian opined that there is nothing peaceful about AB's prolonged life on a ventilator and that keeping her in such a state seems cruel. She also observed that there is no economic incentive motivating CD's decision; it is a decision based purely upon the best interest of AB. The guardian found no disability discrimination. Additionally, the guardian unequivocally states that there has never been any suggestion of neglect or abuse of AB. According to the guardian, the medical technology being employed is both futile and invasive; and, inasmuch as the child receives absolutely no benefit, there is a dignity issue and disrespectfulness to the child from the continued bodily invasions. It was her opinion that prolonging this would have a devastating effect on the family, which the child is a part of, and ultimately not in the child's best interest.

II. Discussion

A. A Survey of New York Case Law

It is without question that dramatic advances in medical technology have made it possible to sustain or maintain the lives of many individuals, including infants who would otherwise have died. As this case illustrates, these advances have outstripped the ability of this State to develop an ethical, moral or legal approach for dealing with problems caused by these new possibilities, including those facing the petitioner and others in similar situations.

This case differs from the usual "right to die" case in that typically family members seek court authorization to have life support systems terminated where the incompetent patient has earlier expressed his/her preference regarding such treatment. In these cases, the underlying rationale is based on the patient's common law right to control his/her own medical care or self-determination. *See e.g. Matter of Westchester County Med. Ctr. ex rel. Mary O'Connor*, 72 NY2d 517 (1988).

The issues presented herein, however, differ significantly from those presented when the incompetent patient has earlier expressed a clear view regarding such treatment. An infant, by definition, is incapable of making any determinations or formulating any preferences for treatment. Traditionally, when the Court cannot determine a patient's preference, it must rely on the common law doctrine of *parens patriae* to decide whether to withdraw life prolonging treatment. *See Matter of Storar*, 52 NY2d 363, 380-82 (1981).

1. The Right of Self Determination

At common law, a competent individual's right of self-determination gives him/her the right to decide what happens to his/her body. See Grace Plaza of Great Neck, Inc. v. Elbaum, 82 NY2d 10, 15 (1993); see generally Delio v. Westchester County Med. Ctr., 129 AD2d 1 (2d Dept 1987). This doctrine includes a person's right to refuse even life-preserving medical treatment. Id. at 22; Grace Plaza, 82 NY2d at 15. "No right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." Union Pacific Ry. Co. v. Botsford, 141 US 250 (1891).

Since the right of self determination can only be made by one who is competent to evaluate his/her own condition, a patient lacking in this capacity is said to have forfeited this right of self determination unless, while competent, the patient expressed his/her preferences. See Matter of Westchester County Med. Ctr. Mary O'Connor, 72 NY2d at 530.

In such a case, this subjective test requires that someone acting on the incompetent's behalf establish the incompetent's preferences by clear and convincing evidence. *Matter of Westchester County Med. Ctr. ex rel. Mary O'Connor*, 72 NY2d at 528-29; *Matter of Storar*, 52 NY2d at 378-79. Thus, a dying patient's right of self determination outweighs the rights of the patient's family, physicians, or other care providers to base a treatment decision on their individual interests or ethical imperatives. *See id.* at 377.

In 1981, the Court of Appeals jointly heard two cases concerning whether a parent or other interested third party could make a decision to withhold treat-

ment for an incompetent child or friend. *Matter of Eichner v. Dillon* and *Matter of Storar*, 52 NY2d 363 (1981). In *Eichner*, Father Eichner, as guardian for Brother Fox, a terminally ill 83 year old in a persistent vegetative state, sought to remove the mechanical ventilator. Before he became seriously ill, Brother Fox had stated that he would not want to have his life extended via extraordinary measures. The Court of Appeals ruled that the ventilator could be removed because there was clear and convincing evidence of Brother Fox's wishes. Accordingly, a competent adult's (or an adult who clearly made her wishes known prior to becoming incapacitated) right to refuse treatment can prevail over the State's *parens patriae* interests.

In *Storar*, the mother of a 52 year old mentally retarded adult with terminal bladder cancer sought to discontinue blood transfusions which her son found disagreeable and resisted, but nonetheless would prolong his sentient life for three to six months. Because he was mentally retarded, Mr. Storar never had the mental capacity to state whether or not he would wish to have his life extended should he become gravely ill. The Court found that "the evidence convincingly shows that the transfusions did not involve excessive pain and that without them his mental and physical abilities would not be maintained at the usual level." Id. The Court thus held that, in such case, the parent's decision to decline treatment must yield to the "States interests, as parens patriae, in protecting the health and welfare of the child." Id. The Court indicated that given that "particularly important personal interests are at stake, clear and convincing evidence should be required." Id. at 318.

2. The Best Interest Test

In cases such as the one before the Court, where a terminally ill patient has never been competent to express his/her wishes regarding medical treatment (therefore precluding the availability of clear and convincing evidence of a patient's wishes), the law in New York is unsettled. It has been held that, where there is no compelling evidence of the incompetent's wishes, the court must determine whether withdrawal of life support will serve the patient's "best interest." *Matter of Beth Israel Med. Center*, 136 Misc 2d 931 (Sup Ct, New York County 1987).

