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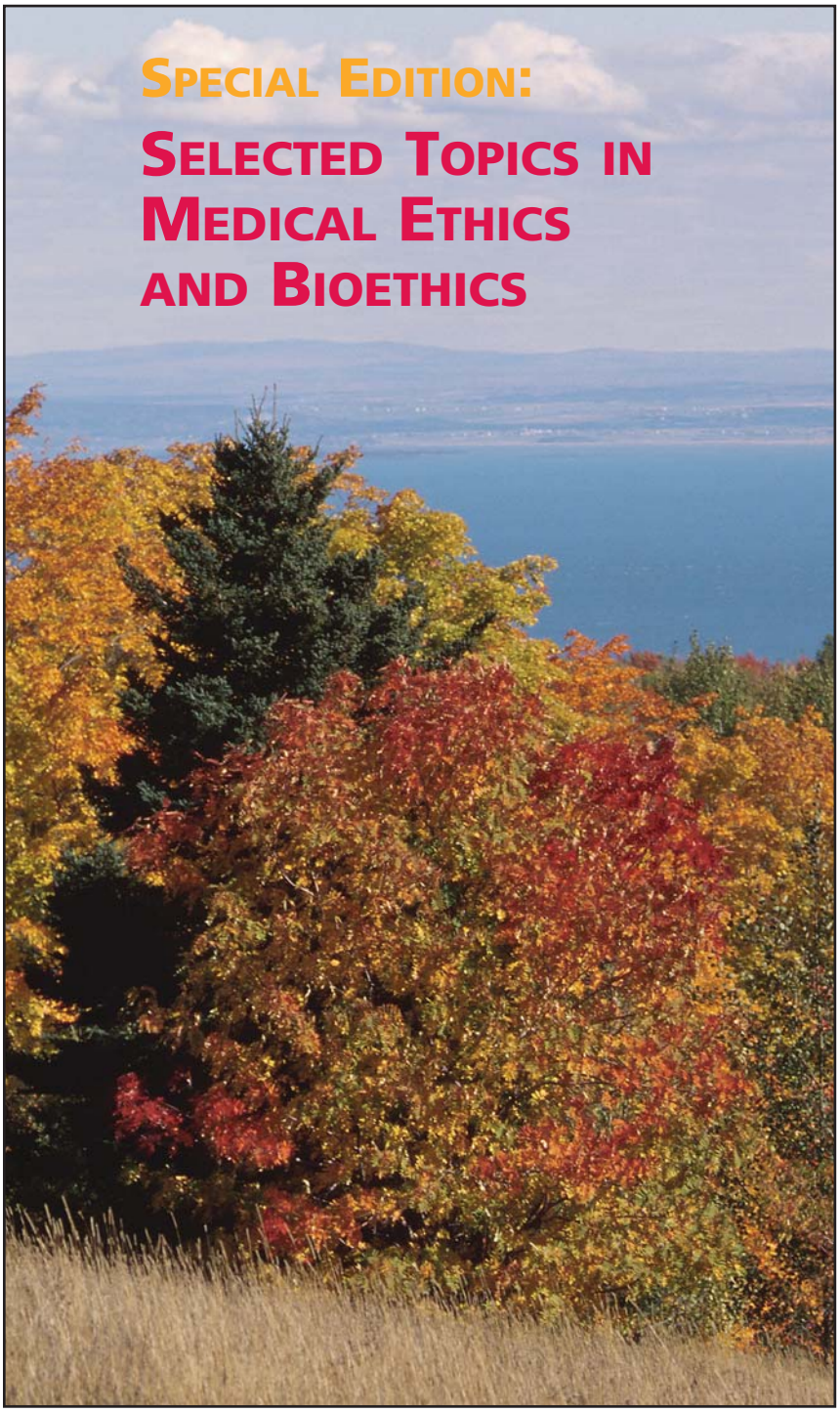
Health Law Journal

A publication of the Health Law Section of the New York State Bar Association



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NYSBA

HEALTH LAW JOURNAL

SUMMER/FALL 2005

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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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A Message from the Section Chair

An Opportunity to Make a Difference

Becoming Section Chair gives me an opportunity to re-live my high school cheerleading days, which is especially gratifying because I can root for a winning team. So here it is: Get more involved with the Health Law Section this year! There are many opportunities to participate in this diverse and active group, comprised of some of the best health lawyers around. If you have energy, inspiration and persistence, you can get it done in the Health Law Section. New members can become active very quickly, and there is ample support for new ideas and perspectives. Please join us!

The Section is coming off an extremely successful year, thanks in large part to outgoing Chair, Phil Rosenberg. The Section will continue to benefit during the coming year as the result of the momentum Phil created by encouraging early program planning. Phil will continue his work with the Section this year as he launches a new pro bono program, which he envisioned, to create a clearinghouse listing opportunities for health lawyers to assist small non-profit health care providers with legal needs.

The Section agenda is already packed with a variety of exciting events, including a revival of our Fall Program scheduled for October 28th and 29th. The program has fallen into place beautifully, from the location at the sumptuous Sagamore on Lake George to the cutting edge content of the program itself. Entitled "The New Medicaid Fraud and Overpayment Initiative: Representing Health Care Providers in Medicaid Audits," the program represents a collective planning effort among Steve Krantz, Regional Director of the Medicaid Fraud Control Unit; Gregor Macmillan, Director, Department of Health Bureau of Medicaid Law; and non-governmental Section members. Chaired by former Section Chair Jim Lytle, the meeting agenda embodies the ambitious spirit of the Section in both depth and focus.

In addition to the comprehensive program planned, the weekend should also provide wonderful opportunities for socializing. In fact, the highlight of the weekend, at least to my 7-year-old daughter, Caroline, will be the children's Halloween party on Friday night. Adults will have an opportunity to sample a variety of New York wines and cheeses at our cocktail reception followed by a relaxed dinner overlooking Lake George. Please, do bring your families to The Sagamore—there are many outstanding activities, and we would love to meet them!

We already have a full schedule of other CLE programs through June 2006. On September 23, 2005, the Section offered a program in New York City entitled "When Your Client's Health Problems Become Your Own and Meet the AUSAs." Our Annual Meeting in New York City on January 25, 2006 will have an especially timely program—"After the Flood: Legal Issues in Public Health Emergencies." Stay tuned for more information.

Other programs planned include: "Mental Health Courts; Better Outcomes from the Legal and Mental Health Systems" (Nov. 4, 2005, in N.Y.C.); "Representing Agencies Funded by the New York State Department of Mental Health," co-sponsored with the Section's Committee on Mental Retardation/ Developmental Disabilities Providers (February 24th in N.Y.C.; March 3rd in Albany); "Representing Physicians and Dentists in the Disciplinary Process" (April 7th in Long Island; April 28th in N.Y.C.; May 5th in Albany; and May 19th in Rochester); and "Long Term Care and the Law: Issues and Skills" (May 12th in Rochester; May 12th in N.Y.C.; and May 19th in Albany).

In another Section development, I recently appointed several new Committee Chairs. I'd like to welcome Margaret Davino of Kaufman, Borgeest & Ryan (Chair, Public Health Committee); Edward Case, Associate General Counsel to University of Rochester Medical Center (Chair, In-house Counsel Committee); Erik Ramanathan, General Counsel to Imclone Systems, Inc. (Chair, Biotechnology and the Law Committee); Mark P. Scherzer, of the Law Offices of Mark P. Scherzer (Co-Chair, Consumer/Patient Rights Committee); Steve Chananie of Garfunkel, Wild & Travis (Co-chair, Fraud, Abuse and Compliance Committee); and Frank Serbaroli of Cadwalader, Wickersham & Taft (Chair, Health Care Providers Committee). I also created two new Committees, and welcome their new chairs as well: Esther Widowski of Widowski & Steinhart (Chair, Special Committee on Insurance and Liability Issues); and Jim Lytle, Manatt, Phelps & Phillips (Chair, Special Committee on Legislative Issues).

Education programs and Committees are not all of the Section's activities. The Section's consistently outstanding *Health Law Journal* represents another valuable contribution to the New York legal community.

Superbly edited by Robert Swidler and, up to this edition, Dale Moore, many of you have contributed, and continue to contribute, to this publication. Dale Moore, who is Associate Dean of Albany Law School, recently stepped down as co-editor of the *Journal*. On behalf of the Section, I want to thank her for her many years of hard work as co-editor of the *Journal*, as well as her previous work as the first editor of the *Journal*'s forerunner—the *Health Law Section Newsletter*.

This edition of the *Journal*, which focuses on current ethical issues in health care, is especially relevant and thought provoking. As an in-house hospital attorney for almost 14 years, I have seen how these issues play out day-to-day at the bedside for real families, patients and providers. This is not just an academic debate. The discussions taking place here and elsewhere, and the potential legislation and case law which may follow, will have a profound effect on patients at critical points in their lives.

I feel that my potential contribution to the present discussion is to advocate on behalf of families and friends caring for an incapacitated loved one. Based on my personal experience, families of patients lacking capacity invariably struggle to do the right thing. The compassion they consistently have exhibited cuts across income and education levels, as well as cultural and ethnic backgrounds.

In the absence of legal guidance, however, many families and friends have been left bereft of authority under New York law to make health care decisions concerning their loved one's care. Despite public education efforts, most people do not execute health care proxies, which name others to make decisions if they cannot. As a result, families with incapacitated—and usually actively dying—loved ones are confronted with satisfying intimidating standards requiring "clear and convincing evidence" of a patient's wishes before artificial life support measures can be terminated. When families cannot provide adequate proof of those wishes—which does actually happen—life support continues, and the dying process is prolonged. What is not often mentioned in theoretical debates is just how painful that prolonged death frequently is for patients and the emotional toll taken on families and health care providers as a result.

Last Spring, the Family Health Care Decisions Act ("FHCDA"), which would have empowered families and friends to make decisions for incapacitated loved ones, failed to make it through either State legislative branch for the 13th straight year. New York families deserve to be empowered, and I strongly urge the legislature to take up the cause again in the Fall Session.

For those of you with an interest in these and other ethical issues, I recommend that you join the Section's Ethics Committee, chaired by Kathleen Burke. The Section has been active in supporting passage of the FHCDA, almost since its inception, and will continue to serve as a resource going forward. Please feel free to contact me if you would like to discuss ways to become more active this year, or with any other ideas or concerns you have.

Lynn Stansel

REQUEST FOR ARTICLES

If you have written an article and would like to have it considered for publication in the ***Health Law Journal***, please submit it to:

Robert N. Swidler, Esq.
Northeast Health
2212 Burdett Avenue
Troy, NY 12180
e-mail: swidlerr@nehealth.com

Articles should be submitted in Microsoft Word or WordPerfect, along with a printed original and biographical information.

In the New York State Courts

By Leonard M. Rosenberg

Federal Court Invalidates New York's Employer Gag Law

Healthcare Association of New York State, Inc. v. Pataki, et al., No. 03 CIV 0413, 2005 WL 1155687 (N.D.N.Y. May 17, 2005). A federal District Court in New York has held that the National Labor Relations Act preempts a New York law that prohibits employers from using state funds, including Medicaid, to either discourage or encourage union organization. Accordingly, the "Employer Gag Law," Labor Law § 211-a, cannot be legally enforced.

The Employer Gag Law became effective in 2002. It prevented employers who received state funds from interfering in any way with a worker's decision to join a union. The law was described by the state as being "labor neutral." However, the plaintiffs in this case, a group of five health care associations whose members operate acute care hospitals and residential health care facilities, argued that Section 211-a was an "ill-conceived statute" enacted by the state "in its fervor to defeat employer opposition to union organization." The effect, according to the plaintiffs, was that the statute prevented employers from communicating both the advantages and disadvantages of unionization.

Plaintiffs argued that Section 211-a is preempted by both the National Labor Relations Act ("NLRA") and the Labor Management Reporting and Disclosure Act ("LMRDA"). Plaintiffs also argued that Section 211-a violated their rights under the First and Fourteenth Amendments of the U.S. Constitution.

The U.S. District Court for the Northern District of New York held that Section 211-a is indeed preempted by the NLRA, and permanently

enjoined the State of New York from enforcing the statute.

The court noted that federal preemption of state law, which originates in the Supremacy Clause of the U.S. Constitution, can be either explicit or implicit. Although the NLRA contains no explicit preemption provision, the court cited a United States Supreme Court decision from 1986, which stated that, "It is now a commonplace that in passing the NLRA Congress largely displaced state regulation of industrial relations." *Wisconsin Dept. of Industry v. Gould Inc.*, 475 U.S. 282, 286, 106 S. Ct. 1057, 1061 (1986).

Prior to deciding the preemption issue, the court looked at whether the statute is sheltered from preemption because it falls within an exception established by the Supreme Court in *Bldg. & Const. Trades Council of Metro. Dist. v. Associated Builders & Contractors of Mass./R.I., Inc.*, 507 U.S. 218, 225-26, 113 S. Ct., 1190, 1195 (1983) ("*Boston Harbor*"). This exception requires courts to distinguish between government as regulator and government as proprietor when deciding whether the NLRA preempts a given local statute, regulation or action. Although the NLRA was intended to replace state labor regulation, it does not preempt actions taken by the state when the state is acting as a "proprietor or mere market participant," meaning when the state is doing what any other private contractor could legally do.

Here, the court found that the state was acting as a regulator through the use of Section 211-a because the statute "curtail[s] an employers' ability to exercise the economic weapon of hiring consultants or attorneys to encourage or discourage unionization or effectively communicating the advantages or disadvantages of unionization." The court also found that Section 211-a "is designed to have a broad social impact, by altering the ability of a wide range of recipients of state money to advocate about union issues."

Once the court decided that Section 211-a served a regulatory function, the statute could not be sheltered from preemption analysis under the *Boston Harbor* market participant exception. The court then found that Section 211-a was preempted by the NLRA, which rendered the question of LMRDA preemption and the constitutional arguments moot.

The court acknowledged the state's "legitimate and laudable goal" of ensuring that state funds, such as Medicaid, are not diverted for other purposes, but noted that, "the state must take care that, in its zeal to act, it does not do so unnecessarily and outside the permissible bounds of its discretion and thereby tread on the federally protected zone of labor rights."

Claim That Hospitals Acted as Debt Collectors Survives Motion to Dismiss

Carlson v. Long Island Jewish Medical Center, No. 04 Civ. 3086, 2005 WL 1631142 (E.D.N.Y. 2005). In this action, plaintiffs sought redress for defendants' billing practices with respect to uninsured patients. [This suit is one of the many "charity care" suits brought nationwide in the last year, most of which have been dismissed in their entirety.] Plaintiffs

voluntarily dismissed all of their federal claims but one pursuant to the Fair Debt Collection Practices Act, 15 U.S.C. § 1692 (the "FDCPA" or the "Act"). Plaintiffs alleged that the hospital defendants conducted "unconscionable collection practices" with assistance from collection agencies, including an entity referred to as the "Regional Claims Recovery Service" ("RCRS"). Plaintiffs alleged that RCRS is an "unincorporated subdivision of the North Shore Health System," and that the hospitals, through, *inter alia*, RCRS, used "abusive, harassing tactics in collecting outstanding bills," in violation of the FDCPA.

The hospitals moved to dismiss the FDCPA claim on two grounds. First, they argued that the hospitals cannot be liable under the statute because they are not "debt collectors" as defined in the FDCPA. Second, even assuming that they are debt collectors, and, therefore, subject to FDCPA liability, the factual allegations described by plaintiffs fell short of those necessary to support a claim under the Act.

The court initially noted that the FDCPA prohibits deceptive and misleading practices by "debt collectors." (15 U.S.C. § 1692e) The statute specifically defines debt collectors as those engaged in "any business the principal purpose of which is the collection of any debts, or who regularly collects or attempts to collect . . . debts owed or due or asserted to be owed or due another." (15 U.S.C. § 1692a(6)) Thus, by its terms, the FDCPA limits its reach to those collecting the debts "of another" and does not restrict the activities of creditors seeking to collect their own debts. In explaining the reason for this distinction, the court stated that when restricting the reach of the FDCPA to exempt creditors, Congress recognized that the activities of creditors seeking to collect their own debts are restrained by the creditors' desire to retain their good will with consumers. Those collecting debts due to another were thought to be not similarly restrained.

The court further explained, however, that a creditor will be deemed a debt collector and, therefore, subject to the strictures of the Act where the creditor attempts to collect its own debts by using "any name other than his own which would indicate that a third person is collecting or attempting to collect such debts." (15 U.S.C. § 1692a(6)) The imposition of liability in this case recognizes the fact that when a creditor uses a name other than his own, the motivation to protect the good will in his own name is absent and the likelihood for abusive debt collections practices returns. Thus, a creditor may be found liable under Section 1692(a)(6) if, in the course of collecting its own debts, it "pretends to be someone else" or "uses a pseudonym or alias." In determining whether this exception applies, the issue is whether, under the circumstances present, the "least sophisticated consumer would have the false impression that a third party was collecting the debt."

The court found in this case that the hospitals did not constitute debt collectors within the meaning of the FDCPA, as their function is not the collection of bills, but the provision of heath care. However, the hospitals allegedly acted as debt collectors by attempting to collect debts through RCRS, an entity that is alleged to have created the false impression that debts were being pursued by a third party. Because this issue was raised in the context of a motion to dismiss, the sole inquiry was whether the complaint pled facts sufficient to support the claim that the least sophisticated consumer would have believed that a RCRS was a third party acting to collect a debt on behalf of the defendant hospitals. The court held that the complaint was sufficient.

As the court stated, the liability of the hospitals on this theory turns on facts that cannot be determined in the context of a motion to dismiss. Among those facts are the business of RCRS, the nature of its corporate relationship with the hospitals and the nature of the contacts among the hospitals, RCRS and plaintiffs.

The court also rejected the defendants' second argument, that, even assuming the debt collector status of the Hospitals, the complaint fails to set forth sufficient facts to state a claim pursuant to the FDCPA. The court found that the facts cited by plaintiffs in the complaint were sufficient to satisfy Rule 8 of the Federal Rules of Civil Procedure, which requires only a "short and plain statement of the claim showing the pleader is entitled to relief."

Court of Appeals Rules That OPMC Can Conduct Comprehensive Medical Record Review Without Issuing Subpoena

Michaelis v. Graziano, 2005 WL 1539535 (Court of Appeals, June 30, 2005). The central issue on appeal in this case was whether the Office of Professional Misconduct ("OPMC") was required to issue a subpoena in order to undertake a comprehensive medical review ("CMR") of a doctor's records. The Court of Appeals affirmed the order of the Appellate Division, holding that a subpoena was not required.

The OPMC informed petitioner by letter that evidence existed of a pattern of inappropriate medical practice and that a CMR of petitioner's patient records would be conducted. The letter also warned that "[a]ny failure by you to comply with the order would constitute professional misconduct as defined in N.Y. Education Law § 6530(15) and will result in a recommendation of prosecution for such misconduct. In addition, you may be subject to an enforcement proceeding, in New York State Supreme Court, pursuant

to Public Health Law ("PHL") § 230(10)(o)(ii)." Petitioner challenged the CMR in a CPLR Article 78 proceeding. The motion court denied petitioner's claims and a divided Appellate Division affirmed.

The Court of Appeals addressed petitioner's argument that the OPMC Director lacked authority to compel a CMR. The Court interpreted PHL § 230(10)(a)(iv)(A) as providing OPMC with specific statutory authority to conduct a review of petitioner's records, and that such power is in addition to the power of the executive secretary to issue subpoenas.

The Court also cited to PHL § 230(10)(o), which provides for judicial review of CMR orders. The Court held that because the physician has an opportunity to be heard at the Section 230(10)(o) proceeding, his or her due process rights are not violated.

The petitioner also claimed that OPMC was required to disclose the nature of any new issues identified subsequent to the interview before issuing a CMR order. The Court of Appeals disagreed, ruling that under the language of PHL § 230(10(a)(iii), the petitioner was entitled to notice of any issue identified before charges relating those issues were brought, but not before producing documents in connection with a CMR.

The court also rejected the physician's claim that the Supreme Court erroneously relied on an *in camera* affidavit, denying him an opportunity to respond fully to allegations charged within, and thereby denying him due process. The Court of Appeals, while agreeing that the use of *in camera* inspections should be limited, said that none of the information that should not have been submitted *in camera* was material to its decision. Therefore, it held that any error allowing material to be submitted without notice was harmless.

The physician did prevail on one point, though. The Court noted that the OPMC's CMR letter to the physician was inaccurate in stating that a physician's failure to comply with the CMR demand would, itself, constitute professional misconduct and result in prosecution, because the Education Law makes an exception for a timely, good faith failure to comply due to a dispute over the availability, scope or necessity of records requested.

Directors and Officers of Not-For-Profit Corporation Need Not Post a Bond as a Condition to the Corporation's Advancement of Defense Costs

Spitzer v. Soundview Health Center, N.Y.L.J., January 27, 2005, at 18. Petitioner New York State Attorney General indicted the Executive Vice President and the Vice President of Operations of Soundview Health Center ("Soundview"), a not-for-profit corporation, alleging misuse of state funds provided to Soundview. Soundview's Board of Directors created a "Legal Defense Fund" to cover attorneys' fees and defense costs in connection with the indictments. The Attorney General's office then moved to compel Soundview to obtain from its officers a bond for the full amount of defense costs advanced, contending that such security was required pursuant to NPCL § 723(c). Section 723(c) states that directors and officers must provide an "undertaking" to repay amounts advanced, if it is later determined that the director or officer is not entitled to indemnification.

The court distinguished an undertaking as used in the context of the CPLR from an undertaking used in the context of the Business Corporation Law, and held that NPCL § 723(c) does not require a bond, only a written agreement to repay the funds advanced.

No Retroactive Effect of the Health Care Decisions Act for Persons with Mental Retardation

In the Matter of M.B., 797 N.Y.S.2d 510 (2d Dep't 2005). In 2003, the New York State Legislature enacted the Health Care Decisions Act for Persons with Mental Retardation (the "Act"). The statute revised Sections 1750 and 1750-b of the Surrogate's Court Procedure Act ("SCPA"), to permit guardians of mentally retarded persons to make health care decisions for their charges, including decisions to withhold or withdraw life-sustaining treatment. Prior to the enactment of this statute, a personal needs guardian appointed for a mentally retarded person had no power to direct the withholding or withdrawal of life-sustaining treatment.

In this case, the primary question was whether the Act could be applied retroactively where the guardian was appointed prior to the revised statute's effective date of March 16, 2003. As with many such appointments, the decree appointing R.B. as guardian for M.B. contained no explicit power to make health care decisions on behalf of M.B. M.B. eventually became gravely ill and required the assistance of a respirator to breathe and a nasogastric tube to receive nutrition and hydration. R.B. requested that all life-sustaining treatment be terminated for M.B.

The Richmond County Surrogate's Court held that the Act could be applied retroactively and the guardian was authorized to make medical decisions for M.B., including a decision directing the withdrawal or withholding of life-sustaining treatment. Mental Hygiene Legal Service, as counsel to M.B., appealed. Although M.B. passed away shortly after the termination of life-sustaining treatment, the appellate court decided to hear and determine the appeal based upon an exception to mootness doctrine, as this issue is

substantial, capable of repetition and would otherwise evade judicial review.

On appeal, the court held that the revised statute should not be applied retroactively because there had been no prior determination that the mentally retarded person did not have capacity to make their own health care decisions. The court observed that some mentally retarded persons may be competent to make their own medical decisions and capable of pursuing their rights without the aid of a guardian. The Act, in recognition of the varying levels of capacity of mentally retarded persons, requires that a guardianship application include a specific determination as to whether the mentally retarded person has capacity to make medical decisions. Retroactive application of the Act would deprive mentally retarded persons for whom a guardian was appointed under the old law, of their right to a determination as to their capacity to make their own medical decisions.

Department of Health's Oral Demand to Surrender Operating Certificate Deemed Sufficient to Trigger Article 78 Limitations Period

Hill Park Health Care Center v. Novello, 12 A.D.3d 1010, 785 N.Y.S.2d 566 (3d Dep't 2004). Petitioner, Hill Park Health Care Center ("Hill Park"), initiated an Article 78 proceeding against the State Commissioner of Health, claiming that the Department of Health ("DOH") had unlawfully revoked its operating certificate. The Supreme Court, Albany County, granted the Commissioner's motion to dismiss the petition as untimely.

In 1997, the DOH issued an operating certificate to Hill Park to operate a residential health care facility. In 2001, DOH recommended that the facility's provider agreement with Medicare/Medicaid be terminated after a series of inspections revealed conditions presenting an "immediate jeopardy" to the health and safety of its residents.

After discussions with the DOH it became clear that due to the series of failed inspections, Hill Park had no option but to submit a formal closure plan for the facility. Thereafter, DOH orally demanded a surrender of the facility's operating certificate, and Hill Park refused. After two additional oral requests, DOH deemed the certificate constructively surrendered. In March 2003, the Center for Medicare and Medicaid services formally terminated the facility's provider agreement, retroactive to the date of closure.

In June 2003, Petitioner commenced a CPLR Article 78 proceeding claiming that DOH had unlawfully revoked the facility's certificate. Respondent answered asserting that the action was untimely. The Supreme Court, Albany County, agreed and rejected Appellant's claim that the statute of limitations had not run because the determination was oral, not written. Petitioner appealed and the Appellate Division, Third Department affirmed.

The court noted that, "An agency determination is deemed final when the agency has issued an unambiguous decision putting the would-be petitioner on notice that all administrative appeals have been exhausted. If the agency creates an ambiguity or uncertainty as to whether there was a final determination, the ambiguity must be resolved against the agency."

The court found no ambiguity in DOH's position that the relinquishment of the certificate was required. Rather, the court found that DOH's oral order should have been sufficient to put petitioner on notice that it clearly viewed petitioner's actions as a final discontinuance of the facility's operations, and thus no written notice was required under the circumstances.

Patient's Bill of Rights Does Not Provide Basis for Breach of Contract Claim

Catapano v. Winthrop University Hospital, 19 A.D.3d 355, 796 N.Y.S.2d 158 (2d Dep't 2005). The Appellant in this case brought an action for medical malpractice and breach of contract against Winthrop University Hospital in the Supreme Court, Nassau County. The motion court granted the hospital's motion to dismiss the complaint as time-barred.

The plaintiff had argued that the action was governed by the six-year statute of limitations applicable to breach of contract actions. The Appellate Division noted established case law holding that, "[a] breach of contract claim in relation to the rendition of medical services by a hospital will withstand a test of legal sufficiency only when based upon an express promise to effect a cure or to accomplish some definite result."

The court then held that the provisions of the "Patient's Bill of Rights" do not constitute the requisite "express promise" or special agreement with the patient so as to furnish the basis for a breach of contract claim. In addition, the court found that the complaint solely pleaded a malpractice action, despite the fact that it also contained some breach of contract language, and thus affirmed dismissal of the complaint as time-barred since it was commenced beyond the 2½-year statute of limitations applicable to medical malpractice actions.

Hospital Not Liable for Autopsy Performed by Medical Examiner Without Consent of Surviving Family Members

Juseinoski v. New York Hospital Medical Center of Queens, 18 A.D.3d 713, 795 N.Y.S.2d 753 (2d Dep't 2005). PHL § 4214(1) prohibits a hospital from ordering the performance of an autopsy within 48 hours of death absent written consent of a person legally entitled to consent. Where an autopsy is performed by

the medical examiner, written consent is not required. (Public Health Law §§ 4210-a and 4210-b) Public Health Law § 4210-a renders it unlawful to make, or cause or procure to be made, any dissection of a human being "except by authority of law." Moreover, Public Health Law § 4210-c(1) provides that, "in the absence of a compelling public necessity, no . . . autopsy shall be performed over the objection of a surviving relative or friend of the deceased that such procedure is contrary to the religious belief of the decedent, or, if there is otherwise reason to believe that a dissection or autopsy is contrary to the decedent's religious beliefs."

In *Juseinoski*, the decedent, a Muslim, collapsed at work and was taken by ambulance to New York Hospital Medical Center of Queens, where he was pronounced dead of cardiac arrest. The surviving members of his family were called to the hospital around 2:00 a.m. and were asked for certain information. Although the hospital's "Notice of Death" form contained questions with respect to whether the family consented to an autopsy, the answers to those questions were left blank. The decedent's wife claimed that she informed hospital personnel that her deceased husband was a Muslim and she wanted to take his body to the mosque. She was told to return at 8:00 a.m. to claim the body. When the family returned to claim the body at around 8:00 a.m., the body was no longer at the hospital. The attending physician had notified the Office of the Chief Medical Examiner of the City of New York. It appears that the Medical Examiner picked up the body at 7:00 a.m. and performed the autopsy at 2:00 p.m.

The family members of the decedent sued the hospital for emotional distress and violation of the Public Health Law based on the Medical Examiner's performance of an unauthorized autopsy. The hospital, in turn, brought a third-party action against the Medical Examiner. The motion court granted the plaintiffs' motion for summary judgment against the hospital on the issue of liability under Public Health Law § 4214(1).

The Appellate Division reversed, holding that PHL § 4214(1) did not apply in this case because the autopsy was not performed by hospital personnel and was not ordered by the hospital. Moreover, where an autopsy is performed by the Medical Examiner, written consent is not required. Although the PHL § 4214(1) claim was dismissed, the court ruled that triable issues of fact existed as to the hospital's alleged negligence in connection with the family's religious objections to the autopsy.

Appellate Division Upholds Court of Claims Award for Violating Public Health Law § 2782

Tatta v. State of New York, 2005 WL 1773974 (3d Dep't 2005). Public Health Law § 2782 prohibits disclosure of confidential HIV-related information to another person without specific written consent from the patient. The Appellate Division for the Third Department affirmed a Court of Claims ruling that state officials at the Eastern Correctional Facility in Ulster County had violated PHL § 2782 by disclosing claimant's medical information to his children, and based on that ruling, imposed a civil penalty of $2,500. The claimant appealed, arguing that the award was grossly inadequate and that the Court of Claims erred by making no award for claimant's claim of emotional distress allegedly inflicted by the disclosure.

In affirming the Court of Claims' decision, the Appellate Court explained that a court has broad discretion in choosing the amount of penalty so long as the court explains its choice and the penalty is not disproportionate to the offense. Here, the Court of Claims had found that the disclosure of claimant's medical information to his children had not been intentional or malicious, and cited this lack of intent as the basis for awarding less than the maximum statutory penalty. As for claimant's claim of emotional distress, the court found that the claimant failed to present competent medical evidence that the defendant's conduct unreasonably endangered his physical safety, having relied only on his own testimony to support his claim.

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

In the New York State Legislature

By James W. Lytle

After the 2005 New York State Legislative Session had concluded and all that remained was the exercise of the Governor's approval and veto authority over the bills delivered by the Legislature, a series of articles appeared in the *New York Times* that threatened to have a more profound impact on health care law than anything debated or passed by the Legislature during the prior six months.

The series, authored by Clifford Levy and Michael Luo, focused on Medicaid fraud and abuse and cited former Medicaid fraud investigators who estimated that as much as 40 percent of Medicaid expenditures in New York constituted either outright fraud or abuse—for a total in excess of $18 billion. Whether this estimate is even remotely accurate or not is probably beside the point: the series identified enough evidence of outright fraud that appeared to have gone undetected to sicken even Medicaid's most ardent defenders. Demonstrating the impact of powerful investigative reporting, the series prompted the Governor's office, the Legislature and the Attorney General to respond with promises of new initiatives, laws and a restructuring of investigative resources to combat fraud in the State's Medicaid program—a program that has already been beleaguered by perennial proposed cutbacks designed to bring the $44.5 billion program under control.

For those Medicaid providers (and their attorneys), who have found themselves involved in defending against an audit and recoupment by the Department of Health or other state agencies or an investigation by the Attorney General's Medicaid Fraud Control Unit, the notion that New York has been lax in policing the Medicaid program may come as a surprise. Large settlements have been extracted by these offices from a wide array of providers, across the various Medicaid-funded service systems, over the last several years. Nevertheless, the pressure to reduce Medicaid spending and the prospect that even some of these tax dollars are being spent fraudulently will be sufficient to result in new resources, new approaches and new laws to police Medicaid fraud and reduce Medicaid overpayments in New York state.

While the actual enactment of new laws to address the issues identified in the *Times* series will await the Legislature's return, it can reasonably be expected that substantial changes will be made, largely prompted by the *Times*' exposé. Based on what has previously been proposed and considered by the Legislature and the responses offered by the various policymakers in the aftermath of the Medicaid fraud series, one can make some reasonable predictions about what might be enacted—either by way of Executive Order or legislation—in the weeks and months to come.

Medicaid Inspector General

Just one day after the series was initiated, Governor Pataki announced a five-point plan to combat Medicaid fraud, including the appointment of his former Director of Criminal Justice and a former federal prosecutor, Paul Schectman, to lead the Administration's efforts in identifying the appropriate strategies to combat Medicaid fraud. Mr. Schectman has been asked to undertake a "comprehensive review of the State's fraud, waste and abuse control infrastructure" and a "comprehensive assessment of the State's current efforts to fight Medicaid fraud, waste and abuse," culminating in "a series of sweeping reforms . . . to improve and expand the state's current Medicaid anti-fraud efforts"—a review that has not been systematically undertaken since the mid-1970s, when, in the aftermath of nursing home scandals, a special prosecutor was named to investigate nursing home and Medicaid abuses.

Mr. Schectman is not expected to make his full recommendations until December 1, 2005, but at least one of the changes recommended by Governor Pataki may be in place before then: a new Medicaid Inspector General. Under the State's Moreland Act, the Governor will create the new position by Executive Order and vest the Medicaid Inspector General with the authority to subpoena and examine witnesses and require the production of records to advance anti-fraud efforts. The Medicaid Inspector General is expected to integrate and coordinate the efforts already undertaken by the Department of Health, the Office of Mental Health, the Office of Mental Retardation and Developmental Disabilities, the Office of Alcohol and Substance Abuse Services, the Office of Children and Family Services and the State Education Department—all of which have been responsible for policing Medicaid fraud and abuse within their respective service systems.

Several months before the publication of *New York Times* series, the New York State Senate had already advanced legislation to create an Office of Medicaid Inspector General through a bill sponsored by Senator Dean Skelos and other members of the State Senate Republican majority. Senate Bill No. 3685-B would create

the Office within the Executive Department, which would be overseen by a board appointed by the Governor and the legislative leaders. The board—rather than, as envisioned by Governor Pataki, the Governor—would appoint the Medicaid Inspector General, who would be responsible for conducting investigations of fraud and abuse and initiating civil recoveries on behalf of the state. Criminal prosecutions for Medicaid fraud would remain the responsibility of the Attorney General and local prosecutors and prepayment claim review and related responsibilities would remain the responsibility of the Department of Health. The new Inspector General would also be responsible for investigating patient abuse, neglect or mistreatment in Medicaid-funded facilities. The Senate passed its Inspector General legislation in early May of 2005. No action was taken on the legislation in the State Assembly.

New Enforcement Tools and Statutes

The Senate initiative would, in addition, authorize the new Medicaid Inspector General to assume responsibility for and improve the automated Medicaid fraud detection system, which is now overseen by the Department of Health and the Attorney General's Medicaid Fraud Control Unit. The Senate proposal envisions the creation of a new state-of-the-art automated system, which would be integrated with other computer-based fraud detection systems to identify billing patterns that are indicative of fraud and abuse.

In addition, the legislation would enact new civil "false claims" statutory authority, which would permit the recovery of treble damages for filing false Medicaid claims, along with civil penalties and attorneys' fees. The new provisions would expressly allow recoveries for false or fraudulent claims that are "knowingly" presented, even in the absence of any specific intent to defraud—although claims filed by mistake or as a result of "mere negligence" would not be subject to these provisions. At the time of this publication, the State Senate announced the introduction of still further reforms, including a proposal that would require the Attorney General's Medicaid Fraud Control Unit to commence prosecutions of cases referred by the Department of Health within a specified timeframe or turn the matter over to local district attorneys to prosecute.

Meanwhile, at the request of Attorney General Eliot Spitzer, Assemblyman Joseph Lentol introduced legislation earlier this spring that would create new criminal provisions and penalties for health care fraud. The legislation, Assembly Bill No. 7594, would create a new crime of health care fraud, which would prohibit schemes to defraud a health plan and prohibit the use of false pretenses to obtain payment for health care benefits. In addition, the bill would authorize prosecution for making false statements, concealing material facts or filing fraudulent documents in connection with the provision of health care services. New anti-bribery provisions would also be enacted, aimed specifically at bribery payments that were intended to discourage referrals for furnishing items or services under the Medicaid program—addressing the risk that new forms of abuse could be encouraged by the state's increasing reliance on managed care and capitated arrangements for the delivery of Medicaid-funded services. This legislation remains before the Assembly Codes Committee and may be among the bills that are considered this fall in hearings that the Assembly has pledged to conduct to address Medicaid fraud and abuse.

All of this activity on the Medicaid fraud, enforcement and recoupment front makes the Health Law Section's upcoming Fall Meeting at The Sagamore on Lake George that much more timely: the top officials from the Department of Health's Medicaid audit bureaus and the Attorney General's Medicaid Fraud Control Unit will be joined by Senator Kemp Hannon, Chair of the Senate Health Committee, and a host of private attorneys with experience in this field in presenting a two-day program, entitled, "The New Medicaid Fraud and Overpayment Initiative: Representing Health Care Providers in Medicaid Audits." See you there.

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

Nursing Home Pharmacy Regulations

Notice of emergency rulemaking. The Department of Health amended § 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. Filing date: April 14, 2005. Effective date: April 14, 2005. *See* N.Y. Register, May 4, 2005.

Enactment of a Serialized Official New York State Prescription Form

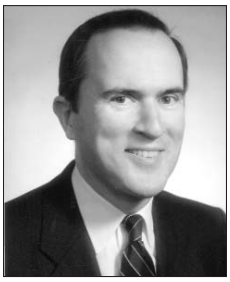
Notice of emergency rulemaking. The Department of Health added a new Part 910 to Title 10 N.Y.C.R.R., amended §§ 85.21, 85.22, 85.23 and 85.25 of Title 10 N.Y.C.R.R. and amended §§ 505.3, 528.1 and 528.2 of Title 18 N.Y.C.R.R. to enact a serialized official New York State prescription form to be used for all prescribing done in New York State in order to prevent prescription fraud. Filing date: April 21, 2005. Effective date: April 21, 2005. *See* N.Y. Register, May 11, 2005.

Newborn Screening

Notice of emergency rulemaking. The Department of Health amended §§ 69-1.1, 69-1.2 and 69-1.3 of Title 10 N.Y.C.R.R. to add thirty-three inherited metabolic disorders to the current New York State newborn screening test panel. Filing date: April 25, 2005. Effective date: April 25, 2005. *See* N.Y. Register, May 11, 2005.

Laboratory Confirmed Influenza

Notice of emergency rulemaking. The Department of Health



amended § 2.1 of Title 10 N.Y.C.R.R. to add laboratory confirmed influenza to the communicable disease reporting list to enable the Department of Health to have more comprehensive and complete information on influenza cases and permit the state and local health departments to channel limited vaccines, anti-viral agents and public health resources to those in greatest need during an influenza outbreak. Filing date: May 2, 2005. Effective date: May 2, 2005. *See* N.Y. Register, May 18, 2005.

Perinatal Regionalization

Notice of revised rulemaking. The Department of Health amended §§ 405.21, 407.14, 708.2, 708.5 and 711.4 and added Part 721 to Title 10 N.Y.C.R.R. to update existing requirements for maternal and newborn care and consolidate standards for perinatal regionalization, which are currently divided among several sections of the New York State Hospital Code. *See* N.Y. Register, May 18, 2005.

Long-Term Ventilator Beds

Notice of proposed rulemaking. The Department of Health gave notice of its intent to add § 709.17 to Title 10 N.Y.C.R.R. to promulgate a need methodology for long-term ventilator beds in residential health care facilities, which will be utilized to evaluate certificate of need applications and ensure that an adequate number of long-term ventilator beds are available to provide access to care and avoid unnecessary duplication of resources. *See* N.Y. Register, May 18, 2005.

Regulated Medical Waste

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend 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. *See* N.Y. Register, May 18, 2005.

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 to obtain easier access to short-term rehabilitation services. Filing date: May 26, 2005. Effective date: May 26, 2005. *See* N.Y. Register, June 15, 2005.

Part-Time Clinics

Notice of emergency rulemaking. The Department of Health amended §§ 703.6 and 710.1 of Title 10 N.Y.C.R.R. to clarify and enhance the requirements that apply to part-time clinics and require prior limited review of all part-time clinic sites in order to ensure the provision of quality health care to underserved populations through preventive health screening programs and other public health initiatives. Filing date: June 14, 2005. Effective date: June 14, 2005. *See* N.Y. Register, June 29, 2005.

Payment for Psychiatric Social Work 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 and prohibit part-time clinics from billing for clinical social services. Filing date: June 14, 2005. Effective date: June 14, 2005. *See* N.Y. Register, June 29, 2005.

Managed Care Organizations

Notice of adoption. The Department of Health amended Subpart 98-1 of Title 10 N.Y.C.R.R. to clarify the applicability of Subpart 98-1 to newly legislated and newly evolved forms of managed care, amend obsolete provisions, and provide clearer guidance to the health care industry concerning the certification and operational requirements for managed care organizations. Filing date: June 14, 2005. Effective date: June 29, 2005. *See* N.Y. Register, June 29, 2005.

Health Provider Network Access and Reporting Requirements for Articles 28, 36 and 40 Facilities

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend §§ 400.10, 763.11, 766.9 and 793.1 of Title 10 N.Y.C.R.R. to require article 28 facilities (hospitals), article 36 facilities (home care agencies) and article 40 facilities (hospices) to establish and maintain health provider network accounts with the Department of Health for the purpose of exchanging information with the Department in a rapid, efficient manner in times of emergency or urgent matters. *See* N.Y. Register, July 6, 2005.

Health Provider Network Access and Reporting Requirements

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend §§ 487.12(k), 488.12(m) and 490.12(k) of Title 18 N.Y.C.R.R. to require adult homes, enriched housing programs and residences for adults to establish and maintain health provider network accounts with the Department of Health for the purpose of exchanging information with the Department in a rapid, efficient manner in times of emergencies or urgent matters. *See* N.Y. Register, July 6, 2005.

INSURANCE DEPARTMENT

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, 362-5.2, 362-5.3 and 362-5.5 (Regulation 171) of Title 11 N.Y.C.R.R. in order to increase the insurance coverage of unemployed workers employed by small businesses by reducing cost, lessening complexity, and adding a second benefit package to the Healthy New York Program. Filing date: June 3, 2005. Effective date: June 3, 2005. *See* N.Y. Register, June 22, 2005.

Minimum Standards for the Form, Content and Sale of Medicare Supplement Insurance

Notice of proposed rulemaking. The Department of Insurance gave notice of its intent to amend Part 52 (Regulation 62) of Title 11 N.Y.C.R.R. in order to adopt revised minimum standards for the form, content and sale of Medicare supplement insurance as a result of changes to the federal minimum standards for Medicare supplement insurance enacted by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Public Law 108-173). *See* N.Y. Register, July 6, 2005.

Compiled by Francis J. Serbaroli. Mr. Serbaroli is a partner in Cadwalader, Wickersham & Taft LLP's 18-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 Vimala Devassy and Jared L. Facher of Cadwalader, Wickersham & Taft LLP, in compiling this summary is gratefully acknowledged.**

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In the Journals

By Dale L. Moore

***DePaul Law Review* (Volume 54, Number 2): Symposium Issue**

- Paul C. Weiler, *Reforming Medical Malpractice in a Radically Moderate—and Ethical—Fashion*
- Jeffrey O'Connell & Evan Stephenson, *Binding Statutory Early Offers by Defendants, Not Plaintiffs, in Personal Injury Suits*
- Frank A. Sloan, Carrie A. Mathews, Christopher J. Conover & William M. Sage, *Public Medical Malpractice Insurance: An Analysis of State-Operated Patient Compensation Funds*
- Michael J. Saks, Daniel Strouse & Nicholas Schweitzer, *A Multiattribute Utility Analysis of Legal System Responses to Medical Injuries*
- Mark A. Hall, *Can You Trust a Doctor You Can't Sue?*
- Neil Vidmar, Paul Lee, Kara MacKillop, Kieran McCarthy & Gerald McGwin, *Uncovering the "Invisible" Profile of Medical Malpractice Litigation: Insights from Florida*
- Lori Andrews, *Studying Medical Error* In Situ: *Implications for Malpractice Law and Policy*
- Tom Baker, *Medical Malpractice and the Insurance Underwriting Cycle*
- Mark Geistfeld, *Malpractice Insurance and the (Il)Legitimate Interests of the Medical Profession in Tort Reform*
- William M. Sage, *Medical Malpractice Insurance and the Emperor's Clothes*
- David D. Woods, *Conflicts Between Learning and Accountability in Patient Safety*
- Richard A. Epstein, *Contractual Principle Versus Legislative Fixes: Coming to Closure on the Unending Travails of Medical Malpractice*
- Robert L. Rabin, *Three Perspectives on Medical Injury: A Commentary*
- Jennifer L. Halser, *Canadian Pharmacies: A Prescription for a Public Health Disaster*

***Journal of Health Law* (Volume 38, Number 1)**

- Margaret Gilhooley, *Heal the Damage: Prescription Drug Consumer Advertisements and Relative Choices*
- David Pursell, Jennifer Marsh, David Thompson & Keith Potter, *Stark II and Physician Compensation Models: Integrating Business and Legal Issues*
- William M. McDonnell, *Will EMTALA Changes Leave Emergency Patients Dying on the Hospital Doorstep?*
- Sarah Kaput, *Expanding the Scope of Fiduciary Duties to Fill a Gap in the Law: The Role of Nonprofit Hospital Directors to Ensure Patient Safety*
- Molly Silfen, *I Want My Information Back: Evidentiary Privilege Following the Partial Birth Abortion Cases*
- Joseph C. Mandarino, *Sample Excess Benefit Tax Opinion*

***The Journal of Legal Medicine* (Volume 26, Number 1)**

- Marshall B. Kapp, *Improving the Quality of Nursing Homes: Introduction to a Symposium on the Role of Regulation*
- Donna R. Lenhoff, *LTC Regulation and Enforcement: An Overview from the Perspective of Residents and Their Families*
- Jennifer L. Hilliard, *The Nursing Home Quality Initiative: Shift in Policy, Shift in Paradigm*
- Susan Nedza, *Driving Improvement in Long-Term Care: Enforcement and Policy Initiatives*
- Rebecca Elon, *The American Geri-Wars: Moving Beyond Our Encampments*
- Olga Cotera-Perez-Perez, *Discharge Planning in Acute Care and Long-Term Facilities*
- Paul M. Kaufmann, *Protecting the Objectivity, Fairness, and Integrity of Neuropsychological Evaluations in Litigation: A Privilege Second to None?*
- Maxwell J. Mehlman, *The Rights of Patients, Third Edition* (book review)
- Edward A. Emmett, *The Company Doctor: Risk, Responsibility, and Corporate Professionalism* (book review)

***Saint Louis University Law Journal* (Volume 49, Number 1)**

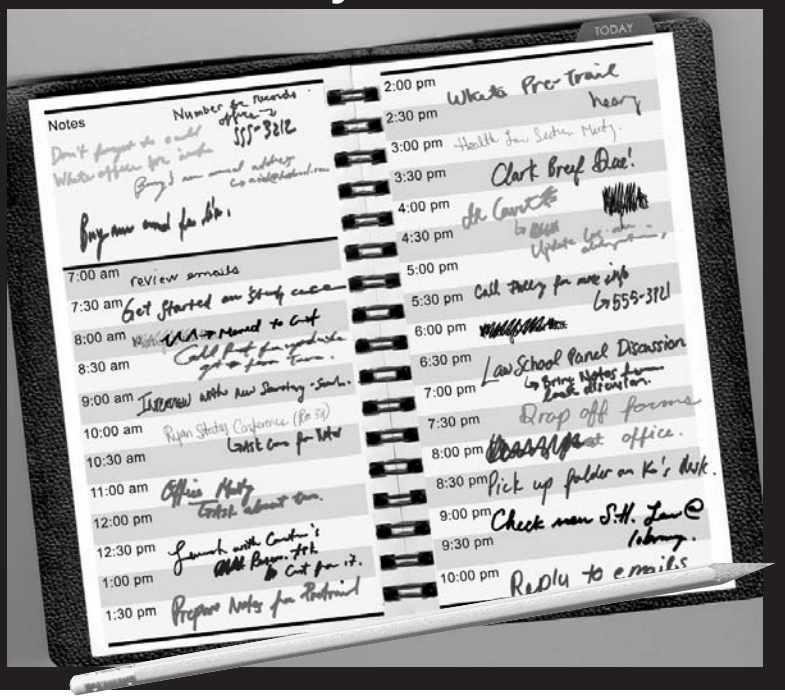
- Timothy Stoltzfus Jost, *Health Law and Administrative Law: A Marriage Most Convenient*

- Alex M. Azar II, *Administrative Law Meets Health Law: Inextricable Pairing or Marriage of Convenience?*
- Eleanor D. Kinney, *Administrative Law Approaches to Medical Malpractice Reform*
- Edward P. Richards & Thomas R. McLean, *Administrative Compensation for Medical Malpractice Injuries: Reconciling the Brave New World of Patient Safety and the Torts System*
- Eric R. Claeys, *The Food and Drug Administration and the Command-and-Control Model of Regulation*
- Margaret Gilhooley, *FDA and the Adaptation of Regulatory Models*
- John M. Griesbach, *Some Observations About the Turn Toward Federal Rulemaking in Health Law*
- Clark Hedger, Daubert *and the States: A Critical Analysis of Emerging Trends*
- Sarah A. Kornblet, *Fat America: The Need for Regulation Under the Food, Drug, and Cosmetic Act*
- Matthew J. Morris, *Secrets Don't Make Friends, But They Do Make Good Business: Perception Versus Reality in Physician Financial Incentive Plans*

Other Articles

- Jessica Berg, *Owning Persons: The Application of Property Theory to Embryos and Fetuses*, 40 Wake Forest Law Review 159 (2005).
- David Caudill & Lash LaRue, *A Non-Romantic View of Expert Testimony*, 35 Seton Hall Law Review 1 (2004).
- Jean M. Eggen, *Toxic Exposures and Workers' Compensation*, 14 Journal of Workers Compensation 9 (2004).
- Thomas L. Greaney & Kathleen Boozang, *Mission, Margin and Trust in the Healthcare Enterprise*, 5 Yale Journal of Health Policy, Law & Ethics (2005).
- Timothy Jost, *The Uses of the Social Transformation of American Medicine: The Case of Law*, 29 Journal of Health Politics, Policy and Law 799 (2004).

Pencil yourself in.



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For Your Information

By Claudia O. Torrey

The following information is to inform, to enlighten, and to keep one young at heart:

1. ***Kadlec Med. Ctr. v . Lakeview Anesthesia Assoc.***[1]—This federal case may have a profound effect on all hospitals across the country, regarding reference request information about their medical staff members to inquiring health care providers. A brief overview of the facts is as follows: The plaintiff made a reference inquiry to the defendant about one of its physicians. The plaintiff was told that the physician in question had served on the staff for four years; however, no further information could be provided due to a large volume of inquiries. The physician was appointed to plaintiff's medical staff, and, along with the plaintiff, was subsequently successfully sued for malpractice. Thus, the plaintiff brought this current complaint asserting that if the defendant had been more candid and forthright, the plaintiff would never have been hired, and the adverse event that gave birth to the malpractice lawsuit would not have occurred. The court agreed with the plaintiff.

   Regarding medical staff reference requests, this case lays the foundation for an informed duty of disclosure. A dismissive disclosure response is unacceptable! For the future, hospital legal staffs will probably want to review their releases, their immunity status, and the potential long-term effect of peer review disputes.

2. **Update**—The Winter 2005 edition of this column[2] enlightened you about the landmark development of the first drug for a specific race. The drug, known as BiDil, was reviewed on June 16, 2005, by the Cardiovascular & Renal Drugs Advisory Committee of the Food and Drug Administration ("FDA"). One week later, the FDA approved BiDil for the treatment of self-identified black patients. According to Dr. Robert Temple, Associate Director of Medical Policy at the FDA, BiDil represents a step toward personalized medicine; the ultimate goal is to discover characteristics that identify people of any race who might be helped by BiDil.[3]

3. **The "Lighter" Side of Health—Witticisms by Benjamin Franklin—**

   "He is ill clothed that is bare of virtue."

   "Good Death, said a Woman, for once be so kind

   To take me, and leave my dear Husband behind;

   But when Death appear'd with a sour Grimace,

   The Woman was dash'd at his thin hatchet face;

   So she made him a Court'sy and modestly sed,

   If you come for my Husband, he lies there in Bed."

   "The tongue offends, and the ears get the cuffing."

Endnotes

1. No.Civ.A.04-0997 (E.D. La. May 19, 2005).
2. New York State Bar Association, *Health Law Journal*, Vol.10, No.1, Winter 2005.
3. http://www.fda.gov/bbs/topics/news/2005/new01190.html.

Claudia O. Torrey, Esq. is a member of several professional organizations, including a Sustaining Member of the New York State Bar Association.

Selections from the New York State Task Force on Life and the Law's Twentieth Anniversary Symposium

***Editor's Note**—The NYS Task Force on Life and the Law was convened by Governor Mario Cuomo in 1985 to make policy recommendations for New York on ethical issues raised by advances in medicine and biology. Over the years the Task Force, composed of members from diverse disciplines and with diverse perspectives, has issued several influential reports, including, most recently "Genetic Testing and Screening in the Age of Genomic Medicine." It has also made specific policy proposals that have led to new laws and regulations, including New York's Health Care Proxy Law. On March 3, 2005, a Twentieth Anniversary Symposium was held at Rockefeller University in NYC. The following three articles are selected transcripts from that symposium.*

The New York State Task Force on Life and the Law Celebrating the Past

Opening Remarks

By Alan Fleischman, M.D.

Senior Advisor, The New York Academy of Medicine
Ethics Advisor, National Children's Study, NICHD, NIH

It is an honor to be here this morning to celebrate the past and to look toward the future of the New York State Task Force on Life and the Law. Membership on the Task Force has been among the most pleasurable and important aspects of my career in medicine. I wish to say, however, that when asked to give this talk, I objected, pointing out that there are wiser and older founding members of the Task Force who could provide this perspective; but I was honored to have my objection overruled. I'm indebted to my fellow members and to the staff who have taught me a great deal over these 20 years. Whatever little contribution I may have made as a member has been more than repaid by the knowledge I have gained, the joy of the collaborative spirit, and my pride in what has been accomplished.

It began December 20, 1984, when executive order #56 created The Task Force on Life and the Law. Then-Governor Mario Cuomo wrote:

> Whereas, major advances in medical science and technology have not been accompanied by a sufficiently thorough evaluation of their ethical, legal and public policy implications; whereas, as a result, society has with increasing frequency, been confronted by complex issues of life and death that eludes simple answers; whereas the challenges posed by these issues require thoughtful debate and consideration, aimed at elevating public understanding of these issues and at developing recommendations as to the appropriate policies to pursue; now, therefore, I, Mario Cuomo, Governor of the State of New York, by virtue of the authority vested in me by the Constitution and the laws of the State of New York, do hereby establish the New York State Task Force on Life and the Law.

And we're quite pleased that Governor Cuomo has sent us a letter congratulating the Task Force on its 20 years of work and wishing us many more successful years in the future.

Prior to this Task Force, there had been a small group of advisors that the Governor convened to talk about these types of ethical issues. Some of the Task Force members were actually part of that initial "kitchen cabinet," or maybe we might call it a "Long Island" cabinet, that morphed into this major effort for New York State.

But what were the critical issues of concern in the early 1980s?

First, the President's Commission had just provided a whole series of reports on issues that would later be addressed by the New York State Task Force. But what was different about this venture? The Governor saw that the President's Commission gave us abstract, carefully thought-through philosophical and legal treatises but with almost all of the issues left for each State to resolve. Almost every one of the issues about which the President's Commission opined required State action to

implement. The Governor thought that there was a need for specific advice, not just abstract thinking.

What else was going on? Medical decisions for newborns were in the news in 1984. Baby Doe, a child with Down's syndrome, had been allowed to die in 1982 when doctors, parents and the courts agreed that such a course of action was permitted in Bloomington, Indiana. In response, the federal government passed regulations to prevent parents and doctors from withdrawing medical interventions and treatments from critically ill newborns that would likely result in their death. In New York, we had Baby Jane Doe, a baby with microcephaly, spina bifida, and a prediction of very poor future quality of life, who was given less than aggressive treatment at the University Hospital in Stony Brook. That case ultimately made its way to the U.S. Supreme Court in 1983, with the result that parents could, with the support of their licensed physician, allow comfort care rather than surgical intervention for a severely affected child. The Governor was well aware of that case and had followed it carefully.

"Task Force members included physicians, lawyers, religious leaders, academics, community representatives, social scientists, and others with demonstrated interest and/or expertise."

The Uniform Determination of Death Act was passed in the United States in 1980, and the issue of brain death determinations was being debated in New York. In 1984, New York experienced an important legal case, *People v. Eulo,* that brought this issue to a head. Two defendants who had been convicted of manslaughter appealed, arguing they should not have been convicted of manslaughter because the people they allegedly killed actually died when their hearts stopped after doctors pronounced them brain dead and withdrew their respirators. The question was, in New York, does brain death equate to death and, therefore, should these convictions stand? The court determined that brain death in New York was death and that the criminals' appeal had no validity. Also affecting the area of organ transplantation, the New York Required Request Law was passed in early 1985 and was in need of regulatory clarification in order to implement this new approach to requesting organs from families of those who had died.

The Do Not Resuscitate (DNR) issue was fascinating to those of us caring for critically and chronically ill patients in hospitals. There had been an Attorney General Grand Jury investigation in 1982 that alleged that a Queens hospital allowed patients to die by withdrawing or withholding treatment, without any process that included the patient or family's knowledge or consent. Those of us who worked in hospitals understood that scenario wasn't unusual because legal counsels to hospitals did not believe that New York law permitted the writing of DNR orders, even with permission. In one Manhattan hospital however, a courageous President with the help of his able attorney determined that DNR orders were, in fact, both ethical and legal and implemented a procedure to allow doctors to write them. There were many other attorneys who reacted to this by opining that writing DNR orders was quite risky because of the lack of a legislative basis and that even state regulations would be inadequate to solve the problem.

There was also the growing field of the new reproductive technologies, including in vitro fertilization, embryo transplantation, and surrogate motherhood, about which debate had been going on for a decade. It was unclear whether such procedures should be permitted and what types of laws and regulations were needed to effect these practices in New York.

With all of these contentious issues to debate, Governor Cuomo understood that if the Task Force was to be effective, it needed to include broad representation from all stakeholders and religious groups, and have representation from advocates for civil liberties and patients' rights. Task Force members included physicians, lawyers, religious leaders, academics, community representatives, social scientists, and others with demonstrated interest and/or expertise. He sought wide diversity of thought in order to generate true consensus so that he could bring these issues to the legislature and to the people with the full knowledge that there was wide acceptance of both the need for action and the recommended course chosen. He asked his Commissioner of Health, Dr. David Axelrod, to chair the Task Force. Dr. Axelrod brought great wisdom and intensity to the discussions. His leadership and commitment were instrumental in the success of the Task Force.

The responsibilities of the Task Force were wide-ranging:

> to study the ethical implications of the process by which medical decisions are made; the definition of death; the discontinuation of life-sustaining thera-

pies; Do Not Resuscitate orders; artificial insemination and embryo transplantation; organ transplantation and such other health-related matters as may be appropriate for study.

The Governor created a very broad, very ambitious, and very challenging agenda.

The Task Force was committed to addressing these challenges. Founding members and staff are listed below.

Members:
Rev. Msgr. John A. Alesandro
Mario L. Baeza, Esq.
The Right Rev. David Ball
Rabbi J. David Bleich
Evan Caulkins, M.D.
Daniel Callahan, Ph.D.
Richard J. Concannon, Esq.
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M. Janice Nelson, Ed.D., R.N.
Maria I. New, M.D.
Ruth O'Brien, Ph.D.
John J. Regan, J.S.D.
Rabbi A. James Rudin
Rev. Betty Bone Schiess
Barbara Shack
Rev. Robert S. Smith
Elizabeth W. Stack
Charles J. Tobin, Jr., Esq.

Staff:
Tracy E. Miller, J.D., Executive Director
Maura A. O'Brien, Ph.D.
Robert N. Swidler, M.A., J.D.
Leslie E. Schneier, MPPM, MPH
Elizabeth Pepe

Under the competent leadership of attorneys Tracy Miller and Robert Swidler, the Task Force prioritized its goals, defined its direction and sought to create procedures that would facilitate open debate and enhance productivity. The first issue was the question of doing ethics and public policy debate entirely in public. Daniel Callahan, then the President of the Hastings Center and a founding member of the Task Force, argued that all meetings should be conducted in public. He believed the primary goal of the Task Force should be public education, not the creation of regulations and legislation. I shared his view initially but was convinced by other Task Force colleagues that if we were going to roll up our sleeves and try to work toward consensus from diverse perspectives to solve complex problems, we needed some time to debate and discuss without public posturing. We needed time for private conversations after obtaining public input and we needed public reaction to ideas before they became final recommendations. Our work needed to be transparent, but in order to be effective we also needed time to do ethics and health policy analysis in private. We were successful in protecting our deliberations from public scrutiny and often surprised ourselves by how many times we changed our views during those confidential discussions.

"[R]egardless of the complexity and potential divisiveness of the issues or the vehemence of the arguments, the Task Force developed an atmosphere of respect for the input of every member and a cohesiveness of purpose that resulted in amazing productivity."

We decided the goal was to impact public policy, not just educate the public. We reasoned that there were three possible recommendations for our reports: public education, state regulation, or legislative initiatives. We always chose legislation as a last resort because of the complexity of that process in New York. We did seek new legislation when it was needed and we obtained the support of colleagues in the legislature many times along the way.

Because of the controversy that surrounded many of the issues we addressed, we decided that unanimity might not always be possible and that dissenting members should be given the opportunity to address their views in minority reports. We developed consensus as best we could through debate, discussion and compromise. What was amazing to me was that regardless of the complexity and potential divisiveness of the issues or the vehemence of the arguments, the Task Force developed an atmosphere of respect for the input of every member and a cohesiveness of purpose that resulted in amazing productivity. We developed broad consensus when we could and when that was impossible we defined those areas of disagreement and laid out

the issues that needed to be resolved in order to make progress. We not only respected each other, we were cognizant of the fact that in recommending public policy we needed to respect the pluralistic society in which we live.

I went back to look at our accomplishments. Within the first full year of the Task Force's existence we had 14 day-long meetings and two 3-day retreats. We produced three major reports by 1986.

We examined the recently passed Required Request Law and recommended a regulatory approach to the Department of Health that would enhance the quality and availability of organs for transplantation, foster coordination in organ procurement, and educate those who would request and procure organs. We looked critically at the question of Do Not Resuscitate orders and concluded that legislation was required to allow this practice in New York. To that end, we developed a complex legislative proposal, presented it to the public and the legislature in 1986, and saw the successful passage of the Do Not Resuscitate law in August 1987.

"We not only respected each other, we were cognizant of the fact that in recommending public policy we needed to respect the pluralistic society in which we live."

In the Determination of Death report, we argued that in New York there was no need for legislation because we had a Court of Appeals decision that defined death as either cessation of heart and lung activity or total, irreversible cessation of brain function. We needed regulatory guidance to assure that brain death determination was done appropriately, so the public could be reassured that proper procedures were maintained when brain death was used to determine death prior to organ procurement for transplantation. Our work became the basis for the subsequent regulations and guidance to the medical community in this area.

In our second year—1987-88—some new members were appointed and we were able to complete four additional reports. As I went back over this period in the life of the Task Force, I was in awe of how hard Tracy Miller and her staff worked. The most important work was *Life-sustaining Treatment: Making Decisions and Appointing a Healthcare Agent,* which resulted in legislation being passed in July 1990. This legislation created the authority for adults to appoint healthcare agents to make surrogate health care decisions when they lose capacity. This report remains the basis of advanced directives for end-of-life care in New York.

During that time, we also published *Transplantation in New York State: The Procurement and Distribution of Organs and Tissues*, which helped create the NYS Transplant Council and defined parameters for the coordination of NYS Procurement organizations, and the screening and testing of donors and organs.

The shortest report of the Task Force on Life and the Law was also completed during this period, *Fetal Extrauterine Survivability*. The Task Force was asked by the Governor to look at the biology of fetal development to determine what was known about the threshold of viability in order to add scientific information to the raging debate about ethical and theological perspectives on abortion. We examined whether complete fetal development could occur in vitro and concluded that it could not. We asked whether research institutions were attempting to support embryos and create humans without the intercession of a human woman and found no such research anywhere in the world. We concluded that fetal organ development and technological support determine survivability outside the uterus, and that 23 to 24 weeks gestation was the biologic and the epidemiologic threshold of viability for human fetuses. Because of some new pharmacologic and technological advances, that threshold has changed a little in these last 15 years, but not much.

Surrogate Parenting was also published at this time. The report made recommendations that ultimately resulted in legislation to discourage such practices in New York. It focused attention on the entrepreneurial nature of the practice, the vulnerability of the young women who choose to become surrogate mothers, and the potential to commodify children through this approach to reproduction.

Through the next decade, the Task Force had new chairs as New York State had three new Commissioners of Health. We acquired new members and new staff. Carl Coleman joined Tracy Miller as Counsel and, when she decided to leave, he became Executive Director, adding his substantial intellectual capacities and hard work to the leadership of the Task Force. He helped produce *When Others Must Choose: Deciding For Patients Without Capacity*, which recommends the Family Health Care Decisions Act, a sorely needed surrogate decision-making bill that has still not become law in New York.

This recommendation has wide support in New York but after 12 years of seeking legislative approval, lack of passage remains a great disappointment and the most unfulfilled challenge of the Task Force.

When Death is Sought: Assisted Suicide and Euthanasia was a landmark report on the issue of physician-assisted suicide. A critically acclaimed report, it became a frequently quoted and referenced part of the Supreme Court deliberations on this issue. What was unique about this report was the unanimity that assisted suicide should not be legal, though Task Force members came to that conclusion from very different perspectives. Some believed it was ethical to assist suicide while others believed it was not, but all agreed that at least, at this point in time, it should not be legal in New York. Members agreed, as the Supreme Court concluded, that there is a constitutionally protected right to palliative care and pain management for those facing terminal and chronic illnesses. The report argued that availability of such treatments might obviate the need for assistance with suicide in many cases.

During the following years, the Task Force published *Assisted Reproductive Technology*, a comprehensive analysis of the field with recommendations about standards for informed consent, regulations for laboratories, and guidance for clinicians. *Genetic Testing and Screening: The Age of Genomic Medicine* provided a template for the burgeoning field of newborn genetic screening and created the basis for public education in genetics.

Today, in 2005, Health Commissioner Antonia Novello leads the Task Force as chair and Donald Berens, DOH General Counsel, is liaison to the Task Force. Dr. Tia Powell serves as Executive Director with staff support from Michael Klein and Kelly Pike. There is a stalwart group of members who were there from the beginning and others who have joined to add their intellectual expertise and competence to the Task Force. The Task Force stands prepared to build on its past successes and set new and exciting goals for the future.

"The New York State Task Force on Life and the Law has been the most effective bioethics commission in the country."

Let me conclude by asking what are the lessons learned that we might apply going forward? I've alluded to most of them. The New York State Task Force on Life and the Law has been the most effective bioethics commission in the country. It has published important treatises on critical issues and has had a serious impact on the development of concrete laws and regulations. It has impacted directly on health policy in New York and elsewhere. The secret of its success is simple. It has had the strong commitment of the Governor of the State, the benefits of an extremely competent staff, and an enduring focus on creating the very best possible recommendations with an abiding respect for the pluralistic nature of our state. This approach, supported by strong Commissioners of Health and legislative champions in both houses, has resulted in major contributions to the well-being of New Yorkers through the development of concrete solutions to complex problems.

Selections from the New York State Task Force on Life and the Law's Twentieth Anniversary Symposium

Panel Discussion on the Current Work of the Task Force: The Family Health Care Decisions Act and Directed Live Organ Donation

Tracy Miller

Let me first of all thank Alan Fleischman for his presentation. One of the great assets of the Task Force has always been what superb advocates and spokespersons all of its members are for the Task Force and its work. I also want to say what a great pleasure it is for me to be here today. As I look out on the audience, I see the former and present members of the Task Force and so many others who entered my life when I was Executive Director of the Task Force and became friends and colleagues.

One of the topics of the panel today, the Family Health Care Decisions Act, is near and dear to my heart. It is both compelling and poignant for many of us who first developed and proposed the legislation in March 1992, in a report titled, *When Others Must Choose: Deciding For Patients Without Capacity*. I'm delighted that we're focusing on the legislation today, but I will admit that when we proposed it, 2005 probably sounded like a good date for a 10th anniversary celebration of the bill's passage rather than the session we have today. The Task Force bills were always considered a heavy lift by those in Albany, and the Family Health Care Decisions Act is obviously heavier than others. But it is central to what the Task Force always sought. We proposed the law on Do Not Resuscitate orders as a framework and a precursor to a bill that would cover all treatment decisions. We made a judgment in 1986 that the State did not have a consensus on the ethical issues posed by decisions to forgo artificial nutrition and hydration. One could wish that we were somewhat less prescient. Without question, however, the Family Health Care Decisions Act (FHCDA) is a stronger, better-crafted law as a result of the DNR law, because of our collective experience and a shared wisdom that emerged from that first legislation in this State on ethical issues at life's end.

The Task Force stated in 1992 that in health care facilities across New York State, thousands of decisions are made for patients unable to decide for themselves: the young, the old, infants, those temporarily impaired, those who will not regain capacity, and those never able to decide about treatment. The question for New York State policy is not whether surrogate decisions will be made, but who will make them and by what criteria. The report went on to state that illness itself brings vulnerability. Patients often experience a loss of autonomy, self-assurance and identity. When illness renders a person unable to decide about treatment or when individuals such as children or the developmentally disabled have not attained the capacity to decide, that vulnerability is more acute. Society has a special duty to incapacitated patients, an obligation to respect them as individuals, to preserve their religious and moral values in these intensely personal choices, and to promote their well-being by facilitating responsible decisions about their medical care. The FHCDA was written to serve those ends. It was written because our laws in New York dictated decisions for incapacitated patients that defied compassion, common sense and sound medical judgment. They still do. The bill is as urgent today as the day we proposed it in 1992.

The FHCDA was written under the leadership of Dr. David Axelrod, and I want to say a few words today about him. The Task Force deliberated for four years in developing the legislation for surrogate decision-making. During that time, David Axelrod was Commissioner of Health and Chairman of the Task Force. Those of you who knew Dr. Axelrod no doubt remember him as a man of extraordinary political courage. Indeed, it may be hard to appreciate now, but it took courage just to convene the Task Force on Life and the Law with as diverse a group as it was. At that time, with the exception of the Required Request Law, New York had not enacted a single piece of legislation to address ethical issues posed by medical advances. Other states had moved ahead. They had enacted legislation on the determination of death and on advance directives, but this had not happened in New York State. As chairman of the Task Force, David Axelrod always extended his exceptional intellect, his keen interest in the issues and a commitment to informed, reasoned debate as the foundation for consensus among the diverse religious, moral and professional views that characterized New York State. He convened the Task Force with the hope that he and the Task Force members could demonstrate that New York State's diversity could be a resource, not an obstacle, in addressing the issues posed by medical advances. He believed that government could lead with integrity on the complex issues of health policy and ethics, and he nurtured the Task Force to fulfill that role. Once it is enacted, the

Family Health Care Decisions Act, like the other bills proposed by the Task Force, will be part of his legacy of leadership and vision for New York State. They are, too, a tribute to the Task Force members—to their extraordinary commitment, to their remarkable ability to listen and learn from one another despite their diversity, and to find common ground that was always greater than the sum of the parts.

One of the lasting gifts that the Task Force bestowed upon many of us has been the opportunity to work with an outstanding group of scholars, civic and religious leaders, lawyers, health care professionals and others with a shared commitment, many of whom—through this experience—became colleagues and friends. That's true for the panelists today and for others as I look out to the audience. I want to comment, as Alan Fleischman did, on the importance of the leadership of Assemblyman Dick Gottfried, who is here today. Without his courage, many bills that are such a heavy lift would never have moved forward.

Tia Powell

Our panel today will focus on two topics that are relevant to the current work of the Task Force. First, we will discuss the Family Health Care Decisions Act. The Task Force was the original author of this legislation and it has been—for these many years—the goal of the Task Force to have this bill passed. We are also going to talk about what will be a topic within the next Task Force report: directed live organ donation. In some ways, live organ donation is a very up-to-the-minute issue. There are Internet advertisements, organ donation billboards and Web sites through which people are seeking organs. But it's also old wine in new bottles. The issues of jumping the queue and of trying to shape organ allocation in a way that disadvantages the many and advantages the few have been concerns of the Task Force from the very beginning. Nancy Dubler will comment for us on this issue.

We will also address the Family Health Care Decisions Act. Its absence in New York creates significant suffering for New Yorkers. New Yorkers by and large do not understand the current context of the law. Those who have been spouses for decades believe they have the right to make health care decisions for their loved ones. They do not have such a right, unless their loved one belongs to that minority who has left either an advance directive or clear and convincing evidence. Parents believe that they have the right to make decisions for their terminally ill children. Until the recent decision in the "Matter of AB," this matter was, as that decision says, "quite unsettled" in New York. We need the Family Health Care Decisions Act to close the gap, to bring New York back to the leadership position from which it has fallen in terms of surrogate decision-making. The Family Health Care Decisions Act has been around a long time. I know there are many people who think that it's a dead letter and cannot pass. For those doubters I will quote my daughter's basketball coach, who is extremely keen on conditioning. He makes the girls run for ages without stopping, and the girls complain bitterly and say, "We can't do this anymore! We won't run back and forth anymore!" He says to them, "Girls, it's the fourth quarter! The *other* team is tired but *we're* not tired, girls." I say to you that it is the fourth quarter for the Family Health Care Decisions Act, but we are not tired and we will not stop until this bill becomes a law.

John Arras
Family Health Care Decisions Act

I left the Task Force in New York in 1995 to move to the University of Virginia. It's good to be back in New York. It's just great to see so many former colleagues and friends and even former students here today. It's also a pleasure to be on a panel with my former colleague, Nancy Dubler, once again. We shared office space for 14 years at Montefiore. It's also a good time to remember friends who are not here, including David Axelrod and Professor John Regan of Hofstra Law School. John was a dear friend of mine and his death was a great loss to all of us.

I served on the Task Force from 1987 to 1995. It was said today that I was one of the founding members, but that's not true. Dan Callahan was the first choice as philosopher for the Task Force, and I don't feel too bad about that. In fact, Dan apparently lost the debate about the proper role for the Task Force and I'm very glad he lost that debate. As I was coming onto the Task Force and Dan was going out, he mentioned to me that he found tinkering with legislation to be excruciatingly boring. After working all those years on the Task Force, I came to the conclusion that Dan had an excessively low threshold for boredom. I have to say that service on the New York State Task Force on Life and the Law was one of the best things that I have ever done. It gave me an opportunity to meet and work with some of the finest people that I've ever known, and to do so in an atmosphere of mutual respect far from the polarized atmosphere that we find today. Even if we disagreed with each other, we would do so respectfully and collegially. It meant a lot to be permitted to deliberate behind closed doors so that we didn't have to posture to people in the balcony.

One title for these remarks might be: The Family Health Care Decisions Act—The Continuing Saga. Another title that comes to mind as a current resident of Virginia would be: "What on Earth Is Wrong with You People?" In spite of the Task Force's leadership, New York stands nearly alone in refusing to grant appropriate but carefully circumscribed discretion to family and friends of incompetent patients without proxies or living wills. I think that only the State of Missouri, along with New York, currently upholds a clear and convincing evidence standard for the vast majority of cases. In other words, you have to present clear and convincing evidence of the patient's former wishes, which is an extraordinarily high standard to meet. I will argue that it is completely unrealistic and very damaging to the people of this State. Even Virginia has established a morally and legally sound system for dealing with these difficult questions. It is important to recognize what sort of state Virginia is in order to grasp the importance of this comparison. It's a state with a truly reprehensible history of legalized racism, a state that is redder than red, a state that recently tried to amend Thomas Jefferson's statute on religious liberty in order to protect our "persecuted Christian majority." It's a state that until recently, when forced to stop by the Supreme Court, was administering capital punishment to the retarded and adolescents. It's a state that almost legally forbade the showing of underwear in public just last month. Even such a backward state as Virginia is more forward, more enlightened, more humane than New York when it comes to death and dying. Isn't it time, at long last, for New Yorkers to do something about this?

I realize that there have been problems with specific aspects of the bill and that there are knotty issues to contend with. Each side in the debates about this bill has brought forward interesting and often valid criticisms of the various versions of this law. You might think, "Well okay, there are a few details to be worked out." One would expect that it would take perhaps a year to work these things out, maybe two or three. But what is it now? Thirteen years? This is the *Bleak House* of bioethics. It just goes on and on. At the risk of preaching to the choir, I'm now going to offer a few reflections on the moral situation.

I'm going to argue first of all that the status quo in New York State may be described by a series of unflattering adjectives. The first of them is that the status quo is *unrealistic*. It assumes that most families can honestly adduce clear and convincing evidence of their loved one's former wishes. New York currently leaves in legal limbo the large numbers who have no proxy or advanced directive and who have not spoken clearly and convincingly to family and friends. Secondly, the status quo is *disrespectful* of families as the proper surrogates for incapacitated patients. Almost everyone believes that families are the proper repository of that kind of authority and that sort of discretion, but New York continues to impose values on its citizens that would not be chosen by the majority of citizens here. Third, the status quo is *morally purblind* in its exclusive focus on patients' former wishes. In other words, this legal status quo has focused exclusively on the issue of the so-called subjective test—i.e., what the patient wanted—and it has ignored a lot of extremely morally relevant issues. Patients' wishes, clearly and convincingly expressed, are only the tip of the iceberg of moral relevance. Beneath such wishes we have long held preferences and values not clearly articulated by the majority of patients, since most people are not articulate about these matters. Most people do not have these wishes tattooed on their chest. This standard also disregards the best interests of patients. Finally, I would also argue that in many situations that I witnessed while working at Montefiore Medical Center and elsewhere, the current law is *cruel*. It doesn't just neglect the best interest of patients. It is actually cruel in its results for both patients and their families.

Some people argue that establishing a high standard of clear and convincing evidence is the best way to respect the autonomy of patients. I disagree. I think it is not the best way to protect autonomy. Less articulate patients are stripped of the remains of what I would call their precedent autonomy, the values that they used to have but are no longer able to express. They are stripped of the remains of their autonomy on a daily basis. Finally, I would argue that the present state of surrogate decision-making in New York is corrosive of respect for law. It presents the family members with a Hobson's choice: either stand by helplessly as life-sustaining treatments are imposed on your loved one by the State, or manufacture proof that fits the State's high standards of evidence. The work of hospitals would grind to a halt, I would argue, if this standard were rigorously imposed and followed to the letter. Sensible and compassionate physicians and lawyers thus have to find a way to make things happen. I argue that they should not have to work around the law in a way that is disrespectful both to them and to the law itself. My plea to all New York State decision-makers is that they find a way to do the right thing. Don't let the perfect be the enemy of the good or, in this case, of the minimally decent.

Carl H. Coleman
Family Health Care Decisions Act

As I was preparing to talk about the Family Health Care Decisions Act, it struck me that it was a particularly appropriate topic to be talking about at the 20th anniversary of the Task Force. For me, it's been the one constant in my work with the Task Force. I started as counsel when Tracy Miller was Executive Director in 1993. Tracy may not remember this, but when she interviewed me for the job, she said, "It's too bad you couldn't start earlier because you'd get to work on this legislative proposal, the Family Health Care Decisions Act. By the time you start in the summer, it will probably be passed already, and we'll have moved on to other things." And yes, Tracy has remained optimistic, as have I. Every year we hope that this will be the year the bill passes. There is a sense of inevitability among those of us who have worked on this bill because it just seems inconceivable to us that New York law will stay the way it has been. It is not only inconsistent with what other states do, but it is also inconsistent with what most people in New York assume the law to be. And, in fact, as John Arras was saying before, the law is very different in Virginia. It's very different in New Jersey. It's very different in every state in this region. There is no reason why New York has to stay this way.

What I'd like to do today is talk about what the bill actually says and update you on its current status. This is very much a live issue. This is not a bill that has gone away. In fact, if anything, activity on the bill has increased in the last two years to the point that it is reasonable to be optimistic about the chances of passage, but only if people take an active interest in it and actually do something to move it forward.

The idea of the bill is very simple. If the patient lacks capacity to make a decision, a family member or close friend would be empowered to make the decision on the patient's behalf, based on the patient's wishes if those wishes are known, or if the patient's wishes cannot be determined, based on a good faith assessment of the patient's best interest. The bill is often referred to as a "right to die" bill. It is not, and it does a terrible disservice to the bill to think of it in those terms. Even in end-of-life situations, the bill is not at all just about the right to die. There are many situations where there are choices to be made among various treatment options, all of which are designed to continue the patient's life, not to allow the patient to die. Somebody has to assess the risks and benefits of those options. Right now under New York law, there is nobody who has the power to do that. Those decisions obviously get made by someone, but there is no legal mechanism for those decisions to be made. In addition, though, and at least as important, the bill is not at all limited to end-of-life situations. There are many situations where patients lack decision-making capacity but are not facing end-of-life issues. There can be psychiatric illnesses where decisions have to be made about, for example, electroconvulsive therapy versus medication, and the patient lacks the ability to make a decision directly; somebody has to make those decisions. There are also patients who lack the capacity to make decisions about ordinary medical treatment, such as dental surgery or other elective medical procedures. The only mechanism for making those decisions under New York law is to go to court and obtain a guardianship or to have the court decide whether a particular treatment is appropriate. In many cases, it is just too complicated, expensive, and time-consuming to go to court, so there are needless delays. Patients may be denied necessary treatment simply because there is no mechanism in the law to do what everyone agrees would be the right thing. That leads, in many cases, to what John Arras described as a Hobson's choice. Nancy Dubler often says that this process invites civil disobedience, since families and doctors try to do the right thing regardless of what the law says. That is obviously not a good solution as a matter of public policy.

The Family Health Care Decisions Act would require the surrogate to decide according to the patient's wishes or, if the wishes are not reasonably known, the patient's best interest. There are important limitations to the surrogate's authority to withhold or withdraw life-sustaining treatment, in light of the fact that the surrogate isn't the patient and has not been directly appointed by the patient. Therefore, there are specific medical criteria that would have to be satisfied before a surrogate would have the authority to refuse life-sustaining treatment. The patient would have to be terminally ill, permanently unconscious, or would have to have an irreversible or incurable condition and the provision of treatment would involve such pain, suffering or other burden that it would reasonably be deemed inhumane or excessively burdensome under the circumstances.

There are numerous safeguards throughout the bill. The bill contains specific procedures for determining incapacity, for providing notice of decisions to both the patient and to family members, for reviewing controversial decisions by a dispute mediation process within the facility, and for judicial review in appropriate cases. I am often asked why the bill is so long. It is longer than laws in other states on surrogate decision-making because the bill contains so many safeguards and provisions for oversight of these decisions.

There is reason to be optimistic about the current status of the bill. The bill has always had many supporters, both individuals and organizations. The problem is that for many years, there has been no single organization or individual who has taken ownership of the bill and who has decided that passing this bill is a key priority for them. As I'm sure you're aware, in New York State and probably in many states, it's often easy to stop legislation from being enacted. It's much harder to actually get a proposal passed. Because the bill seems complicated and controversial, there has been a sense of inertia for many years. Things haven't happened even though there is remarkably little opposition. In fact, the opposition that exists does not go to the heart of the bill. There is virtually unanimous consensus in this State that family members and close friends should be able to make these surrogate decisions. The concerns are limited to peripheral issues and specific situations. But again, without any single individual or organization pushing this bill forward as a priority, those limited concerns have been enough to let this bill languish. In the last two years, there has been a renewed effort among supporters of the bill to change that. There is a group of approximately 40 organizations throughout the State that have long supported this bill and that have joined together in the last two years to form the Family Decisions Coalition. This group has a small steering committee that last year solicited many of you for individual contributions—which were very generously made—to support the hiring of a professional lobbyist. We were able to hire a lobbyist in the last legislative session who, in one year, accomplished tremendous things, more than had happened in the 5 to 10 years before that, including introduction of the bill in both the Senate and the Assembly by committed sponsors in both houses. That's the first time we have ever had the bill introduced in both houses by sponsors who are committed to getting the bill passed. Through this process, we were also able to reduce the number of outstanding issues surrounding the bill.

This year we were fortunate to receive a grant to continue this lobbyist's work for another year. It is an unrestricted grant that allows direct political lobbying. In the foundation world, it is rare to get a grant that allows legislative advocacy. The lobbyist who worked for us last year and was so successful has been engaged to work again this year. She is actively trying to bring people together to get more sponsors for the bill in both the Senate and the Assembly and to work through some of the differences between the two houses. Because of this ongoing effort, there is reason to be optimistic, but the bill can't pass without a continued push by advocates. It's frustrating for many of us who have been involved in this for so many years, that every year there is another call to renew your commitment, but it really is critical. What we always find when we go to Albany is that the legislators are not hearing from either individual constituents or organizations that this bill is a priority. There is not a strong voice out there saying this bill needs to pass. There is a general sense that there is support in the State for it, but people are not coming forward and making it a priority. As members of organizations, please, go to your organization, whether it's a hospital, medical association, or legal association, and get them to contact the legislature to tell them this bill is a priority. Even more importantly, perhaps, as individuals, you can contact your own Senators and Assembly members and let them know that this bill matters.

I feel like a broken record. It's been years of me and Tracy Miller saying that this is going to be the year this bill will pass. One of these years we'll be right. But it will only happen if people take the initiative. I reaffirm the plea that John Arras made. Please, don't think of this bill as something that will never happen. It can happen but it does take commitment and continued advocacy on the part of the people who care about this.

Nancy Dubler
Directed Organ Donation

It is an honor and a pleasure to be here, and it's wonderful to see old friends. I will begin, as I always do when speaking of medical ethics, by highlighting that the single, greatest ethical dilemma in modern American medicine is the lack of access to regular and effective care for those who are uninsured or underinsured in our society. I point out to you that my concern extends not only to the 45 million persons who are usually quoted as the uninsured. Two years ago, The Robert Wood Johnson Foundation demonstrated that in any three-month period, up to 73 million people were uninsured. That is virtually one-third of the nation. All other ethical matters pale in comparison. Every discussion of medical issues in medicine, including the ones we will focus on today, must be related to this larger issue.

This morning, I would like to argue that organ donation is an extremely critical part of the bioethics agenda and should be a vibrant part of the Task Force agenda as well. The one area in which justice has been the clear and effective focus of bioethical analysis and a dominant focus of practice and policy has been in the arena of organ transplantation. The prior work of the Task Force established New York State as a self-consciously just community that precludes multiple listings. This has become the fair and just model for the rest of the nation. In the domain of solid organ trans-

plantation, New York has been, and should continue to be, the real leader.

I draw your attention, at this point, to the work of George Annas, who looked at various rationing schemes for organ allocation. He describes four approaches to rationing organs: 1) the market approach; 2) the committee selection process; 3) a lottery scheme; and 4) physician selection. Annas argued for a combination scheme, just as we have in New York State. This approach uses medical screening with ethics input, and a candidate pool that is fairly distributed with the ability to jump the queue for dying patients. It is a critical and, indeed, a successful part of New York State policy that grows directly out of the work of the Task Force. The rest of the country, disappointingly, has not done quite as well in focusing on justice and fairness in allocation practice.

Let me offer a comment on history: the U.S. Department of Health and Human Services (DHHS) convened a committee in 1997 to explore whether Medicare and Medicaid patients had equal access to solid organ transplantation and whether the system for solid organ allocation was fair and just. This working group determined that the allocation system was not fair, despite the fact that we had clear national policies, the procedures of the United Network for Organ Sharing (UNOS), and work of the local organ procurement organizations (OPOs). In fact, they found that if you were poor, you had less access to care, which should not be surprising. Needless to say, the poor don't have equal access to many of the goods of society, but the arena of organ transplantation, I would argue, is one in which I think we must correct this injustice. We ask donors and families to donate as if the system were fair and just. This creates an obligation to ensure the characteristics that we preach. As a result of past Task Force recommendations, New York has real cooperation and sharing among its OPOs. If you look at the map of how organ procurement organizations are structured elsewhere, the situation is less positive. In Texas, for instance, there is one OPO that has a piece in one corner of Texas, a piece in another corner of Texas and a piece in the middle of Texas. This arrangement reflects the fact that powerful medical institutions get what they want in Texas.

In an effort to enforce just and fair systems nationally, DHHS came up with what it called "The Final Rule,"which, in 1998, decreed that there should be a sharing across OPOs, and the creation of a level national playing field, which would mean that all patients similarly situated would be treated in the same fashion. It was designed to permeate the fixed boundaries of OPOs so that a person who was very sick on one side of a line would not lose to a far less sick person on the other side of a line. In order to ensure that the policy was grounded in scholarship and evidence, DHHS turned to the Institute of Medicine (IOM) for analysis and suggestions. Having sat on the DHHS panel, I was delighted to continue the discussion on the IOM working group. This group looked particularly at live liver distribution, a topic where again, New York State has been a leader. After an enormous statistical review of the UNOS data, IOM determined that waiting time on the transplant list was not a morally relevant characteristic to be used in the process of allocating organs. They did so because who gets placed on a liver list correlates with patients who have access to care. Physicians who follow their patients' liver tests generally place them on a transplant list in case they will need a liver transplant in the future. That system distinguishes the medical "haves" from the "have-nots." IOM determined that if they revised the districts in the nation so that each had about 9 million people, they would decrease the possibility of people who were less sick getting livers that other people needed more. The findings and recommendations of the IOM were clear: establish different organ allocation areas, and discontinue waiting time as a criterion for ranking on the list.

A most important finding of the IOM was that African-American patients are less likely than white patients to: 1) be referred for evaluation; 2) be placed on a list; and 3) receive a liver. That finding was the first time that anyone had looked at racial disparities in this section of medicine in depth. It threw our moral evaluation of a very complex and important system into a quandary. The IOM suggestions and the DHHS final rule, which would have resulted in greater sharing and greater equity, were never instituted. This was not a surprise. In fact, when the DHHS rule came out, Tommy Thompson, who was then the governor of Wisconsin and went on to be the Secretary of DHHS, said there is no way that any of the livers from Wisconsin are going to Chicago.

Let me offer you a quote: "The chief business of the American people is business." When I looked this quote up on the Internet, it turns out that there is a following sentence: "Of course, the accumulation of wealth cannot be justified as the chief end of existence." We generally quote the first sentence of that passage and not the second. I leave you to contemplate why. There are people who want and need livers and kidneys, and there are other people who have and might be willing to dispose of pieces of livers and kidneys. We are trying, in America, to figure out how to make that happen fairly. There are many options for improving our arcane system of

allocating donated organs. We now have a complex and essentially fair system, but for the problems that I noted previously.

Today, we examine an additional problem with justice in organ allocation: solicitation of organ donation. A kidney for sale appeared on eBay, only for an hour-and-a-half, and then disappeared—but it appeared. Would-be recipients have begun to advertise on the Craig's list Web site and elsewhere on the Internet. Church newsletters solicit organs from people in their communities for others in the community who need them. Altruistic strangers offer to donate their kidneys when they read the stories of those in need. Dr. Mark Fox, Chair of the UNOS ethics subcommittee, described an altruistic stranger who came forward in Philadelphia to give away a kidney, and said he might like to give away his second kidney as well. This example and others throw facilities into an ethical quandary when they try to determine whether they should transplant organs obtained under these circumstances.

UNOS made the following statement in response to this problem of solicitation of organs: "OPTN/UNOS Board of Directors opposes any attempt by an individual transplant candidate (or his/her representatives) to solicit organ donation from a deceased donor ahead of other waiting candidates." UNOS has not yet made a policy statement about solicitation of donation from living donors. The American Society of Transplant Surgeons supports directed donation of living and deceased donors only to family members and friends where there has been a pre-existing emotional relationship. They do not support directed donation from altruistic strangers. However, attention in New York State to living donors occurred precisely where there was a pre-existing emotional relationship between a donor and recipient. A donor's widow claimed that the donor had been intimidated by his family into giving a piece of an organ that he did not want to give. That donation resulted in the donor's death.

Three years ago, New York State convened a committee to look at live liver donation. This committee's recommendations require a vital emotional relationship between donor and recipient. They decided that the donor, in addition to medical assessment, needed an independent donor advocate to ensure that all issues are understood, and also to intervene between a donor and whatever pressure was being put upon that donor. Recently, Tia Powell and I sat on a committee for New York State that looked at the transplantation of extended criteria livers. New York State has more than its fair share of people with hepatitis C, and health care in this State is heavily in need of livers for transplantation. We now have excellent guidelines for the use of livers that are not pristine. These livers may not get used in Minnesota and Washington and Wisconsin, but in New York we have found that they are well tolerated and help patients who would die in lieu of this intervention. We are willing to transplant a wider range of livers because our patients would be dying without them.

I urge you to go on the Internet to www.organassociates.com, which is a link that Elaine Berg, at the New York OPO sent to me. I quote: "We are a party to special arrangements through which you can get the new kidney or liver you need immediately. Our exclusive arrangements bring you the very best surgeons for kidney and other transplants." That's a powerful inducement if you have the money to do it. They don't tell you where these services are, though I assume they are largely in India and Thailand and other developing nations. But what do we, as a State, want to do about this? How do we want to think about matters of justice and protection in this changing market for organs? How can we be certain that all of the citizens in this State have equal access? I think this is an issue that cries out for Task Force thought and suggestions. We should be alert to the work of a new committee at the IOM that is going to consider the various ways that gifts and enticements can be given to families to donate organs. Here, we have an opportunity to be at the cutting edge of public policy on an issue that is medically critical and morally complex. Let us hope that the Task Force will provide the analysis and recommendations that are so desperately needed to resolve upcoming ethical problems in transplantation. Thank you very much.

End of speaker comments

Tia Powell

We have time for a few questions and answers.

Barbara Shack

I've been a member of the Task Force on Life and the Law since its founding. I'm also part of the coalition for the Family Health Care Decisions Act that's trying to get the bill passed. There is a special entity that George Soros has set up called the Open Society Policy Center that gives direct grants to entities to help them do legislative lobbying. It is not bound by the rules that would govern a 501(c)3 or a public charity. I'm part of the working group that is trying to pass the bill; many of you here have helped. This is a plea to help us and join us. If you are a member of one of the 40 organizations that are in the coalition, we'd like you to come with us when we plan our next lobbying trip to Albany,

be a participant and talk to legislators about the need for the Family Health Care Decisions Act. We're close to getting the bill passed. We're having a lobbying trip at the end of March. If you want to come up, our lobbying firm will arrange appointments appropriate to your particular interests, whether its your own legislator or one of the leaders of the houses of the legislature that we're trying to reach. So do help us. You've helped us in the past with your funds. We have the funds this year and now we need you. We'd love you to participate with us and we look forward to working together.

Larry Amsel

I'm from Columbia University and Tia and I took a bioethics course together at Yale in our first year of medical school. Just to comment on organ donation, a researcher at Columbia named Eric Johnson published a piece in the last few years on default decision-making, looking at European organ donation. It turned out that 95% of the people would agree with whatever the default was. If you had to opt in to organ donation at the end of life, then 95% of the people would not donate. If you had to opt out, 95% of the people would donate. I'm wondering about whether making donation a default to get a driver's license, for example, wouldn't solve the problem of the shortage of organs.

Nancy Dubler

I will provide two examples of different societies. Belgium is a coherent society with universal access to care and a Town Hall in which every person is registered. Those people who did not want to donate organs went to their Town Hall and registered. There exists in Belgium a group of Orthodox Jews who do not accept brain death criteria for the determination of death and they registered as non-donors. Almost everyone else stayed within the pool. Belgium's donation rate went up to 65%. In Spain, which is not such a coherent society with organized Town Halls, opting out still worked very, very well. In every Spanish hospital, there are physicians who meet with the family and explain that the organs will be taken. Do I think we could do that here? No. One, I think it is very difficult to make an argument for a default position for donation in a society that does not provide health care for its citizens. The sort of community of patients and providers that exists in Europe, in for instance in Scandinavia and in Spain, doesn't exist here. Number two, the data are very clear that people of color are discriminated against in the receipt of organs. It would be very difficult to argue that minorities have an obligation to give organs when they are not equally likely to receive them. I know that HLA matching and lots of factors undergird this problem, but the most important factor is the lack of access to care. And third, we are a wild west country. We want to be able to make our own decisions and so I think the chances of a legislature in New York or any other state passing a presumed consent law would be very slight.

John Arras responds

I think that Nancy is probably right in her gloomy prognostication, but I would like to think that she's wrong because I do think that presumed consent is a good idea. I don't view presumed consent as a threat to autonomy as long as there is a clearly articulated way to opt out of the system, both for individuals and their families. I have a friend and colleague at the University of Virginia Law School, Richard Bonnie, who is currently working up a proposal that might skirt some of Nancy's worries. Richard Bonnie is trying to yoke a presumed consent policy to a kind of guaranteed access to transplantation. I'm a little skeptical about the way the finances work. However, he assures me that he has thought long and hard about this and that the money saved from dialysis can fund transplants for everybody who needs one under a system of this sort. At least in theory, the idea of yoking a presumed consent policy to a policy that would guarantee access to transplantation might be a way to get beyond the impasse. It's an interesting possibility.

Nancy Dubler

It's very interesting. Were I convinced, and Richard Bonnie is probably one of the few people who could convince me, that the issues of justice would override the patterns of neglect, then I think it could be very promising. I'm skeptical.

Robert Swidler

I'm a former staff attorney for the Task Force. Going back to the Family Health Care Decisions Act, I'm a strong supporter, a long-time supporter, and I'd love to see it pass. One thing that's been on my mind has been that the problem that the FHCDA is seeking to address was created by court decisions, by *Storar* and *O'Connor* in the 1980s. It's surprising to me that there hasn't been more erosion of those court decisions over the past 20 years, but there hasn't. I'm wondering if there were a court decision that changed the standard from clear and convincing evidence to simply preponderance of the evidence, would that obviate the need for the Family Health Care Decisions Act? Is there a valuable alternative strategy of litigation that should be pursued? My guess is that Nancy Dubler is going to say yes, that would be great, and Carl Coleman will say no, that would be okay, but not as good. I'm curious about this.

Nancy Dubler

I just want to say how distressing it is to me to see a former staff member with slightly graying hair.

Robert Swidler

It's from kids, not from this issue.

Nancy Dubler

Two years ago there was the case of "AB," which involved a 3-year-old child in a persistent vegetative state in one of the New York City Health and Hospitals Corporation hospitals. There was a wide collaboration in that case between, and among, Alan Fleischman, myself, various people around the nation and HHC to present the data, arguments and the affidavits that would permit this mother to make a decision for her child. It's a beautiful decision by a courageous Supreme Court judge and it dealt with the issue of children. We would have to do that for every category, but I would be all for it.

Carl Coleman

The AB case did deal with the issue of children, but only children in a persistent vegetative state, so it left open a lot of questions. I think that one of the concerns about a litigation approach is that it would be very piecemeal. I would not necessarily oppose that, but I think it's even more unrealistic than getting the legislature to pass a presumed consent law in New York. The courts have repeatedly said, not only in New York but in many other states, that they don't see this as an issue that they are capable of addressing or want to address. I think the Court of Appeals resolved *Storar* and *O'Connor* as it did not because it necessarily felt that clear and convincing evidence was the best standard, but because they thought that the legislature was more suited to dealing with these issues. They wanted to create a conservative standard and then let the legislature decide, on the assumption that the legislature would act. That assumption was clearly not right, but that was the thinking. It would be a great thing if courts could move in that direction. Just to compare New York to New Jersey, New Jersey also lacks a surrogate decision-making law, but there are court decisions that recognize that decisions to withhold or withdraw life-sustaining treatment can be made for incapacitated patients, even without specific evidence of the patient's wishes. While these opinions are actually fairly narrow, they at least recognize that these decisions could be acceptable in some circumstances. As a result of these decisions, the climate in New Jersey is very different from the one that exists in New York. There isn't a sense in New Jersey that the default is to do everything. There's a sense that the family should be part of the process. So I think litigation would be a possible solution. I just don't think that, given the history of where litigation has gone in this State, it's any more realistic than thinking the legislature will act.

Nancy Dubler

I want to add a word about a litigation strategy, having said that I think it might be interesting. I think it won't happen. When the case of "AB" was unfolding, I called most of the major New York City law firms who had anything to do with health to see if they would take the case. There was a different reason from each firm why they could not do it. The case was an endless task with largely terrible publicity. Legal Aid took the case and did a brilliant, brilliant job. But they no longer have the resources to do that and the resources in the pro bono system are very small. I think that while there is the possibility we could succeed by litigation, it's unlikely.

Carl Coleman

I agree that the "AB" case was a brilliantly written decision. Nobody appealed the decision because no one had an interest in appealing it. But I think there was a concern that if it were appealed, who knows what the result would have been. It has some precedental value in the sense that it's out there, but you have to remember that the Supreme Court in New York is the lowest court in the State. The highest court in the State is the New York Court of Appeals. It did not go even to the intermediate Appellate Court, so it really has no binding precedental value.

Tracy Miller

I have the distinct recollection of being in a forum at which Judge Sol Wachtler was speaking, shortly after the Task Force made its recommendations on the determination of death. We had concluded that New York State did not need legislation because of the decision in *Eulo* that involved a criminal case where the victim's organs were donated. The person who shot the victim claimed that he hadn't killed the person but in fact that death had occurred when physicians removed the victim's organs. The court held that the determination of death could depend upon brain criteria. We had recommended a regulation that piggybacked onto the *Eulo* case, and Judge Wachtler expressed his outrage that we had circumvented the legislative route and relied instead on his court decision. He expressed his strong view that these matters belong in the legislative arena. It was interesting, from his perspective, that we had inappropriately piggybacked onto his court ruling.

Ruth Fischbach

I'm from Columbia University Center for Bioethics. First, I want to commend the Task Force for its enduring effort to get this billed passed. I support it and I'd like to join the entourage making its way to Albany. I do want to just ask whether this bill, if it goes through,

will also allow surrogates to make consent decisions for research. This is an issue that is very important. You have vast needs for research, particularly in psychiatry, but in other fields of medicine as well. Patients come into an emergency room where they could get treatment with a surrogate and yet this same treatment three years before was part of a research protocol, for which surrogates cannot now give consent. I'm just wondering if this act will somehow serve as a catalyst to get this next step forward.

Carl Coleman

The bill doesn't say anything specifically about research. However, the federal regulations governing research with human subjects state that consent must be provided either by the subject or the subject's legally authorized representative, a phrase that is understood generally to look to State law about who is legally authorized to make decisions for the patient. It would be a plausible interpretation, one that has been approved by federal agencies in other contexts, to rely on the surrogate decision-maker who has authority to make treatment decisions. That doesn't mean that New York State courts would necessarily agree. However, for research where there is a potential to benefit the subject directly, so-called therapeutic research, there would be a very strong argument. It would be more of a stretch for research where there is no prospect of direct benefit to the individual subject. There was a set of recommendations issued by a work group in the State health department several years ago. It called for regulations that would allow surrogates to make decisions about research, even if there is no prospect of direct benefit to the individual subject, assuming minimal risk or a minor increase over minimal risk and certain other safeguards. That proposal was never enacted. I think that may have been right in the absence of a surrogate decision-making law about treatment. It would be odd to have surrogates empowered to involve people in research that isn't going to benefit them, but not to consent to treatment. Once the Family Health Care Decisions Act is enacted, I think that proposal would gain momentum, too. Even without those regulations, a strong argument could be made that the bill would empower surrogates to decide about research where there is a prospect of directly benefiting the subject.

Ruth Fishbach

The problem with the New York State law is that there is no definition of who is the legally authorized representative other than a court-appointed guardian. That's why I'm hoping that passage of this bill will really promote the research aspect. Good luck.

Carol Levine

I'm with the United Hospital Fund, and I am concerned about the use of HIPAA to restrict information to family members. Until the bill is passed, and let's hope that happens, what do you recommend that family members do? Isn't an advance directive and health care proxy adequate in New York State? Could a proxy have a clause saying, "I appoint this person to be my HIPAA representative under the law?" Do we have any recourse until we get the bill passed?

Nancy Dubler

There's good news and bad news. The bad news is that when you look at patients over 65 coming into Montefiore Medical Center, 1.6% had advance directives. The advance directive is a failed public policy, as is evident to all who look at it. If you do have a health care proxy, which I urge everyone to go out and sign if you don't have one, the way hospitals are interpreting that now is that a health care proxy deals with all of the aspects of decision-making, including HIPAA. The problem is that if there is no health care proxy, not only are decisions for the patient a problem, HIPAA decisions are a problem. It's just one more catastrophe.

Carl Coleman

On the proxy issue, I just wanted to comment on my own personal experience with creating a health care proxy. I had been involved in the Task Force for a long time and I'd been doing a lot of public speaking about the proxy. I was at a conference about the health care proxy and somebody asked how many people in the audience had a health care proxy. Perhaps two people raised their hands and I was not one of them. I was so embarrassed that I then went out and signed one. It was not fear of terrible things happening at the end of life that did it. It was the embarrassment of not being able to raise my hand at the conference that actually got me to do it. I would imagine that if the question were asked of this audience a majority of people in this room do not have proxies. There's something about taking that step that is difficult no matter how much you support it in theory.

How many people here have proxies? (Laughter). Certainly not a majority. . . .

Elaine Berg

I'm the head of the New York Organ Donor Network. I am, unfortunately, neither a lawyer nor an ethicist, but first of all, thank you. I thought this was really a great morning. It struck me that there is an interrelationship between the lack of the Family Health Care Decisions Act and organ donation. I don't know if

everyone's aware of it, but New York State has one of the lower organ donation rates in the country. I've never really given any thought to whether the lack of this act might have something to do with that and I am going to give that some thought. The other thing I wanted to mention is that at this moment, if you sign up for the New York State Donor Computerized Registry, that is not considered clear and convincing evidence. When you register that you want to be a donor, your family can override that wish. I find it a contradiction that families can't make decisions about health care but they can override clear and convincing evidence that you want to be a donor. The only way they legally can't is if you have a document of gift that's witnessed by two people. I think that's something we need to think about in this State.

Carl Coleman

I think there is a direct relationship between the lack of the Family Health Care Decisions Act and organ donation. I think the relationship is that the absence of this law and the court decisions requiring clear and convincing evidence of the patient's wishes have created a climate of fear among providers in this State surrounding end-of-life issues. The safest thing is to do everything to continue the patient's life. When I was working at the Task Force I received many phone calls from providers and family members that reflected misinterpretations about what existing law says. There were cases where you have clear and convincing evidence that was not accepted because it wasn't in writing or because of all sorts of requirements that were assumed to exist but that didn't exist. In New Jersey, the law doesn't give family members unlimited authority, but there is not this sense that you can get into trouble so easily. There's just a very different climate.

Also, I think that even though it's anomalous that families can overrule the written decision of a patient to donate their organs, hospitals' unwillingness to override family wishes is understandable. How would you feel if you were a surgeon or a member of the health care team, and you got a consent to donation from the patient, but the family, anguished and hysterical, is balking at what they perceive as a final violation of their loved one. Even though I think the spirit of the law would have the patient's wishes prevail, there may be pragmatic reasons not to do so in some cases.

John Arras

The interests are very different when we are talking about somebody who has already died; that person does not have interests anymore. You're talking about respecting their wishes during life. That is a different level of interest from that of somebody who is currently alive and may be suffering. I would wonder if a person who had signed an organ donor card and knew that their family was so upset about the donation would still want their organs donated. The fact that the family is objecting so strongly may really affect what their wishes would be if they knew that would happen.

Panelist

Lots of people like to upset their families.

John Arras

That's true.

Kathy Meyer

I'm a member of the Task Force and General Counsel of Continuum Health Partners. I used to work a fair amount on health care decisions. I'm a part of hospital administration now and I want to give that perspective and just suggest that some of the climate in which these decisions about end-of-life are made may be changing and not necessarily for reasons that are good. In the past, when there were disputes about surrogate treatment, physicians were basically always offering care, whether because they were afraid of liability or because of whatever the clinical practice pattern was. What you're seeing now is that the financial pressures on these institutions are enormous. They've laid off the last housekeeper that they can lay off, and you can't reduce the number of nurses any more and the length of stay has dropped. What's left, for the first time, is to go after the way medical care is practiced. It's always been the unfettered right of the doctor to order every test he wants, to keep that patient going as long as he wants, and no one has looked at and questioned that except perhaps some managed care companies. Even they have changed the way they reimburse so they don't take the hit on that. I think you're going to see these practices changing. You're going to see a move towards protocol medicine, standardization and decisions being made by clinicians as a group as to what we are and are not going to offer. There is the beginning of a real change in the way health care is going to have to be practiced in New York.

Carl Coleman

I think that's all the more reason to support the bill. In fact, it may suggest a different strategy in advocating for the bill. I started out by saying this isn't just a right-to-die bill. In a climate where patients may not even be offered all the potentially applicable options, you really need to have someone who's empowered to be an advocate for the patient, who has access to the medical records, who has a right to make decisions, and who can insist on being offered all the options and can advocate for treatment, not just for ending treatment.

Nancy Dubler

I think that Kathy raises an interesting point, but I think we're going to get there much more slowly. I would argue that the political change in the last decade has been palliative care; you can offer families different choices within a care system, and one of them is palliative care. If palliative care were clearly within the options to be offered, that would be a huge and uncontroversial step that should bring all of the hospital counsel, and all of the trade organizations together. We need a rethinking of approaches to this issue that neither depend on the legislature nor the courts, but depend on physicians taking responsibility for the quality of care they practice.

Donald McKinney

I am a former member of the Task Force and one who felt very excited about the passage of the health care proxy bill and was persuaded by the wonderful discussions we had on this issue. It was viewed as so important that having a proxy was going to be part of every hospital admission. We, naively I guess, assumed it was going to be very much a part of the care of physicians with their patients, not only private patients but also in clinics. Why have so few people signed them? Why hasn't there been some kind of educational program that would inform people about what seems to me the most sensible approach to this problem? