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Inside

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THE HEALTH LAW SECTION
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Cover artwork: *Autumn Landscape* by Vincent Van Gogh (1885)

A Message from the Chair

As of July, I have had the honor, following Lynn Stansel of Montefiore Medical Center, of assuming the leadership of the Health Law Section of the State Bar Association. The Section has had over the previous years a very distinguished history, functioning as a forum for the exchange of legal and policy information among many communities of attorneys in New York State. Our constituency ranges from attorneys affiliated with health care consumers to health care providers to public health authorities, from those who represent physicians, hospitals, mental health facilities and nursing homes to those who represent pharmaceutical, biotechnology and managed care companies. Our work as a Section, in short, encompasses the full range of legal, economic and policy issues that attend health care today, which represents about one-seventh of the national economy and even more of our State's economic activity.

Our Section, under Lynn's able leadership in 2005-2006, took on the issues of State Medicaid funding and appeals, in our first Annual Fall Retreat at The Sagamore Hotel on Lake George. Our Annual Meeting program, in January 2006, considered the public health law and other implications of our nation's inadequate, halting response to Hurricane Katrina, and debated the meaning of that catastrophe for our own region, particularly our vulnerability to terrorist strikes. These are exactly the kind of programs on which our Section is poised to act as a forum and classroom for attorneys from all over New York State who care about vital issues that face—of course—our clients, but that we as citizens also face We will continue this high level of public discussion in our Fall 2006 meeting, which will concentrate on the necessity of downsizing tertiary care facilities, in an age in which neither the state nor federal government has the resources to support institutions that are more costly than their outpatient alternatives. The loss of community jobs, the displacement of workers, providers and patients—these are issues we all shall soon face in New York State, as elsewhere. We have only in our State to remember the bitter and prolonged public agony over the closure of Sydenham Hospital in the Koch mayoral administration in New York City to know that this process will not be easy and likely will not be accomplished without the law being used as a tool by all sides to defend their economic and moral interests.

Our Section has a proud recent history of leadership on other critical issues as well. One of the Section activities of which we are all understandably proud has been, under the able editorship of Robert Swidler, the regular publication of this *Journal*. We are all deeply grateful to Robert for his sustained efforts in making available in this format a resource that no other state bar health law section offers: publication of pertinent articles, scholarly but with a practical bent, that analyze the most controversial issues we encounter in our daily practices.

Another issue on which our Section has labored for years has been in support of the passage of the Family Health Care Decisions Act—a proposed law that has languished in our State Legislature for over a decade. Our state, unlike many other states that tend to lead—not follow—the development of modern law, has failed, in statutory and common law, to define exactly how and in what circumstances a hierarchy of family members will be allowed to make medical decisions for incapacitated patients. In many twists and turns of the Albany legislative process our Section has been in the halls of the Assembly and Senate, seeking legal clarity for providers and personal comfort for patients and their families, all of whom are disfavored by the legal confusion in this area.

"Our state, unlike many other states that tend to lead—not follow—the development of modern law, has failed, in statutory and common law, to define exactly how and in what circumstances a hierarchy of family members will be allowed to make medical decisions for incapacitated patients."

In this issue of the *Journal*, Carl Coleman of Seton Hall Law School, who has been a Section and statewide leader on this issue for many years, offers his insights on where we stand now in this latest attempt to get the Act passed.

I want to thank all members of the Section, and especially Lynn Stansel, for the help and support that they already have generously offered to me and to the other new officers of the Section for our 2006-2007 activities. All Section members should feel free to call on me or any of our officers with any concerns or suggestions, and we look forward to this program year, our Fall retreat, January Annual Meeting, CLE programs, Committee activities and this *Journal* itself, and to the colleagueship that we have come so to value as Section members.

Mark Barnes

In the New York State Courts

By Leonard M. Rosenberg

Court Holds That Expense Reimbursement Provision Contained in Judicially Disapproved Contract for Sale of Hospital's Assets Is Unreasonable and Unenforceable Under New York Not-For-Profit Corporation Law § 511

64th Associates, L.L.C. v. Manhattan Eye, Ear, & Throat Hospital, 11 Misc. 3d 1067A, 816 N.Y.S.2d 701, 2006 WL 722151 (Sup. Ct., N.Y. Co. 2006). Plaintiff 64th Associates, L.L.C. ("Plaintiff") sued Manhattan Eye, Ear, & Throat Hospital (the "Hospital") for breach of a contract by which the Hospital agreed to sell substantially all of its assets, including three buildings located on the Eastside of Manhattan, to Memorial Sloan-Kettering Cancer Center and to Plaintiff. Such a sale requires judicial approval pursuant to Section 511 of the New York Not-For-Profit Corporation Law ("NPCL § 511"). The contract provided that if the sale did not occur due to lack of required approvals, the purchaser had the right to the return of its down payment with accrued interest, plus "be reimbursed for its out-of-pocket costs associated with this transaction up to a maximum of" $1.6 million. After the Court denied the Hospital's Section 511 application to sell substantially all of its assets, Plaintiff sued to recover $1 million in out-of-pocket expenses (as well as $2 million in damages) under the expense reimbursement provision.

The trial court held that under NPCL § 511, the judicial disapproval of the sale rendered the entire agreement void, including any expense reimbursement provisions. The Appellate Division affirmed. The Court of Appeals reversed the Appellate Division, and held that judicial disapproval did not render the entire contract void; rather, the Court must review separately any reimbursement or similar provision under the NPCL § 511 standard to determine whether the provision is fair, reasonable and in furtherance of the not-for-profit's purpose. The Court then remanded the

case back to the trial court for a determination on that issue.

NPCL § 511 requires that the terms of a sale are fair and reasonable to the corporation. The Court ruled that the expense reimbursement provision was not fair and reasonable for several reasons. First, the reimbursement clause shifted all risk to the Hospital in the event of judicial disapproval. Second, the sale itself was motivated by the Hospital's precarious financial condition, and assumption of a $1.6 million debt after disapproval could have rendered the Hospital insolvent or nearly so. Third, the risk-free reimbursement clause was particularly inappropriate given that the sale price was $5 million less than the lowest appraised value of the real estate. Fourth, nothing in the record indicated that the Hospital's Board of Trustees was aware of the $1.6 million reimbursement clause at the time it voted to approve the sale. Fifth, because the record indicated that the reimbursement clause was, for plaintiffs, an "essential element" of the deal, the Court held that the clause was designed to facilitate "an improper change in the corporate purpose" (i.e., impliedly terminating the Hospital's existence), in violation of NPCL § 511. Accordingly, the Court ruled that the expense reimbursement clause was invalid, and dismissed the complaint.

Second Circuit Holds That PAIMI Grants Access to State Hospitals' Peer Review Records to Connecticut's Office of Protection and Advocacy for Persons with Disabilities

Protection & Advocacy for Persons with Disabilities v. Mental Health & Addiction Services, 448 F.3d 119 (2d Cir. 2006). Enacted in 1986, the Protection and Advocacy for Individuals with Mental Illness Act ("PAIMI") "provides federal funds for states . . . that have qualifying P&A systems that monitor the care of individuals with disabilities and mental illness in facilities providing care and treatment." Connecticut's Office of Protection and Advocacy for Person with Disabilities ("OPA") is authorized to "represent and investigate suspected abuse of individuals with disabilities or mental illness in facilities in Connecticut." [Ed. Note: The OPA functions similarly to the New York State Commission on Quality of Care for the Mentally Disabled; *see* New York's Mental Hygiene Law §§ 45.09 and 45.10].

This action involves the deaths of two mentally ill and/or disabled patients at two different Connecticut hospitals. OPA opened investigations into both incidents and sought all of the hospitals' records relating to the patients' care. The Connecticut Department of Mental Health and Addiction Services (the "Department") is the administrator of the two hospitals. The Department turned over all records relating to the patients' care except for their peer review records, which were withheld on the ground that peer review documents are privileged under Connecticut law. OPA then commenced this action seeking a declaration, under PAIMI, that it is entitled to the peer review records regarding the patients. The District Court for the District of Connecticut held that OPA was entitled to the peer review records, and granted an injunction requiring the Department to provide OPA with the records. The Department appealed to the Second Circuit.

The Second Circuit affirmed the rulings of the District Court. PAIMI provides that a P&A system such as OPA shall have access to "all records of . . . any individual" whose records it has permission or statutory authority to obtain. PAIMI provides that the term "records" includes "reports prepared by any staff of a facility

rendering care and treatment." The Second Circuit joined the Third and Tenth Circuits in finding that PAIMI's reference to "all records" unambiguously includes peer review records. Moreover, the Court found that PAIMI did not conflict with Connecticut law protecting peer review records from civil discovery, as the records are only protected "in the context of a civil action against a health care provider in certain circumstances." Notably, "OPA sought the peer review records as part of a statutorily-authorized investigation, not a civil action arising out of the subject of the peer review proceedings." Although the Court found no actual conflict between PAIMI and state law, to the extent a conflict does exist, the Court found that PAIMI governs.

Federal Court Dismisses Physician's Discrimination Suit, Finding That Voluntary Attending Physician with Staff Privileges at Hospital Is Not an Employee Under Title VII or New York State Human Rights Law

Salamon v. Our Lady of Victory Hospital, No. 99-CV-0048E, 2006 WL 625839, at *1 (W.D.N.Y. Mar. 10, 2006). Plaintiff, a private attending physician with medical staff privileges at defendant Hospital, sued Our Lady of Victory Hospital (the "Hospital") for sexual harassment and discrimination. The physician alleged that the Hospital violated both Title VII and New York State Human Rights Law ("NYHRL") by initiating peer review and disciplinary proceedings against her. She claimed that the Hospital's actions substantially damaged her reputation and career, and effectively eliminated her existing prospective patient referral sources.

In reaching its decision to grant the Hospital's motion for summary judgment on the ground that the physician was not an employee of the Hospital, the Court noted that in *Community for Creative Non-Violence v. Reid*, 490 U.S. 730 (1989), the Supreme Court has instructed courts to rely on principles of common law agency to determine who is an "employee" when construing Federal employment discrimination statutes. Reid identified thirteen relevant factors to assess whether a person is an employee, the most significant of which is the hiring party's right to control the manner and means by which the work is accomplished. The Court applied the thirteen Reid factors to determine that the minimal degree of control the Hospital had over the physician's work was insufficient to demonstrate the existence of an employment relationship.

The Court also held that the Hospital had no right to control the "manner and means" by which the plaintiff performed her gastroenterology duties on her patients nor did it have the right to control the plaintiff's diagnoses or how she reached them. Furthermore, the Court noted that the remaining Reid factors were either irrelevant or they weighed in favor of non-employment. For example, the Court found that the Hospital's "on call" requirement was merely a by-product of being a physician rather than an indicia of employment. Accordingly, the Court reasoned that a physician's control over her individual hours, albeit within the confines of a hospital's hours of operation, also favored a finding of non-employment. In addition, the physician was neither paid by the Hospital, nor did she receive any benefits or vacation days. Lastly, the physician was required to provide her own professional liability insurance and was free to seek referrals from non-hospital doctors.

Although the plaintiff contended that the Hospital exerted sufficient control over her through its peer review process, operating policies, procedures and protocols, she admitted that she maintained professional independence with respect to diagnosing and treating her patients. Moreover, the Court determined that she retained her own patients and was only occasionally obligated to treat the Hospital's patients. By plaintiff's own admission, she diagnosed and treated her patients based on her independent professional judgment. Thus, the Court determined that the Hospital did not have "the right to control" her practice.

The Court also rejected the plaintiff's argument that the Hospital's mandatory guidelines required her to abide by its rules at the expense of her patients' best interests, stating that "[i]f such were true, plaintiff would be in violation of her professional duties and obligations to her patients and, as such, is opening herself up to malpractice and negligence suits," because no physician can permit an outside agency to control the professional medical treatment of his or her patient. Thus, the Court held that the Hospital's regulations were implemented "to maintain standards of patient care, to keep appropriate records, and to follow established procedures," not to control the manner and means by which the plaintiff conducted her practice.

In the alternative, plaintiff claimed that if the Court found she was not an employee of the Hospital, it was nonetheless liable for interfering with her future employment opportunities. The Court rejected the plaintiff's alternative theory of "indirect" liability under Title VII, holding that regardless of the plaintiff's employment status at the hospital, she nonetheless lacked the requisite employment relationship with her patients that is necessary to support such a claim. Patients are not the employers of their physicians because they do not exert any control over their physicians. Instead, physicians control the relationship as well as the manner and terms under which it is carried out. Patients are paying for a service, not serving as an employer. Plaintiff did not allege that the Hospital was under an obligation to refer patients to her, but merely claimed that referrals from the Hospital stopped. As such, plaintiff had no claim under Title VII and the NYHRL.

Court Holds That Association of Psychiatrists Does Not Have Standing to Challenge Regulations Promulgated by Department of Education

New York State Psychiatric Association, Inc. v. Mills, 29 A.D.3d 1058, 814 N.Y.S.2d 382 (3d Dep't 2006). An Asssociation of psychiatrists and a

confederation of groups that provide facilities for psychoanalytic education (the "Association") commenced an Article 78 proceeding challenging regulations promulgated by the Department of Education which set forth licensing requirements for psychoanalysts. The Supreme Court, Albany County, dismissed the petition for lack of standing, and the Appellate Division affirmed.

The Appellate Division found that "[t]o establish standing, an association or organizational group, such as petitioners, must show that at least one of its members would have standing to sue, that it is representative of the organizational purposes it asserts and that the case would not require the participation of individual members." The Court listed the first requirement of the associational standing test as requiring a petitioner to demonstrate "an injury-in-fact to one of its members and that the injury falls within the zone of interests or concerns sought to be promoted or protected by the statutory provision under which the agency has acted."

The Association claimed that the challenged regulations dilute the training necessary to be qualified as a psychoanalyst, resulting in detriment to the public and a loss of confidence in the profession of psychoanalysis. The Court found that this purported "injury" to the public was speculative, and that any injury to the Association's members, i.e., harm to their economic interests, was tenuous. Moreover, the Court found the intended beneficiaries of the legislation are mental health care patients, not the Association's members, and therefore any injury to the members does not fall within the regulation's zone of interest.

Court Holds Women's Health and Wellness Act (WHWA) Does Not Violate Free Exercise Provisions of State and Federal Constitutions

Catholic Charities of the Diocese of Albany et al. v. Serio, 28 A.D.3d 115, 808 N.Y.S.2d 447 (3d Dep't 2006). In Catholic Charities, plaintiffs are religious organizations that do not qualify as "religious employers" under a narrow statutory exemption of the Women's Health and Wellness Act (WHWA). The WHWA requires employers who provide their employees with group insurance coverage for prescriptions to include prescription contraceptives in that coverage. Plaintiffs appealed from an order of the Supreme Court, Albany County, granting defendant's motion for summary judgment dismissing the complaint.

Although plaintiffs admitted they did not satisfy the exemption requirements of the statute, they alleged that this "contraceptive mandate" was contrary to their religious tenets and therefore sought declaratory and injunctive relief, and moved for a preliminary injunction prohibiting enforcement of the WHWA. Plaintiffs' constitutional challenges to the WHWA all fell within the religion clauses of the United States and New York Constitutions.

First, the Court noted that the WHWA and its provisions were applicable to every group health insurance policy in New York, and was generally applicable, as it did not selectively impose any burden on conduct motivated by religious belief. Second, the WHWA as a whole was facially neutral. Its object—to increase women's access to health care—did not target religious practices. Therefore, although it incidentally imposed a burden on plaintiffs' free exercise rights, the Court found that it did not violate the Free Exercise Clause of the First Amendment.

Plaintiffs contended that the standard of review to be employed for state free exercise claims should be a "compelling interest" test. However, following precedent set forth by the Court of Appeals, the Court concluded that the defendant need not show a "compelling" state interest. Rather, the Court applied a balancing test to plaintiffs' state constitutional free exercise claims. Applying this test, the Court held that the WHWA did not violate the New York Constitution, concluding that the balance tipped away from the plaintiffs' right to free exercise and in favor of the WHWA.

The Court also rejected plaintiffs' assertions that they would be perceived as endorsing contraceptives, particularly in light of the context in which plaintiffs were required to provide contraceptive coverage. Instead, the Court stated that plaintiffs would be perceived as nothing more than complying under protest with a statutory mandate generally applicable to all employers who offered group health insurance coverage to its employees.

Plaintiffs also asserted challenges to the contraceptive coverage mandate under the Establishment Clause of the First Amendment. The Court determined that these claims were also without merit because the narrow exemption set forth in the statute did not distinguish between religions or sects.

In the Court's final analysis, it noted that while the contraceptive coverage mandate did burden plaintiffs' right to freely exercise their religious beliefs, a review of the WHWA and its exemption for "religious employers" led the Court to conclude that the WHWA did not offend any constitutional or statutory provisions invoked by the plaintiffs.

Court Denies Physician's Petition Seeking to Compel OPMC to Produce Its Investigative File

DiBlasio v. Novello, 28 A.D.3d 339, 814 N.Y.S.2d 51 (1st Dep't 2006). A physician defending a professional misconduct proceeding brought by the Department of Health's Office of Professional Mental Conduct ("OPMC") brought an Article 78 proceeding seeking to compel OPMC to comply with an administrative hearing officer's ("AHO") order to produce its investigative file for *in camera* review. Petitioner claimed that the investigative file contained exculpatory evidence. The Supreme Court, New York County, granted *mandamus* relief for the physician, and OPMC appealed.

The Appellate Division reversed the trial court and denied the physi-

cian *mandamus* relief. The Court held that the physician did not exhaust his available administrative remedies, and was therefore not permitted to bring an action in a court of law. Specifically, the Court found that "it is undisputed that even if petitioner had been required to go forward with the hearing without the *in camera* review, and the Committee had ultimately sustained findings of professional misconduct against him, he still would have been afforded the opportunity to seek administrative and judicial review of both the Committee's determination, and his argument that OPMC's refusal to comply with the AHO's order [to disclose its investigative file] deprived him of a fair hearing." The Court concluded, "[t]hus, petitioner has an adequate remedy in his right to institute an article 78 proceeding following a final agency determination."

Moreover, the Court found that even if the exhaustion requirement did not apply, the petitioner failed to establish another prerequisite to *mandamus* relief, stating "[f]undamentally, *mandamus* is an extraordinary remedy, available, as against an administrative officer, only to compel the performance of a duty enjoined by law." Because the physician did not establish a "clear legal right" to the relief requested, he was not entitled to *mandamus* relief. The trial court relied on the AHO's statutory authority to rule on motions to compel disclosure, to conduct hearings in an impartial manner, and to punish a party who unreasonably fails to comply with a disclosure order in finding that petitioner had a "clear legal right" to the *mandamus* relief.

The Appellate Division, in reversing the trial court, pointed to the Department of Health ("DOH") regulations [10 N.Y.C.R.R. § 51.8(a)] which expressly state that "[e]xcept as provided in subdivision (b) of this section or as otherwise agreed to by all parties, there shall be no disclosure" in these disciplinary proceedings. That same regulation also provides that "[a] hearing officer may not require disclosure." Subsection (b) of the regulation permits "limited forms of discovery in cases where OPMC is seeking revocation of a physician's license (i.e., witnesses' names, a list and copies of documents intended to be introduced at the hearing and a brief description of other types of evidence)"; however, the Court noted that it does not mention exculpatory evidence.

Petitioner also relied on another exception in the regulations to the general prohibition on disclosure, which states, "[w]hen the parties agree to any form of disclosure the hearing officer shall ensure that all parties proceed in accordance with the agreement of the parties" [10 N.Y.C.R.R. § 51.8[a]]. Petitioner argued that the statement made by OPMC's counsel that "[o]bviously, we'll endeavor to comply" with the AHO order constitutes an enforceable agreement under the DOH regulations. However, the Appellate Division found that this statement did not constitute a voluntary agreement because it "was made under the perceived compulsion of the AHO." Moreover, the Court found that OPMC later rescinded its statement and clearly opposed the AHO's order, thereby withdrawing any agreement that may have existed.

Finally, petitioner argued that a 1997 policy memo announcing DOH's policy of disclosing exculpatory material to an accused is evidence of an enforceable agreement to disclose such evidence. The Court found that the "DOH policy is only a 'voluntary' internal policy that is 'not required by statute, regulation or case law.' An agreement to disclose between the 'parties' requires assent by both petitioner and respondents, and such mutual assent is lacking here with respect to the disclosure ordered." The Court then held, "[i]n light of the absence of any statute or regulation expressly authorizing the AHO to order disclosure or *in camera* review of exculpatory evidence, and the existence of a general regulatory prohibition against ordering disclosure, petitioner has failed to demonstrate a 'clear legal right' to enforcement of the AHO's order and *mandamus* relief should not have been granted."

Prior *Cy Pres* Proceeding Relevant in Determining Whether to Grant Charity's Subsequent Petition for *Cy Pres* Relief

In re Estate of Othmer, 12 Misc. 3d 319, 815 N.Y.S.2d 444 (N.Y. Sur. 2006). The Surrogate's Court, Kings County, recently held that, where a charity to which the Court granted prior relief under the *cy pres* doctrine, pursuant to Estates Powers and Trusts Law § 8 1.1(c), seeks additional *cy pres* relief, the doctrine of collateral estoppel may be applied for two parts of the three part test utilized in determining such petitions. Before applying the doctrine of *cy pres*, courts require a charity to meet three conditions: (1) that the gift or trust be charitable in nature; (2) that the donor must have demonstrated a general, rather than a specific, charitable intent; and (3) that circumstances have changed subsequent to the gift that render literal compliance with the restriction impossible or impracticable.

In *Othmer*, the Long Island College Hospital (the "Hospital") filed a *cy pres* petition for the release of funds from the Othmer Endowment Fund, a restricted fund consisting of bequests made to the Hospital under the Wills of Dr. Donald F. Othmer and his wife, Mildred Topp Othmer. Prior to this petition, the Hospital brought a successful *cy pres* petition by which the Kings County Surrogate's Court modified the restrictions on the Othmers' bequests to enable the Hospital to secure new financing for strategic capital projects and working capital and to acquire and renovate its facilities. In granting the initial petition, the Court found it compelling that dramatic changes in the health care industry, which negatively impacted the financial status of New York hospitals in general, left the Hospital in dire financial straits.

When reviewing the subsequent petition, the Kings County Surrogate's Court applied the doctrine of collateral estoppel in determining that the Othmers' bequests were charitable in nature and that the Othmers demonstrated a general, rather than a specific, charitable intent, both of which were

established in the prior proceeding. However, the Court found that the Hospital could not rely upon the prior decision in establishing the third part of the test, that the specific charitable purposes are no longer capable of being performed. Rather, the Court determined that public policy requires a showing that events since the prior decision have made the original plan, approved in the prior proceeding, ineffectual in achieving the goal of saving the Hospital. The Kings County Surrogate's Court granted the subsequent petition finding that, since the approval of the initial petition, the Hospital had been further damaged by the economic forces driving that petition.

Health Care Decisions Act for Persons with Mental Retardation Grants Full Health Care Decision-Making Authority to Existing Guardians

In the *Matter of M.B.*, 6 N.Y.3d 437, 846 N.E.2d 794, 813 N.Y.S.2d 349 (2006). In *Matter of M.B.*, Mental Hygiene Legal Service ("MHLS") brought an action on behalf of a mentally retarded person seeking a determination that M.B.'s guardian did not have the authority to withhold or withdraw life-sustaining treatment. M.B., a person with Down's Syndrome, lived with his mother until his brother was appointed as guardian under Article 17-A of the Surrogate's Court Procedure Act. M.B.'s condition steadily declined to the point that he was placed on a respirator with a nasal gastric tube. M.B.'s physicians concluded that his illness was terminal, his condition irreversible, and that the life-sustaining treatment currently being provided imposed a substantial burden on him. Based on the physician's opinions, M.B.'s guardian asked that the respirator be disconnected.

A guardian of a mentally retarded person has no common law authority to end life-sustaining treatment. The Health Care Decisions Act for Persons with Mental Retardation ("HCDA"), which became effective after M.B.'s brother was appointed as guardian, grants that authority, subject to various procedural requirements and protections.

MHLS argued that the HCDA did not retroactively authorize guardians to make decisions involving cessation of life-sustaining treatment for mentally retarded persons. Rather, they argued that guardians appointed prior to the effective date of the HCDA had to obtain, through a separate judicial proceeding, an amended guardianship order that specifically recognizes his or her authority as encompassing the power to end life-sustaining treatment.

The Court disagreed, and held that such proceedings were not required. The Court noted that the Legislature did not expressly authorize existing guardians to petition for enlargement of their power. Instead, the HCDA states that all guardians have the authority to make any and all health care decisions unless they are specifically prohibited by the Court.

NOTE: This decision is the Editor's Selected Court Decision and is reprinted in this edition on p. 60.

Fair Debt Collection Practices Act Does Not Apply to Debt Collector When Debtor Is Not in Default

Healy v. Jzanus Ltd., No. 02 CV 1061, 2006 WL 898067 (E.D.N.Y. Apr. 4, 2006). In *Healy*, the plaintiff received medical services at Maimonides Medical Center (the "Hospital"). Plaintiff alleged that Jzanus Ltd. ("Jzanus") violated the Fair Debt Collection Practices Act, 15 U.S.C. § 1692 ("FDCPA") when it sent plaintiff a letter seeking information to assist in securing Medicaid coverage for the cost of her treatment at the Hospital. Jzanus is a corporation, licensed by New York City as a debt collector, that assists hospitals in obtaining payments from insurers to cover the costs of patients' treatment. It also provides debt collection services.

Plaintiff had signed a document by which she agreed to "pay the entire remaining balance immediately upon notification by the Medical Center in the event that these services are not paid in whole or in part by the insurance carrier or other third-party payor." Six months after she was discharged, plaintiff received a letter from Jzanus. The letter stated that a balance of $12,000 was owed for services. The letter stated that "our office represents the above-mentioned hospital in pursuit of Medicaid coverage for the above patient. In order to complete this Medicaid application, additional information is necessary. We need your cooperation in this matter. As the City of New York imposes time limits on these applications, it is essential that you contact us immediately." The letter also contained a validation notice that is required by the FDCPA when a debt collector initially communicates with a debtor. The notice states, in part: "This is an attempt to collect a debt, and any information obtained will be used for that purpose. This communication is from a debt collector." Medicaid covered all but $1,272 of the patient's hospital bill. Thereafter, the patient sued.

The Court noted that the FDCPA is a strict liability statute, and the consumer need not prove intentional conduct to recover damages. The FDCPA requires that a validation notice must be included in a debt collection letter to provide the consumer information necessary to challenge the debt allegedly owed. The validation notice must include the amount of the debt, the name of the creditor, a statement that the debt's validity would be assumed unless disputed within 30 days, and an offer to verify the debt and provide the name and address of the original creditor, if the consumer so requests.

The Second Circuit has held that the FDCPA applies when an entity pursuing any outstanding debt is classified as a debt collector and the debt in question is in default. Jzanus alleged that the FDCPA should not apply since the debt in question was not in default.

The Court held that the plaintiff's debt could not be considered to have been in default for purposes of the FDCPA at the time Jzanus sent the letter. Even though the letter contained

the FDCPA validation notice, the letter sent by Jzanus only sought information from plaintiff to pursue Medicaid insurance on her behalf. It did not seek to collect the debt. In addition, the Court looked at the agreement between the Hospital and Jzanus, and noted that Jzanus was not hired to collect debts that were in default. Instead, Jzanus was hired to help the Hospital identify Medicaid-eligible patients. Thus, since the Hospital clearly retained Jzanus for the purpose of seeking Medicaid reimbursement on plaintiff's behalf, Jzanus' self-identification as a debt collector in its letter did not render plaintiff's debt in default.

Federal Court Denies Motion to Dismiss Antitrust Complaint by Radiologist and Imaging Service Provider Against NYU School of Medicine and NYU Radiologist

New York Medscan LLC v. New York University School of Medicine et al., 430 F. Supp. 2d 140 (S.D.N.Y 2006). New York Medscan LLC ("Medscan"), a provider of diagnostic imaging facilities, and Karolyn Kerr, M.D., a radiologist ("Dr. Kerr") ("Plaintiffs") filed an antitrust lawsuit in the U.S. District Court for the Southern District of New York. The suit alleged that CareCore National LLC ("CareCore") a radiology benefit management company, together with Dr. Litt, CareCore's chairman, and also a vice president at New York University School of Medicine ("NYU"), and NYU ("Defendants") engaged in an unlawful group boycott and unreasonable restraint of trade in violation of federal antitrust laws.

In 2002, NYU entered into a three-year agreement with Medscan whereby Medscan would provide office facilities, equipment, and services for NYU radiologists for a PET/CT outpatient scanning practice at Medscan's premises. Medscan became a CareCore-approved facility, which approval allowed Medscan to provide PET/CT scans to patients covered by CareCore plans. In 2004, Medscan entered into a practice management agreement with Dr. Kerr, then a CareCore-approved radiologist. That agreement was to commence on expiration of Medscan's agreement with NYU.

The complaint alleged that during contract renewal negotiations, Dr. Litt advised Medscan that if it did not agree to NYU's renewal terms, then Medscan and Dr. Kerr would lose their CareCore approvals. Medscan did not agree, the NYU agreement expired, and CareCore terminated Medscan and Dr. Litt's approved provider status. Thereafter, CareCore refused to pre-certify or pay for services provided by Medscan or Dr. Kerr. CareCore-covered patients were redirected to an NYU facility that used different scanning devices than those provided by Medscan.

Medscan sued, alleging that, in violation of the Sherman and Clayton Antitrust Acts, Defendants engaged in a course of dealing that suppressed competition in the market for PET/CT scanning services. The Sherman Act declares illegal every contract, combination . . . or conspiracy, in restraint of trade or commerce. The Sherman Act also prohibits monopolies and attempts, combinations, or conspiracies to monopolize trade or commerce. Section 4 of the Clayton Act provides a private right of action, with the recovery of treble damages, to any person who has been injured in his business or property by reason of anything forbidden in the antitrust laws.

The CareCore Defendants settled with Plaintiffs, and the remaining Defendants filed a motion to dismiss the complaint. The motion asserted that Plaintiffs did not have antitrust standing and did not allege an antitrust injury. To survive a motion to dismiss, an antitrust complaint must adequately (1) define the relevant market, (2) allege an antitrust injury, and (3) allege conduct in violation of the antitrust laws.

The Court held that Medscan did allege an antitrust injury. Specifically, Medscan alleged that Defendants' conduct caused reduced competition in the provision of PET/CT services, reduced competition in the price of these services, and fixed pricing for all CareCore-approved providers, which affected a dominant share of the New York City market. The Court noted that these are the types of injuries that the antitrust laws were designed to prevent. The Court also noted that Medscan alleged that Defendants' conduct caused the quality of services to decrease, and that a decline in quality is also considered an antitrust injury.

The Court further noted that all of the parties are competitors of one another, and Plaintiffs had defined the relevant market as the provision of PET/CT services, a market in which the parties participate either by owning or operating a PET/CT facility or selling PET/CT services to health plans.

The Court, however, pointed out that its ruling was based solely on standards applicable to a motion to dismiss, and whether Plaintiffs would be able to survive a motion for summary judgment is another matter. The Court noted that the federal courts repeatedly reject the antitrust claims of disappointed physician competitors who are excluded from exclusive contracting arrangements, denied participation in managed care arrangements, or otherwise are excluded from business opportunities.

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In the New York State Legislature

By James W. Lytle

2006 State Legislative Roundup

The summer column for this space is almost always devoted to a wrap-up of a legislative session, which is generally described as landmark, tumultuous, disappointing, contentious or routine—or, as in 2006, all of the above.

The typically frenzied close of the legislative session was focused principally on resolving most of the issues that had remained undecided during the budget-making process. Many key health-related components of the State budget had been passed by the Legislature, vetoed by Governor Pataki, enacted through overrides of the Governor's vetoes and threatened not to be implemented by the Governor. By the recess of the Legislature in late June, the Governor and the Legislature reached agreement on most of the disputed aspects of the State budget and either passed or reached agreements on many other key health issues, including the long-debated mental health parity legislation (known as "Timothy's Law") and comprehensive legislation to establish a Medicaid Inspector General and new tools to investigate and enforce Medicaid fraud and abuse. On the other hand, the Legislature was unable to reach an agreement on the Fair Share for Health Care Act (requiring large employers to bear a portion of the cost of health insurance for employees) or the Family Health Care Decisions Act.

Budget issues: In April, the Legislature enacted a $112.4 billion budget, representing a $1.8 billion increase over the budget proposed by the Governor. The Governor vetoed $2.9 billion of the Legislature's restorations of proposed cuts and new spending, claiming that some of the Legislature's tinkering with the proposed budget was unconstitutional. As a result, after the Legislature overrode those vetoes, the Governor

refused, on constitutional grounds, to recognize the validity of many of the spending items restored or added by the Legislature. Governor Pataki contended that various proposals to limit eligibility for Medicaid (by eliminating so-called "spousal refusal" and applying new transfer of assets limitations to home care) should be implemented in light of this constitutional standoff. Compromises were, in the end, reached on these and other budget matters, resulting in the enactment of approximately $800 million in restorations and additional funding for Medicaid and other health programs.

In addition to these budgetary actions, the following bills were passed by both houses of the Legislature that relate to health and related legal issues:

- **Medicaid State Plan Amendments (S.8179/A.11809).** This legislation would have required the Department of Health to notify the Legislature of its intent to submit Medicaid state plan amendments to the federal government for approval. Prompted by the budget-related standoff related to the Administration's intention to limit Medicaid eligibility without legislative concurrence, the bill would have provided for public hearings and comment on the amendments prior to their submission to the Center for Medicare and Medicaid Services. This bill was vetoed by the Governor.
- **Child Abuse Medical Provider Program (S.7643A/A.11636A).** This bill establishes the Child Abuse Medical Provider Program (CHAMP) in statute. CHAMP is a network of medical professionals who improve access to quality medical care for suspected child abuse victims by providing information, continuing education, and mentoring to certain individuals mandated to report child abuse. The statute establishes the CHAMP program operated by the Child Abuse Referral and Evaluation (CARE) Program of the SUNY Upstate Medical University, and provides for other similarly qualified organizations to operate CHAMP programs. The 2006-07 State budget includes a $500,000 appropriation for CHAMP.
- **Medicaid Coverage of Colon and Prostate Cancer (A.6763A/S.4691A).** This bill expands Medicaid eligibility for persons screened or referred for screening for colon or prostate cancer by the cancer services screening program, and diagnosed with cancer. These individuals would be eligible for Medicaid if their income is at or below 250% of the federal poverty level. Eligibility would be determined without regard to applicant resources. The bill provides for presumptive eligibility for those individuals who have been diagnosed with breast, cervical, colon or prostate cancer and provides for medical assistance for the duration of the cancer treatment.
- **Health Insurance and Domestic Violence (S.7229/A.11448).** This bill prohibits insurers from disclosing the address and telephone number of a person covered by an order of protection to the subject of the order, if any person covered by a group insurance policy delivers a valid order of protection against another person covered by the group policy.

- **Physician Claims Processing and Credentialing (S.8417/A.11996).** This bill requires health plans to provide 30 days written notice to physicians before engaging in overpayment recovery efforts, other than for recovery of duplicate payments. It prohibits a health plan from initiating overpayment recovery efforts more than 24 months after the original payment was received by the physician. No time limit would apply when there is reasonable belief of fraud, other intentional misconduct or abusive billing; where the recovery is initiated at the request of a self-insured plan; or where it is required by a state or federal government program. The legislation also requires health plans to complete reviews of a health care professional's application to participate in the plan's network within 90 days of receiving the completed application. This legislation requires health plans to use the American Medical Association's CPT codes as well as the CMS HCPCS coding system when processing health care claims submitted by a physician. It also requires health plans to publish on their websites and in newsletters the name of the claims editing software that the plan uses and any significant edits to the software.
- **Healthy NY Union Demonstration Program (A.12014/S.8448).** The bill creates the Healthy NY/Labor-Management Benefit Demonstration Program, through which $25 million in Healthy NY stop-loss funds will be made available to labor-management funds that will act as insurers participating in the Healthy NY program. The goals of the demonstration are to leverage employer participation in Healthy NY, increase insurance rates among unionized, lower-wage workers and decrease public expenditures for health care. The bill requires that the health benefits provided under the demonstration be more generous than the standard Healthy NY benefits and that beneficiary cost sharing be lower than the cost sharing required under Healthy NY. The demonstration will be administered by the Superintendent of Insurance, who will select three to five qualifying health benefits funds through an RFP process. The legislation requires a report on or before June 30, 2007 by the Superintendent of Insurance to the Governor and the Legislature on the demonstration program.
- **Sole Proprietor Health Insurance (S.6015B/A.9308A).** This bill limits premiums for sole proprietor policies to no more than 115 percent of the premiums payable for policies issued to traditional groups.
- **Disclosure of Social Security Numbers (A.10076D/S.6909C).** This bill prevents businesses and other organizations from printing social security numbers on membership cards and other materials, from requiring the use of a social security number to access a website, and from requiring the transmission of a social security number over the internet unless the site is secure.
- **All-Inclusive Program for Children with Life-Limiting Illnesses (A.8219A/S.4927A).** This bill creates a pilot program for Medicaid-eligible children with life threatening illnesses to assist them in living more comfortably at home. Under the bill, hospices and certified home health agencies would jointly provide a range of palliative and hospice services and expressive therapies. Services would be reimbursed on a per diem basis.
- **Home-Based Primary Care for the Elderly (A.11720/S.8275).** This bill creates a demonstration program to authorize up to three nursing homes to offer primary health care services in patients' homes as part of a continuum of long-term care services.
- **Cash and Counseling (A.11650A/S.6986).** This bill would create a Medicaid demonstration program in up to 12 counties that would provide self-directing individuals with disabilities with a budget to pay for the services, supports and equipment necessary to live independently. Under this program, responsible relatives could be paid to provide the necessary assistance and care for program participants.
- **Dental X-Rays (S.2863B/A.6780).** This bill requires the use of a thyroid collar when taking dental x-rays, unless inappropriate under the circumstances.
- **Dental Assistants (S.3304E/A.7369E).** This bill amends the definition of dental assisting to expand the services an assistant may perform, subject to the approval of the Education Department and excluding the performance of any surgical or irreversible procedure.
- **Radiologic Technology (A.4882B/S.5606A).** This bill updates Public Health Law provisions governing the practice of x-ray technology to reflect new technologies and responsibilities, including the administration of contrast media by radiologic technologists.
- **Children's Mental Health Act (S.6672C/A.9649C).** This bill directs the Commissioner of Mental Health to develop a children's mental health plan that would provide for comprehensive assessments and services for children from birth to age 18.
- **Geriatric Chemical Dependence Act (A.11243/S.7930).** This bill establishes a geriatric chemi-

cal dependence demonstration program to provide grants to providers of chemical dependence services for the elderly.

- **Rural Health (A.8155A/S.7324).** This bill directs the Office of Rural Health to conduct a study of incentive options to encourage physicians and nurse practitioners to practice in rural areas.
- **Palliative Care (A.11162B/S.7458A).** This bill provides for competitive grants to support education and training in palliative care at "palliative care certified" medical schools and hospital- and non-hospital-based residency programs. It also directs the Commissioner of Health to designate "palliative care centers for excellence" and "palliative care practitioner resource centers" and creates a "palliative care education and training council." This bill was vetoed by the Governor.
- **Disposition of Remains (A.8988A/S.5917A)**: This bill amends legislation enacted last year regarding the rights of individuals to control the disposition of a decedent's remains. Among other provisions, it modifies the definition of domestic partner. This bill has been signed by the Governor.
- **Community Housing Waiting List (A.2895A/S.3653A).** This bill directs the Commissioner of the Office of Mental Health to develop and maintain a waiting list for adults seeking community housing in the Office of Mental Health service system.

Mr. Lytle is a partner in the Albany office of Manatt, Phelps & Phillips, LLP. **Mr. Lytle would like to acknowledge the assistance of his colleague from that office, Karen Lipson, with the preparation of this article.**

In the New York State Agencies

By Frank Serbaroli

HEALTH DEPARTMENT

Regulated Medical Waste

Notice of adoption. The Department of Health amended Part 70 of Title 10 N.Y.C.R.R. to update regulated medical waste regulations by clarifying terminology, adding flexibility to existing regulatory requirements, and codifying advisories for medical waste management. Filing date: February 23, 2006. Effective date: March 15, 2006. *See* N.Y. Register, March 15, 2006.

Statewide Perinatal Data System

Notice of continuation. The Department of Health gave notice of its intent to add to § 400.22 of Title 10 N.Y.C.R.R. to establish a State Perinatal Data System to provide useful data on the births and maternal health for perinatal care providers and the Department of Health and to promote expedited Medicaid eligibility determinations for newborns. *See* N.Y. Register, May 3, 2006.

Enactment of a Serialized New York State Prescription Form

Notice of emergency rulemaking. The Department of Health added Part 910 and amended Parts 80 and 85 of Title 10 N.Y.C.R.R., and amended § 505.3 and repealed §§ 528.1 and 528.2 of Title 18 N.Y.C.R.R. to enact a serialized New York State prescription form to combat and prevent prescription fraud by curtailing theft or copying of prescriptions by individuals engaged in drug diversion. Filing date: April 19, 2006. Effective date: April 19, 2006. *See* N.Y. Register, May 10, 2006.

Language Assistance and Patient Rights

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend §§ 405.7 and 751.9 of Title 10 N.Y.C.R.R. to strengthen language assistance pro-

grams in hospitals to address the needs of individuals who do not speak English or do not speak it well and to add two rights to the Patient's Bill of Rights to be consistent with the Public Health Law. *See* N.Y. Register, May 17, 2006.

Self Attestation of Resources for Medicaid Applicants and Recipients

Notice of emergency rulemaking. The Department of Health amended § 360-2.3(c)(3) of Title 18 N.Y.C.R.R. to allow an applicant for or recipient of Medicaid to attest to the amount of his or her resources unless the applicant or recipient is seeking Medicaid payment for long-term care services. Filing date: May 16, 2006. Effective date: May 16, 2006. *See* N.Y. Register, May 31, 2006.

Controlled Substances in Emergency Kits

Notice of continuation. The Department of Health gave notice of its intent to amend §§ 80.11, 80.47, 80.49 and 80.50 of Title 10 N.Y.C.R.R. to allow Class 3a facilities (nursing homes, adult homes and other long term-care facilities) to maintain controlled substances in emergency kits and administer them to a patient in an emergency situation. *See* N.Y. Register, June 7, 2006.

Nursing Home Pharmacy Regulations

Notice of continuation. The Department of Health gave notice of its intent to amend §§ 415.18(g) and (i) of Title 10 N.Y.C.R.R. to make a wider variety of medications available in nursing home emergency kits and to allow verbal orders from legally authorized practitioners in order to respond quickly to the needs of nursing home residents. *See* N.Y. Register, June 7, 2006.

Neonatal Herpes Infection Reporting and Laboratory Specimen Submission

Notice of emergency rulemaking. The Department of Health amended §§ 2.1 and 2.5 of Title 10 N.Y.C.R.R. in order to enable proper identification and treatment of infected mothers and detection of early causes of neonatal herpes with the goal of assisting in diagnosis, prevention and effective management of neonatal herpes. Filing date: May 31, 2006. Effective date: May 31, 2006. *See* N.Y. Register, June 21, 2006.

New York State AP-DRGs, Service Intensity Weights and Group Average Arithmetic Inlier Lengths of Stay

Notice of emergency rulemaking. The Department of Health gave notice of its intent to amend §§ 86-1.62 and 86-1.63 of Title 10 N.Y.C.R.R. to update the current regulations to make them consistent with changes made to the diagnosis-related group ("DRG") classification system used by the Medicare prospective payment system and to modify existing DRGs and add new DRGs to more accurately reflect the use of health resources. Filing date: June 27, 2006. Effective date: June 27, 2006. *See* N.Y. Register, July 12, 2006.

Payment for Federally Qualified Health Centers Psychotherapy and Offsite Services

Notice of emergency rulemaking. The Department of Health amended § 86-4.9 of Title 10 N.Y.C.R.R. to permit Medicaid billing for individual psychotherapy services provided by certified social workers in Article 28 Federally Qualified Health Centers. Filing date: June 27, 2006. Effective date: June 27, 2006. *See* N.Y. Register, July 12, 2006.

INSURANCE DEPARTMENT

Rules Governing Individual and Group Accident and Health Insurance Reserves

Notice of emergency rulemaking. The Department of Insurance repealed Part 94 and added a new Part 94 (Regulation 56) to Title 11 N.Y.C.R.R. to prescribe rules and regulations for the valuation of minimum individual and group accident and health insurance reserves including standards for valuing certain accident and health benefits in life insurance policies and annuity contracts. Filing date: April 5, 2006. Effective date: April 5, 2006. *See* N.Y. Register, April 26, 2006.

Healthy New York Program

Notice of emergency rulemaking. The Department of Insurance added § 362-2.7 and amended §§ 362-2.5, 362-3.2, 362.-4.1, 362-4.2, 362-4.3, 362-5.1, 362-5.2, 362-5.3 and 362-5.5 of Title 11 N.Y.C.R.R. in order to increase the insurance coverage of uninsured workers employed by small businesses by reducing cost, lessening complexity, and adding a second benefit package to the Healthy New York Program. Filing date: May 19, 2006. Effective date: May 19, 2006. *See* N.Y. Register, June 7, 2006.

Claims for Personal Injury Protection Benefits

Notice of emergency rulemaking. The Department of Insurance amended §§ 65-3.12 and 65-3.13 (Regulation 68-C) of Title 11 N.Y.C.R.R. to require insurers to issue no-fault denials with specific wording so that applicants will be aware that they can apply for special expedited arbitration to resolve the issue of which eligible insurer is designated for first party benefits. Filing date: June 23, 2006. Effective date: June 23, 2006. *See* N.Y. Register, July 12, 2006.

Arbitration

Notice of emergency rulemaking. The Department of Insurance amended § 65-4 (Regulation 68-D) of Title 11 N.Y.C.R.R. to provide the procedures for administration of the special expedited arbitration for disputes regarding the designation of the insurer for first part benefits. Filing date: June 23, 2006. Effective date: June 23, 2006. *See* N.Y. Register, July 12, 2006.

Compiled by Francis J. Serbaroli. Mr. Serbaroli is a partner in Cadwalader, Wickersham & Taft LLP's 15-attorney health law department. He is the Vice Chairman of the New York State Public Health Council, writes the "Health Law" column for the *New York Law Journal*, and serves on the Executive Committee of the New York State Bar Association's Health Law Section. 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 Mr. Keary Wan, a summer associate at Cadwalader, Wickersham & Taft LLP, and Mr. Jared Facher, an associate at Cadwalader, Wickersham & Taft LLP, in compiling this summary is gratefully acknowledged.

In the Journals

***Journal of Health Law*, Vol. 38, Number 4 (Fall 2005)**

- *Schiavo's Lessons For Health Attorneys When Good Law Is All You Have: Reflections Of The Special Guardian Ad Litem To Theresa Marie Schiavo,* Jay Wolfson
- *Living and Dying In a Post-Schiavo World*, Thomas Wm. Mayo
- *Medicare Reimbursement for Clinical Trial Services: Understanding Medicare Coverage in Establishing a Clinical Trial Budget*, Mark Barnes and Jerald Korn
- *The Debate Over Specialty Hospitals: How Physician-Hospital Relationships Have Reached a New Fault Line Over these "Focused Factories,"* Anne S. Kimbo
- *Understanding the Physician-Owned Specialty Hospital Phenomenon: The Confluence of DRG Payment Methodology and Physician Self-Referral Laws*, Suzanne Strothkamp
- *Physician Contract Checklist: Recruitment, Employment, and Independent Contractors*, Robert A. Wade

***Journal of Legal Medicine*, Vol. 27 (June 2006)**

- *Encouraging Translational Research Through Harmonization of FDA and Common Rule Informed Consent Requirements for Research with Banked Specimens,* Barbara J. Evans and Eric M. Meslin
- *Sperm, Egg, and a Petri Dish: Unveiling the Underlying Property Issues Surrounding Cryopreserved Embryos*, Laura S. Langley and Joseph W. Blackstone
- *Operation Cyber Chase and Other Agency Efforts to Control Internet Drug Trafficking: The "Virtual" Enforcement Initiative Is Virtually Useless*, John Richard Castronova
- *Using Race in Clinical Research to Develop Tailored Medications: Is the FDA Encouraging Discrimination or Eliminating Traditional Disparities in Health Care for African Americans?* Michael D. Ruel

***41 Wake Forest L. Rev.*, Vol. 41 (2006)**

- *Symposium: Rethinking Health Law*
  - *Introduction*, Mark A. Hall, Carl E. Schneider, and Lois Shepherd
  - *The History and Future of Health Care Law: An Essentialist View*, Mark A. Hall
  - *Can Health Law Become a Coherent Field of Law?* Einer R. Elhauge
  - *Some Thoughts on Academic Health Law,* Henry T. Greely
  - *After Autonomy*, Carl E. Schneider
  - *Assuming Responsibility*, Lois Shepherd
  - *Responsibility in Health Care: Spanning the Boundary between Law and Medicine,* Carol A. Heimer
  - *The Process Paradigm: Rethinking Medical Malpractice*, Roger B. Dworkin
  - *Our Broken Health Care System and How to Fix It: An Essay on Health Law and Policy,* Timothy Stoltzfus Jost

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- *Autonomy and End-of-Life Decision Making: Reflections of a Lawyer and a Daughter,* R.D. Madoff, 53 Buffalo L. Rev. 963 (Summer 2005)
- *The Care for Reform: How New York State's Secret Charity Care Pool Funds Fail to Help Uninsured and Underinsured New Yorkers,* E. Benjamin and K. Gabriesheski, 8 NYU J. Leg. And Public Policy 5 (2004/05)
- *Come on in, the Water's Fine: Opening up the Special Needs Pooled Trust to the Eligible Elderly Population,* J. Farinella, 14 Elder L. J. 127 (2006)
- *The Controversy over Charges to the Uninsured—No Heroes, No Villains,* B. Coehn, 51 Villanova L. Rev. 95 (2006)
- *Discrimination Against the Unhealthy in Health Insurance*, M. Corssley, 54 U. Kansas L. Rev. 73 (2005)
- *Does My Health Insurance Cover It? Using Evidence-Based Medicine and Binding Arbitration Techniques to Determine What Therapies Fall Under Experiental Exclusion Clauses in Health Insurance Contracts,* J. B. Clamon, 54 Drake L. Rev. 473 (Winter 2006)
- *Duties to Subjects in Clinical Research*, C. H. Coleman, 58 Vanderbilt L. Rev. 387 (2005)
- *EMTALA: All Bark and No Bite,* D.E. Schaffner, 2005 U. IL L. Rev. 1021 (2005)
- *Health Courts: Panacea or Palliative?* C.W. Tobias, 40 U. Richmond L. Rev. 49 (2005)
- *Hospital Vicarious Liability for Negligence by Independent Contractor Physicians: A New Rule for New Times,* H. Levin. 2005 U. IL L. Rev. 1291 (2005)
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- *Medicaid and the Enforceable Right to Receive Medical Assistance: The Need for a Definition of "Medical Assistance,"* K.R. Wiggins, 46 Wm. And Mary L. Rev. 1487 (2006)
- *New York State's Medical Malpractice Plan: Unfunded, Unworkable and Unconstitutional,* M.A. Haskel, 78 J. NYS Bar Assn 30 (Feb. 2006)
- *Not If But When: Pandemic Influenza, the Law and Public Health*, D. O'Brien, 39 MD Bar J. 12 (2006)
- *One Step Forward, Two Steps Back: The Impact of* Aetna v. Davila *on ERISA and Patients' Rights,* C. Krier, 38 Tex. Tech L. Rev. 127 (Fall 2005)
- *Poor on Paper: An Overview of the Ethics and Morality of Medicaid Planning*, J.S. Karp and S.I. Gerhbein, 79 Fl. L. Rev. 61 (2005)
- *Public Health and the Limits of Religious Freedom,* H. Payne and N. Doe, 19 Emory Int'l L. Rev. 539 (2005)
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- *Schiavo and its (In)significance*, J.A. Robertson, 35 Stetson L. Rev. 101 (Fall 2005)
- *The Suitability of IRB Liability,* S. Hoffman and J.W. Berg, 67 U. Pitt. L. Rev. 365 (2005)
- *Superbug Me: the FDA's Role in the Fight Againt Antibiotic Resistance*, V.K.S. Bricenco, 9 NYU J. Legislation and Public Policy 521 (2005/06)
- *Teaching Without Harming the Living: Performing Minimally Invasive Procedures on the Newly Dead,* K.V. Iserson, 8 J. Health Care Law and Policy 216 (2005)
- *Whose Body is it Anyway? An Updated Model of Healthcare Decisionmaking Rights for Adolescents*, K.M. Mutcherson, 14 Cornell J. of Law and Public Policy 251 (2005)

For Your Information

By Claudia O. Torrey

Professional responsibility in almost any profession today requires cultural competence. It is no longer good enough to just know the "nuts and bolts" of law, or medicine, or any other profession. In order to serve the "whole client" or the "whole patient," cross-cultural competence is becoming a must.[1] Ms. Ellen Hemley, Training Director of the Massachusetts Law Reform, asserts that cultural competency is a component of whole client representation.[2] When we understand the nuances of clients' experiences and the lenses through which they see the world, we are in a better position to serve and achieve the best outcomes on their behalf.[3] Misunderstood cultural differences can negatively affect the representation of a client.[4]

Cultural competence is just as important in the medical profession. More and more hospitals, as well as medical schools, are sensitizing staff and students.[5] Although people from two different cultures ostensibly speak the same language, it does not mean that they truly understand one another.[6] In a recent report by the Institute of Medicine, it was discovered that medication mistakes injure more than 1.5 million Americans every year,[7] and at least one-quarter of the errors are **preventable.**[8] One can be sure that cultural competency among physicians could help decrease these numbers. "It is fortuitous that 'patients' and 'patience' are pronounced the same. Their link as homophones continually reminds us that physicians communicating with their patients—and the patience it involves—is essential to good doctoring. When one factors in different languages and different cultures, communicating becomes an even more layered process requiring additional patience—and perseverance."[9]

"In order to serve the 'whole client' or the 'whole patient,' cross-cultural competence is becoming a must."

It has been five years since the fateful day of September 11, 2001—an excellent example of how psychological phenomena may affect a lawyer/client or physician/patient relationship.[10] "[E]motional intelligence—or emotional competence . . . — is necessary for competent lawyering."[11] Such competence turns an ordinary professional visit into something special for all involved.[12]

Endnotes

1. Hemley, E., "*Representing the Whole Client,*" 36 Clearinghouse Rev. 483 (2003).
2. *Id.*
3. *Supra.* n.1 at 483.
4. *Supra.* n.1 at 484.
5. Chen, A., *Doctoring Across The Language Divide,* 25 Health Affairs, #3, p. 808 (May/June 2006).
6. *Id.*
7. *Report finds drug errors injure more than 1.5 million,* http://www.usatoday.com/news/health/2006-07-20-drug errors_x.htm.
8. *Id.*
9. *Supra* n.5 at 808.
10. Silver, M.A., *The professional responsibility of lawyers: Emotional competence, multiculturalism and ethics,* 13 J. of Law and Medicine #4, pp. 431-438 (May 2006).
11. *Id.* at 432.
12. *Cedars-Sinai's traveling Torah brings blessings,* Medical Ethics Advisor, pp. 80-81, July 2006.

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Administrative Hearings Involving Involuntary Discharge of Nursing Home Residents

By James F. Horan

Under Federal[1] and New York State Regulations,[2] a nursing home resident holds certain rights in regard to transfer or discharge. A nursing home may discharge a resident against the resident's wishes only under a limited number of circumstances[3] (Discharge Grounds) and the resident may request a hearing before the New York State Department of Health to challenge the proposed discharge.[4] This article will discuss the standards for involuntary discharges, the procedures for discharge hearings and common issues that arise in the discharge hearings.

Standards for Discharge

A transfer or discharge includes the movement of a resident to a bed outside of the nursing home whether the bed is in the same physical plant or not, but transfer or discharge does not refer to the movement of a resident to a bed within the same nursing home.[5] A nursing home must permit each resident to remain in the facility and may transfer the resident only if:

- the transfer or discharge is necessary for the resident's welfare and the facility cannot meet the resident's needs,
- the transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services the facility provides,
- the safety of individuals in the facility is endangered,
- the health of individuals in the facility would otherwise be endangered,
- the resident has failed, after reasonable and appropriate notice, to pay for a stay at the facility, to pay the resident's share for the stay at the facility or to have Medicaid or Medicare pay for a stay at the facility, or,
- the nursing home ceases to operate.[6]

The nursing home must ensure complete documentation in a resident's clinical record for transfer or discharge under any of the six Discharge Grounds that I listed above. In cases in which the nursing home proposes discharge due to resident welfare or improvement in resident condition, the resident's physician and interdisciplinary care team, as appropriate, shall prepare the documentation.[7] In cases in which the nursing home proposes discharge due to health or safety being endangered, the physician must prepare the documentation.[8]

Before a nursing home transfers any resident, either on a voluntary or involuntary basis, the facility must notify the resident, and if known, a family member or legal representative, about the discharge and the reasons for the move, in writing and in a language and manner the resident understands.[9] The facility must also record the reasons in the resident's clinical record.[10] The written discharge notice must include:

- date of notice/with postmark,
- the resident's identity,
- the effective date for the proposed transfer or discharge,
- the location to which the nursing home proposes to discharge the resident,
- the reason for the discharge or transfer, including a brief statement of facts that clearly support the determination to discharge or transfer,
- the statement that the resident holds the right to a hearing to appeal the discharge by phone or mail (with relevant numbers and address) to the Department of Health Centralized Complaint Intake Program (CCIP),
- notice that the resident must remain in the facility (except in cases of imminent danger) pending the decision in the appeal hearing, if the resident requests the appeal within fifteen days of receiving the discharge notice,
- notice that in cases involving a pre-hearing discharge for imminent danger, the resident may return to the bed the resident occupied prior to the discharge if the resident prevails at the hearing, and,
- the name, address and phone number of the New York State Long Term Care Ombudsman.[11]

For residents with developmental disabilities or for residents who suffer from mental illness, the notice must also contain the mailing address and phone numbers for the Commission on Quality of Care and Advocacy for Persons with Mental Disabilities.[12] The nursing home may

make the notice as soon as practicable before transfer in cases in which:

- the health or safety of residents at the facility would be endangered,
- the resident's health has improved sufficiently to allow a more immediate transfer or discharge,
- the resident's urgent medical needs require a more urgent transfer or discharge, or,
- a resident has not resided in the facility for more than thirty days.[13]

In all other cases, the facility must provide the notice to the resident at least thirty days prior to the discharge or transfer.[14]

If the resident contacts CCIP to request a hearing, the request will go to the Case Resolution Bureau (CRB) at the Department of Health's Division of Quality and Surveillance for Nursing Homes. The CRB will then contact the facility and the resident for further information such as contact information for attorneys or information on resident behavior. If the resident has exhibited aggressive behavior, CRB will instruct the facility about the need to supply security for the hearing. The CRB will also make an initial review on the adequacy of the discharge notice. If the CRB finds the notice invalid, they will advise the facility that the discharge process must stop and that the facility must issue a new notice. The CRB will also inquire about the possibility of settling the matter. If no settlement appears likely and the CRB finds the discharge notice valid, then the CRB will refer the matter to the Department of Health's Bureau of Adjudication for a discharge appeal hearing. The referral will take place within two days from the receipt of the hearing request.

The Hearing Process

The Department of Health's Bureau of Adjudication conducts administrative hearings for approximately two dozen programs within the Department, pursuant to the New York Public Health Law, the New York Social Services Law, the New York Elder Law and various State and Federal Regulations. The Administrative Law Judges (ALJ) in the Bureau are all attorneys, admitted to practice in New York, with extensive experience in administrative hearings. At the time the Bureau receives the hearing request, the Chief ALJ assigns an ALJ to the case and that ALJ will select the hearing date and time. The Bureau will then mail the parties the Notice of Hearing to inform the parties as to the time, date and location of the hearing. The parties may request adjournments in the date that the ALJ chooses.

The Bureau of Adjudication became responsible for conducting the hearings in 2004, at the same time as the Department of Health adopted an Interim Policy for the hearings. The Interim Policy will apply to the hearing procedures while the Department amends the State Regulations to reflect more fully the standards for the hearings under the Federal Regulations. The Department devised the Interim Policy from the Federal and State Regulations. A copy of the Interim Policy appears as an attachment to the Notice of Hearing that the parties receive from the Bureau of Adjudication.

The resident may remain in the nursing home pending the final decision in the hearing,[15] so the hearing request acts as a stay on the discharge. An exception exists in cases in which the nursing home cites imminent danger to other persons or patients' health or safety as grounds for the discharge.[16] In these imminent danger cases, the nursing home may make an involuntary discharge prior to a hearing, but the facility must hold the resident's bed until a final hearing decision.[17] If a hearing decision finds an imminent danger transfer appropriate, then the facility may charge a private pay patient for the time the facility held the bed. [18] If a hearing decision finds the imminent danger transfer inappropriate, the facility must readmit the resident to his or her bed on a priority basis.[19]

The hearing usually takes place at the nursing home. One exception would occur in the imminent danger pre-hearing discharges, in which the resident no longer resides at the facility. For hearings that do take place at the nursing home, staff from the Bureau of Adjudication will contact the nursing home to arrange for the facility to set aside a conference room in which to hold the hearing.

The basic hearing procedures in the Interim Policy require first that the Bureau of Adjudication issue a Notice of Hearing to the resident and the nursing home that advises the parties concerning the date and time of the hearing and that explains that the resident may represent himself/herself, or may appear by legal counsel, a relative, friend or other spokesperson. Although the Notice of Hearing makes no statement about non-attorney representation for the nursing home, facilities often appear by a staff member, rather than counsel. Non-attorney representatives or staff may appear in administrative hearings in New York without violating the ban on the unauthorized practice of law, because an administrative hearing is not a court of record.[20]

The resident and the resident's representative hold the right to examine, at a reasonable time before the hearing and during the hearing:

- all facility records pertaining to the resident's care, and,
- all documents the Nursing Home will use at the hearing.[21]

During the hearing, the resident and resident's representative may:

- present witnesses,
- establish all pertinent facts and circumstances,
- present an argument without undue interference,
- question or refute any testimony or evidence, and,
- confront and cross-examine adverse witnesses.[22]

The ALJ presiding at the hearing may obtain medical and psychological consultations.[23] Under the general authority in N.Y. Administrative Procedure Act (SAPA) Article 3, an ALJ may:

- administer oaths and affirmations,
- sign and issue subpoenas,
- regulate the course of the hearing and set the time and place for continued hearings, and,
- direct the parties to appear and confer to consider simplifying the issues.[24]

The ALJ may also exclude irrelevant or unduly repetitious evidence from the record.[25]

The nursing home bears the burden to prove the transfer/discharge necessary and the discharge plan appropriate. [26] Neither the Federal nor State Regulations define the burden of proof for the discharge hearings. Under SAPA, substantial evidence constitutes the usual standard of proof in administrative hearings. [27] Substantial evidence means such relevant proof as a reasonable mind may accept as adequate to support conclusion or fact; less than preponderance of evidence, but more than mere surmise, conjecture or speculation and constituting a rational basis for decision.[28]

The record from the hearing consists of:

- all papers and requests filed,
- a transcript or recording of the hearing, and,
- the decision by the ALJ.[29]

The Bureau of Adjudication will arrange for the hearing reporter who will record the hearing and prepare the transcript. The Interim Policy provides for the ALJ to issue the hearing decision a week after the hearing. The ALJ must issue the decision in writing and the decision must summarize the facts in the case, specify the reasons for the decision and identify the regulations that support the decision. [30] The Interim Policy requires that the ALJ decision also provide directives on how to carry out the hearing decision. The ALJ decision represents the final decision in the matter, with no administrative appeal within the State Health Department. A party aggrieved by the decision may proceed to State or Federal Court.

Common Issues

As I have noted above, the hearing decides whether the nursing home proposes a necessary discharge on one of the six Discharge Grounds under Title 42 C.F.R. § 483.12(2) and Title 10 N.Y.C.R.R. § 415.3(h)(1)(i) and whether the nursing home proposes an appropriate discharge plan. The ALJ will issue a decision that makes one of three findings:

- that the nursing home has proposed a necessary discharge and has proposed an appropriate discharge plan and that the discharge may proceed,
- that the nursing home has failed to prove the discharge necessary for the reason or reasons that the nursing home cited, so the resident remains in the facility, or,
- that the nursing home has proven the discharge necessary, but has failed to identify an appropriate discharge plan.

The discharge hearing is not a disciplinary action against the nursing home, so the hearing does not provide a forum for the resident to raise complaints about his or her care in the home. If the resident attempts to raise such complaints at the hearing, the ALJ may likely refer the resident to submit the complaint to the Nursing Home Hotline. A nursing home may seek discharge for more than one reason under Title 42 C.F.R. § 483.12(2) and Title 10 N.Y.C.R.R. § 415.3(h)(1)(i), but the nursing home must cite each reason in the discharge notice. If the nursing home attempts to present evidence concerning reasons for discharge, in addition to those the home cited in the discharge notice, then the ALJ will likely exclude the evidence concerning the additional reasons, or offer to delay the hearing so the nursing home could issue a new, expanded notice of discharge. In my experience in such instances, the nursing home usually chooses to proceed with the hearing immediately, rather than to delay the matter in order to expand the discharge grounds.

The hearing usually takes a half day or less. The ALJ receives evidence regarding both the necessity for discharge and the appropriateness of the discharge plan on the same hearing day, rather than make the decision on necessity and then return to consider appropriateness on another day. The parties should have all evidence and witnesses ready to go forward on the date listed on the hearing notice. If a problem exists over having all witnesses and evidence ready to go forward on the listed hearing date, the parties should advise the ALJ and each other. In a case in which the ALJ has found the discharge necessary, but the discharge plan inappropriate, the hearing record will remain open until the facility offers an appropriate plan. In such cases, the ALJ may require the

submission of additional documentation and may require that the hearing reconvene, either at the original hearing site or by conference call.

Among the permissible grounds for discharge, most hearings concern whether a resident's condition has improved sufficiently so that the resident no longer requires nursing home care. These hearings often involve persons fifty years old or younger who have entered a nursing home for rehabilitation and who then seek to remain in the facility after the facility claims that the resident has satisfied or met all rehabilitation goals. A large number of hearings also involve health and safety issues and nonpayment. Hearings concerning health and safety often involve allegations that a resident has engaged in conduct that poses a danger to other residents or staff, such as violent behavior. Hearings involving payment issues concern both allegations that a private pay patient refuses to pay his or her bill or that a Medicaid eligible resident refuses to pay over the Net Available Monthly Income from Social Security Benefits that the resident agreed to pay as a condition to enter the nursing home.

The number of discharge hearings has increased for each year that the Bureau of Adjudication has been conducting the hearings. Among the cases that go to the Bureau for hearing, about 20% of the cases settle, the resident withdraws the hearing request or the nursing home withdraws the discharge notice prior to the time the ALJ renders a decision.

Endnotes

1. 42 C.F.R. §§ 431.220, 431.240-242, 431.244-245 and 483.12.
2. Title 10 N.Y.C.R.R. § 415.3(h).
3. Title 10 N.Y.C.R.R. 415.3(h)(1)(i).
4. 42 C.F.R. §§ 431.220(a)(3) and 431.241(c); Title 10 N.Y.C.R.R. § 415.3(h)(2).
5. 42 C.F.R. § 483.12(a)(1); Title 10 N.Y.C.R.R. § 413.3(h).
6. 42 C.F.R. § 483.12(2); Title 10 N.Y.C.R.R. § 415.3(h)(1)(i).
7. Title 10 N.Y.C.R.R. § 415.3(h)(1)(ii).
8. *Id.*
9. 42 C.F.R. § 483.12(a)(4).
10. *Id.*
11. 42 C.F.R. § 483.12(a)(6); Title 10 N.Y.C.R.R. § 415.3(h)(1)(v).
12. Title 10 N.Y.C.R.R. § 415.3(h)(1)(v)(c).
13. Title 10 N.Y.C.R.R. § 415.3(h)(1)(iv).
14. *Id.*
15. Title 10 N.Y.C.R.R. § 415.3(h)(2)(i)(b).
16. Title 10 N.Y.C.R.R. § 415.3(h)(2)(i)(a).
17. Title 10 N.Y.C.R.R. § 415.3(h)(2)(iv).
18. *Id.*
19. *Id.*
20. *In re Board of Education of Union Endicott School District v. PERB,* 233 A.D.2d 602, 649 N.Y.S.2d 523 (3d Dep't 1996); N.Y. Administrative Procedure Act § 501 (McKinney Supp. 2006).
21. 42 C.F.R. § 431.242(a).
22. 42 C.F.R. § 431.242(b-e).
23. Title 10 N.Y.C.R.R. § 415.3(h)(2)(ii).
24. SAPA § 304.
25. SAPA § 306(1).
26. Title 10 N.Y.C.R.R. § 415.3(h)(2)(iii).
27. SAPA § 306(1).
28. *Stoker v. Tarantino,* 101 A.D.2d 651, 475 N.Y.S.2d 562 (3d Dep't 1984), *appeal dismissed*, 63 N.Y.2d 649.
29. 42 C.F.R. § 431.244(c).
30. 42 C.F.R. § 431.244(d) and (e).

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HIXNY: Building a Regional Health Information Organization (RHIO) in the Capital District of New York

By Chris Baldwin

Information technology has transformed almost all manufacturing industries, resulting in significant improvements in productivity. The Internet has transformed communication and commerce and as consumers, we now take for granted the multitude of ways the web has improved the way we interact in our business and personal lives. With the underpinnings of a technology driven society in place it would seem logical that clinicians should be given access to our health care information online and in real-time to ensure the highest quality of care is rendered. Regional Health Information Organizations (RHIOs) are a relatively new construct in health care that are intended to provide an organizational framework for achieving this objective.

In Albany, New York and the surrounding communities an exciting initiative is underway to form a RHIO. Health Information Xchange New York (HIXNY) is a 501(c)(4) non-profit corporation that is on the path to becoming a RHIO for the Capital District.

Centralize or Decentralize?

In January 2005 a group of chief information officers from several area hospitals, physician groups and payors met to discuss the concept of making our respective organizations' information systems interoperable. The goal was to interconnect health information systems already in place throughout our communities so that information could be accessible by caregivers as patients move throughout the continuum of care. Implicit in the way all the CIOs viewed the problem was the notion of a decentralized design. Because substantial health information systems and technology already existed within the various organizations throughout the region, these stakeholders were interested in finding ways to interconnect systems in order to share data with those who have a legitimate need for access. That is not to say this approach is ideal for all communities. In regions where little infrastructure exists, a centralized solution, which collects and shares information through common databases, could be the most rational and economical approach. But in a region dominated by large hospitals, payors and physician groups that already have implemented systems to meet their respective needs, interoperability was the logical objective.

Fundamental Technology Tenets

Building consensus on fundamental technology tenets turned out to be straightforward. Because the group of CIOs started from a common vantage point there was a great deal of common thinking. Over time, there would emerge many different opinions regarding optimum technologies, as well as differences on many core business issues. But it only took three meetings to form unanimous consent on the fundamental technology tenets and they have generally held up over time.

- Build a *Community Patient Index* that references available information for on-demand retrieval;
- Adherence to *Standards-based, Secure, Open-systems technologies;*
- Enable *Information Portability* to allow data to move with the patient;
- Maintain *Information Responsibility* within each organization that collected the data;
- Build a *Rapid Timeline for Implementation* to demonstrate progress.

The notion of a rapid timeline was highly valuable in the early going, since it allowed the group to stay focused on delivering something of value. But as the endeavor expanded and received more broad-based support it became clear that success would have to be measured in terms of years.

HEAL NY Creates the Opportunity for Broad-Based Progress

In the summer of 2005, New York State announced its HEAL NY initiative intended to fund core areas of investment that would facilitate changes to improve both the quality and cost of health care across New York State.[1] The first $52M, known as HEAL phase I, was specifically targeted to foster the adoption of health information technology, including e-prescribing, as well as to fund infrastructure to enhance standards-based interoperability between existing electronic health record systems. Up to this point the group had referred to itself as a "task force." The Iroquois Healthcare Alliance (a major upstate hospital association) and the New York Health Plan Association (the statewide payor association) took an active interest in the activities of the task force. Both these organizations were the "founding fathers" of HIXNY, which had been in place since 1999 and was originally established as a vehicle for health information technology (HIT) collaboration, with a primary focus on advancing HIPAA transaction standards between payors and providers.

With the prospect of receiving a multi-million dollar grant, HIXNY embraced the work of the task force, recognizing that combined they could best take advantage of the HEAL grant opportunity to build an organization that could evolve toward a true RHIO. At this time HIXNY saw fit to overhaul its governance structure so that all stakeholders, physicians (including the region's federally qualified community health centers), hospitals and payors could all work together to construct an organization that would look out for the interests of all stakeholders in a fair, even-handed manner.

Evolving from a task force, with the singular goal of interoperability, to the much more ambitious undertaking of building toward a RHIO dramatically expanded the scope and complexity of the undertaking. To succeed, HIXNY had to become an organization that could effectively resolve the conflicting interests of its often competing constituents; develop a financial management and organizational structure as a non-profit corporation; develop solutions to legal issues that were still uncharted; develop short- and long-term business plans much like any new "start-up"; establish a clear vision and mission as well as immediate priorities that would align to the underlying purpose for HIXNY to improve the region's quality of care; and finally, execute and make decisions on a day by day basis with little staffing infrastructure.

As a result, the organization's bylaws were changed to establish an active Board of Directors and committee structure that could meet these challenges and do the hard work involved in building an organization from the ground up. A total of twenty organizations joined the initiative. Each designated a representative to sit on the Board of Directors which was empowered to make all key decisions. A committee structure was established to tackle the many challenges and complete the work at hand. The committees included finance, legal/privacy, planning, clinical, governance, technology, electronic data interchange and an executive committee. Eventually, an executive director search committee was established to explore the need for staffing, starting with one person who would lead and coordinate the HEAL NY phase I project activities.

At this time, HIXNY has received commitments of over $2M in funding, including approximately $1.7M from HEAL. In the past ten months HIXNY has made significant progress with its short-term plans for implementing a clinical data share infrastructure that will enable access to patient-specific information by clinicians across our region. The initial data that will be shared includes patients' medication history, deemed one of the most crucial data sets by the physicians on the clinical committee.

Obviously, the sharing of such medical information raises legal issues under HIPAA and New York State law. Those concerns are reduced, though not erased, by the basic premise that all information sharing through HIXNY will be solely for treatment, payment or health care operations purposes. HIXNY and its participating organizations, as they proceed, are carefully identifying and addressing applicable privacy and security requirements, as well as antitrust, fraud and abuse, tort liability and other legal issues.

The challenges to become a RHIO are still daunting, but all twenty organizations that codified their interest through memorandums of understanding have stayed actively engaged in building the organization around the concept of "competitive collaboration." There is recognition that only an organization such as HIXNY can leverage technology advances to drive a true regional approach to health care information sharing for the benefit of all health care stakeholders, most importantly, our patients.

Endnote

1. The Health Care Efficiency and Affordability Law (HEAL) grant program is codified at N.Y. Public Health Law § 2818 (2005).

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Blame It on the RHIO:[1] Potential Liability Concerns with Electronic Health Information Exchange

By Douglas Anning, Jody Joiner, and Maia Thiagarajan

I. Introduction

The future of healthcare over the next decade will be inextricably bound to the development of technology organizations that can assure the efficient, private, secure, and accurate exchange of electronic health information. In 2001, the Institute of Medicine, a branch of the National Academy of Sciences, called for a "nationwide commitment to build an information infrastructure to support health care delivery."[2] In the 2004 State of the Union Address, President Bush laid out his goal that, within the next decade, almost every American will have an electronic, interoperable health record capable of exchange among healthcare providers utilizing diverse technological platforms and architectures.[3] In the 2006 annual survey on health information technology conducted by *Modern Healthcare*, healthcare executives indicated that the development and exchange of electronic healthcare records is their number one priority.[4]

Whether these organizations that facilitate the exchange of electronic health records are called health information networks (HINs), regional health information organizations (RHIOs), or labeled with some other moniker and resulting acronym, health information exchange will prove to be as complex legally as it is advanced and sophisticated technologically. RHIOs[5] will face a myriad of legal issues: Health Insurance Portability and Accountability Act (HIPAA) privacy and security, intellectual property, tax-exemption, labor and employment, antitrust, anti-kickback and self-referral, and liability issues will all have to be addressed for a RHIO to be legally compliant. While the issues collectively can fill a substantial monograph (and the American Health Lawyers Association has in fact published such a comprehensive monograph[6]), this article will focus solely on potential liability issues for RHIOs.

II. RHIO Basics

RHIOs may be loosely defined as local organizations engaged in the creation and exchange of electronic health records (EHRs) among healthcare providers in a regional area. RHIOs hopefully will eventually serve as a platform for a national "network of networks" linking doctors, hospitals, laboratories, and pharmacies throughout the nation, currently being referred to as the National Health Information Network, or NHIN.

The parties involved in a RHIO generally fall into three categories: (1) data contributors; (2) data managers; and (3) data users.

- Data contributors include the individuals and entities that contribute health information to an information repository that is managed by the RHIO. Such data contributors generally include healthcare providers and healthcare plans, including both independent and employer-based plans that hold the individual patient's health information in various forms. The patient, who generally has access to and the right to edit the EHR, can also be a data contributor.
- Data managers include the individuals responsible for managing the data that is in the possession of the RHIO. This can include employees of the RHIO as well as outside vendors with whom the RHIO contracts for hardware, software, service support, and hosting.
- Data users are those persons or entities that will use the data from the RHIO's network to provide and participate in the delivery of healthcare. This can include hospitals, physicians, pharmacies, and laboratories.

When a patient is injured and believes the cause is, in whole or part, due to information obtained from the RHIO, the patient will look to the RHIO for recompense. While it is possible for the RHIO to be legally at fault, it may also be one or more of the other parties to the data exchange (the data contributors, users, or managers) that may bear some or all of the liability. The rest of this article discusses possible scenarios in health information exchange that can result in injury to the patient, analyzes which party or parties may be legally at fault, and suggests steps RHIOs can take to protect themselves from liability.

III. Potential Liability Concerns and Risk Mitigation Strategies

Before a RHIO can be found legally liable, the injured patient must state a legal cause of action. With RHIOs this will generally mean some type of negligence or contract claim. The particular state in which a RHIO is incorporated and/or conducts a substantial part of its business will ordinarily dictate the specific liability concerns for a

RHIO. However, common principles of tort and contract law offer a glimpse of the general liability issues facing the RHIO.

A. Tort and Contract Liability

Negligence Generally

A RHIO may face liability under general negligence theories. The elements of a negligence claim are duty, breach, causation, and damages.[7] While breach, causation, and damages are issues of fact, law will dictate the specific duty owed by a RHIO.

The relationships between a RHIO and the individuals or entities using its services arguably create a variety of affirmative duties between the parties. Generally, when a party undertakes to render services to another, there is a duty to use reasonable care in providing such services.[8] From this duty to use reasonable care in providing services could be implied various correlative duties such as a duty to ensure the integrity of the electronic data disseminated to the data users, the duty to provide adequate technical support to maintain the data exchange network, or the duty to provide data users with the necessary training to properly use the data exchange network. Such duties will be owed to the individuals for whose benefit the services are rendered.[9] In the case of a RHIO, this duty may be owed to the data users to whom a patient's health information is transmitted or to the patients treated by such data users.

Medical Malpractice

Although a RHIO could potentially face liability under state medical malpractice laws, it is unlikely because a RHIO would probably not qualify as a healthcare provider under most state medical malpractice statutes. In some states, a medical malpractice statute may specifically exclude RHIOs from the definition of a healthcare provider.[10] Further, state law may require a doctor-patient relationship or some affirmative communication between a doctor and a patient prior to imposing medical malpractice liability. A regional repository for a patient's health information is not likely to satisfy the doctor-patient relationship or be considered a healthcare provider. Thus, in many (or most) jurisdictions, a RHIO is not likely to be subject to liability under that state's medical malpractice laws.

Negligent Hiring, Retention, Training, and Supervision

A theory of liability that has gained popularity in the last decade is based on an entity's duties with respect to its employees. Specifically, an organization may be held liable for negligence in hiring or retaining employees who lack the necessary qualifications or in failing to provide adequate training and supervision of such employees in the performance of their jobs.[11] Because electronic data exchange is so technologically sophisticated, a RHIO could be liable for failure to hire, retain, train, or supervise employees who are technologically competent to provide the services the RHIO promises, or the failure to contract with competent third-party vendors who can supply such services in the absence of RHIO employees providing the services.

Invasion of Privacy and/or Emotional Distress

If a RHIO improperly discloses a patient's health information, the RHIO could be liable under an invasion of privacy action[12] (not to mention civil penalties under HIPAA). Similarly, the RHIO could be liable under an infliction of emotional distress claim.[13] Some states only recognize an intentional infliction of emotional distress while others recognize a merely negligent infliction of emotional distress. Further, some states do not allow damages for emotional distress absent physical injury.[14] In such states, it is possible that the RHIO's negligent disclosure of a patient's sensitive health information could lead to the patient's emotional distress but not to a physically manifested injury. Thus, in such states the existence of physical injury could be determinative of the RHIO's liability.

Breach of Contract and Breach of Warranties

The RHIO will likely have a contractual relationship with data contributors, data users, data managers (such as information technology service providers), and, most importantly for determining liability for patient injury, contracts with patients. Patients who are injured may bring a breach of contract or breach of express or implied warranty claim against the RHIO. For example, the agreement between the RHIO and the patient may allow the patient to block certain sensitive parts of the patient's EHR (e.g., information related to substance abuse, mental health issues, or STDs). Disclosure of information the patient has requested to be blocked could result in a breach of contract claim. The RHIO may also claim that its e-prescribing function will identify and warn against potential adverse drug interactions between two drugs being prescribed to the same patient. If the software fails to identify and/or warn about an adverse interaction, an injured patient may bring a breach of warranty claim.

B. Risk Mitigation and Limitation Strategies

As with any business that faces potential tort or contractual liability, there are a number of steps a RHIO can take to limit or mitigate its risk exposure.

Arbitration Clauses

A RHIO may wish to incorporate arbitration clauses into its contracts with various parties, including patients. If a patient is injured, the RHIO may well desire to have the decision maker be an arbitrator versus a jury. State law will dictate whether an arbitration clause is binding and the kinds of actions that an arbitration clause may cover. For instance, in some states, the court will only allow arbitration clauses to cover actions arising from breach of contract claims but not from tort claims.[15]

Jurisdiction and Venue

If the RHIO operates in multiple states, it may want to put a jurisdiction and venue clause in its contracts. One state may have more favorable tort and/or contract laws that would affect jurisdiction selection. Similarly, if a jury trial cannot be avoided, one county's juries may be more pro-defense or pro-plaintiff and this may affect venue selection. The enforceability of jurisdiction and venue selection provisions will vary from state to state.

Disclaimers

Parties to a contract often include provisions disclaiming or limiting liability. The enforceability of such provisions may vary from state to state.[16] Often, state law requires such provisions to be clear and unequivocal, particularly where a party is attempting to release itself from liability for its own negligence.[17]

Complete disclaimers of liability may raise public policy issues that could affect their enforceability. What is more common, and more commonly enforceable, is a disclaimer of express and implied warranties. Thus, for example, a RHIO might disclaim any express or implied warranty regarding the ability of its software system to properly identify potential adverse drug interactions between two drugs being prescribed to the same patient.

Indemnity Provisions

A RHIO may wish to include indemnity language in its contracts with the various RHIO parties. For example, the RHIO may seek an indemnity from data contributors for any damages resulting from incomplete or inaccurate data, from data users (such as a physician) for any damages resulting from the physician's use of the data in the delivery of healthcare, and from the data manager (such as a technology service provider) for any damages resulting from the failure of the software (e.g., the failure to identify a potential adverse drug interaction).

Waivers

Because a RHIO is often merely a passive conduit of information flowing between various healthcare providers and health plans, the RHIO should consider obtaining waivers of liability from patients whose information is stored on its network. The theory is that inaccurate or incomplete data would be the fault of the data contributor and lapses in the delivery of care would be the fault of data users. By the patient waiving any claims against the RHIO, the patient is forced to proceed directly against the parties at fault (the data contributors and/or users) rather than against the RHIO who would then be forced to seek indemnity from the parties at fault.

Although waivers may be obtained by the traditional written signature, the electronic nature of EHRs creates the possibility of obtaining "click-through" waivers from patients. For example, in order to activate or access an EHR on the RHIO's network, the patient would have to agree to waive liability. With the click of a mouse, patients could agree to terms and conditions which would include, among others, a waiver presented in electronic form. Such automated transactions are contemplated under the Uniform Electronic Transactions Act (UETA), which was designed to facilitate the use of technology by providing for the enforceability of electronic transactions.[18] In states that have adopted the UETA, a RHIO may be able to use click-through waivers as well as enforce transactions formed using electronic signatures.

Finally, the RHIO may also want to seek waivers, written or electronic, from data users and data contributors. For example, the RHIO may want the data user to waive any liability for incomplete or inaccurate data since that would presumably be the fault of data contributors.

Insurance

As with any business facing risk, a RHIO may seek insurance (general liability, medical malpractice, etc.) to help minimize its risk. As a nascent industry, with unknown risks and claims histories, such insurance may be harder to get or subject to higher premiums, but as the industry matures and risks and claims histories become more predictable, the number of underwriters willing to insure RHIOs should increase and the cost of premiums should decrease.

Immunity

Both the federal and many state governments are considering legislation to accelerate the adoption of technologies that will foster the exchange of EHRs. If governments are sincere in the belief that this is a public good, and if the policy argument can be made that RHIOs are merely passive conduits of information from one user to another, then some legislatures may consider granting immunity, or limited immunity, to RHIOs. RHIOs or associations of RHIOs may want to consider lobbying for such immunity.

IV. Practical Suggestions to Specific Concerns

Integrity of Data Issues

The data disseminated from a RHIO is only as reliable as the data coming into a RHIO. False, incomplete, inaccurate, and untimely data will always pose potential problems for RHIOs and could conceivably result in harm to a patient. To mitigate against this risk, the RHIO should attempt to get indemnification from any data contributors in the event they submit corrupt data or from data managers (such as software vendors) in the event the hardware or software corrupts the data. Further, the RHIO should also seek to get waivers from data users and patients releasing the RHIO from any liability for corrupt data that is the fault of data contributors or data managers.

Service Provider Issues

While some RHIOs may perform all technology functions in house, the more likely scenario, at least at the

early stages, is that the RHIO will contract with outside vendors for software and hardware support, internet hosting, and other IT services. It is easy to imagine potential problems that could result in injury to patients: a physician could request information on Patient A but get information on Patient B (the so-called "false match" problem); the internet host could be down making access to the system impossible; promised features of the software such as the ability to identify potential adverse drug interactions may not perform as promised, and on and on. To mitigate against these risks, the RHIO needs to seek indemnification from its vendors in their service contracts. As mentioned above, the RHIO also may want to seek waivers or releases of liability from both data users and patients for such errors that are the fault of third-party vendors and outside the control of the RHIO.

Patient Restrictions in Use of Data

The more options given to patients to block some or all of their EHR, the more potential liability the RHIO is exposed to for disclosures of the blocked information. For example, patients may choose to block their whole record or just sensitive parts (e.g., mental health or substance abuse information), and the improper disclosure of blocked information could expose the RHIO to liability. HIPAA grants many of these rights to patients, so not allowing the patient to require such blocks may not be an option. If the RHIO outsources all of its IT support, it may want to consider seeking indemnity from the service providers against improper disclosures. Further, the RHIO may want to seek a waiver from data users and the patient for any improper disclosures that are the fault of the service providers.

Quality of Care Issues

Ultimately, quality of care rests with the data user or physician. While RHIOs hold great promise in facilitating the exchange of health information and improving the quality of care, nothing is an adequate replacement for the traditional doctor-patient relationship. Thus, while there may be system downtime, the doctor and the patient should not abdicate their traditional responsibilities of the doctor to ask probing questions and of the patient to provide full medical histories. While the software may fail to identify a potential adverse drug interaction, doctors cannot evade their responsibilities to analyze what medications patients are taking before prescribing more medications, nor can patients evade their responsibilities to give full and complete disclosure to their doctors about the medications they are taking. To protect against such quality of care concerns, the RHIO should seek indemnification from the data users/physicians and waivers of liability from patients.

V. Conclusion

RHIOs have the potential to serve as catalysts for transforming the delivery of healthcare in our communities. RHIOs have the potential to reduce errors and improve the quality of care. However, given the newness of the concept of a regional network of health information, let alone a national network, the potential for liability is a concern for the RHIO. Any party undertaking the development of a RHIO must carefully consider the potential areas of liability discussed herein when designing the structure of the RHIO.

Endnotes

1. With due apologies to Stanley Donen (director), Michael Caine (actor), Larry Gelbart (writer), and all the others who made the 1984 20th Century Fox film *Blame It on Rio*.
2. Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* 1, 5 (Mar. 2001), *available at* www.iom.edu/Object.File/Master/27/184/Chasm-8pager.pdf.
3. *See Transforming Health Care: The President's Health Information Technology Plan, available at* www.whitehouse.gov/infocus/technology/economic_policy200404/chap3.html.
4. Joseph Conn, *EHRs: Still in hot pursuit, Annual IT Survey Shows continuing focus on patient-care improvements*, *Modern Healthcare*, Feb. 13, 2006 at S1.
5. For consistency, the authors use the acronym RHIO throughout to refer generically to any organization or joint venture engaged in the creation and exchange of electronic health records.
6. *See* Marilyn Lamar and Kristen Rosati, eds., *The Quest for Interoperable Electronic Health Records: A Guide to Legal Issues in Establishing Health Information Networks, available at* www.healthlawyers.org.
7. RESTATEMENT (SECOND) OF TORTS, § 328-A (1965).
8. *Id.* at § 323.
9. *Id.* at §§ 323, 324-A.
10. *See, e.g.*, MO. ANN. STAT. § 538.205 (4) (2005).
11. *See, e.g.*, RESTATEMENT (SECOND) OF TORTS, § 877.
12. *See id.* at §§ 652A-E.
13. *See, e.g., id.* at § 46.
14. RESTATEMENT (SECOND) OF TORTS, § 436-A.
15. *See, e.g., Rhodes v. Amega Mobile Home Sales, Inc.*, 2006 Mo. App. LEXIS 80, *11 (Mo. App. 2006).
16. In Missouri, parties may limit their liability through contracts so long as the terms are clearly stated. *See Purcell Tire & Rubber Co. v. Executive Beechcraft, Inc.*, 59 S.W.3d 505, 509 (Mo. 2001).
17. *See, e.g., Util. Serv. & Maint., Inc. v. Noranda Aluminum, Inc.*, 163 S.W.3d 910, 913 (Mo. 2005).
18. *See, e.g.*, MO. ANN. STAT. § 432.225 (2005).

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The Case of Vioxx: A Prescription for Disaster?

By Mitchell A. Adler, M.D., J.D.

> It is in everyone's best interest for drugs to be approved as quickly as possible. But drugs also should be as safe as possible. The war between speed and safety is often fought on the messy desk of the FDA medical officer. The casualties of that war are primarily the people who take the drugs, not the ones who make, prescribe, dispense or approve them.[1]

Introduction

The recent withdrawal from the market of Vioxx[2] (and more recently of Bextra[3] as well) has drawn attention once again to the fact that new drugs are not necessarily the safest or most effective drugs available. "[The FDA's] medical officers know better than anyone that the FDA's stamp of approval is not the all-protecting, medical Good Housekeeping Seal the public [and physicians] often imagines it to be."[4] Newly approved drugs do not have the proven safety record that would warrant their rapidly displacing older drugs that have been in clinical use for years or decades. Many of these older drugs have proven track records, and are not necessarily less effective than the newly released medications. And they are almost invariably less expensive. The greater cost of newer drugs is, in fact, one important factor behind the aggressive marketing of newer drugs by the pharmaceutical industry.

The harm ascribed to Vioxx since its FDA approval in 1999[5] has been estimated by some to be quite significant, "contribut[ing] to as many as 139,000 heart attacks and strokes and up to 40,000 deaths worldwide."[6] How can drugs such as this be approved by the FDA in light of the potential danger they pose? Are the post-approval surveillance protocols of the FDA optimal for limiting morbidity and mortality of approved drugs that are subsequently shown to pose significant risks? And specifically with regard to Vioxx and the other Cox-2 inhibitors, why have so many patients been prescribed these drugs if other medications are available that are equally efficacious and whose risks have been very well delineated?

This article will address these questions, and will make recommendations as to what might be done differently in the future to limit the harm done from newly approved drugs, particularly those that during extensive clinical use are found to pose a danger to patients. An additional benefit of closer post-marketing surveillance might also be that certain drugs will be found to pose some danger, but might continue to be marketed with stricter guidelines as to their use because they provide a therapeutic benefit that warrants their use under certain circumstances and with appropriate warnings. Vioxx may itself be a medication whose benefits outweigh the risks in certain subclasses of patients, but the significant damage (both to patients and to the public's confidence in drug safety) caused by its widespread, indiscriminate use has now created a huge hurdle to be overcome if it is ever to be re-released.

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FDA Drug Approval

To put the problem in perspective it would be useful to briefly review the process by which new drugs are reviewed and approved by the FDA, and how the safety of an approved drug is subsequently monitored after its approval (post-approval or post-marketing surveillance). When the current process was first instituted in 1938, it was relatively straightforward and limited in scope. Subsequent amendments in 1962 complicated and prolonged the process, presumably to better ensure the safety of newly approved drugs. In the past fourteen years the process has undergone further changes that have expedited drug approval, possibly at the expense of ensuring the safety of newly approved drugs.

Food and Drug Act of 1906

Although there was some federal legislation in the 19th century regulating food and drugs in the United States, the first legislation to deal generally with the safety or effectiveness of food and drugs throughout the United States was the Food and Drug Act of 1906. In 1879, Dr. E.R. Squibb had proposed a national food and drug law. Legislation was introduced in Congress ten days later, but the general sentiment was that this regulation should be left to the states, and no significant action was taken until 1902, when several children died after receiving tetanus-infected diphtheria vaccine. The Biologic Act of 1902 required drugs sold in interstate commerce to be licensed and produced in licensed establishments.[7] Concern about

the prevalence of food adulteration from various sources grew, and the USDA Division of Chemistry was instrumental in bringing about the enactment of the Food and Drug Act of 1906.[8] This Act forbade the interstate commerce of adulterated or misbranded food and drugs. Among its many shortcomings, however, was the "lack of . . . any restriction upon the use of many of the most virulent poisons in drugs[.]"[9]

Food, Drug, and Cosmetic Act of 1938

To fill the many gaps in the 1906 Act, the Food Drug and Cosmetic Act (FDCA) of 1938 was enacted.[10] This Act gave the FDA exclusive authority to approve all new drugs and required such approval before drugs could be marketed.[11] Requirements for approval at that time were not as stringent as they currently are. The rules were meant to serve as pre-market notification rather than approval. Pharmaceutical companies were required to notify the FDA of new drugs in the form of a new drug application (NDA). If the FDA did not respond to the NDA within sixty days, the manufacturer could proceed with further testing and development.[12] And unless the "FDA found and reported to [the] manufacturer that it lacked sufficient information to determine [the] drug's safety, [the] drug would automatically be approved."[13]

The FDCA underwent further amendments in 1962 that expanded the FDA's authority to review and approve drugs prior to their being marketed. The drugs had to meet certain safety and efficacy standards. "[T]he FDA gained control over the design and structure of clinical trials, and required manufacturers to prove that a new drug was effective under the 'substantial evidence' standard."[14] And the time given to the FDA for this approval process was expanded from 60 to 180 days. Because of these amendments, the regulation of drugs became the FDA's primary responsibility. These changes were meant to increase the safety of new drugs, but also had the effect of prolonging the process of obtaining new drug approval. Essentially, what had been simply a drug notification process became a drug approval process. Drug manufacturers had no choice but to adapt to the FDA's slower approval process.[15] "[B]y the 1970s, the FDA began to encounter criticism for its time-consuming process of premarket review, approval, and clearance of all new consumer drugs."[16]

PDUFA

By the 1990s, the pharmaceutical companies were becoming increasingly concerned about the cost and delays involved in getting a new drug approved. In addition, patient advocate groups concerned about the lack of treatments for new conditions such as AIDS were exerting political pressure to speed up the process of new drug approval.[17] Congress responded by enacting the Prescription Drug User Fee Act of 1992 (PDUFA).[18] Under this Act, the FDA was authorized to charge fully integrated biopharmaceutical companies (FIBCOs) a substantial "user fee" for each new drug application. The funds raised were to be used by the FDA to hire additional drug reviewers so the new drug approval process could be expedited. In addition, PDUFA mandated that the FDA meet certain performance standards to assure that the drug approval process became more efficient.[19]

PDUFA successfully expedited the FDA's new drug approval process. User fees were used to hire 600 new drug reviewers and the average time for drug approval was reduced from thirty months to fifteen. In 1995, FDA Commissioner David Kessler, M.D., reported that many of the FDA's performance goals were reached, thereby dispelling the notion that the United States experienced a lag in drug approvals as compared to other countries.[20]

Many felt that because the source of the additional resources was the pharmaceutical manufacturers themselves, there was a conflict of interest on the part of the FDA and its reviewers between their duty to ensure a drug's safety and their perceived obligation to the companies providing their funding.[21]

Despite the success of PDUFA in expediting the approval of new drugs, the time and costs associated with regulatory review at the FDA continued to generate substantial criticism from the pharmaceutical industry. FIBCOs and other critics of the FDA pushed for further accelerating the review process for certain drugs that treated life-threatening conditions or addressed certain unmet medical needs. PDUFA's five-year term was about to expire and the stage was set for passage of the Food and Drug Administration Modernization Act of 1997 (FDAMA),[22] which established the current scheme of FDA regulation of new drug development.[23]

FDAMA

In FDAMA, Congress addressed the need for procedures and goals that would reduce the time necessary for a drug to get through the clinical testing phases.[24] The FDA was to continue receiving increased resources provided by the user fees, but was expected to set forth and comply with more ambitious performance goals for providing speedier reviews over the next five years. These expedited reviews reduced the time required for a manufacturer to get a drug through the development phase. This typically had been fifteen years prior to the enactment of PDUFA,[25] but it still took up to seven years after FDAMA's implementation.[26]

FDAMA successfully expedited the approval of new drugs and made more drugs available, but correspondingly, and not surprisingly, increased the likelihood of approving unsafe drugs. "[Drug reviewers] are aware that any decision other than 'yes' will be second-guessed by drug company executives, physicians and Wall Street analysts, many of whom regard FDA medical officers as little more than human speed bumps on the road to pharmaceutical success."[27] "In 1998, the Public Citizen

Health Research Group conducted a provocative survey of FDA reviewers, finding many who felt the industry, FDA senior officials, and Congress were pressuring them to approve questionable drugs."[28]

Ultimately, the drug reviewer must reconcile the tension between speedy drug review and safety, and it appears that, as a consequence of FDAMA's ambitious performance goals, a reviewer's productivity is linked to the number of drugs approved. Reviewers are under tremendous pressure to approve drugs from drug manufacturers, physicians, and Wall Street. In fact, the FDA appears to be working too closely with drug manufacturers during the review process. Such a relationship could result in a conflict of interest leading to fatal approval errors. In fact, the FDA removed a record number of recently approved drugs in 1998 that proved to be harmful.[29]

The FDA is faced with the difficult task of protecting the public from drugs that can be dangerous without delaying the availability of useful treatments. Before FDAMA was enacted, a reviewer who approved an unsafe drug would suffer tremendous consequences, while a reviewer who delayed or denied drug approval would be overlooked. Congress was confident that FDAMA's provisions would not cause public health concerns; however, since FDAMA's enactment, the FDA appears to focus on marketing drugs as quickly as possible, which may be detrimental to the FDA's duty to protect public health.[30]

The conflict between getting effective drugs to market quickly and protecting the safety of the public's health remained a major dilemma of the new drug approval process. "The current system of testing new drugs may be too brief to detect harmful reactions that could surface after repeated use. Therefore, drug safety experts suggest that more follow-up studies should be conducted on drugs that have been approved rapidly."[31] That would mean putting more emphasis on post-approval surveillance.

Post-Approval Surveillance

"Once a new drug has been approved by the FDA for marketing, current FDA regulations require a new drug to be continually monitored for its safety and efficacy in light of new information that the applicant is required to periodically submit to CDER [Center for Drug Evaluation and Research]. This is often referred to as 'post-marketing' or 'post-approval' surveillance."[32] This reporting is under the supervision of the Office of Drug Safety (ODS), which is a subdivision of the CDER. Given the relatively limited studies done prior to approval of many new drugs (several thousand patients over several months),[33] ongoing surveillance is necessary to ensure that previously undetected or unsuspected side effects are discovered. The responsibility for this rests primarily with the manufacturer. Although the FDA has oversight of this process, great discretion is given to the manufacturers in terms of reporting, analysis, and follow-up investigations. There is an inherent conflict of interest between the manufacturer's need to promote a new drug for the sake of maximizing profit and the responsibility to report adverse events, which entails the possibility of restrictions being placed on the drug, or adverse publicity. "It defies belief that any company whose fortunes are riding on a blockbuster drug will be hard-nosed when assessing unexpected consequences."[34] Furthermore, adverse events are initially reported by the prescribing physicians, and it is felt that only a very small percentage of adverse events are actually reported.[35] The FDA estimates this percentage to be as low as 10%.[36]

Medical officers also know that the system for catching these problems after approval is woefully inadequate. A commentary in the *Journal of the American Medical Association* argued that "vital safety monitoring tasks" were being "largely neglected." And, back in April, a *JAMA* study and editorial pronounced that over 100,000 Americans die each year from adverse reactions to prescription drugs, making drug reactions the fourth-leading cause of death in this country.[37]

In the case of Vioxx, suspicions arose shortly after the drug was approved. The VIGOR (Vioxx Gastrointestinal Outcomes Research) study confirmed Vioxx's reduced incidence of gastrointestinal side effects compared with a traditional anti-inflammatory medication, naproxen. The incidence of myocardial infarction, however, was five times as high in the group of patients given Vioxx compared with naproxen.[38] Merck's interpretation of this data was that "the small number of events reflected the play of chance or that naproxyn was actually cardioprotective."[39] The FDA simply accepted Merck's explanation and did not mandate further study. "However, epidemiologic studies of possible cardioprotection afforded by naproxen have proved inconclusive."[40]

Finally, in 2004, after Vioxx had been withdrawn from the market, an independent review was done of all available studies comparing Vioxx with either another drug or placebo. Meta-analysis was performed, namely the pooling of all data from the various studies to assess the different effects (beneficial or detrimental) of Vioxx. This analysis revealed that the relative risk of myocardial infarction in patients taking Vioxx was 2.30, based on data available by the end of 2000, and 2.24 with additional data available one year later. This relative risk did not differ if the control group was placebo or some other drug such as naproxen.[41] The author's conclusion was that "[Vioxx] should have been withdrawn several years earlier. The reasons why manufacturer and drug licensing authorities did not continuously monitor and summarise the accumulating evidence need to be clarified."[42] Other

scientists also indicated that such data was previously available, and that in fact advice had been given that further studies were warranted. An FDA advisory committee declared in 2001 that "based on the clear-cut excess number of myocardial infarctions associated with [Vioxx] . . . it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of th[is] agent[]."[43]

The reasons are self-evident why Merck would be hesitant to perform further studies that would only risk having restrictions placed on its blockbuster drug. But why did the FDA fail in its duty to insure the public's safety concerning a new drug it had approved as being safe? One possible explanation is that the group within the FDA responsible for overseeing post-approval surveillance, the Office of Drug Safety (ODS), is a subordinate branch of the CDER. It is felt that the CDER would be loath to admit that it had prematurely or mistakenly approved the safety of a drug subsequently shown to be unsafe. Concerning Vioxx, "[i]nternal memos show disagreement within the FDA over a study by one of its own scientists, Dr. David Graham, that estimated Vioxx had been associated with more than 27,000 heart attacks or deaths linked to cardiac problems."[44] Dr. Graham of the ODS had his concerns overruled by his supervisors in the CDER.

[T]he FDA's Office of Drug Safety co-exists in the same centre—the Centre for Drug Evaluation and Research (CDER)—as the Office of New Drugs, the part of the agency that works most closely with industry to license new medicines. Once a licensing approval has been made it is naturally in CDER's own interests to stand by its original decision. CDER's reputation would be damaged if its licensing judgments were constantly challenged by its own staff. This understandable but dangerous tendency to discourage dissent makes the Office of Drug Safety, which sits lower in the hierarchy of CDER than the Office of New Drugs, weak and ineffective.[45]

There is little doubt that the FDA's surveillance of newly approved drugs needs to be strengthened. "The FDA itself has asked the Institute of Medicine of the National Academy of Sciences to study the effectiveness of the drug safety system. As the institute proceeds with this task, it needs to determine whether the pendulum has swung too far in favor of the manufacturers and should be pulled back in favor of consumer safety."[46]

Post-Approval Marketing

[M]any doctors and patients too often ignore even strong warnings about adverse reactions and interactions that appear on drug package inserts. Such cautionary messages compete with more than $10 billion a year in upbeat pharmaceutical marketing, including an extra billion unleashed since August [1997], when the FDA loosened its rules on advertising prescription drugs directly to consumers.[47]

Once a new drug is approved by the FDA, its manufacturer is finally able to actively market the drug for the purpose of generating revenue. Recovering development costs and generating profit are strong counterweights to any company's altruistic motives. Patent protection for new drugs runs for twenty years from the date of filing for the patent.[48] Given that FDA approval occurs seven to fifteen years after a drug's patent filing, that leaves as few as five years during which the original manufacturer has exclusive marketing rights. Research and development of a new drug costs somewhere between $200 and $800 million,[49] and this must be recouped before any real profit is realized. Pharmaceutical companies therefore strive to maximize use of their new drugs as soon as FDA approval is obtained.

Unfortunately, the initial period during which new drug promotion is most aggressive is the period during which its safety will really be tested. Drug approval is based on studies involving thousands of patients, but post-approval use generally involves millions of patients. Not only does the manufacturer try to drive sales while there is still patent protection, but there is little incentive to do further studies investigating the drug's safety, even when there is data to suggest that the drug may in fact be unsafe, as was seen in the case of Vioxx. Rather, the manufacturers have many reasons to interpret all findings in the most favorable light, and to resist or refuse to do further studies. Such resistance is frequently dispositive since most drug studies these days are funded by the pharmaceutical company whose drug is being studied.

There are various marketing strategies for the promotion of a new drug. The targets of this marketing include the physicians who prescribe the medications and the patients who use them.

DTC Advertising

Merck, the producer of Vioxx, spent "more than $100 million per year in direct-to-consumer [DTC] advertising—another activity regulated by the FDA and a critical mechanism in building the 'blockbuster' status of a drug with annual sales of more than $1 billion. Prior to Vioxx's withdrawal, every month has seen more than 10 million prescriptions for [Vioxx] written in the United States alone."[50]

It is a basic economic premise that increased marketing will stimulate sales, which is the goal of all manufacturers. Because of the potential conflict of interest between a pharmaceutical company's profit motive and its public responsibility to insure the safe use of its products, advertising has been restricted in the past by various state laws and FDA regulations. As early as 1976, however, the Supreme Court limited restrictions on the advertising of competitive prices of drugs by pharmacists. The Court held that the government may regulate pharmacies, "[b]ut it may not do so by keeping the public in ignorance

of the entirely lawful terms that competing pharmacies are offering."[51] The Court reiterated this in 1996, when it delineated the current standard that truthful, non-misleading commercial speech cannot be restricted.[52] The following year the pharmaceutical industry spent a record $1 billion on DTC advertising.[53]

The current FDA standard is that in addition to being truthful and non-misleading, DTC advertising "cannot omit facts that are material to representations made in the advertisement, and must have 'fair balance' in the presentation of risks and benefits."[54] "Fair balance" is a somewhat subjective standard, however, and the balance between risks and benefits can often be blurred. "Research indicates that general warnings (for example, see your doctor) in [direct-to-consumer] advertisements do not give the consumer a sufficient understanding of the risks inherent in product use. Consumers often interpret such warnings as a 'general reassurance' that their condition can be treated, rather than as a requirement that 'specific vigilance' is needed to protect them from product risks."[55]

Another group's objective analysis of DTC television ads has revealed that:

> First, the ads gave consumers about 30 percent less time to absorb facts about risks than about benefits. Clearly, fair balance cannot be achieved if statements about benefits are more fully explicated than those about risks. . . . Second, we observed that some risk statements lacked important contextual information. . . .Third, most of the ads presented risk information in one continuous segment. FDA studies show that consumers perceive ads in which risk information is given in one continuous segment by a different announcer as emphasizing risks to a lesser extent than ads in which that information is interspersed.[56]

Some feel that the pharmaceutical manufacturers are best situated to educate the public about their products, but others argue that the incentive to maximize profit creates an unacceptable countervailing conflict.[57] Despite the First Amendment's protection of pharmaceutical manufacturers' rights to advertise, unbiased consumer education seems to be outweighed by the corporate profit motive.[58] Recently New Zealand's health minister has decided that the potential benefits of "direct to consumer advertising" do not justify the harms and so plans to ban it in 2005. That will leave the United States as the only industrialized country allowing full direct to consumer advertising of prescription medicines.[59]There is good evidence that the pharmaceutical manufacturers' influence affects patient preferences, possibly to the point of being considered true market manipulation.[60] This influence probably affects which drugs are prescribed and to what degree. That is certainly the hope and expectation of the manufacturers. The concerns are how much the market is influenced and whether new drugs are being inappropriately prescribed. In other words, how often are new drugs being prescribed when older, safer, cheaper medications are available that are equally effective? And how often does this lead to adverse consequences, sometimes fatal, as in the case of Vioxx?

The ultimate safeguard in this entire process is the physician, who has ultimate control over what is prescribed, and presumably has the role of the learned intermediary. The physician should know all the risks and benefits and should be able to properly balance them in making the decision as to what is the best drug for a given patient. That leads us to examine the relationship between pharmaceutical manufacturers and physicians.

Marketing to Physicians

The physician's primary role is that of safeguarding the patient's welfare. In the pharmaceutical manufacturers' eyes, however, the physician is the essential force that drives the market. Therefore, it is no surprise that these companies will resort to various means to influence the prescribing behavior of as many physicians as possible. Just as with consumers, advertising is a powerful tool for persuading physicians to use certain products. Because of the "educational" role of drug advertisements, they cannot be as strictly regulated as DTC advertising. There are guidelines, however. But even here the pharmaceutical companies try to evade the restrictions.

A study in the *Annals of Internal Medicine* determined that 92% of a sample of pharmaceutical advertisements in professional journals failed to comply with FDA criteria in one or more of the twenty-eight categories examined. Of those advertisements, 20% "were judged to have no educational value," 37% had little, 33% contained some, and only 4% included a great deal of educational value. Regarding the kind of impact such advertisements could have upon prescribing behavior, "[o]nly 44% of reviewers felt that the advertisement would lead to proper prescribing if a physician had no other information about the medicine other than that presented in the advertisement." The reviewers also stated that only four percent of the ads would have been acceptable without change under peer review guidelines typical for professional journal articles.[61]

Although advertising to physicians is ubiquitous throughout the medical literature, "[t]he most prevalent method for marketing pharmaceutical drugs . . . remains direct solicitation of physicians. The magnitude of such promotions should not be underestimated: the salespersons responsible for making personal visits to physicians and hospital staff, often called detailers, spent more than $5,000 for every physician in the United States in 1988."[62]

Physicians justify this type of contact with the industry by claiming this is how they educate themselves about the drugs they prescribe, but most of the evidence indicates that the information provided by these "drug reps" is biased and intended to promote the use of the drugs.[63] Physicians respond that they are aware of the bias and are not influenced by it. But empirical data show that not only do most physicians fail to seek other sources of information to counter the bias, but that their prescribing practices are indeed influenced by the drug reps. "[S]ystematic reviews of the literature confirmed a direct relationship between the frequency of contact with reps and the likelihood that physicians will behave in ways favorable to the pharmaceutical industry. Physicians who spend more time with reps are less likely to prescribe rationally."[64]

In the past, pharmaceutical companies used even more blatant methods to influence physicians' prescribing practices. One notable example was the awarding of frequent flyer miles to physicians based on how many prescriptions they wrote for a particular drug.[65] Although this and similar practices were subsequently prohibited by FDA regulations, the pharmaceutical companies are always devising new and more insidious ways to achieve their marketing goals by exerting influence over physicians. Another example is the use of sham studies in which physicians are paid to recruit patients for a study that is purportedly investigating some effect of an approved medication. No aspect of the medication is being legitimately investigated; the purpose is simply to get more physicians prescribing and more patients using the drug.[66]

A more recently developed tactic is known as "late-breaking clinical trials." With this approach, the pharmaceutical company arranges for the presentation of the latest experimental data about one of their drugs at a legitimate medical educational conference. The problem is that the data being presented are derived from a recent investigation that has not been peer-reviewed. One cannot be sure of the accuracy of the findings or their interpretation. The only thing one can be sure of is that the findings will cast the drug involved in a favorable light. And the great hype with which the data are presented usually attracts more attention at the conference than the truly educational material legitimately being presented elsewhere, often with much less fanfare.[67]

Generally, the pharmaceutical companies use several vehicles for disseminating product information, some of which do not fall within the traditional spheres of FDA regulation. Of these, educational and scientific programs are considered by FDA officials and medical professionals to be no more than thinly veiled advertising fairs, presenting biased or inaccurate information.[68] As a result, the influence of pharmaceutical companies over physicians' prescribing practices is an adverse one. "Although the vast majority of practitioners perceived themselves as paying little attention to drug advertisements and detail men, as compared with papers in the scientific literature, their belief about the effectiveness of the index drugs revealed quite the opposite pattern of influence in large segments of the sample."[69]

The physician, who can and should rely on his education, intelligence, experience, professional integrity and ethical standards, has apparently failed to adequately resist the marketing efforts of the pharmaceutical companies. The result is that newly approved medications tend to be over-prescribed. "Even if the situation is not as dire as [some] commentators suggest, one should at least consider the possibility that the combination of direct-to-consumer advertising and promotional efforts targeted at physicians has resulted in suboptimal prescribing and consumption of pharmaceutical drugs."[70] When, as in the case of Vioxx, that drug is unsafe, patients are harmed to a greater degree than is necessary. This situation must not be allowed to continue.

Proposal

As seen from the discussion above, there are numerous problems with the current method of approving new drugs and monitoring them for safety after their approval. Many conflicts of interest exist and need to be remedied, either voluntarily or by regulatory mandate. Political pressure may induce the FDA to improve its performance under its current structure or possibly with some reorganization. Congressional action is already occurring in the form of hearings. Statutory enactment may follow.[71] Physicians must become more aware of the insidious influences on their behavior and how this adversely affects their professional performance. They must also heed their own ethical guidelines.[72] Tort action for damages caused by unsafe drugs will hopefully provide incentive to the pharmaceutical industry to monitor its own activity more responsibly.

In the meantime, I propose a modest modification to the current system that should serve two useful purposes:

1) limiting the use of newly approved drugs to the treatment of appropriate conditions in properly selected patients; and

2) providing more complete adverse events data to both the FDA and the manufacturer than is currently being reported.

This proposal focuses on the post-approval phase of the process because "[t]he current system of testing new drugs may be too brief to detect harmful reactions that could surface after repeated use. Therefore, drug safety experts suggest that more follow-up studies should be conducted on drugs that have been approved rapidly."[73]

The requirements of the proposal are relatively straightforward and simple to implement. They are as follows:

1. Approval of all new drugs by the FDA will be probationary. The probationary period will last for a given period of time (e.g., 3-5 years) or until data from a given number of patients (e.g., 100,000) is obtained. During this probationary period, all guidelines listed below must be followed.
2. Before prescribing a probationary drug, a physician must complete a simple form confirming that the patient meets proper criteria for taking the medication. No off label prescribing will be allowed. The patient must take this form to the pharmacy in order to be allowed to fill the prescription.
3. Pharmacies may not fill initial prescriptions without the properly completed physician form. The initial prescription and all subsequent refills are limited to a one month supply.
4. All subsequent refill requests must be accompanied by a simple form completed by the patient about possible adverse events.
5. All forms from the physician and the patient must be retained by the pharmacist, with copies forwarded by the pharmacist to both the manufacturer and the FDA.

With the use of computers and health information technology, completion of the forms and compilation of the data could be simplified and expedited. This would facilitate the proposed process for physicians, patients, pharmacists, and subsequent analysts.

The first purpose of the proposal is to insure that the prescribing physician is aware of what conditions the drug may be used to treat, which patients are appropriate users of the drug, and whether or not a safer alternative is available. The patients using the drug as well as the conditions being treated will also be documented for review by the FDA and manufacturer. By actually documenting, and in a sense certifying, that the drug is being used under the proper circumstances, the physician will appropriately limit his prescribing of the drug. If the drug eventually is shown to be unsafe, the harm caused will thereby be mitigated. Imagine how many lives could have been spared if such a system had limited the inappropriately excessive use of Vioxx.

The second purpose is to improve the reporting of adverse events. By requiring such reports from patients for every monthly refill, much more data will be acquired than is currently being reported. Not only will the FDA be aware of all the possible adverse events, but it will also know how many patients have used the drug. Therefore, both the numerator and the denominator will be available to determine not just the incidence, but the actual prevalence of adverse events. And trends and statistically significant occurrences of side effects will be apparent much sooner, with far fewer total users, and without formal studies that may or may not have been deemed necessary by either the manufacturer or the FDA.

From a pharmaceutical manufacturer's perspective, the above proposal would limit the marketing of its new drugs during the probationary post-approval period. I therefore propose one additional aspect to this process that would make it more palatable for drug developers. Extending the patent life of new drugs for the duration of this probationary period would alleviate to some extent the great pressure to aggressively market new drugs. And with the more thorough tabulation of adverse events, this probationary period would actually constitute an additional phase of safety testing, at little or no cost to the manufacturer. Furthermore, discovery of adverse events severe enough to warrant drug withdrawal could occur before mass marketing effected widespread use of the medication. Such a system of post-approval surveillance would probably have prevented a substantial amount of morbidity and mortality from Vioxx. The potential financial benefit to Merck in terms of avoided litigation costs is obvious. Another potential benefit is the possibility of better defining the subclasses of patients in whom a drug can be used safely, limiting the use of the drug but avoiding outright withdrawal from the market.

Conclusion

The number of patients who suffered illness or death from taking Vioxx seems to have been shockingly large. It was certainly higher than it might otherwise have been if the system of drug approval and subsequent oversight by the FDA had not failed so miserably. It would be easy to pin the blame on one or several key actors in this drama. All those involved in the system (from the original manufacturer of a drug to the end user, and all the intermediaries) must improve their behavior in ways that reduce the potential for future damages. In the meantime, however, the proposal put forth in this article tries to provide some specific, systemic remediation of the problem by enhancing the safe use of newly approved medications without unduly delaying their introduction into the market. It is within the power of the FDA (with some Congressional support) to amend its regulations to implement this or some alternative proposal, as well as whatever other changes are needed to enhance the safe use of new and established medications. The FDA not only has the authority to take such actions, but it has the responsibility to do no less.

Glossary

CDER	Center for Drug Evaluation and Research (FDA)
DTC	Direct-to-consumer
FDA	Food and Drug Administration
FDAMA	Food and Drug Administration Modernization Act
FDCA	Food, Drug and Cosmetic Act (1938)
FIBCO	Fully Integrated Biopharmaceutical Company
NDA	New Drug Application
PDUFA	Prescription Drug User Fee Act
ODS	Office of Drug Safety (FDA/CDER)
OND	Office of New Drugs (FDA/CDER)
USDA	United States Department of Agriculture

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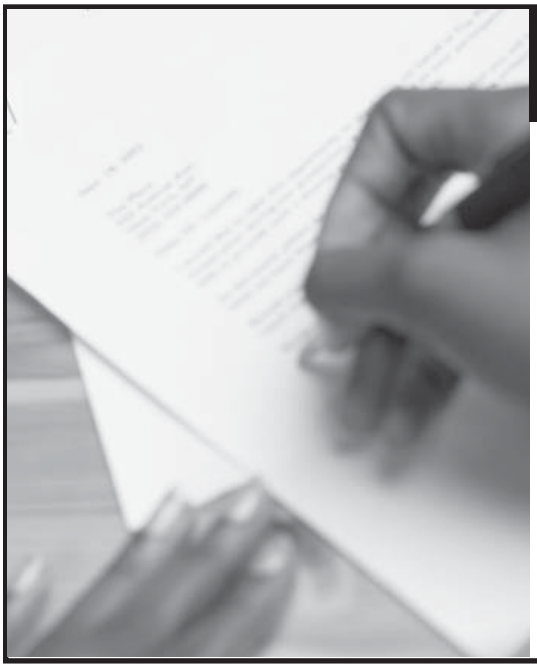

Medical Orders for Life-Sustaining Treatment (MOLST): A Paradigm Shift in Advance Care Planning

By Patricia A. Bomba, M.D., F.A.C.P.

Patient preferences for care at the end-of-life are not consistently followed, despite the presence of legal documents completed in accordance with state law. Clinical scenarios as illustrated below regularly unfold where the focus of conversation is purely on choice of interventions rather than a person-centered, goal-based discussion.

> *Patient is an 80-year-old retired successful businessman, former semi-professional athlete who now resides in a nursing home. He has a 25-year history of Parkinson's disease currently in the final stages, associated with dementia for the past ten years and a host of other medical problems. Presently he is totally dependent in all activities of daily living, rarely "recognizes" his wife but does not recognize other family members. Two years ago he was moved from a private to semi-private room and became delirious. The delirium lasted several months. He has a properly executed Health Care Proxy and Living Will completed when he had decision-making capacity. His wife, his designated Agent, has intact decision-making capacity. The nursing home staff raises the issue of a Do Not Resuscitate (DNR) order. While his wife realizes this was her husband's wish, both she and her son are emotionally conflicted. His daughter believes her father's wishes should be honored, regardless of personal feelings. A family meeting is held to focus on goals for future care. All are in agreement that the patient's quality of life is the primary goal. Further discussion reveals that the family does not understand what cardiopulmonary resuscitation (CPR) entails or the anticipated poor survival rate for patients with complex medical conditions and frailty. The son's perception hinges on a comment from the evening shift nurse, "Your father has a strong heart." When provided with the medical evidence base for CPR in the face of the current clinical scenario and empathetically acknowledging their emotions, the family is prepared to make a decision consistent with the patient's previously expressed wishes and accept a natural death, unattached to life support. Through focusing on the patient's quality of life as the goal for care, they are open to discussion of additional life-sustaining treatment and potential hospital transfer.*

Recognizing and accepting death as inevitable helps one to appreciate life fully, to live in the present moment and to help others plan for the unavoidable. An individual has the right to make health care decisions, a right that persists in the final chapter of life. When *our* final chapter is written, will *our* wishes about the type of care we want to receive be followed? Will anyone know what *we* want? Have *we* chosen the most effective surrogate decision-maker, shared *our* values and beliefs and completed *our* own Health Care Proxy? Have *we* spoken with *our* agents, family, loved ones, physicians and health care providers? Is *our* document accessible and reviewed on a regular basis? Will they follow *our* wishes?

"An individual has the right to make health care decisions, a right that persists in the final chapter of life. When our *final chapter is written, will* our *wishes about the type of care we want to receive be followed?"*

Do the terms "terminal" and "irreversible" provide sufficient clarity for health care professionals? What does the person with Alzheimer's disease prefer when the final phase of the disease arrives and the desire for food diminishes, swallowing problems lead to aspiration, pneumonia and fever? Without antecedent focused discussion, how does the health care professional proceed in the face of a terminal illness with a superimposed potentially reversible pneumonia?

If *you* had an advanced chronic condition or serious illness and would likely die in the next year, would you want to know? Would this impact your goals for care? Would *you* focus on the quantity or quality of your life? Would this impact the treatment decisions *you* make? What would *you* do differently to ensure the type of care *you* want to receive while you still have intact decisional capacity?

Summary

Honoring patient preferences is critical to providing quality end-of-life care, consistent with the individual's values and beliefs, based on informed medical decision-making and evidence-based medicine. To enable physicians and other health care professionals to discuss and convey wishes of patients with advanced chronic or

serious illness, the **Medical Orders for Life-Sustaining Treatment (MOLST)** form (Appendix A on pages 47-50 of this issue) was created. Based on Oregon's **Physician Orders for Life-Sustaining Treatment (POLST),** MOLST is a physician order form used to record actionable medical orders pertaining to life-sustaining treatments including cardiopulmonary resuscitation (CPR). The MOLST form improves the communication of patient wishes by centralizing all life-sustaining treatment orders on one bright pink form that is easily recognized in case of an emergency. Once completed, the MOLST form accompanies the patient across care settings. Approved by the New York State Department of Health (NYSDOH) for institutional use, MOLST is spreading to hospitals, long-term care facilities, hospice agencies and home care agencies throughout the state.

Although MOLST can now be used *in facilities*, the ultimate goal is to also use MOLST *in the community* and to improve EMS personnel's ability to treat according to patient wishes. Governor Pataki signed the MOLST bill **(A.8892, S.5785)** establishing a pilot of the MOLST program in Monroe and Onondaga Counties on October 11, 2005. This bill allows for the use of the MOLST form ***in lieu of*** the New York State Nonhospital Do Not Resuscitate (DNR) form. A Chapter Amendment **(A.9479, S.6365),** signed by Governor Pataki on July 26, 2006, permits EMS to honor Do Not Intubate (DNI) instructions prior to full cardiopulmonary arrest in Monroe and Onondaga Counties during the MOLST Pilot and provides a carve out for persons with mental retardation and developmental disabilities *without* capacity.

Introduction

Advances in health care and changing demographics have led to an aging population facing increasingly complex end-of-life care. Life expectancy and prevalence of chronic disease has increased. Adding to the complexity are increased comorbidities and frailty with advancing age, changing families, health care systems, society and marketplace demands. Finally, and perhaps most importantly, we exist in a culture where death is viewed as "optional."

In the midst of these evolving realities, it is critically important to focus on the patients' perspective of quality end-of-life care. Singer and colleagues identified and described the patients' perspective of quality end-of-life care as receiving adequate pain and symptom management, avoiding inappropriate prolongation of dying, achieving a sense of control, relieving the burden on loved ones and strengthening the relationship with loved ones.[1] McGraw and colleagues added respecting the uniqueness of individual, providing an appropriate environment, addressing spiritual issues, recognizing cultural diversity, and effective communication between the dying person, family and professionals.[2]

Unfortunately, humane care for the dying is a social obligation not adequately met in our country, including New York State. Too often, death is considered a medical failure rather than the inevitable last chapter of life. As a result, many people approach death fearing abandonment, profound suffering of self and family and a protracted, and an over-treated ending. Their fears are not unsubstantiated. Life-sustaining procedures are frequently administered in direct contradiction to the patient's wishes. Despite the growing proclivity to administer life-sustaining treatments, research indicates that increases in interventions have not reduced mortality rates.[3] In many cases, life-sustaining treatments only prolonged the dying process. Reducing unwanted, unnecessary and futile interventions at end-of-life will realign the intensity of care more with patient preferences without adversely impacting mortality rates.

Currently, conversations about death are too often avoided until a crisis occurs, resulting in inadequate Advance Care Planning and patient preferences not being known or honored. For example, more than 70 percent of surveyed Americans indicated that they wish to die at home. Yet, only 25% of Americans die in their home while the other 75% die in institutions (i.e., hospitals, nursing homes).[4] In place since the Patient Self-Determination Act (PSDA) passed in 1991, the current system of communicating end-of-life care wishes solely using traditional advance directives, such as the Health Care Proxy and Living Will, has proven insufficient.

Traditional Advance Directives

Anyone can face sudden, unexpected life-limiting illness or injury. Thus, advance care planning is appropriate for all adults 18 years of age and older, not only the subset of Americans with life-limiting illness (Figure 1).

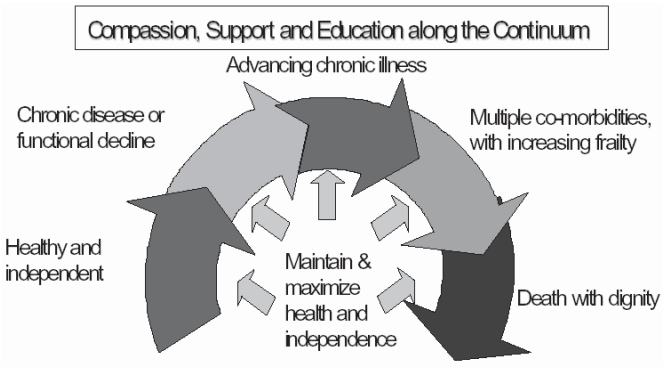

Figure 1

The health-illness continuum. Advance care planning is appropriate for all adults 18 years of age and older, not only the subset of Americans with life-limiting illness. People who are healthy and independent can face sudden, unexpected life-limiting illness or injury. These individuals should complete traditional advance directives. Individuals with advancing disease benefit from more intensive discussion while they have capacity and should complete actionable medical orders like the MOLST form. Thus, advance care planning should be incorporated along the entire continuum of care.

The process determines future medical care preferences if decisional capacity is lost. Advance care planning focuses on conversation, selection of a trusted surrogate to represent the patient when the capacity to represent oneself is lost, and clarification of values and beliefs. The result is accessible legal documents completed in accordance with state law. Advance care planning helps a patient to maintain control, achieve peace of mind and is an important step to assuring that wishes are honored. Absence of legal documents can result in situations illustrated by Karen Ann Quinlan, Nancy Cruzan and Terri Schiavo.

When advance care planning occurs and is done well, traditional directives like the Health Care Proxy are completed and conversation occurs with family, loved ones, physician and other trusted individuals. A Health Care Proxy applies only when decision-making capacity is lost. Patient goals guide care and should continue to do so even when the patient loses capacity. Documents are regularly updated and are available in an emergency.

Too often, advance care planning does not occur and the resulting conflict manifests in a variety of ways. The Agent and family may disagree with the physician assessment. Alternately, the Agent and physician may agree while another family disagrees and interferes. There may be a disagreement regarding the goals for care, with the Agent and family focused on quality of life while the physician recommends extending quantity of life. There may be disagreement among physicians. The clinical situation becomes more complicated when a patient lacks capacity and no Agent or family exists. Complicating matters, the language used frequently results in unintended consequences.

Unfortunately, advance directives are not widely used. The advance directive completion rate in the United States has not significantly increased since the passage of the Patient Self-Determination Act. In 1991, the year the PSDA passed, 75% of Americans approved of a living will, yet only 20% had some form of advance directives.[5] A 2002 study showed no improvement in the advance directives completion rate. The completion rate remained at 15-20%.[6] Completion rates were no better for higher risk individuals. Only 20% of nursing home residents had any form of advance directive.[7] A November 2005 poll by the *Pew Research Center for the People and the Press* revealed Americans are increasingly likely to plan for future health care. A recent poll performed after the Schiavo case unfolded before the nation indicated 29% of Americans have advance directives.[8]

Moreover, even if advance care planning occurs traditional advance directives are often unavailable, overlooked, ignored or not communicated once the individual enters the health care system. In spite of these potential drawbacks, traditional advance directives, notably the New York State Health Care Proxy, retain a critical role in identifying a trusted individual to serve as the appropriate surrogate decision maker for patients if they lose capacity, particularly in the absence of surrogacy laws aside from cardiopulmonary resuscitation.

Medical Orders for Life-Sustaining Treatment (MOLST)

To complement the use of traditional advance directives and facilitate the communication of medical orders impacting end-of-life care for patients with advanced chronic or serious illness, the Medical Orders for Life-Sustaining Treatment (MOLST) program was created. In contrast to a Health Care Proxy, the MOLST applies right now and is *not* conditional on losing decision-making capacity. The MOLST program is based on the belief that individuals have the right to make their own health care decisions, including decisions about life-sustaining treatments, describe these wishes to health care providers and to receive comfort care while wishes are being honored. This community-wide program provides a framework for facilitating the communication and documentation of an individual's goals and wishes regarding life-sustaining treatments across care settings, while educating the health care system and its providers to be responsive to patient wishes.

The aim of MOLST is to express patients' treatment goals as actionable medical orders that are based on communication with patients and/or surrogates, using the informed consent process. MOLST brings together multiple professionals from across the health care system to meet the goals of patients. The process results in completion of the MOLST form (Appendix A) which may be used either to limit medical interventions or to clarify a request for all medically indicated treatments including cardiopulmonary resuscitation (CPR). The form provides explicit direction about resuscitation status if the patient is pulseless and apneic. It also includes directions about other types of intervention that the patient may or may not want. For example, decisions about transport, ICU care, antibiotics, artificial nutrition, etc. The form accompanies the patient, and is transferable and applicable across care settings (i.e., long-term care, EMS, hospital). It is uniquely identifiable, standardized, and a uniform bright pink color. MOLST should be reviewed and renewed periodically as required by New York State and Federal laws or regulations, if the individual's preferences change, if the individual's health status changes, or if the individual is transferred to another care setting.

The process includes training of health care professionals across the continuum of care about the goals of the program, implementation, use of the form and a plan for ongoing monitoring of the program.

Development of MOLST, a POLST Paradigm

The *Community-wide End-of-life/Palliative Care Initiative*, a Rochester, New York-based initiative aimed at improving end-of-life care in New York, developed the original MOLST form in 2003. When initially formed in 2001, the Initiative set forth community goals to be developed locally and shared regionally.[9] These included:

1. All adults 18 years of age and older should have an opportunity to complete a traditional Advance Directive.
2. The health care community should adopt a comprehensive Advance Directive that all area practitioners and institutions will honor.
3. Patients should be referred to Hospice earlier so that the social, spiritual and psychological components of suffering can be addressed.
4. Practitioners and Health Care Facilities should establish comprehensive pain assessment and treatment standards at every site of care.
5. Health Care Institutions should be encouraged to set performance goals and track basic statistics regarding end-of-life care.

A review of the literature for preferred practices revealed the *Physician Orders for Life-Sustaining Treatment (POLST)* program developed in Oregon in the early-mid 1990s. A decade of research in the state of Oregon has proven that the POLST program more accurately conveys end-of-life preferences that are more likely followed by medical professionals.[10] The POLST program has been a key vehicle in Oregon's successful efforts to increase the effectiveness of advance care planning and decrease unwanted hospitalizations at the end of life.[11]

MOLST was developed to incorporate New York State law. The MOLST Program was designed to:

1. Align medical orders with patient wishes.
2. Document the patient's treatment preferences regarding life-sustaining treatments including cardiopulmonary resuscitation (CPR), intubation and mechanical ventilation.
3. Communicate patient wishes regarding care across health care settings.
4. Improve emergency medical services (EMS) personnel's ability to provide emergency treatment according to the individual's wishes.
5. Reduce repetitive documentation while complying with New York State law and the federal Patient Self-Determination Act.

In collaboration with the New York State Department of Health, Excellus BlueCross Blue Shield revised the MOLST form in 2005. The revised MOLST is consistent with state law and approved for use as an inpatient Do Not Resuscitate form in all health care facilities in New York State.

POLST is spreading across the country as part of the National POLST Paradigm Initiative. New York State's MOLST Program is one of six endorsed POLST Paradigm Programs. To learn more about the POLST Paradigm Initiative and other states that are replicating this goal-based paradigm, see www.polst.org. States with endorsed programs may vary in name and format but share essential core elements, as exemplified by New York State's MOLST.

Appropriate Use of MOLST

Predicting and outlining guidance for all possible clinical scenarios is difficult. Advance directives are rarely sufficiently precise to dictate patient preferences in a specific situation as disease progresses. Thus, for a patient with advanced chronic illness or a serious health condition, conversion of patient-centered treatment goals into actionable medical orders while the patient retains capacity provides a more effective means of communicating and ensuring patient preferences are honored than traditional advance directives. Anyone residing in a long-term care facility or anyone eligible for long-term care but who chooses to age in place at home is an appropriate candidate to complete the MOLST. Completion of the form is also important for any patient who may die in the next year, including patients with metastatic cancer, end-stage cardiac or pulmonary disease or advanced dementia. Additional appropriate candidates include those who wish to limit certain interventions or choose to allow and embrace natural death, unattached to life support, and choose a DNR order.

American Bar Association expert Charlie Sabatino points out: "The message behind the term 'do not resuscitate' is predominantly negative, suggesting an absence of treatment and care. The reality is that comfort care and palliative care are affirmative and, for these patients, more appropriate interventions."[12]

Physicians tend to overestimate the likelihood of survival of in-hospital cardiopulmonary arrests to hospital discharge. The literature reports an average survival rate of 15%. At least 44% of the survivors have significant decline in functional status at the time of discharge.[13] Chronic illness, more than age, determines prognosis in the elderly; elderly with chronic illness have an average survival rate of less than 5%. For those with advanced illness, survival rates are often less than 1%.

Improved survival rates with good functional recovery are reported with the duration of CPR shorter than 5 minutes and CPR occurring in the ICU.[14] Poor outcomes at all sites of care are associated with unwitnessed arrest,

asystole, electrical-mechanical dissociation, greater than 15 minutes of cardiopulmonary resuscitation, metastatic cancer, multiple comorbidities and sepsis. Patients and families have significant functional health illiteracy with regards to life-sustaining treatment, adding to the burdens of medical decision-making. Studies have shown that physicians speak to patients 75% of the time, often using medical jargon.[15] Further studies reveal that after discussions related to cardiopulmonary resuscitation, 66% of individuals did not know that many patients need mechanical ventilation after resuscitation, 37% thought ventilated patients could talk and 20% thought ventilators were oxygen tanks.[16]

The survival rate misconceptions are likely further complicated by the fact that 67% of resuscitations are successful on television.[17] Actually, attempts to educate patients are successful. In one study of 371 patients, age greater than 60 years of age, 41% wanted cardiopulmonary resuscitation. After learning the probability of survival, only 22% wanted cardiopulmonary resuscitation.[18]

Completing MOLST Using the 8-Step MOLST Protocol

The MOLST must be completed by a health care professional, based on patient preferences and must be signed by a New York State licensed physician to be valid. Verbal orders are acceptable with follow-up signature by a physician, in accordance with facility or community policy. The original form should remain in the patient's possession as the readily pink color makes it easier to locate in an emergency. Photocopies and faxes of signed MOLST forms are legal and valid. Completion of the entire form is strongly recommended; any section not completed implies full treatment. HIPAA permits disclosure of MOLST to other health care professionals as necessary.

Issues surrounding medical decision-making for patients increasingly challenge physicians. Many studies have shown that most patients either do not have advance directives or, for those patients with advance directives, they do not adequately provide health care professionals with explicit instructions for making critical decisions.[19] As a result, health care professionals may withhold or initiate treatments that are either not medically indicated or desired by the patient.[20] Further, health care decisions are often made in the face of significant functional health illiteracy with respect to the benefits and burdens, particularly of life-sustaining treatment.

Appendix B on page 51 illustrates the 8-Step Protocol that outlines the suggested process for completion of the MOLST. Informed medical decision-making is assisted by framing the following questions:

- Will treatment make a difference?
- Do burdens of treatment outweigh benefits?
- Is there hope of recovery? If so, what will life be like afterward?
- What does the patient value? What is the goal of care?

Documentation of the patient's and surrogate's preferences will improve the poor concordance often seen between the patient's preferences and the treatments their physicians and their spouses thought they wanted. Discussion of preferences for goals of care, treatment options and setting of care should occur with the patient/family unit *as designated by the patient*.

Cultural factors strongly influence patients' views about serious illness and may impact the advance care planning process. Appreciating and respecting cultural values and beliefs is essential. It is equally important to recognize that variation exists within a culture. The best method for understanding cultural factors that may impact the patient is simply to ask the patient.

Page 1 of the MOLST provides resuscitation instructions for the patient/resident in cardiopulmonary arrest with no pulse and/or no respirations. By agreeing to CPR, the patient agrees to the entire battery of treatments, including intubation and mechanical ventilation, typically required if the patient/resident survives. To issue a DNR order, Section A, a subsection of B and Section C must be completed. Section A provides resuscitation instructions, a subsection of B provides consent and Section C provides for the physician signature. Consent can be provided by the patient, resident, a duly appointed Health Care Agent or a surrogate decision-maker, in accordance with NYS Public Health law (PHL § 2977). For patients who lack capacity, and/or for therapeutic or medical futility exceptions, and/or for residents of OMH, OMRDD or correctional facilities, relevant sections of the Supplemental Documentation Form for Adults must also be completed. For Minor patients, the Supplemental Documentation Form for Minors must also be completed.

As per Public Health Law § 2967(4)(b), a parent may give a verbal consent in the presence of two witnesses, one of whom must be an M.D. affiliated with the hospital in which the patient is being treated. The decision must be noted in the patient's medical chart.

Page 2 provides for medical orders for other life-sustaining treatment and future hospitalizations if the patient/resident has a pulse and/or is breathing. Additional treatment guidelines are provided, including a recognition that comfort measures are always provided, regardless of the level of intervention chosen. Other choices include intubation and mechanical ventilation instructions in the event of progressive or impending pulmonary failure without cardiopulmonary arrest, future

hospitalizations and transfer instructions, use of artificially administered fluids and nutrition, antibiotics, and other individualized instructions (e.g., dialysis, implantable defibrillators, etc.). The physician may complete the MOLST form with the patient who has capacity or with a Health Care Agent. If a Health Care Agent makes a decision regarding artificial hydration and nutrition, the decision must be based on reasonable knowledge of the patient/resident wishes. For the incapacitated patient/resident without a Health Care Agent, the MOLST can be completed with clear and convincing evidence, established in *In re Westchester County Medical Center, on behalf of Mary O'Connor.* "The ideal situation is one in which the patient's wishes were expressed in some form of a writing, perhaps a 'living will,' while he or she was still competent. The existence of the writing suggests the seriousness of purpose and ensures that the court is not being asked to make a life-or-death decision based upon casual remarks."[21] The decision went on to state, "Of course, a requirement of a written expression in every case would be unrealistic. Further, it would unfairly penalize those who lack the skill to place their feelings in writing. For that reason, we must always remain open to applications such as this, which are based upon the repeated oral expressions of the patient." Patients with mental retardation and developmental disabilities *with capacity* can complete the MOLST form. The physician should consult legal counsel for patients with mental retardation and developmental disabilities without capacity, and follow in accordance with Surrogate's Court Procedure Act 1750B.

The physician should review and renew MOLST periodically, if the individual's preferences change, if the individual's health status changes, and if the patient is transferred to another care setting. The physician must review and renew DNR order at least every 7 days in the hospital, at least every 60 days in the nursing home/SNF, and at least every 90 days in the nonhospital/community setting.

Establishing Plans of Care for Patients Who Lack Decision-Making Capacity

The incidence of cognitive impairment increases with age. Assessing the patient's ability to make decisions is recommended. Capacity is the ability to take in information, understand its meaning and make an informed decision using the information. Intact capacity permits functional independence. Capacity requires a cluster of mental skills people use in everyday life and includes memory, logic, the ability to calculate and "flexibility" to turn attention from one task to another. Medical determination of capacity is often difficult to determine. There is no standard "tool." Capacity assessment is a complex process and is not simply determined by the Mini-Mental Status Exam (MMSE). Capacity assessment should involve a detailed history from the patient, collateral history from family, focused physical examination, including cognitive, function and mood screens and appropriate testing to exclude reversible conditions. Capacity requirements vary by task. For example, the capacity to choose a trusted individual as an appropriate Health Care Agent differs from the capacity to agree to a medical procedure or treatment.

From a legal perspective, capacity depends on ability to understand the act or transaction, understand the consequences of taking or not taking action, understand the consequences of making or not making the transaction, understand and weigh choices, make a decision and commit to the decision.

Advance care planning for patients lacking decision-making capacity requires special consideration to ensure maximal patient participation with appropriate surrogate involvement.[22] Using effective communication skills focused on patient values and goals of care helps surrogate decision makers recognize that goals guide care and the choice of interventions. A mutual appreciation of the patient's condition and prognosis must be reached by physician and family. A choice between life prolongation and quality of life should be offered instead of the choice between treatment and no treatment. The full range of end-of-life decisions from do not resuscitate orders to exclusive palliative care should be addressed.[23] Conversation should be focused to provide evidence of previous repeated oral expression of wishes instead of applying a literal interpretation of an isolated, out-of-context, patient statement made earlier in life. When appropriate, the principle of substituted judgment should be applied, in which the surrogate attempts to establish with as much accuracy as possible what decision the patient would have made if that patient were competent to do so. This standard seeks to preserve the patient's right of self-determination by placing the patient's own preferences at the center of deliberation, while recognizing that it is the exception rather than the rule that the patient will have articulated his or her preferences in advance.

MOLST Pilot Program Legislation

Approved by the New York State Department of Health (NYSDOH) for institutional use, MOLST is spreading to hospitals, long-term care facilities, hospice agencies and home care agencies throughout the state. Although MOLST can now be used *in facilities*, the ultimate goal is to also use MOLST in the community and to improve EMS personnel's ability to treat according to patient wishes.

Governor Pataki signed the MOLST bill **(A.8892, S.5785)** establishing a pilot of the MOLST program in Monroe and Onondaga Counties on October 11, 2005. This bill allows for the use of the MOLST form ***in lieu of*** the New York State Nonhospital Do Not Resuscitate

(DNR) form. Do Not Intubate (DNI) is not covered in Nonhospital DNR Law (PHL § 2977). A Chapter Amendment **(A.9479, S.6365)**, signed by Governor Pataki on July 26, 2006, permits EMS to honor Do Not Intubate (DNI) instructions prior to full cardiopulmonary arrest in Monroe and Onondaga Counties during the MOLST Pilot and provides a carve out for persons with mental retardation and developmental disabilities without capacity.

The *Monroe and Onondaga Counties MOLST Community Implementation Team* was formed to help introduce and oversee the pilot. Team members include representatives from hospitals, long-term care facilities, hospice and home care agencies, EMS personnel, NYSDOH Western Region—Rochester and Syracuse offices, local medical societies, local bar associations and the respective county health departments. The Team facilitates implementation of the pilot and aims to ensure adequate regional training and appropriate utilization of the MOLST form and program. Appropriate utilization will be audited through collecting and reviewing quality EMS and facility-based data. Standardized quality metrics are under development and will be tracked. To assist facility implementation throughout the state, sample Policies and Procedures, Facility Implementation and Education Workplans from the pilot counties are available for replication. The ultimate goal is the creation of a system that ensures that the form and program are appropriately used as the project moves beyond the pilot phase.

Periodic e-mail updates on the MOLST Pilot are sent. Contact patricia.bomba@lifethc.com.

Community Resources

Final products will be produced as a result of the MOLST Pilot Project. Several are currently available, including:

- MOLST 8-Step Protocol, a framework for discussion using the MOLST.
- MOLST Guidebook, a nuts and bolts summary of MOLST.
- MOLST Patient & Family Trifold Brochure, in English and Spanish.
- MOLST Patient & Family Web Flyer, in English and Spanish.
- MOLST FAQs.
- MOLST Train-the-Trainers Manual for Facilities.
- Sample Hospital and Long Term Care Facility Policies & Procedures.
- Sample Hospital and Long Term Care Facility Implementation and Education Workplans.
- MOLST Training Manual, a Train-the-Trainers manual created to ensure consistency of training in the MOLST Pilot counties.
- Advance Care Planning Booklet outlines key elements of the process including the choice of the surrogate decision-maker and the discussion of values, beliefs and preferences.
- Community Conversations on Compassionate Care, a community workshop on advance care planning.
- EMS educational "tools" including a standardized EMS training curriculum and provider protocols. Training will include First Responders (Fire and Police), EMS Personnel and Medical Control (designated Emergency Department Physicians who back up EMS personnel).

For further information about MOLST, see www.compassionandsupport.org.

Next Steps

The MOLST Pilot affords the opportunity to initiate ongoing monitoring of quality, a critical component of the MOLST Program. Evaluation of the effectiveness of the MOLST Pilot Project will build the foundation for statewide expansion of the community-wide implementation of the MOLST form and program. Quality measures will be established for ongoing monitoring of the MOLST Program, including accuracy of completion, appropriate utilization and patient/family and professional satisfaction.

The National Quality Forum Framework and Preferred Practices for Quality Hospice and Palliative Care[24] outlines five preferred practices for advance care planning:

- Document the designated surrogate/decision maker in accordance with state law for every patient in primary, acute, and long-term care and in palliative care and hospice care.
- Document the patient/surrogate preferences for goals of care, treatment options, and setting of care at first assessment and at frequent intervals as conditions change.
- Convert the patient treatment goals into medical orders and ensure that the information is transferable and applicable across care settings, including long-term care, emergency medical services, and hospital, such as, the Physician Orders for Life-Sustaining Treatment (POLST) Program.
- Make advance directives and surrogacy designations available across care settings, while protecting patient privacy and adherence to HIPAA regulations, e.g., by Internet-based registries or electronic personal health records.

- Develop health care and community collaborations to promote advance care planning and completion of advance directives for all individuals, e.g., Respecting Choices, Community Conversations on Compassionate Care.

The legal community and health care community have an opportunity and professional obligation to collaborate and make these preferred practices a reality in New York State.

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Dr. Patricia Bomba, Vice President and Medical Director, Geriatrics, Excellus BlueCross, Rochester, New York chairs the MOLST Community Implementation Team and has worked with the New York State Department of Health on the MOLST revision and on the MOLST Pilot legislation. She serves as a member of the Review Committee of the National Quality Forum's "Framework and Preferred Practices for Quality Palliative and Hospice Care," the New York State representative on the National POLST Paradigm Task Force, and a New York State delegate to the 2005 White House Conference on Aging.

APPENDIX A

SEND FORM WITH PATIENT/RESIDENT WHENEVER TRANSFERRED OR DISCHARGED

MOLST

Medical Orders for Life-Sustaining Treatment

Do-Not-Resuscitate (DNR) and other Life-Sustaining Treatments (LST)

Last Name of Patient/Resident

First Name/Middle Initial of Patient/Resident

Patient/Resident Date of Birth

This is a Physician's Order Sheet based on this patient/resident's current medical condition and wishes. It summarizes any Advance Directive. If Section A is not completed, there are no restrictions for this section. When the need occurs, *first follow* these orders, then contact physician. Any section not completed implies full treatment for that section.

This form should be reviewed and renewed periodically, as required by New York State and Federal law or regulations, and/or if:

- The patient/resident is transferred from one care setting or care level to another, or
- There is a substantial change in patient/resident health status (improvement or deterioration), or
- The patient/resident treatment preferences change

Section A

Check One Box Only

RESUSCITATION INSTRUCTIONS (ONLY for Patients in Cardiopulmonary Arrest):

(If patient/resident has no pulse and/or no respirations)

☐ **Do Not Resuscitate (DNR)*** **[DNR = No cardiopulmonary resuscitation, endotracheal intubation or mechanical ventilation]**

☐ **Full Cardio-Pulmonary Resuscitation (CPR) – No Limitations**

* For incapacitated adults; and/or for therapeutic or medical futility exceptions; and/or for residents of OMH, OMRDD or correctional facilities, also complete relevant sections of Supplemental DNR Documentation Form for Adults. For minor patients, also complete Supplemental DNR Documentation Form for Minors. For patients in the community, also complete NYS DOH Nonhospital DNR Form, unless located in Monroe or Onondaga Counties.

Section B

Patient/ Resident/ Health Care Agent or Surrogate Decision-Maker Consent for Section A

DNR (CPR) CONSENT OF PATIENT/RESIDENT WITH DECISION-MAKING CAPACITY:

Section A reflects my treatment preferences.

Patient/Resident Signature ☐ Check if verbal consent	Print Patient/Resident Name	Date
Witness of Patient/Resident Signature or Verbal Consent	Print Witness Name	Date

DNR (CPR) CONSENT OF HEALTH CARE AGENT (HCA) OR SURROGATE DECISION-MAKER FOR PATIENT / RESIDENT WITHOUT DECISION-MAKING CAPACITY: **This document reflects what is known about the patient/resident's treatment preferences. For Patient/Resident without decision-making capacity, or when medical futility or therapeutic exception is used, Supplemental MOLST Documentation Form MUST be completed and should always accompany this MOLST Form. If patient/resident has a legal and valid DNR previously completed while patient/resident had capacity, attach to MOLST. ☐ Prior form attached ☐ Supplemental Documentation Form completed**

Complete one of the subsections of Section B

HCA/Surrogate Signature ☐ Check if verbal consent	Print Name	Date

Relationship to Patient/Resident: _____

Witness Signature	Print Witness Name	Date

(Must witness HCA/surrogate signature or verbal/telephone consent)

Section C

Physician Signature for Section A and B

Physician Signature for Sections A and B:

Physician Signature *(Must Witness Patient/Resident Signature or Verbal Consent)*	Print Physician Name	Date

Physician License #: _____ **Physician Phone/Pager #:** _____

It is the responsibility of the physician to determine, within the appropriate period, (see below) whether this order continues to be appropriate, and to indicate this by a note in the person's medical chart. The issuance of a new form is NOT required, and under the law this order should be considered valid unless it is known that it has been revoked. This order remains valid and must be followed, even if it has not been reviewed within the appropriate time period. The **physician must review these orders** as follows: **Hospital: at least every 7 Days; Nursing Home/Skilled Nursing Facility: at least every 60 Days; Nonhospital/Community Setting: at least every 90 Days**

Section D

ADVANCE DIRECTIVES: **Patient/Resident has completed an additional document that provides guidance for treatment measures if he/she loses medical decision-making capacity:**

☐ **Health Care Proxy** ☐ **Living Will**

Section E

HIPAA Permits Disclosure of MOLST to Other Health Care Professionals as necessary

ORDERS FOR OTHER LIFE-SUSTAINING TREATMENT AND FUTURE HOSPITALIZATION: (If patient/resident has pulse and/or is breathing)

This Section is "optional" depending on clinical circumstances and setting. Complete only those sub-sections that are relevant. Blank subsections can be completed at a later date. If patient has decision-making capacity, patient should be consulted prior to treatment or withholding thereof. After confirming consent of appropriate decision-maker, physician must sign and date each subsection at the time of completion.

Physician may complete form for patient with capacity or with Health Care Agent. Include Section E consent.

ADDITIONAL TREATMENT GUIDELINES: (Comfort measures are always provided.)

☐ **Comfort Measures Only** – The patient is treated with dignity and respect. Reasonable measures are made to offer food and fluids by mouth. Medication, positioning, wound care, and other measures are used to relieve pain and suffering. Oxygen, suction and manual treatment of airway obstruction are used as needed for comfort. *Do Not Transfer to hospital for life-sustaining treatment. Transfer if comfort care needs cannot be met in current location.*

☐ **Limited Medical Interventions** - Oral or intravenous medications, cardiac monitoring, and other indicated treatments are provided except as specified in Sections A or E. Guidance about acceptable/unacceptable interventions relevant to this patient/resident may be written under "Other Instructions" below. *Transfer to the hospital as indicated.*

☐ **No Limitations on Medical Interventions** - All indicated treatments are provided except as specified in Sections A. *Transfer to the hospital is indicated, including intensive care.*

MD Signature: *Date:*

Physician may complete form for incapacitated patients without Health Care Agent only with clear and convincing evidence. Include Section E consent.

ADDITIONAL INTUBATION AND MECHANICAL VENTILATION INSTRUCTIONS: If patient/resident is DNR, and has progressive or impending pulmonary failure without acute cardiopulmonary arrest:

☐ **Do Not Intubate (DNI)**

☐ **A trial period of intubation and ventilation**

☐ **Intubation and long-term mechanical ventilation, if needed**

MD Signature: *Date:*

FUTURE HOSPITALIZATION / TRANSFER: (For long-term care residents and home patients)

☐ **No hospitalization unless pain or severe symptoms cannot be otherwise controlled.**

☐ **Hospitalization with restrictions outlined in Sections A and E.**

MD Signature: *Date:*

Physician should consult legal counsel for MR/DD patients without capacity. See Surrogate's Court Procedure Act §1750-B.

ARTIFICIALLY ADMINISTERED FLUIDS AND NUTRITION: (If Health Care Agent makes decision, it must be based on knowledge of patient/resident's wishes.)

☐ **No feeding tube** (offer food/fluids as tolerated)

☐ **A trial period of feeding tube**

☐ **Long-term feeding tube, if needed**

☐ **No IV Fluids** (offer food/fluids as tolerated)

☐ **A trial of IV fluids**

MD Signature: *Date:*

ANTIBIOTICS:

☐ **No antibiotics** (except for comfort)

☐ **Antibiotics**

MD Signature: *Date:*

OTHER INSTRUCTIONS: (May include additional guidelines for starting or stopping treatments in sections above or other directions not addressed elsewhere.)

_____

_____

_____

MD Signature: *Date:*

Section E Consent

CONSENT FOR SECTION E OF PERSON NAMED IN SECTION B: Significant thought has been given to life-sustaining treatment. Patient/resident preferences have been expressed to the physician and this document reflects those treatment preferences. As the medical decision-maker, I confirm that the orders documented above in Section E reflect patient/resident's treatment preferences.

_____ _____ _____

Signature ☐ **Check if verbal consent** **Print Name** **Date**

SEND FORM WITH PATIENT/RESIDENT WHENEVER TRANSFERRED OR DISCHARGED

RENEW / REVIEW INSTRUCTIONS

MOLST (DNR and Life-Sustaining Treatment)

This form should be reviewed and renewed periodically, as required by New York State and Federal law or regulations, and/or if:

- **The patient/resident is transferred from one care setting or care level to another, or**
- **There is a substantial change in patient/resident health status (improvement or deterioration), or**
- **The patient/resident treatment preferences change**

Last Name of Patient/Resident
First Name/Middle Initial of Patient/Resident
Patient/Resident Date of Birth

How to Complete the MOLST Form

- **MOLST must be completed by a health care professional, based on patient preference and medical indications.**
- **MOLST must be signed by a NYS licensed physician to be valid. Verbal orders are acceptable with follow-up signature by a physician in accordance with facility/community policy.**
- **If patient/resident has a legal and valid DNR previously completed while patient/resident had capacity, attach to MOLST.**
- **Use of original form is strongly encouraged. Photocopies and FAXes of signed MOLST are legal and valid.**

How to Review MOLST Form:

Step 1: **Review Sections A through E**

Step 2: **Complete Section F below:**

2a. If no changes, sign, date and check the "No Change" box.

2b. For additions to Section E "optional" directives, complete the relevant subsections(s) after securing consent from the appropriate decision-maker, sign and date subsection(s) in Section E. Then sign, date and check "Changes-Additions only" in box below.

2c. For substantive changes, (i.e. reversal of prior directive), write "VOID" in large letters on pages 1 and 2, and complete a new form. Check box marked "FORM VOIDED, new form completed". (RETAIN voided MOLST form in chart or medical record, or as required by law.)

2d. If this form is voided and no new form is completed, full treatment and resuscitation will be provided. Write "VOID" in large letters on pages 1 and 2 and check box marked "FORM VOIDED, no new form." (RETAIN voided MOLST form in chart or medical record, or as required by law.)

Section F *(Review of this Form)*

Review of this MOLST Form

Date	Reviewer's Name and Signature	Location of Review	Outcome of Review
			☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, *no* new form
			☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, *no* new form
			☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, *no* new form
			☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, *no* new form
			☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, *no* new form

Pages 3 & 4 contain directions and renewals only. **Continue Section F on Page 4**

SEND FORM WITH PATIENT/RESIDENT WHENEVER TRANSFERRED OR DISCHARGED

Section F *(Review of this Form)*	Review of this MOLST Form *(Con't from Page 3)*			
	Date	**Reviewer**	**Location of Review**	**Outcome of Review**
				☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, ***no*** new form
				☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, ***no*** new form
				☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, ***no*** new form
				☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, ***no*** new form
				☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, ***no*** new form
				☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, ***no*** new form
				☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, ***no*** new form
				☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, ***no*** new form
				☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, ***no*** new form
				☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, ***no*** new form
				☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, ***no*** new form
				☐ No Change ☐ Changes – Additions only ☐ FORM VOIDED, new form completed ☐ FORM VOIDED, ***no*** new form

APPENDIX B

Medical Orders for Life-Sustaining Treatment (MOLST)*

8-Step MOLST Protocol

1. Prepare for discussion
   - Review what is known about patient and family goals and values
   - Understand the medical facts about the patient's medical condition and prognosis
   - Review what is known about the patient's capacity to consent
   - Retrieve and review completed Advance Care Directives and prior DNR documents
   - Determine who key family members are, and (if the patient does not have capacity), see if there is an identified "Agent" (Spokesperson) or responsible party
   - Find uninterrupted time for the discussion

2. Begin with what the patient and family knows
   - Determine what the patient and family know regarding condition and prognosis
   - Determine what is known about the patient's views and values in light of the medical condition

3. Provide any new information about the patient's medical condition and values from the medical team's perspective
   - Provide information in small amounts, giving time for response
   - Seek a common understanding; understand areas of agreement and disagreement
   - Make recommendations based on clinical experience in light of patient's condition / values

4. Try to reconcile differences in terms of prognosis, goals, hopes and expectations
   - Negotiate and try to reconcile differences; seek common ground; be creative
   - Use conflict resolution when necessary

5. Respond empathetically
   - Acknowledge
   - Legitimize
   - Explore (rather than prematurely reassuring)
   - Empathize
   - Reinforce commitment and nonabandonment

6. Use MOLST to guide choices and finalize patient/family wishes
   - Review the key elements with the patient and/or family
   - Apply shared medical decision making
   - Manage conflict resolution

7. Complete and sign MOLST
   - Get verbal or written consent from the patient or designated decision-maker
   - Get written consent from the treating physician, and witnesses
   - Document conversation

8. Review and revise periodically

*MOLST is a medical order form designed to provide a single, community-wide document that would be easily recognizable and enable patient wishes for life-sustaining treatment to be honored. It is a tool created by a workgroup of the Community-Wide End-of-life/Palliative Care Initiative in Rochester, New York. MOLST is adapted from the Oregon Physician Orders for Life-Sustaining Treatments (POLST) and incorporates New York State Law.

End-of-Life Decision Making and the Politics of the Fetus

By Carl H. Coleman

During the 1990s, I worked on the staff of the New York State Task Force on Life and the Law, a bioethics commission established by Governor Mario Cuomo in 1985. During my interview for the job, in the spring of 1993, I learned that the Task Force had recently proposed legislation that would authorize family members to make treatment decisions for incapacitated patients, including decisions about life-sustaining measures, and that New York was one of only a small handful of states that did not already have case law or legislation giving family members these rights. However, I was told that I would probably not have an opportunity to work on the legislation because, by the time I would be able to start work in the summer, the bill would probably already have been enacted.

"The reasons the. . . [Family Health Care Decisions Act] . . . has been held up all these years are not the ones you might suspect. . . . [T]he main reason the bill has not become law has to do with one word: 'fetus.'"

Thirteen years later, the legislation, now known as the Family Health Care Decisions Act, is still languishing.

The reasons the bill has been held up all these years are not the ones you might suspect. The "sanctity of life" versus "quality of life" issues that dominated the national debate over withdrawing Terri Schiavo's feeding tube have been largely absent from the discussion in New York. In fact, hardly anyone has opposed the basic goals of the legislation. On all sides of the political spectrum, there is widespread consensus that the current legal standard—which requires physicians to provide all life-sustaining measures, no matter how burdensome, unless there is "clear and convincing evidence" of the patient's prior decision to refuse them—is both unworkable and inhumane.

Instead, the main reason the bill has not become law has to do with one word: "fetus." Specifically, the Senate version of the bill states that, for patients who are pregnant and whose wishes about treatment cannot be determined, the surrogate shall consider "the impact of treatment decisions on the fetus and on the course and outcome of the pregnancy." The Assembly version does not contain this language. Neither house seems willing to budge.

What is so interesting about this debate ("tragic" would probably be a better adjective) is that virtually everyone agrees that the "fetus language" has no practical significance for how decisions would be made for incapacitated patients. The language appears in the section of the bill that defines the "best interests" standard, which is the standard that applies to patients whose wishes cannot be determined. That section provides that, in assessing the patient's best interests, the surrogate should take into account any factor that "a reasonable person in the patient's circumstances would wish to consider." The impact of treatment decisions on the pregnancy is offered as one of several examples of such factors. The bill does not tell the surrogate *how* to consider the impact of treatment decisions on the fetus; it simply points out that this is a factor the surrogate should take into account. Admittedly, it is hard to imagine that any surrogate would need to be reminded of this, but the same could be said for many of the other factors that are specifically mentioned—for example, "the possibility and extent of preserving the patient's life" and "the relief of the patient's suffering." The bill emphasizes that the surrogate's consideration of all the best-interests factors "shall be patient-centered" and "consistent with the values of the patient."

All of the major pro-choice groups in the state examined the language and decided that it was innocuous. In fact, one of them (the New York Civil Liberties Union) testified that the language actually "creates greater protections for pregnant women and strengthens reproductive rights by requiring the surrogate to adhere to the woman's values and by eliminating the possibility of intervention by the State or third parties unknown to the patient who may wish to impose their values and beliefs upon the incapacitated woman." Similarly, on the anti-abortion side, the New York State Catholic Conference has acknowledged that, as much as they had hoped that the legislature would use this opportunity to recognize "fetal rights," the fetus language, as currently written, does not do that. In discussions with legislators—both supporters and opponents of the fetus language – there has been nearly unanimous agreement that the language would not change the decision-making standards in any way at all.

Why, then, has the fetus language proved to be such a stumbling block? On the Assembly side, some members have taken the position that simply mentioning the word "fetus" creates a dangerous legislative precedent. If fetuses are mentioned in this bill, the argument goes, they might be mentioned in another one next year, and even if this bill mentions the fetus is an acceptable way, next year's bill may not. In other words, for some members of the Assembly, "fetus" has become a dirty word.

This position is both illogical and, for anyone concerned about reproductive rights, dangerous. It is illogical

because it would be impossible to have a legal system that never mentions fetuses. According to my research assistant, the word "fetus" appears 42 times in New York State statutes and regulations; the words "pregnant" or "pregnancy" appear an additional 479 times. These words appear in diverse areas of the law, ranging from food labeling requirements to laws giving pregnant women access to specialized medical services. In general, whenever the word "fetus" or "pregnancy" is mentioned it is to the benefit of pregnant women.

"[F]or some members of the Assembly, 'fetus' has become a dirty word."

From a reproductive rights perspective, it is also a dangerous position, as it reinforces the mistaken view that "pro-choice" means "anti-fetus." Being pro-choice means supporting the right to decide *whether or not* to become or remain pregnant, and people who are pro-choice decide to remain pregnant every day. Those people care as much about their fetuses as opponents of abortion.

Yet, while I believe the Assembly is wrong to object to the fetus language, it is also true that the entire problem would disappear if the Senate were willing to amend their bill to omit the disputed words. Given that everyone acknowledges that the language has no practical significance, there is no reason for the Senate to insist on keeping it. Just like the Assembly, the Senate is playing politics with the word "fetus"—in this case insisting on keeping the word in the statute to score symbolic points with anti-abortion voters.

Meanwhile, countless families are suffering because of New York's antiquated laws.

"[C]ountless families are suffering because of New York's antiquated laws."

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Rethinking the Social Role of Physicians: The Importance of Physicians' "Symbolic Acts"

By John Balint, M.D.

". . . be like a god, savior of slaves, of paupers, of rich men, of princes and to all be a brother."

—Inscription on the Shrine of Asclepius

In this article I propose a change in the role of physicians from one focused on the patients in their practice to one that broadens their responsibilities to addressing the socio-economic and psycho-social factors that impact health. There is convincing evidence, which will be reviewed herein, that poverty, lack of education and other social and economic inequalities are major causes of poor health. Physicians are witnesses to the harmful effects of socio-economic and psycho-social stresses on the health of their patients (1-6). Therefore, based on the principles of beneficence and justice, which are fundamental to our duties to patients, it is incumbent on us to take action to recognize and minimize these harms. Physicians as members of a learned profession have influence that can be used to affect public policy for the good of our patients.

There is growing concern on grounds of justice about the fairness and adequacy of the health care systems of both rich and poor countries (1-6). In the U.S. there are now about 45 million people with no health insurance, a number that is projected to rise to 55 million by 2008 (7). This has stirred debate about the need to assure universal access to health care and the role of market forces in the delivery of health care. In both Eastern and Western Europe, experiments in privatized medicine are changing the mode of health care delivery, often with questionable results in respect to equity and economic viability (2,5). At the same time there have been dramatic increases in income disparities among groups of citizens within a given country and among nations (2,4,8). Research in public health indicates that such disparities are associated with poor health outcomes among those in the lower socio-economic groups even in those countries that provide universal access to care (9,10,11).

What should be the response of physicians, in line with their proposed broader role, to these social, economic and public policy problems that impact the health of their patients? Virchow said almost 150 years ago that "Medicine is a social science" and that "Physicians are the natural advocates for the poor . . . and the social problems should largely be solved by them" (12). More recently Black (1), based on his studies of health outcomes in relation to socio-economic factors in the UK, stated, "Because doctors are also citizens, they have opportunities to observe and perhaps mitigate the effects of poverty; and they should be in Virchow's words 'the natural advocates of the poor'" (1). The recent report of the Commission on Macroeconomics and Health (CMH) of the World Health Organization (WHO) highlights the strong connections between poverty, health, life expectancy and economic productivity (13). The important role of physicians in addressing issues of human rights and ethics in public health was eloquently advocated by Mann (6) and is another aspect of physician involvement to be considered.

The Concept of "Symbolic Action"

Physicians have a personal responsibility for the health of their patients. Most physicians have many patients usually from varied social and ethnic groups. Therefore, physicians have a responsibility to develop a social contract with their patients which commits them to advocacy on behalf of all their patients. Jonsen and Jameton (14) support this idea, but argue that arising out of these primary duties to a group of patients flow secondary even broader social and political responsibilities. A dilemma arises in trying to balance the physician's personal responsibility to the individual patient against the physician's stewardship responsibility to the larger society for the proper use of public resources which Angell has called the problem of "double agency" (15). These conflicts are further elaborated by Bloche in the specific setting of HMO controls of the costs of care and utilization of diagnostic and therapeutic interventions (16,17). There is, however, an opportunity in the larger social contract that may allow physicians to influence social attitudes and public policy. Jonsen and Jameton argue that physicians must undertake social and political activism in the form of what they called "symbolic acts" (14). They suggest that physicians who see the scientific evidence of harm to groups of patients or individuals must draw public attention to the forces in the larger society which impair the health of patients or populations, even when these forces, or factors, are outside the customary boundaries of medicine and the patient-physician relationship—such as poverty, lack of education, or social and occupational stress. Physicians have not always been willing to act on their observations as urged by Virchow, Black, and Jonsen and Jameton (12,1,14). "Symbolic Acts" by physicians involve taking public positions and using their status as both physicians and respected citizens to influence public policy on issues which adversely affect the health of their patients. The need for such action was stressed by Virchow (12) and Black (1) as noted previously and by Geiger (3), who said "Too many of us still treat the rat bite and ignore the rats; treat the lead poisoning and ignore the plaster and the crumbling tenements" (3). Physicians for Social Respon-

sibility, Physicians for Human Rights and Mann (6) have taken such symbolic actions by their advocacy for human rights and a true ethic of public health. Physicians for Human Rights also led the fight against land mines. Their efforts gained them the Nobel Peace Prize. Medicines Sans Frontieres in their work with devastated populations have set another recent example that deservedly earned them the Nobel Peace Prize. These are examples of physicians firmly stating political positions and calling for appropriate remedies, as was also done by McCally and colleagues in their paper titled "Poverty and Ill Health: physicians can, and should, make a difference" (4). Sulmasy, in a challenging examination of the role of professional oaths as these apply to physicians, notes that oaths are "performative utterances" (18). He suggests that all such physicians' oaths in fact commit physicians to work for greater net social happiness and altruistic service (18). These views and actions are consistent with the concept of "symbolic acts" as proposed by Jonsen and Jameton (14).

Review of some major social and economic problems that are strongly associated with significant harmful effects on the health of many of our patients will illustrate the data that calls on all health care professionals to engage in the kinds of "symbolic acts" called for by Jonsen and Jameton (14). This data base also provides the scientific basis for such action.

Socio-Economic Factors and Their Influence on Health Status

There is mounting evidence to demonstrate the influence of socio-economic status of individuals and groups on their health outcomes. This evidence is even more significant when examined in light of the current debate over universal access to health care. It is argued by some protagonists of universal access to care that achieving this goal would correct what ails our health care system (19). Indeed, Light (20) makes a strong case to show that universal access to care is an absolute requirement for managed care to achieve its goals. But this does not prove that universal access is enough to ensure good and just health care for all (21). Pincus et al. present compelling evidence from work in the UK, Canada and the U.S, that there are major differences in health outcomes among groups of patients of different socio-economic status for any given diagnosis, despite full access to care (21). Marmot and colleagues (11,22) showed that at a time when life expectancy at birth for all men in the UK, Japan and Singapore, among others, had increased from 64-68 years in 1965 to 71-78 years by 1990, the reduction in standardized mortality rates in the UK was largely confined to men with high education levels. Mortality in this group fell from 6 to 3 per 1,000 from 1960 to 1986, whereas in those with low education the fall was from 9 to 8 per 1,000. Ten year mortality rates for all causes of death among British civil servants aged 40 to 64 years, all covered by the National Health Service (NHS), rose stepwise from 5% for the top rank (administrative) through professional and clerical to 15% in other ranks. The differentials were similar for coronary heart disease (CHD) (11,22). Similar differentials were noted for patients participating in the B-blocker heart study in the U.S. (23). A report based on U.S. mortality data related to the size of income differentials in the 50 states demonstrated that the larger the income differential between the highest and lowest 10% of the population, the greater the standardized mortality rate in that state (24). The Robin Hood index, i.e., the percentage of earnings from the highest income group that would need to be transferred to the group with lowest income to achieve income parity, was calculated. This index was significantly and linearly related to standardized mortality rates for all deaths, as well as for death rates from CHD, cancers and other causes (24). On a global scale, life expectancy at birth reaches a plateau in relation to per capita GDP at about $5,000 per annum, but falls off sharply at lower per capita incomes (25). These are disturbing statistics when examined in the context of the progressive growth in income disparity in the U.S. (8) and worldwide (4). The worldwide negative relationship between life expectancy at birth, infant mortality and mortality in the first 5 years of life and per capita income was clearly demonstrated by the report of the CMH (13).

The evidence cited above and many similar studies (21) show that absolute poverty as seen in some developing countries and relative poverty as seen in the industrialized nations have profound influences on health outcomes. But further analysis of the data presented in the B-blocker heart study in this country (23) and the Whitehall studies

Social Responsibilities of Medicine—Should There Be Limits?

A. Socio-Economic Issues:
1. Social deprivation (poverty) and health.
2. Universal access to care.
3. Education and health.
4. Social support services.
5. Home care—dying at home.

B. Ethical and Policy Issues:
6. The genetic revolution/genetic determinism.
7. Privacy and confidentiality.
8. Informed consent.
9. Evidence-based medicine.
10. Preventable transplants.

C. Societal Issues:
11. Addictions—alcohol, tobacco, illicit drugs.
12. Guns.

D. Economic Issues:
13. Lifetime limits on health coverage, etc.
14. Health care as a market commodity.
15. Pharmaceutical industry problems—costs, profits and research.

Figure 1

by Marmot and his colleagues in Britain (11,22) shows that the socio-economic differences do not explain all the findings in respect to the higher mortality rates among those in the lower socio-economic strata. In the studies by Marmot et al. (11,22) the largest influence on relative risk of death from CHD was due to unexplained factors, after correcting for the effects of blood pressure, smoking and serum cholesterol. Life stresses, social isolation and educational level all influence health outcomes as shown in the Whitehall studies and the B-blocker study (11,22,23). Thus socio-economic disadvantages influence health outcomes through their effects on educational opportunities, social isolation, and stresses at work and in life in general. As Marmot et al. (11) point out, those in the lower ranks of the British civil service, while not poor by world standards and having access to health services through the NHS, still have higher standardized mortality rates than those in executive positions. Marmot et al. suggest that some forms of job stress, perhaps frustration over lack of control over workloads, and job assignments, may be a major factor influencing health (11,22).

The Hastings Center International Project proposed four goals for medicine (27): (1) Prevention of disease and injury, and promotion and maintenance of health; (2) relief of pain and suffering caused by maladies; (3) the care and cure of those with a malady and the care of those who cannot be cured; (4) the avoidance of premature death and the pursuit of a peaceful death.

These goals will only be attainable if we follow the call by Jonathan Mann (6) to develop medical ethics and ethics in public health to include attention to human rights and justice in assuring access to care and appropriate resources (6). Both Mann (6) and the CMH report (13) demonstrate that there are huge discrepancies in availability of and access to care across the different parts of our planet. But even in the industrialized countries large differences are present as noted (9,11,22). Thus there are major problems in terms of distributive justice in all societies.

The preceding brief review of epidemiological studies looking at social and economic influences on health outcomes strongly suggests that the differing health care systems in the U.S., Canada, Britain, and in the countries of Eastern Europe and the developing world are not preventing disease evenly across our societies and we are failing to prevent premature death for the lower socio-economic groups in a just manner as advocated by the Hastings Center International Project (27). In the U.S. these failures can in part be attributed to the fact that about 45 million of our citizens do not have access to appropriate preventive care and this situation is even worse in the third world. But that is not the full explanation since even among those with health insurance, mortality rates both in this country (23,24) and in the UK (11,22) are significantly related to socio-economic factors. These factors include education, social isolation, relative poverty, lack of control over life events at work and at home, and the growing income disparities in all Western societies and elsewhere (2,8). These are not issues normally regarded as within the purview of physicians. They are considered social, political or economic rather than strictly medical, although several have a medical component. This larger social context has profound effects on our ability to attain the four goals of medicine (27). For example the system of economic incentives in Western society may explain the trend for pharmaceutical companies to focus new drug development on the needs of wealthy populations, rather than on those in the developing world who lack the resources to pay for new medications so urgently needed for the control of HIV infection and drug resistant malaria and tuberculosis (13,28). Recent social and political pressure has resulted in some easing of this problem in relation to cost of medications for the treatment of HIV in the developing world (29).

What Actions Symbolic or Otherwise Are We Taking Now?

There have been many suggestions about ways physicians and other health care professionals could respond to these social problems that affect the health of those we are committed to care for. An important long-term measure is to educate future physicians while still in medical school about the importance, clinically and ethically, of the social, economic, and educational influences on the health of their future patients. Fortunately, all U.S. medical schools are now addressing these issues (30). And furthermore, the successes and failures of these programs are being studied (31,32,33). At Albany Medical College, for example, there is a required four-year seminar course for medical students called "Health, Care and Society," which addresses these concerns especially in the setting of case conferences in the clinical years. Requirements of accreditation of medical residency programs also require formal programs in medical and clinical ethics. These programs offer the opportunity to raise awareness of these problems with young physicians in training. Our medical students and residents have shown interest in learning more about the problems in health care related to socio-economic factors both in the U.S. and worldwide. Efforts at enhancing public and professional understanding of the links between health, level of education and economic and social policy have also been urged by Watt (34). But these educational efforts, even if successful, will take many years to effect the needed changes. What can be done in the meantime? Major efforts to enhance the health of children have been widely recognized as likely to yield important benefits (2,35,36,37,38). Black (1) quotes Donald Court's phrase, "Childhood illness casts long shadows forward." Both Acheson (2) and Frank (37) emphasize the critical importance of prenatal and early childhood care and education in ensuring healthy development of children. While efforts in this direction have started at both state and federal levels in the U.S., there is more to be done (38). There is strong evidence to show that better pre-school education and nutrition result in higher educational attainment, better physical and mental health,

fewer teen pregnancies, and fewer people on welfare rolls (2,37). The present political environment where health care for children is recognized as a crucial issue by candidates for political office offers an opportunity to urge a more complete attack on barriers to child health including education and nutrition. A great opportunity for "symbolic acts."

The King's Fund in the UK stressed the importance of addressing problems associated with the physical environment, social and economic factors, access to health care and other barriers to a healthy life (39). But how these aims can be achieved is not clear. Efforts to increase services to the poor in the UK by providing bonuses to physicians who made efforts to provide better primary care were not fully successful (2). Much of the extra care went to the wealthiest patients (2). Two editorials have urged major public policy interventions (40,41). Davidoff and Reinecke in a plea for a more just health care system propose a constitutional amendment to establish a right to health care in the U.S. (40), which would bring the U.S. into line with the UN Charter, the Universal Declaration of Human Rights and the Convention on the Rights of the Child (40). "The London Declaration" produced by a conference organized by Action on International Medicine and the WHO is the subject of the other editorial (41). This declaration specifies actions that health care professionals should advocate including: policies to reduce poverty and improve health; dissemination of information on trends in health and poverty and successful and failed attempts to remedy these problems; decentralization of health care delivery; better training for front line health care workers; preventing marginalization of vulnerable populations like the elderly, the disabled and refugees; and influencing public opinion and lobbying politicians to achieve these goals (41). This is an ambitious program of political action for social justice, public education and lobbying to effect change. It shows the complexity and challenge of taking "symbolic action" (14). (See Figure 1 on p. 55).

A Proposal for Action

What should we do to promote recognition of the urgent need to move us worldwide to a more just health care system? Black, Geiger and McCalley et al. have noted the problems we face (1,3,4). I believe we must follow the lead given by Jonsen and Jameton (12) and take "symbolic action." As Black has written, "This article is open to the criticism of being political. My reason is that this is basically a political problem whose radical solution will require a return to distributive justice. Why write about it in a medical journal? Because doctors are citizens" (1). Similar sentiments were expressed by McCalley et al. (5) and Haines and Smith (41) recently. We can no longer separate our professional roles from our roles as citizens. We need to persuade our patients to join us in mutual education and citizen action as part of a patient-physician alliance (42).

Major inequalities in resources between the wealthy and the less well off in all western industrialized nations are becoming more pronounced (2,4,8). Similarly, disparities between first and third world nations are growing (5,20). This has happened during a period of economic expansion in the U.S.A. and much of Western Europe and remarkable increases in personal wealth among the more fortunate (8). Many of these nations have experienced budget surpluses until recently. The time has come for some redistribution of financial resources within and between countries as suggested by the CMH report (13). The CMH suggests that an additional 0.1% of GDP annually be transferred from the wealthy to the poor nations (13). Many conservative political and financial leaders have argued that such redistribution of wealth will lead to economic recession because of inherent inefficiencies. They maintain that creation of personal wealth in an unfettered capitalist system is the only way to lift the poor out of poverty. They cite the failure of the Soviet system and the apparent success of western capitalist societies. However, the failure of the Soviet system and of the British Labor Government's effort after 1945 were due more to the economic weakness of both Russia in 1917-18 and of Britain in 1945-46. These weaknesses were compounded in the case of the Soviet Union by excessive bureaucracy, corruption, lack of personal incentives, and civil war and in Britain by the economic devastation of two world wars, and loss of the Empire and its resources. This was clearly not the case in the U.S. of 2001, or even now during a war against terrorism and an economic recession that is forecast to be relatively short. The CMH study estimates that the investment they propose would save eight million lives and result in an enhanced economic output ten-fold greater than the suggested investment (13).

John Rawls (43) in his "Theory of Justice" puts forward the suggestion that if one were asked to design a political-economic system behind "the veil of ignorance" one would choose a system of distributive justice that would be far more egalitarian than the one we now have. This represents a patterned approach to social policy with defined rules and responsibilities. In sharp contrast the views expressed by Nozick (44) represent a libertarian unpatterned social system that emphasizes individual freedom. Western democratic societies will not tolerate a situation in which their citizens are unable to obtain health care and will provide emergent care on a charity basis as they have done for many years. It would seem more humane and more cost effective to provide access to preventive health care to all our citizens. This is an accepted norm in all western industrialized nations except the U.S. (5).

A libertarian social development in the U.S. was predicted by de Tocqueville 180 years ago (45). He wrote, "Individualism is a calm and considered feeling which disposes each citizen to isolate himself from the mass of his fellows, and withdraw into the circle of family and friends; with this little society formed to his taste, he gladly leaves

the greater society to look after itself" (45). A more communitarian view, similar to western European custom, is advocated by Rabbi Dorff based on Jewish social ethics (46), where the focus is not so much on the individual but on the community, even though Jewish scholars stress the value of each individual created in the image of God (46). The difference between our libertarian, capitalist view of the world and the more communitarian Jewish view is that we hold that individuals may choose to form groups or communities, whereas Jewish philosophy holds that all Jews already belong to a community (46). In the Declaration of Independence the Founding Fathers spoke of "inalienable" and "self-evident" rights. Judaism starts with the concept of duties as contained in the Ten Commandments (46). In line with this concept, we have accepted community-based responsibilities for public education, even though this is currently being challenged, as well as for police, fire and sewage services. Why the reluctance to accept health care in a similar way as a community responsibility?

In light of the reluctance of politicians to accept health care as a communal responsibility, physicians must begin a program of advocacy for universal access to health care in an improved social setting. Therefore, based on the foregoing review, we should advocate the use of budgetary policies to: 1. enhance public education to assure a sound education at least through high school. This has been shown to influence health outcomes favorably (2,34); 2. improve public transportation to enhance access to health care for those in rural and inner city areas (2); 3. provide universal access to health care for all our citizens (19,41); 4. support medical education at all levels to reduce the burden of debt on young physicians that limit their career choices (47,48); 5. support special research aimed at improving workplace relationships to reduce stress levels which affect health outcomes (22,23). As a part of this program of "Advocacy," we as physicians should invite our patients (42) to join us to support these goals. As physicians we must try to raise public awareness of these issues, and their impact on the health of our citizens. We must stimulate public debate on these matters, in order to develop possible solutions, and a social consensus. To arrive at such a consensus we will need open discussion of the social factors affecting health. In line with the concept of "symbolic acts," physicians have a responsibility to initiate and actively participate in broad public and political discussions of health care and social justice. We must examine all the facts and then consider possible solutions. We must develop an informed social consensus about these complex matters. Arriving at such societal consensus will not be easy. Many studies, as recently reviewed by Ubel (49), demonstrate that measuring community views on health care and social priorities is fraught with methodological problems. Community and individual choices are significantly influenced by how the question is framed (49). But the experience in Oregon involving the community broadly in the discussions leading to the Oregon Experiment with extending Medicaid coverage to all their citizens might be a model to follow in this effort. We should accept this challenge. Undertaking social and political activism as advocated here is consistent with the view of physician professionalism espousal by Sullivan (50). He said, "It is hard to see how medicine can resolve its own crisis of legitimacy without simultaneously seeking to redefine its identity around a public mission. Both this mission and enlightened self interest commit the profession to work toward universal inclusion, not on the basis of consumer sovereignty, but on the basis of social membership. This is the task of 'civic professionalism'" (50). These views are also supported by the recently published "Physician Charter" by the Medical Professional Project of the American College of Physicians—American Society Internal Medicine and the European Federation of Internal Medicine and the American Board of Internal Medicine (51). They include the principle of social justice among their three fundamental principles that they believe the profession must promote, and specifically include the commitment to improving universal access to care (51). As a foundation for building support from our patients for change in the health care system, we nned an effective and trusting partnership between socity and the medical profession—and we need it soon (42,52).If we do not begin the social debate advocated herein, we will face a profound crisis of health care and public health. It is indeed time for the "symbolic action" called for by Jonsen and Jameton (14).

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Editor's Selected Court Decision

***In the Matter of M.B. (Anonymous)*. Mental Hygiene Legal Service, Appellant, Staten Island Developmental Disabilities Services Office, et al., Respondents.**

March 23, 2006.

Jean Lin, for appellant.
Lisa Volpe, for respondents.

GRAFFEO, J.:

Under the Health Care Decisions Act for Mentally Retarded Persons, a guardian can make health care decisions for a mentally retarded person, including the decision to terminate life-sustaining medical treatment, under carefully prescribed circumstances. The issue in this case—solely one of statutory interpretation—is whether the Act applies only to guardians appointed after its March 2003 effective date or whether it also affects the authority of persons already serving as guardians before March 2003. Based on the language and history of the Act, we conclude that the Legislature also granted existing guardians full health care decision-making authority, subject to the detailed procedures set forth in the statute.

Background

Under New York common law, a competent adult generally has the right to make health care decisions, including the right to refuse life-sustaining treatment (*see Matter of Fosmire v Nicoleau, 75 NY2d 218* [1990]). If the individual suffers an illness or injury resulting in a loss of decision-making capacity, family and friends may obtain a court order authorizing the cessation of treatment if they can prove—by clear and convincing evidence of the patient's previously-expressed views—that the individual would have refused life-sustaining treatment if capable of making that decision (*id.* at 225).[1]

Although a guardian of a mentally retarded person was imbued under the common law with the authority to make a broad spectrum of health care decisions, this authority did not encompass the power to end life-sustaining medical treatment. Viewing the guardian's role as comparable to that of a parent—who could not deprive a child of lifesaving treatment—this Court concluded in *Matter of Storar* (52 2 363, *cert denied* 454 US 858 [1981]) that the guardian of a 52-year-old mentally retarded man lacked the authority to order the cessation of blood transfusions. Predicating our analysis on principles developed under the common law, we indicated that the Legislature could establish procedures governing the discontinuance of life-sustaining treatment for incompetent individuals if it determined this was desirable or appropriate, noting that any "change should come from the Legislature" (*id.* at 383]).

In the wake of *Storar*, a distinction arose between the common-law rights of competent adults, who could make their wishes concerning end-of-life care known to family and friends, and mentally retarded persons who had never been competent to make their own health care decisions and for whom life-sustaining treatment could not be refused. When these mentally retarded individuals became irreversibly, terminally ill they were, in effect, ineligible for hospice or other palliative care because their guardians were unable to refuse more intrusive, acute medical treatments aimed at extending life for as long as possible.

As a consequence of this disparity, family members, care-givers and advocacy groups for the mentally retarded sought relief from the Legislature. They shared the stories of mentally retarded patients forced to suffer painful, intrusive life- sustaining medical treatments after it was clear that they would never regain any quality of life because the requests of their guardians (usually parents or siblings) to end life-sustaining measures could not be honored. This was the situation the Legislature sought to remedy when it enacted the Health Care Decisions Act for Mentally Retarded Persons (*see* Bill Jacket, L 2002, ch 500) (HCDA).

The Statutory Scheme

The HCDA was passed by both Houses and signed by the Governor in the fall of 2002 but it did not become effective until 180 days later—March 16, 2003 (L 2002, ch 500, § 4). The legislation added a new paragraph to Surrogate's Court Procedure Act § 1750, the provision that addresses the guardianship of mentally retarded persons. Before the enactment of the HCDA, section 1750 stated that, upon the certification of appropriate medical personnel that a mentally retarded person was "incapable to manage him or herself and/or his or her affairs by reason of mental retardation and that such condition is permanent in nature or likely to continue indefinitely," a guardian "of the person or of the property or of both" could be appointed (SCPA 1750[1]). A guardianship "of the person" was viewed as authorizing some degree of medical decision-making power, but the scope of this authority was unclear, particularly in the aftermath of *Storar*.

The new provision—SCPA 1750(2)—imposes an additional certification requirement, clearly applicable to all future guardianship proceedings. Along with filing a certification from medical professionals that the mentally retarded person is incapable of managing his or her affairs, prospective guardians now must also file a "specific determination by such [medical personnel] as to whether the mentally retarded person has the capacity to make health care decisions, as defined by [*Public Health Law § 2980(*3)], for himself or herself" (SCPA 1750[2]). In the event the mentally retarded individual has the ability to make health care decisions, the HCDA allows a guardian to be appointed to make other types of decisions. If not, the guardian is granted full medical decision-making power. In the latter event, the HCDA removed any uncertainty concerning the scope of that authority, clarifying that health care decisions include "any decision to consent or refuse to consent to health care" (*see* SCPA 1750-b[1], cross-referencing *Public Health Law § 2980[*6]). Thus, under the HCDA, a guardian can, under certain circumstances, order the cessation of life-sustaining medical treatment for a mentally retarded person who never had capacity to make such a decision.

The HCDA also amended Article 17-A of the Surrogate's Court Procedure Act by adding a new section 1750-b governing health care decision-making for mentally retarded persons. Section 1750-b establishes a "[d]ecision-making standard" requiring that guardians base all health care decisions "solely and exclusively on the best interests of the mentally retarded person and, when reasonably known or ascertainable with reasonable diligence, on the mentally retarded person's wishes, including moral and religious beliefs" (SCPA 1750-b[2]). This provision lists the factors that must be considered in determining the mentally retarded person's best interests, which include "the dignity and uniqueness" of the individual; "the preservation, improvement or restoration of the . . . person's health;" "the relief of the mentally retarded person's suffering by means of palliative care and pain management;" the effect of treatment, including artificial nutrition and hydration, on the mentally retarded person; and the patient's overall medical condition (SCPA 1750-b[2][b]). A medical decision cannot be based on financial considerations or a failure to afford the mentally retarded individual the respect that would be afforded any other person in the same circumstances (SCPA 1750-b[2][c]). In addition, the statute imposes on the guardian "the affirmative obligation to advocate for the full and efficacious provision of health care, including life-sustaining treatment" (SCPA 1750- b[4]), defined as "medical treatment which is sustaining life functions and without which, according to reasonable medical judgment, [the] patient will die within a relatively short time period" (*see* SCPA 1750-b[4], cross-referencing *Mental Hygiene Law § 81.29[*e]).

In the event a guardian contemplates the withdrawal or withholding of life-sustaining treatment, SCPA 1750-b imposes a decision-making procedure that must be followed before the decision can be carried out. The threshold requirement is that the mentally retarded person's physician confirm to a reasonable degree of medical certainty, after consultation with another physician or a licensed psychologist, that the person currently lacks the capacity to make health care decisions (SCPA 1750-b[4][a]). The attending physician and another concurring physician must further attest that the mentally retarded person has one of three types of conditions: a terminal condition, permanent unconsciousness or "a medical condition other than such person's mental retardation which requires life-sustaining treatment, is irreversible and which will continue indefinitely," and life-sustaining treatment imposes or would impose an extraordinary burden on the patient in light of the patient's medical condition and the expected outcome of the life-sustaining treatment (SCPA 1750-b[4][b][i], [ii]). In the case of the withdrawal or withholding of artificially provided nutrition or hydration, the two physicians must also confirm that "there is no reasonable hope of maintaining life" or that the artificial nutrition or hydration itself "poses an extraordinary burden" on the patient (SCPA 1750-b[4][b][iii]). These conclusions by medical professionals are a condition precedent to any valid decision to end life-sustaining treatment—without them, life- sustaining treatment must be afforded to the patient.

If the requisite medical conclusions are made, the next step is for the guardian to express a decision to end life- sustaining treatment either in writing, signed by a witness, or orally in the presence of the attending physician and another witness, and the decision must be included in the patient's chart. The physician can then issue the appropriate medical orders or object to the guardian's decision but, in either case, the decision to end life-sustaining treatment cannot be implemented for 48 hours (SCPA 1750-b[4][e]). During that time, the physician must notify various parties including, in some circumstances, the mentally retarded person. The Act grants a number of persons and organizations automatic standing to lodge an objection—the mentally retarded person, a parent or adult sibling, the attending physician, any other health care practitioner providing services to the patient, the director of a residential facility that formerly cared for the patient, the Commissioner of the Office of Mental Retardation Developmental Disabilities (OMRDD), and, if the patient was treated in a residential facility, the Mental Hygiene Legal Services (MHLS)(SCPA 1750-b[5]).

Upon objection, the guardian's decision is suspended (unless the suspension would itself result in the death of the patient) while a judicial proceeding is conducted "with respect to any dispute arising under this section, including objecting to the withdrawal or withholding of

life-sustaining treatment because such withdrawal or withholding is not in accord with the criteria set forth in this section" (SCPA 1750-b[6]). If at the conclusion of the 48-hour period there is no objection the guardian's decision to withdraw or withhold life-sustaining treatment is put into effect, without judicial involvement.

Thus, the HCDA clarifies that guardians can make health care decisions for mentally retarded persons who themselves were never competent to make those decisions, including a decision to end life-sustaining treatment. But it imposes a series of procedural hurdles—intended to safeguard the interests of the patient and prevent an improvident decision by the guardian—that must be satisfied prior to the implementation of such a decision.

The issue now presented to us is whether the Legislature intended to authorize guardians appointed prior to the effective date of the HCDA to make health care decisions for mentally retarded persons in accordance with the Act's strict decision-making structure without having to obtain, through a separate judicial proceeding, an amended guardianship order that specifically recognizes their authority as encompassing the power to end life-sustaining treatment. We conclude that the Legislature did intend that authorization.

Facts

M.B., a profoundly retarded 42-year-old man with Down's Syndrome who never possessed the capacity to make health care decisions, lived with his mother until her death in December 2002. In January 2003, M.B.'s brother R.B. was appointed his guardian under Article 17-A of the Surrogate's Court Procedure Act. At that time, the HCDA had been passed but was not yet effective. The guardianship decree therefore named R.B. as "guardian of the person" of M.B. but the court did not specifically address R.B.'s authority to make health care decisions for M.B.

After his mother's death, M.B. lived in a residential facility specializing in the care of mentally retarded persons. He later became seriously ill and was transferred to Staten Island University Hospital where he was diagnosed with pneumonia, hypertension and hypoxia. His physical condition steadily declined to the point that he lost consciousness and was placed on a respirator, with a nasal/gastric tube inserted for feeding and hydration. M.B.'s physicians concluded that his illness was terminal, his condition irreversible and that the life-sustaining treatment currently being provided imposed a substantial burden on him. Based on the physicians' opinions concerning M.B.'s medical condition and prognosis, on October 14, 2003 R.B. requested that the respirator be disconnected, with the understanding that this would soon result in M.B.'s death. As required by the HCDA, the hospital notified various parties of the decision, including OMRDD and MHLS. The next day, MHLS filed a written notice of objection, which resulted in suspension of R.B.'s order to discontinue life-sustaining treatment.

Uncertain of how to proceed, R.B. and his sister appeared *pro se* in Richmond County Surrogate's Court on October 17, 2003, asking the Surrogate to authorize the hospital to honor R.B.'s request, but the matter was adjourned so that MHLS could initiate formal proceedings. By order to show cause and petition dated October 20, 2003, MHLS sought a declaration that R.B. lacked the authority to issue an order ending life-sustaining treatment because he was appointed guardian two months before the effective date of the HCDA. Having retained private counsel, R.B. opposed the objection. The New York Attorney General's office appeared on behalf of the Staten Island Developmental Disabilities Services Office (SIDDSO), a regional division of OMRDD.[2] Initially taking no position on the controversy, SIDDSO ultimately supported R.B.'s position.

At a proceeding three days later, MHLS asserted that it agreed with R.B.'s conclusion that the cessation of life-sustaining treatment would be in the best interests of M.B. and that it was satisfied that the guardian had complied with all of the procedural and substantive safeguards required under the HCDA. MHLS explained that its objection was not predicated on the facts of this particular case, but on its interpretation that the HCDA did not empower guardians appointed prior to March 16, 2003 to make decisions involving the cessation of life-sustaining treatment for mentally retarded persons. Rather, MHLS argued that these previously-appointed guardians could not exercise such authority unless they individually petitioned Surrogate's Court for an expansion of their guardianship power. As for the current dilemma facing M.B.'s guardian, MHLS contended that the proceeding could be converted into a guardianship expansion proceeding so that R.B. could be granted the authority to render end-of-life decisions for his brother.

R.B.'s attorney countered that it was evident from the plain language and history of the HCDA that the Legislature had intended to extend to all guardians, regardless of the date of appointment, the power to request the termination of life-sustaining treatment under the new procedures set forth in SCPA 1750-b. R.B. reasoned that, had the Legislature intended to require previously-appointed guardians to petition for new powers, it would surely have said so, rather than including language in the HCDA suggesting precisely the opposite.

Surrogate's Court rejected MHLS' objection, concluding that R.B. was empowered under the HCDA to order the cessation of life-sustaining treatment for his brother, even though R.B.'s guardianship order was issued before the effective date of the Act. Pursuant to the Surrogate's order, M.B. was removed from the respirator and died within hours.

Acknowledging that M.B.'s death mooted its objection, MHLS nonetheless pursued an appeal, contending that the case fell within the exception to the mootness doctrine as it was capable of repetition, likely to evade review and involved a substantial legal issue. Considering the appeal under the mootness exception, the Appellate Division reversed and granted MHLS' petition. Focusing on the legislative history of the HCDA, a majority of the court held that the Legislature had not intended to extend to existing guardians the end-of-life decision-making powers now recognized in the HCDA. The majority was concerned that mentally retarded persons with guardians appointed prior to the effective date of the new legislation lacked an opportunity to have their capacity to make health care decisions specifically considered. If the legislation was interpreted to apply to all guardians, the majority believed that mentally retarded individuals who might be able to make such decisions for themselves would not be adequately protected. The Court therefore concluded that previously-appointed guardians must petition for enlargement of guardianship authority so that the capacity issue could be directly explored for each mentally retarded person. The dissent would have affirmed the order denying the objection, reasoning that the plain language of the HCDA indicated a legislative intent to authorize existing guardians to make all necessary health care decisions, including end-of-life decisions. The Appellate Division granted SIDDSO leave to appeal to this Court.[3]

After the Appellate Division ruling, both Houses of the Legislature passed bills that, if enacted, would have altered the guardianship enlargement procedure envisioned by the Appellate Division majority (2005 NY Senate Bill S 5803; 2005 NY Assembly Bill A 8906). Both the Senate and Assembly sponsors of the new legislation stated that the legislative intent of the HCDA had been to retroactively confer full health care decision-making authority on the tens of thousands of existing guardians without a requirement that they seek new guardianship orders from the courts (Mem in Support of Senator Hannon, Bill S 5803; Mem in Support of Assembly Member P. Rivera, Bill A 8906). Although he agreed with the sponsors' view of the scope of the HCDA, the Governor vetoed the legislation, concluding that the proposed amendment was premature in light of the pending appeal to this Court (Gov. Pataki Veto Message No. 121 of 2005).

Analysis

Like the Appellate Division, we address this appeal under the exception to the mootness doctrine because the issue presented is substantial, likely to recur and involves a situation capable of evading review (*Matter of Hearst Corp. v Clyne*, *50 NY2d 707* [1980]). Both SIDDSO and MHLS emphasize that this case presents an issue of statutory interpretation. MHLS did not contend below and does not assert here that there is any constitutional impediment to interpreting the legislation in the manner urged by SIDDSO. As such, our task—as it is in every case involving statutory interpretation—is to ascertain the legislative intent and construe the pertinent statutes to effectuate that intent.

We begin with the statutory text, which is the clearest indicator of legislative purpose (*Majewski v Broadalbin-Perth Central School*, *91 NY2d 577*, 583 [1998]). If the "language . . . is clear and unambiguous, courts must give effect to its plain meaning" (*State of New York v Patricia II*, 6 NY3d 160, ___ [2006], quoting *Matter of Tall Trees Constr. Corp. v Zoning Bd. of Appeals of the Town of Huntington*, *97 NY2d 86*, 91 2001]). When the terms of related statutes are involved, as is the case here, they must be analyzed in context and in a manner that "harmonize[s] the related provisions . . . [and] renders them compatible" (*Tall Trees*, 97 NY2d at 91).

In this case, SIDDSO relies on two provisions of the HCDA as evidence that the Legislature intended to grant existing guardians the right to make end-of-life decisions. First, SIDDSO points to the new paragraph added to SCPA 1750. After directing that guardianship proceedings include a certification by medical personnel concerning the mentally retarded person's capacity to make health care decisions, the Legislature provided: "The absence of this determination in the case of guardians appointed prior to the effective date of this subdivision shall not preclude such guardians from making health care decisions" (SCPA 1750[2]). The Legislature thus explicitly exempted existing guardians from the new requirement that guardianship proceedings specifically address the mentally retarded person's capacity to make health care decisions.

Second, SIDDSO cites the language in the first subsection of the new SCPA 1750-b, entitled "Scope of Authority," which provides:

"*Unless specifically prohibited by the court after consideration of the determination, if any, regarding a mentally retarded person's capacity to make health care decisions*, which is required by section [1750] of this article, *the guardian of such person appointed pursuant to section [1750] shall have the authority to make any and all health care decisions, as defined by [Public Health Law § 2980(6)], on behalf of the mentally retarded person that such person could make if such person had capacity*. Such decisions may include decisions to withhold or withdraw life-sustaining treatment, as defined in [*Mental Hygiene Law § 81.29(*e)]. The provisions of this article are not intended to permit or promote suicide, assisted suicide or euthanasia; accordingly, nothing in this section shall be construed to permit a guardian to consent to any act or omission to which the mentally retarded persons could not consent if such person had capacity" (SCPA 1750-b[1] [emphasis added]).

We agree with SIDDSO that the phrasing of the first sentence of subsection 1750-b(1) is telling—not only in

what it says but also in what it does not say. The Legislature did not declare that a guardian has authority to make medical decisions only if the court has expressly authorized the guardian to do so—language one would expect to find if the Legislature had intended to require existing guardians to petition for enlargement of their power as MHLS maintains. Instead, the Legislature has provided that all guardians "*have* the authority to make any and all health care decisions," "unless specifically prohibited by the court" (SCPA 1750-b[1] [emphasis added]).

The phrase "if any" in the beginning of section 1750- b(1) further illuminates the legislative intent. Since guardians appointed after the effective date of the HCDA must include a certification concerning the mentally retarded person's health care decision-making capacity, this clause—which clarifies that health care decisions can be made even in the absence of such certification—can only be understood as referring to the authority of existing guardians who would not have obtained this certification. This interpretation of 1750-b(1) is consistent with the clear statement in the newly-added section 1750(2) exempting guardians appointed prior to the effective date of the HCDA from the specific health care decision-making competency certification requirement. Read together, sections 1750(2) and 1750-b(1) reflect the intention of the Legislature to authorize guardians appointed prior to March 16, 2003 to make end-of-life decisions, provided those decisions are made pursuant to the exacting procedures specified in section 1750-b. The legislation does not indicate that existing guardians are to petition for new guardianship orders specifically expanding their health care decision-making authority.

The legislative history of the HCDA supports this construction. The Assembly sponsor stated that the purpose of the bill was to "allow the legally appointed guardians of mentally retarded individuals to have the authority to make medical decisions on behalf of such person, including decisions dealing with the withdrawal or withholding of life-sustaining treatment" (Luster Mem in Support, 2002 NY Assembly Bill A 8466D [NYS Legis. Retrieval Serv.]). In his memorandum in support, the Senate sponsor repeatedly notes that the legislation was not viewed as a significant change in the law but was a clarification of the power the Legislature had always intended guardians of mentally retarded persons to possess under SCPA article 17-A. The sponsor stated:

"This bill clarifies that guardians of persons with mental retardation have the authority to make health care decisions, including decisions regarding life-sustaining treatment under certain circumstances" (Hannon Mem in Support, NY Senate Bill S 4622B, 2002 NYS Legis. Annual at 279).

Echoing the language in the legislation, the Senate sponsor asserted that guardians "have the authority"—not that guardians must now seek to obtain health care decision-making authority. He described the purpose of the legislation as follows:

"In general, the bill reflects four overarching motives: (1) to clarify that decisions regarding life-sustaining treatment are part of the natural continuum of all health care decisions, (2) to allow decisions to end life-sustaining treatment only where the need is clearest . . ., (3) to utilize existing legal standards wherever possible, and (4) *to maintain judicial oversight of close decisions*, with a statutory structure incorporating a workable standard for the court" (*id*. [emphasis added]).

Thus, the role of the courts is described as "oversight of close decisions" relating to medical treatment, a clear reference to the objection process and resulting judicial proceeding referenced in subsections 1750-b(5) and (6).

The Commission on Quality of Care for the Mentally Disabled likewise observed that the bill would "clarify that guardians can make medical decisions on behalf of persons with mental retardation based upon the best interests and reasonably known wishes of the person[s] . . . including, when appropriate, withdrawal of life-sustaining treatment" (Mem of Commn. on Quality of Care for the Mentally Disabled, Bill Jacket, L 2002, ch 500, at 10). Nowhere in the extensive Bill Jacket is there any suggestion that the Legislature intended previously-appointed guardians to have to initiate new court proceedings in order to acquire such authority. Such an interpretation would be inconsistent with the Legislature's repeatedly expressed view that it was clarifying the powers it vested in Article 17-A guardians of mentally retarded persons, notwithstanding this Court's holding in *Storar*.

To be sure, the HCDA imposes a new obligation on guardians appointed after its effective date that was not—and is not—applicable to previously-appointed guardians. In addition to the long-standing requirement that medical personnel certify that the mentally retarded person is "incapable to manage him or herself and/or his or her affairs" (SCPA 1750[1])—a certification all previously-appointed guardians would have filed—the HCDA now requires that prospective guardians also file a certification by medical personnel specifically addressing the mentally retarded person's capacity to make health care decisions (SCPA 1750[2]). Previously-appointed guardians are expressly exempted from filing this health care capacity certification (SCPA 1750[2]).

It does not follow—as MHLS argues—that the Act must be construed to require existing guardians to obtain new appointment orders because any other interpretation would be inconsistent with the Legislature's overriding concern that the rights of mentally retarded persons, including those capable of making health care decisions, be protected. This argument turns on the assumption that the Legislature's decision to add a health care capacity

certification requirement to the guardianship appointment procedure going forward indicated a belief that the former procedure was inadequate. This assumption is not supported by the statutory scheme or the pertinent legislative history. After all, each existing guardian was appointed based on a certification that the mentally retarded person was "incapable to manage him or herself and/or his or her affairs" (SCPA 1750[1]). And the history shows that the Legislature did not view the prior appointment procedure as flawed—it merely sought to clarify the decision-making powers of future guardians.

Critically, the HCDA does not exempt previously-appointed guardians from any of the strict SCPA 1750-b procedures governing specific health care decision-making, including end-of-life decision-making. If a guardian seeks to withhold or withdraw life-sustaining treatment, the threshold step in the statutory decision-making structure is the requirement that the patient's attending physician, in consultation with at least one other medical professional, confirm that the patient lacks the capacity to make health care decisions (SCPA 1750-b[4][a]). Because it requires two health care professionals to assess the mentally retarded person's capacity to make health care decisions, this requirement mimics the health care capacity certification undertaken in new guardianship proceedings. Thus, newly-appointed guardians will have to address the health care capacity issue twice (when initially appointed and again when making end-of-life decisions) while previously-appointed guardians will do so only when making a specific decision to end life-sustaining treatment. But the fact remains that the capacity of each mentally retarded person to make health care decisions will be explored before any decision by any guardian to end life-sustaining treatment is implemented, no matter when the guardian was appointed. In every meaningful respect, the authority of existing and newly-appointed guardians is exercised in an identical fashion under the HCDA because all guardians must comply with each step of the decision-making structure in SCPA 1750-b.

MHLS reads the first clause in the new section 1750-b(1)—"unless specifically prohibited by the court"—as preserving the court's supervisory role over medical decision-making by guardians. This is true. Going forward, under the health care capacity certification process applicable to guardians appointed after the effective date of the HCDA, courts must consider the mentally retarded person's capacity to make health care decisions and, in appropriate cases, may limit the guardian's authority in that realm. Moreover, courts are clearly empowered to resolve disputes concerning particular health care decisions made by guardians. But, by choosing to phrase the power granted guardians expansively—stating that they have health care decision-making authority unless the court specifically states otherwise—the Legislature recognized that guardians already possess that authority.

MHLS attempts to limit the import of the phrase "if any" in section 1750-b(1), arguing that it means only that existing guardians—who it claims must petition the court to expand their powers—are relieved from filing the specific health care capacity certification that new guardians must file under SCPA 1750(2). But this interpretation undercuts the primary premise of MHLS' argument—that the Legislature could not have intended to authorize all guardians, even those appointed prior to the HCDA, to make health care decisions in the absence of certifications specifically addressing health care decision-making capacity. If, as MHLS suggests, the Legislature meant for existing guardians to apply for expansion of their power to specifically encompass health care decision-making, why did it expressly exempt them from the central requirement of that procedure by dispensing with the certification process through which the capacity of the mentally retarded person is determined?

In essence, MHLS suggests that SIDDSO's interpretation of the HCDA cannot be effectuated because this would result in distinctions between the obligations of existing and future guardians. However, MHLS relies on a construction that also treats previously-appointed guardians differently from new guardians since MHLS recognizes that SCPA 1750(2) relieves the former from the health care decision-making capacity certification requirement. Since both parties proffer interpretations that result in differences between the two classes of guardians, the presence of such distinctions does not itself provide us with a basis to resolve the controversy.

The Legislature made a policy decision that newly-appointed guardians need to meet a specific health care capacity certification requirement. Given the thousands of previously-appointed guardians, state lawmakers chose not to impose the new capacity certification requirement on existing guardians or otherwise require them to commence court proceedings seeking expansion of guardianship authority. In light of the significant procedural protections afforded in SCPA 1750-b, the Legislature concluded that the rights of mentally retarded persons would be safeguarded absent such a requirement.

MHLS is certainly correct that the HCDA provides for judicial oversight of end-of-life decisions by guardians. But, in the case of previously-appointed guardians, such judicial oversight occurs when a guardian reaches an end-of-life decision, the necessary parties are notified, and someone objects to the decision. The Legislature determined that it would serve no significant purpose to require each previously-appointed guardian to commence proceedings for the expansion of health care decision-making authority (which would have to occur even if no issue concerning end-of-life decision-making is pending or even likely to arise) given the procedural steps all guardians must follow under SCPA 1750-b, which

includes an inquiry into the mentally retarded person's capacity to make health care decisions.

MHLS responds that this inquiry is not equivalent to the initial guardianship certification process contemplated under the new SCPA 1750(2) because it occurs after the mentally retarded person is in medical crisis and therefore fails to adequately account for the possibility that the patient might once have had the capacity to make health care decisions. But whether judicial intervention is sought in the context of a guardianship expansion proceeding or a SCPA 1750-b objection, the court must render a determination based on the present capacity of the mentally retarded person—not abilities the patient may have once possessed. MHLS' contrary view of the statute would, in effect, prevent any existing guardian from obtaining the power to withdraw life-sustaining treatment if the patient was already in a terminal medical crisis when the HCDA became effective, excluding a class of patients—ironically, those in immediate need of the rights afforded by the legislation—from the protections of the HCDA, a result not intended by the Legislature.[4]

Moreover, in circumstances where the mentally retarded person formerly had some capacity to make medical decisions, the guardian is nonetheless required to base medical decision-making "on the best interests of the mentally retarded person and, when reasonably known or ascertainable with reasonable diligence, on the mentally retarded person's wishes, including moral and religious beliefs" (SCPA 1750-b[2][a]). Thus, the wishes of a mentally retarded individual who once had capacity to make health care decisions are not disregarded under the new statutory scheme.

In sum, while MHLS and the Appellate Division are understandably concerned that the interests of mentally retarded individuals be scrupulously protected, the Legislature designed the statutory scheme to meet that important objective. First, SCPA 1755 authorizes any person (including a mentally retarded person) at any time to seek judicial review of the scope of a guardianship order and "request[] modification of such order in order to protect the mentally retarded person's . . . personal interests." In other words, even prior to the enactment of the HCDA, the authority granted a guardian with respect to a particular mentally retarded person was subject to judicial review in the event of a concern regarding the guardian's exercise of any aspect of that authority, including health care decision-making. The HCDA did not alter this procedure. As such, a mentally retarded individual who has health care decision-making capacity—or any party on his or her behalf, including MHLS—may petition the court for curtailment of the existing guardian's power in that arena.

Second, as this case demonstrates, the notification and objection process in SCPA 1750-b provides substantial protection to mentally retarded patients. Guardians must base health care decisions on the advice of qualified medical professionals and must follow a multi-step procedure before any end-of-life decision will be honored by a health care facility. In any case where a disagreement arises between the guardian and one of a host of other interested parties (family members, the patient's medical caregivers, OMRDD, a residential director of a facility or MHLS), the statute mandates that the conflict be resolved by the courts. MHLS does not dispute the efficacy of this procedure, nor does it assail the Legislature's choice not to require judicial approval of health care decisions in circumstances where all parties agree that the guardian is acting in the mentally retarded individual's best interests. Although the Legislature could have charted a different course, the decision not to require previously-appointed guardians to seek new appointment orders was for the Legislature to make and, absent constitutional challenge, it must be upheld by this Court.

Accordingly, the order of the Appellate Division should be reversed, without costs, and the order of Surrogate's Court reinstated. The certified question should not be answered upon the ground that it is unnecessary.

Order reversed, without costs, and order of Surrogate's Court, Richmond County, reinstated. Certified question not answered upon the ground that it is unnecessary. Opinion by Judge Graffeo. Chief Judge Kaye and Judges G.B. Smith, Ciparick, Rosenblatt, Read and R.S. Smith concur.

Decided March 23, 2006

Endnotes

1. In addition to the rights recognized under the common law, a competent adult can, of course, relieve family and friends of the burden of seeking such a court order by executing a health care proxy pursuant to *Public Health Law § 2981* naming a surrogate health care decision-maker who can make binding decisions in the event the appointing adult loses the capacity to make such decisions. A person can also express his or her wishes regarding life-sustaining treatment in what is known as a "living will."
2. SIDDSO is a division of the State Office of Mental Retardation and Developmental Disabilities. OMRDD operates fourteen regional DDSOs in New York State, which coordinate and deliver services to mentally retarded and developmentally disabled individuals (and their families) whether they reside in state-operated facilities, group homes or family settings (Information for Individuals and Families <www.omr.state.ny.us/hp_individuals.jsp> [last updated February 14, 2006]).
3. In granting leave, the Appellate Division certified the question: "Was the opinion and order of this court dated June 13, 2005, properly made?"
4. In this case, MHLS took the position that R.B. could apply for enlarged guardianship powers under SCPA 1750(2), thereby obtaining authority to make medical decisions for M.B. and to withdraw life-sustaining treatment, even though M.B. was already in medical crisis, urging the court to pursue this procedural route rather than the objection procedure set forth in SCPA 1750- b(5) and (6).

Recent Section Programs

NEWS flash

What's Happening in the Section

- **Long-Term Care and the Law.** In May, the Section held a program in three cities on Long-Term Care and the Law. The program was chaired by Ari Markenson of Epstein Becker & Green. P.C. It included panels with key policymakers and long-term care providers

- **Forum on National Licensure of Health and Mental Healthcare Professionals.** The Section recently co-sponsored a forum on national licensure of health and mental healthcare professionals. The forum was held on September 12 in New York City at the Association of the Bar of the City of New York. The Association's committees on health law, mental health and legal problems of the aging co-sponsored the event. Speakers included officials from the U.S Department of Health and Human Services and the N.Y.S. Department of Health.

- **Managed Care**. The Health Law Section and the Committee on Continuing Legal Education of the New York State Bar Association co-sponsored a program on Managed Care in New York State. The program focused on the obligations and liabilities imposed by statute and regulations as well as on contractual arrangements between payors and providers. Professionals from a wide variety of disciplines addressed the impact of recent revisions to New York State Department of Health Managed Care Regulations. The seminar provided a forum for the presentation and discussion of health care delivery from a variety of perspectives. Current issues between providers and payors in various health care organizational structures and trends anticipated for the future were also presented.

  The program was co-chaired by Harold N. Iselin, Esq. of Greenberg Traurig, LLP in Albany, and Kathleen Duffett, R.N., J.D. of Cold Spring.

Upcoming Program

- **Fall Retreat/Program on Rightsizing**. The Fall Retreat will be held this November 3-4 (Friday-Saturday) at the Equinox Resort and Spa in Manchester Village, Vermont. The Equinox is a renowned and beautiful inn, the nearby village is charming, and the surrounding Green and Taconic mountains will be especially picturesque that time of year. The retreat and program organizers will provide plenty of time for networking, exploring and relaxing. Consider staying for the weekend.

  The program will address the impending proposals of the Commission on Health Care Facilities for the 21st Century, also known as the "Rightsizing Commission" or sometimes the "Closing Commission." By statute, the Commission will make recommendations in December relating to reorganizing the allocation of hospital and nursing home beds in New York, including by closing specified hospitals and nursing homes. Its recommendations, if approved by the Governor and not blocked by the Legislature, will become law. Speakers, including speakers associated with the Commission, will examine legal and policy aspects of the rightsizing process, including the background and terms of the rightsizing statute, the rights of affected facilities, and the constitutional issues raised by the process.

  Peter Millock of Nixon Peabody, LLP and Ross Lanzafame of Harter Secrest and Emery, LLP are organizing the program.

The Equinox Resort and Spa, Manchester, VT

Upcoming Journal Edition

- The Winter '07 edition will be a special edition on "Legal Issues in Managed Care in N.Y." Harold Iselin, who is a partner in Greenberg Traurig in Albany, will be Special Editor. The edition will include articles from authors with a variety of perspectives. Persons wishing to submit an article for the edition should contact Harold Iselin at iselinh@gtlaw.com.

Further information about upcoming programs is always available at www.nysba.org/health. Just click on "Events"

Section Committees and Chairs

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

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