In determining the patient's "best interest", at minimum, there should be evidence that the burdens of prolonged life outweigh any physical pleasure, emotional enjoyment, or intellectual satisfaction that the patient may still be able to derive from life. *See id.* at 938. It is clear, however, that medical treatment may not be withheld from an incompetent simply because a third party believes that the incompetent's quality or prognosis is less than optimal. *See e.g., Matter of Westchester County Med. Ctr. ex rel. O'Connor*, 72 NY2d 517, 533 (1988) (authorizing hospital, despite daughters' wishes, to

insert feeding tube into a 77 year old woman who was not in a vegetative state, but was awake and conscious, could feel pain and respond to simple questions); *Matter of O'Brien*, 135 Misc 2d 1076, 1078 (New York County 1986) (refusing to authorize removal of feeding tube for elderly incompetent who could understand some questions and respond with an affirmative squeeze of the hand).

In *Matter of Storar*, the Court of Appeals determined that because the necessary blood transfusions did not involve excessive pain (even though the incompetent patient expressed a dislike for them), and that without them, his mental and physical abilities would not be maintained at the same level, the trial court should have granted the application for permission to continue the transfusions, over the objections of the patient's mother. Id. at 381-82. "However, the fact that the [C]ourt [of Appeals] did not permit the mother to withhold transfusions should not be interpreted as foreclosing the possibility of humane actions through surrogate decision-making which may involve withholding lifeprolonging treatment for persons who never spoke on the issue." Matter of Beth Israel at 937. Further, complete foreclosure is not necessarily what the Court of Appeals intended as it was careful to state that "any guidance we may provide for future cases is necessarily limited . . . Our role . . . is limited to resolving the issues raised by facts presented in particular cases". Matter of Storar at 370; see also Matter of Beth Israel at 937.

Here, unlike the 52 year-old adult incompetent patient John Storar, it is undisputed that the infant patient AB would not derive any benefit from having her life prolonged through mechanical ventilation because of her persistent vegetative state. Indeed, there is irrefutable evidence that AB has sustained massive irreversible brain damage, confirmed by diagnostic tests, and remains in a persistent state of unconsciousness. Further, unlike in *Storar*, where the physicians recommended treatment which was refused by the mother, in the case of AB, all treating physicians, the hospital, AB's parents, family and the guardian *ad litem*, concur that the continued maintenance of the ventilator is not in AB's best interest.

Further, it is undisputed that AB has no quality of life to preserve. Unlike John Storar, AB does not have a sapient existence; she cannot play, talk, or feel physical sensation. In fact, Professor Nancy Dubler, a bioethicist at Albert Einstein College of Medicine and New York University Law School concluded, after an intensive review of this case, that the maintenance of the mechanical respirator in AB's case only "imposes a medical intervention", without providing any concomitant "health benefit" to AB.

New York Courts have held that the removal of life sustaining treatment where, as in AB's case, the incom-

petent "has no quality of life whatsoever" is permissible. *See Matter of Christopher*, 177 Misc 2d 352 (Sup Ct, Queens County 1998); *Matter of Beth Israel Med. Ctr.*, 136 Misc 2d 931 (Sup Ct, New York County 1987).

In *Christopher*, Parkway Hospital sought to insert a feeding tube into the stomach of a 79 year old woman diagnosed with Alzheimer's disease. Her son opposed the application stating that his mother would not have wished it. While the mother was not in a persistent vegetative state or a coma, the Court noted that "for all intents and purposes, she is brain-dead, unable to walk, incontinent and in pain." *Matter of Christopher*, 177 Misc 2d at 356. Stating that such decisions would best be left between medical personnel and family members, the Court held that the Hospital's application to insert the feeding tube would be against her wishes, futile, and unnecessary. *Id*.

Similarly, in Matter of Beth Israel Medical Center, a hospital sought authorization to perform an emergency amputation of the leg of an 74 year old partially paralyzed and aphasic woman, Sadie Weinstein. 136 Misc 2d at 932. The surgery was opposed by Ms. Weinstein's sister. As a result of a second stroke, Ms. Weinstein was bed bound, could not speak, and had little cognitive function. She was fed through a naso-gastric tube. A neurologist determined that her condition was irreversible and would only decline. Her physical responses were haphazard. The Court noted that while Ms. Weinstein was not completely comatose, she was "more mentally and physically debilitated than the patient in Storar." Id. at 942. The Court determined that Ms. Weinstein "should be permitted to die with dignity" because the proposed surgery would "at best, unnecessarily prolong the natural process of her dying" and that there was "no human or humane benefit to be gained" from its performance. Id.

B. The Law in Other Jurisdictions

The highest courts in other jurisdictions have favored putting decisions such as the one which is before this Court in the hands of loving and caring parents of the infant, without the need for judicial intervention. See In re L.H.R., 253 Ga 439, 447, 321 SE 2d 716, 723 (1984) (holding that the decision to forego or terminate life support measures where the infant is terminally ill with no hope of recovery and in a chronic vegetative state is "simply a decision that the dying process will not be artificially extended" and that the "decision can be made only by the surrogate of the infant"); In re Barry, 445 So 2d 365 (Fla 1984) (holding that it is the right and obligation of the parents of a terminally ill child who is wholly lacking in cognitive brain functioning, completely unaware of his surroundings and with no hope of development of any awareness to exercise the responsibility and prerogative of making an informed determination as to whether extraordinary life prolonging measures should be continued); *Matter of Quinlan*, 70 NJ 10, 355 A2d 647 (holding that a trustworthy and loving parent could assert an infant patient's constitutional right to privacy to support a request, in the patient's name, to withdraw life prolonging treatment).

In L.H.R., the Supreme Court of Georgia was called upon to determine who may make treatment decisions, and whether judicial intervention is required in cases where the diagnosis is made that the infant is in a persistent vegetative state with no reasonable possibility of attaining cognitive function. L.H.R., 253 Ga at 439. Like the case at bar, the infant L.H.R. suffered a "medical catastrophe". Id. It occurred fifteen days after her normal birth and she remained hospitalized for the next several months during which a neurologist determined that the infant was in a "chronic vegetative state" with the "absence of cognitive function". Id. The physicians estimated that approximately eighty-five to ninety percent of her brain tissue had been destroyed and her condition was described as "irreversible" with no hope of recovery. Id.

Similar to the case at bar, the physicians, parents, the guardian *ad litem*, and the hospital's Infant Care Review Committee all agreed that she should be removed from life support. *Id.* The Hospital filed a petition for declaratory relief. The trial court enjoined the hospital and physicians from interfering with the wishes of the infant's parents and guardian to withdraw the life prolonging measures. After obtaining a court order, the life support systems were removed and the infant died within thirty minutes. *Id.*

The Georgia Supreme Court limited its holding to cases like the one at bar which concern terminating treatment of hopelessly or terminally ill patients in a chronic vegetative state, for whom there is no possibility of attaining (or regaining) cognitive function. The Court determined that "the decision whether to end the dying process is a personal decision for family members or those who bear a legal responsibility for the patient", and not the judiciary. *Id.* at 446. The Court further stated that "the courts remain open to assist if there is disagreement between the decisionmakers [sic] or question of abuse". *Id.* at 447.

The Court recognized the role of the family in such decisions:

"In any discussion of who will exercise the incompetent patient's constitutional right to refuse treatment, we must recognize the importance of the family in our society. This recognition is particularly crucial when the patient is a child. . . . The right of the parent to speak for the minor child is so imbedded in our

tradition and common law that it has been suggested that the constitution requires that the state respect the parent's decision in some areas. (citations omitted) . . . We now hold that this right [a competent adult's right to instruct a physician to withhold or withdraw life sustaining procedures] rises to the level of a constitutional right which is not lost because of the incompetence or youth of the patient ... We conclude that the right to refuse treatment or indeed to terminate treatment may be exercised by the parents or legal guardian of the infant after diagnosis that the infant is terminally ill with no hope of recovery and that the infant exists in a chronic vegetative state with no reasonable possibility of attaining cognitive function . . ."

L.H.R., 253 Ga at 445-47.

Similarly, in *In re Barry*, where the parents sought to discontinue life support systems for their ten-month old son who was in a persistent vegetative state, the Florida District Court of Appeals reasoned that "the constitutional right of privacy would be an empty right if one who is incompetent were not granted the right of a competent counterpart to exercise his rights." 445 So 2d at 370. After the parents were appointed as legal guardians of their infant son, Andrew, they petitioned the trial court for approval to terminate the use of his life support system. Andrew was in a chronic permanent "vegetative coma", did not have any cognitive brain function, and was terminally ill. The petition was accompanied by three supporting physician's affidavits.

With regard to whether the petitioners could exercise the right to privacy on behalf of their child Andrew, even in the absence of evidence of Andrew's intent, the Court held that:

"in the case of a child who has not reached maturity, it is the parents and their medical advisors who generally must make these decisions. And, where judicial intervention becomes necessary or desirable, the court must be guided primarily by the judgment of the parents who are responsible for their child's well-being, provided, of course, that their judgment is supported by competent medical evidence."

445 So 2d at 371.

Finally, the Court declared prospectively that prior judicial authority or review is not required because

"decisions of this character have traditionally been made within the privacy of the family relationship based on competent medical advice and consultation by the family with their religious advisors, if that be their persuasion". *Id.* at 372. The Court stated:

[W]here, as here, the question concerns a young child, we do not think the parents must always qualify as legal guardians and seek judicial sanctions to discontinue these extraordinary measures. A decision by parents supported by competent medical advice that their young child suffers from a permanent, incurable and irreversible physical or mental defect likely to soon result in the child's death should ordinarily be sufficient without court approval.

445 So 2d at 372.

In *Matter of Quinlan*, the seminal case on this issue, the New Jersey Supreme Court concluded that Karen Ann Quinlan had a right, grounded in the right of privacy protected by the U.S. Constitution, to refuse unwanted medical care. 70 NJ at 41. Karen fell into a persistent vegetative state after suffering brain damage of an unknown origin. Karen's father petitioned the trial court for an order to appoint him as Karen's guardian and specifically requested authority to disconnect a respirator that the physicians believed necessary for her survival. The trial court denied the father's petition holding that there was inconclusive proof of Karen's preferences for treatment.

The New Jersey Supreme Court reversed and granted the father's petition. The Court entertained no doubt "that if Karen were herself miraculously lucid for an interval . . . and perceptive of her irreversible condition, she could effectively decide upon discontinuance of the life-support apparatus, even if it meant the prospect of natural death". 70 NJ at 39. Thus, the Court ruled that Karen should not lose her right simply because her condition prevents her exercise of such choice.

C. Surrogate's Court Procedure Act

Like many other jurisdictions, New York's law involving the right of a patient, or a surrogate, to decline medical treatment has evolved over the last decade. In this regard, the New York Legislature has enacted certain statutes which have gone far towards solving the problems presented by these types of cases.

Most recently, the Legislature enacted a new law which grants to guardians of individuals suffering from mental retardation the authority to withhold life-prolonging treatment. This authorization is derived from the new Health Care Decisions Act for Persons with

Mental Retardation ("HCDA" or the "Act"), which went into effect on March 16, 2003. While this statute specifically addresses guardians of individuals with mental retardation appointed under Article 17-A of the Surrogate's Court Procedure Act ("SCPA"), it also reflects an evolving consensus in this State that the law must better allow health care practitioners, patients and their families to make decisions in the best interest of their children when faced with tragic circumstances.⁴

While the statute is not directly applicable to AB's situation in that it is limited to mentally retarded persons, the analytical process established by the Legislature for surrogate decision-making is an appropriate framework for analysis in the instant case. In fact, according to the medical testimony presented to this court, AB's condition is far more profound than that of a person who is mentally retarded, as she totally lacks the ability to interact with her environment, unlike someone who is mentally retarded.⁵

When it appears to the satisfaction of a court that a person is mentally retarded, section 1750 and newly enacted section 1750-b of the SCPA authorize the appointment of a guardian to act on behalf of a mentally retarded person on the certification of two doctors that the patient is mentally retarded and is incapable of making health care decisions. A guardian so appointed, "shall have the authority to make any and all health care decisions on behalf of the mentally retarded person that such person could make if such person had capacity" including "decisions to withhold or withdraw lifesustaining treatment". SCPA 1750-b (1).

The guardian is to base all advocacy and health care decision-making solely and exclusively on the best interest of the mentally retarded person and, when reasonably known or ascertainable with reasonable diligence, on the mentally retarded person's wishes. SCPA 1750-b (2)(a). Pursuant to the statute, the assessment of "best interest" must include the following considerations: "(i) the dignity and uniqueness of every person; (ii) the preservation, improvement or restoration of the mentally retarded person's health; (iii) the relief of the mentally retarded person's suffering by means of palliative care and pain management; (iv) the unique nature of artificially provided nutrition or hydration, and the effect it may have on the mentally retarded person; and (v) the entire medical condition of the person." SCPA §1750-b (2)(b).

In this case, the guidelines established by the Health Care Decisions Act for Persons with Mental Retardation, by analogy, have been exceeded. The diagnosis requirement by two physicians articulated by the Act has been exceeded in that numerous physicians, including treating physicians and independent experts,

have certified that AB is in a persistent vegetative state from which there is no possibility of recovery. *See* SCPA 1750. Additionally, given that AB is three and a half years old and is permanently unconscious, there is no question that she lacks capacity to make health care decisions for herself and her wishes are not "reasonably known or ascertainable." *See* SCPA 1750-b (2)(a).

Further, the scope of the authority conveyed on the guardian by the Act is similar to the authority sought by the mother here—to make all health care decisions for her child—including the decision to withhold or withdraw life-sustaining equipment.

In addition, the decision-making analysis employed by the mother, with the guidance of AB's treating physicians and Kings County Hospital Center's Ethics Committee, in arriving at the conclusion that the withholding of mechanical ventilation is medically and ethically appropriate under the existing circumstances, is similar to the "best interest" standard articulated in the Act.

See SCPA 1750-b (2)(b). CD testified at the April 9, 2003 hearing that the essence of her child's uniqueness has been permanently lost, as her child is a mere unconscious "shell" of her former self. Additionally, Dr. Goldman concluded that AB has "no possibility of recovery" and that her care now consists of managing medical catastrophes which will inevitably occur and ultimately lead to her death. The relief of AB's suffering is not a factor because, as Professor Dubler concluded, the mechanical ventilator "will do nothing but maintain her in a state beyond comfort and care from which she will not recover." In addition, Dr. Goldman testified that, "suffering and joy or pleasure are permanently beyond this child's capacity". With respect to the entire medical condition of AB, sadly, there is no question that AB has no chance of recovery.6

In fact, it is uncontested by all of those involved in this case, including three qualified physicians and the guardian, that CD is acting in the best interest of her daughter. The record clearly establishes that she is a loving mother who has no financial or other interest in making the decision to withdraw life support except to ensure that her daughter dies peacefully.

The SCPA further requires that the health care decision not be subjected to discrimination based upon disability or influenced by financial factors of the guardian and should be based upon full and complete medical information. *See* SCPA 1750-b (2)(c), (3). Here, this has been satisfied in that there is no allegation of disability-based discrimination and the mother has no financial incentive to decide to withdraw the mechanical ventilator since AB's medical care is covered by insurance. Further, there have been numerous regular meetings with the treating physicians, family, and members of

the Hospital's ethics committee, and thus CD is fully informed.

Where the health care decision to be made by the guardian concerns terminating life-sustaining treatment, the Act provides that certain additional steps be followed. See SCPA 1750-b (4). As explained below, each of these additional requirements have been satisfied in the case of AB. The requirement that there be a diagnosis, confirmed by two physicians with a reasonable degree of medical certainty, that the patient has one of the following conditions has been met: (A) a terminal medical condition; (B) permanent unconsciousness; or (C) an irreversible condition which will continue indefinitely. See SCPA1750-b (4)(b)(i). As testified to by Dr. Goldman, the child AB has met all three conditions in that she has a "terminal condition" and is in a "state of permanent unconsciousness" with "no possibility . . . that this child can ever recover from the vegetative state". Independent confirmation that AB is permanently unconscious, and that this state is irreversible and will continue indefinitely, has been established by two other physicians, Dr. Fleischman and Dr. Lantos.

The section which requires a finding by two physicians that the life sustaining treatment imposes an extraordinary burden on the patient in light of his/her medical condition and expected outcome of the treatment has also been met. See SCPA 1750-b (4)(b)(ii). Dr. Goldman testified that the mechanical ventilator is essentially prolonging AB's dying process without providing her any medical benefit. He further stated that if kept on the ventilator, in all likelihood, the child would experience one or several catastrophic episodes typically involving the lungs; the introduction of bacteria through the tubing into the lung would likely create a severe bacterial or chemical pneumonia which would lead to a reaction that would make it impossible to provide oxygen and remove carbon dioxide, leading to a deprivation of oxygen to the vital organs. Additionally, in support of the determination to remove AB's mechanical ventilator, Dr. Fleischman states that "technical intervention to suspend AB in her present condition is unsupported by the medical and ethical standards which our society has widely embraced".7

The requirement that the guardian, in this case AB's mother, express the decision to withdraw life-sustaining equipment in writing or orally has been met. *See* SCPA 1750-b (4)(c). In addition, Section 1750-b (4)(d), which requires this request to be entered into the patient's chart, has also been satisfied. ⁸

Accordingly, the Court finds that AB's case exceeds the standards set forth in the Health Care Decisions Act for Persons with Mental Retardation for authorizing a guardian, in this case the mother, to make the decision to withhold or withdraw life sustaining treatment.

D. American Medical Association Guidelines

The decision to withdraw life-prolonging treatment from a patient in a persistent vegetative state has long been recognized in the medical community to be appropriate. See Council on Ethical and Judicial Affairs, American Medical Association, Withholding or Withdrawing Life Prolonging Medical Treatment, Mar. 15, 1986. Guidelines have been proposed by the American Medical Association ("AMA") in formulating an opinion concerning their ethical analysis of treatment decisions for seriously ill newborns. Although not expressly applicable as it concerns only newborns, the AMA guidelines provide another analytical framework in this case, similar to the newly amended and enacted sections of the SCPA discussed previously. Specifically, the AMA proposes a best interest standard which:

"requires a weighing of the benefits and burdens of treatment options including nontreatment as objectively as possible. Factors that should be considered when making decisions about life-sustaining or life-saving treatment for a seriously ill newborn include: 1) the chance the therapy will succeed, 2) the risks involved with treatment and nontreatment, 3) the degree to which the therapy if successful will extend life, 4) the pain and discomfort associated with the therapy and 5) the anticipated quality of life for the newborn with and without treatment."

American Medical Association, Council on Ethical and Judicial Affairs⁹ Opinion 2:215, *Treatment Decisions for Seriously Ill Newborns*, June 1992. ("1992 Report").

In the 1992 Report, the Council proposed that the patient's family should be given the authority to make treatment decisions:

"In the case of seriously ill newborns, the parents should be responsible for making treatment decisions for their child based on the child's best interest. Due to the love that parents have for their children, they are most likely to make decisions that promote their children's best interest. Parents are more likely to treat if their child was a person rather than a symbol for a cause. In addition, society has recognized the importance of family autonomy and privacy from outside intervention".

Id. Furthermore, when an infant suffers extreme neurological damage, such as when an infant is in a persistent vegetative state like AB, "and is consequently

not capable of experiencing either suffering or joy, a decision may be made to withhold or withdraw life-sustaining treatment upon the parents' request." ¹⁰ *Id.*

Lastly, as part of the AMA's recommendations, "physicians must provide full information to parents of seriously ill newborns regarding the nature of treatments, therapeutic options and expected prognosis with and without therapy, so that parents can make informed decisions for their children about life-sustaining treatment." *Id*.

Applying such factors to the case of AB, the decision to withhold mechanical ventilation satisfies the best interest standard articulated by the AMA. AB is incapable and will permanently remain incapable of experiencing suffering or joy or interacting meaningfully with her environment because of her PVS. Additionally, AB is subject to many physical intrusions including catheterizations, feeding tubes, IV's and mechanical ventilation on a daily basis and if kept on a mechanical ventilator, she faces increasing physical invasions to her body, and will undoubtedly suffer more infections and a deterioration of her condition with no benefit. In fact, the mechanical ventilator is merely prolonging her eventual death. Thus, AB's case meets or exceeds the standards set forth by the AMA Council on Ethics and Judicial Affairs' Ethical Opinion concerning the decision to withhold or withdraw life sustaining treatment.

E. Parental Rights and Public Health Law Section 2504(2)

CD's authority to exercise her judgment as the parent of AB is also grounded on traditional parental values and responsibilities. Every parent has a "fundamental right" to rear his or her own child. Matter of Hofbauer, 47 NY2d 648, 655 (1979) (citing Matter of Bennett v. Jeffreys, 40 NY2d 543, 546 (1976); Quilloin v. Walcott, 434 US 246, 255, reh denied 435 US 918 (1978). While this right is not absolute, "great deference must be accorded a parent's choice as to the mode of medical treatment to be undertaken and the physician selected to administer the same." Id. In fact, the "filial bond is one of the strongest . . . and most inviolable of all relationships". Id. (citing Matter of Corey L. v. Martin L., 45 NY2d 383, 392 (1978)); see also Weber v. Stony Brook Hosp., 60 NY2d 208 (1983), cert denied 464 US 1026 (providing that caring and nurturing for a sick child is a parent's "most private and most precious responsibility"). "Obviously, for all practical purposes, the average parent must rely upon the recommendations and competency of the attending physician since the physician is both trained and in the best position to evaluate the medical needs of the child." Matter of Hofbauer, 47 NY2d at 655-56.

Furthermore, pursuant to New York State Public Health Law Section 2504, parents have the right to pro-

vide effective consent concerning medical service for their children. Public Health Law Section 2504(2) states:

> "Any person who has been married or who has borne a child may give effective consent for medical, dental, health and hospital service for his or her child".

Under this statute, Courts have held that a parent can compel her child to undergo medical treatment, even when it is against the vigorous objections of the child, because children are considered to be "lacking in judgment" as their "normal condition is that of incompetency". *See e.g., Matter of Thomas B.,* 152 Misc 2d 96, 99 (Family Court, Cattaraugus County 1991) (a child who was phobic of needles was required to undergo biopsy of tumor).

Moreover, parents have the right to determine or refuse treatment for their children even where, unlike here, the parents' decision is contrary to their child's treating physician's medical opinion. 11 See Matter of Hofbauer, 47 NY2d 648 (1979). In Matter of Hofbauer, the New York Court of Appeals upheld the parents' right to reject the conventional modes of radiation and chemotherapy and opt to use alternative nutritional therapy for their child diagnosed with terminal Hodgkin's disease. *Id.* at 657-58; Matter of Matthews v. Mental Hygiene Legal Services, 225 AD2d 142 (3d Dept 1996) (upholding that parents' authority to refuse placement of feeding tube in lieu of continued oral feeding of malnourished mentally retarded adult son was reasonable where supported by treating physician); Matter of Felicia D., 263 AD2d 399 (1st Dept 1999) (upholding mother's right to refuse to consent to child's placement in residential mental health facility); Alfonso v. Fernandez, 195 AD2d 46, 52 (2d Dept 1993)(holding that, under Public Health Law § 2504(2), parents have the right to consent to child's participation in a voluntary condom distribution program at schools).

In this case, AB is beyond choosing treatment modalities. She is in a persistent vegetative state. AB's treating and independent pediatricians all agree that there is no hope for AB's recovery. There is no treatment that CD can elect which will improve AB's prognosis. The only "mode of treatment" that CD can select which she believes will ameliorate AB's condition is the removal of the mechanical ventilator. AB's treating physicians all concur with CD's decision. Pursuant to *Matter of Hofbauer* and Public Health Law 2504(2), CD is authorized to make this choice for her daughter. ¹² 47 NY2d at 655.

III. Conclusion

It is unrefuted that AB has sustained massive irreversible brain damage and has no hope of recovery

from her permanent state of unconsciousness, known as PVS. She is subject to many physical intrusions on a daily basis, including catheterizations, feeding tubes, IV's and mechanical ventilation, and is incapable of experiencing any physical or emotional pleasure. If kept on a mechanical ventilator, the child faces more physical invasions to her body, and she will undoubtedly suffer increasing infections and a deterioration of her condition with no benefit. It is clear to the Court, as it is to AB's mother, the treating physicians, independent physician experts and the guardian *ad litem*, that the extraordinary "life-prolonging" measures are merely prolonging AB's death.

The Court observes that it is readily apparent that CD is not making this decision lightly. All who have reviewed this case, including the treating physicians, independent medical experts, hospital's medical ethics team and the court appointed guardian ad litem, concur that CD is a loving mother who is acting in the best interest of her child. She has consulted with AB's doctors on a daily basis since the December 31, 2002 incident and was provided complete detailed information about AB's condition and prognosis. She has met with the Hospital's ethics committee many times. In addition, CD has discussed her decision thoroughly with her family and it is supported by the father of the child. The mother's decision is not rooted in financial reasons as her daughter's care is covered by health insurance and there are no life insurance or other financial motivations prompting such decision.

Absent extraordinary circumstances such as incapacity, conflict of interest, or disagreement between parents, a parent of a minor child with an established diagnosis of persistent vegetative state should have the right to decide whether to terminate life support in the best interest of the child, without the necessity of judicial intervention. While the courts are always available to assist if there is a disagreement or question of abuse, the decision to end the dying process of a minor child is a personal decision for the parents, in consultation with the child's medical providers, as they bear the legal, moral and ethical responsibility for their child. Both the HCDA and the AMA guidelines, by analogy, as well as Public Health Law §2504(2) and New York's case law, fully support the proposition that CD, as mother and natural guardian of AB, is fully authorized to make a decision to withhold mechanical ventilation because it is in the best interest of her child.

Thus, this Court holds that it is CD's right, as a parent and natural guardian of AB, to exercise her responsibility and prerogative to make this decision to withhold extraordinary life-prolonging measures, with the assistance of treating physicians. CD's parental choice, made in the best interest of her child, to allow her daughter to pass away peacefully and with dignity are

to be honored. This decision respects the values of family privacy without compromising a patient's rights or overstepping the State's legitimate interests.

Having sought judicial intervention, CD has proven by clear and convincing evidence that it is in the best interest of her child to remove the mechanical ventilator. As CD sought intervention, this Court has employed the best interest standard, weighing whether the burdens of prolonged life outweigh any physical pleasure, emotional enjoyment, or intellectual satisfaction that the child may still be able to derive from life. See Matter of Beth Israel Med. Center, 136 Misc 2d at 938. In addition to the factors listed in SCPA 1750-b, the Court has also employed the considerations listed in the AMA 1992 Report in determining that there is clear and convincing evidence that it is in the best interest of AB to remove the mechanical ventilator. In evaluating best interest, the Court is also guided by the judgment of the parents.

Because AB will remain in a vegetative state, with no hope of any improvement or recovery, CD's request that this Court order HHC to honor CD's good faith determination to terminate mechanical ventilation because it is in the best interest of her child is granted. There can be no State interest great enough to compel AB to remain subjected to this extraordinary life-sustaining measure. To do so would merely prolong the death of a terminally ill child, wholly lacking in cognitive brain functioning, completely unaware of her surroundings, and with no hope of ever regaining awareness, while subjecting her to daily physical intrusions including catheterizations, feeding tubes, IV's and increasing infections.

Accordingly, having held a hearing over the course of two days and having heard the testimony of the mother CD, Dr. Gilbert M. Goldman, and the guardian *ad litem* and upon review of Petitioner's 1 (the medical records of the child) and Petitioner's 2 (the report of the guardian *ad litem*) and the other exhibits, and upon all the affirmations supporting the Order to Show Cause which include those of Dr. Alan R. Fleischman, Dr. John Lantos, and Nancy Dubler, LLB, it is Ordered that

Petitioner's application is granted, to the extent that CD, mother of AB, is granted authority to consent to the removal of mechanical ventilation for AB, a minor child; and it is further

ORDERED that New York City Health & Hospital Corporation honor CD's wishes as mother and natural guardian to stop mechanical ventilation for her child AB.

This constitutes the written decision and order of the court.

Endnotes

- The Court issued an oral decision and order on the record prior to the release of this decision which is incorporated herein. Given the tragic circumstances, this Court did not want to prolong AB's family's agony by waiting until the written decision was finalized.
- 2. The Court acknowledges the valuable assistance of Court Attorney Donna Albano.
- 3. For the purposes of this proceeding, the Court granted petitioner's application to use the name "CD" and "AB" for her child.
- The purpose of the new law is to "explicitly provide guardians of mentally retarded persons with the authority to make health care decisions for such persons, including decisions regarding life-sustaining treatment under certain circumstances." H.R. S4622B, New York State Senate Introducer's Memorandum in Support of S4622B. As was observed: "Recent case law has disallowed that authority [of guardians], particularly in the area of life-sustaining decisions. . . . [The] lack of clear authority regarding provision of life-sustaining treatment has, on occasion, obstructed the guardian's role or, worse, created catastrophic obstacles to relieving desperate health care emergencies." Id. This new law "provides a carefully controlled legal and medical process for withholding or withdrawing life-sustaining treatment while safeguarding the rights, liberties and best interests of persons with mental retardation." H.R. A8466-b, New York Assembly Memorandum in Support of Legislation A8466-b. As was recognized on the floor during the vote for the new law: [S]imilar legislation is also urgently needed dealing with health care decision-making for the rest of New Yorkers ...". Assembly Debate Transcripts, 2002 Chapter 500, page 103, 108, (June 20,2002) (Statement of Assemblyman Richard Gottfried).
- 5. At the outset of this analysis, it is important to distinguish between the condition of persistent vegetative state and mental retardation. At the April 9, 2003 hearing before this Court, Dr. Goldstein testified that someone in a persistent vegetative state is at the "very far end of a spectrum" of neurological functioning. At the opposite end of this spectrum is a fully functioning, conscious person. He further stated that mental retardation "is probably closer to normal function" than a person in a PVS, because a retarded person has consciousness and "is capable of interacting with the environment."
- 6. The withdrawal of artificial nutrition is not an issue in this case. SCPA 1750-b (2)(b)(iv).
- 7. Section 1750-b (4)(b)(iii), discussing the issues of withdrawal of hydration and nutrition, does not apply in this case.
- The remainder of this statute does not apply to this case because it concerns notice to the patient and how to handle objections to the withdrawal of treatment, of which, there are none.
- The Council on Ethical and Judicial Affairs (CEJA) is charged with maintaining and updating the AMA Code of Medical Ethics, which is widely considered the most comprehensive ethics guide for physicians.
- 10. Although AB is three and a half years of age, not a newborn, this Ethical Opinion is persuasive because she, like a newborn, was never competent to express her opinion about life sustaining treatments. Dr. Goldman has noted that this Ethical Opinion is appropriately applied in this case.
- Indeed, parents have the right to sign "Do Not Rescuciate Orders" for their minor children who are, as here, permanently unconscious. See Public Health Law §2967(3).
- 12. A 1989 survey of case law throughout the United States concerning the withdrawal of life support for children who are in a persistent vegetative state found numerous cases where Courts permitted the withdrawal of life support for such children and none where a Court ordered the continuation of ventilator support. Lantos, J.D., et al, *The Linares Affair*, 17 Law, Medicine and Health Care, 17:308 (1989).



Legal Manual for New York Physicians Available

The Legal Manual for New York Physicians, published by the NYSBA, became available in May 2003. The Manual—which is the only book that focuses on New York health laws—is the result of a collaboration between the Health Law Section and the Medical Society of the State of New York. It is designed to give physicians and their staffs a fundamental understanding of many of the legal and regulatory requirements that affect their practice. It will also be a valuable reference for health law attorneys.

Long Term Care Committee Created

A Committee on Long Term Care was recently created, and is already quite active. The Committee will serve as a forum within the Health Law Section for health law attorneys who advise providers, payors and consumers in the long term care industry. The first Chair of the new Committee is Ari Markenson, an attorney with Epstein Becker & Green, P.C. and a frequent contributor of articles to the *Journal*. As Ari explained, "One of my goals for the committee is to create cooperative/liaison relationships between the committee and DOH regulators, NYS trade associations and federal regulators in long term care." At a recent meeting, the Committee members agreed to produce a Special Edition of the *Journal* in Winter 2004, which will focus on Long Term Care issues in New York.

Health Law Fundamentals Program a Success

In May, the Section presented in four cities a program on Fundamentals of New York Health Law. The program, planned by Lynn Stansel, Esq. of Montefiore Medical Center, was both well-attended and well-received. The topics covered included an overview of health care delivery systems, health care reimbursement, regulation of health care systems, labor issues in health care, HIPAA—medical information security, government enforcement actions, malpractice and insurance claims, and current issues in ethics. Audiotapes are available from NYSBA.



Section Chair Interviewed About SARS

Before his tenure ended in June, Section Chair Salvatore Russo appeared on MSNBC, on behalf of the Health Law Section, to discuss legal issues relating to SARS—particularly the prospect of compulsory treatment.

Upcoming Programs on Representing Health Law Professionals

In October, the Section and the NYSBA CLE Department will offer half-day seminars on "Representing Physician, Nurses and Allied Health Care Professionals in Disciplinary Proceedings." The seminars will be offered in Melville, Long Island; New York City; Albany; and Rochester. Hermes Fernandez of Bond Schoeneck & King, and Kenneth Larywon of Martin Clearwater & Bell are co-chairs. For more information, see the NYSBA Web site.

An Index to Feature Articles in the NYSBA *Health Law Journal*: 1996-2003

This comprehensive index, the first to appear in the *Journal*, is offered to help our readers identify articles from past editions that may be of interest to them. But, admittedly, it is also offered to showcase the formidable content of the *Journal*. As this index shows, for the past eight years the *Journal* has offered its readers informative, timely and accessible articles, by accomplished and prominent authors, on a broad range of health law topics—The Editors.

Journal back issues are available free of charge to Section members online at www.nysba.org/health. (Click on the "Member Materials" tab to access issues). To obtain your user name and password, e-mail webmaster@nysba.org or call (518) 463-3200. Nonmembers may purchase back issues online at www.nysba.org/health by clicking on the "Publications" tab.

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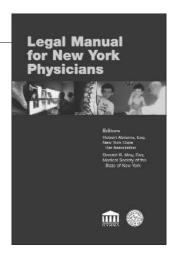
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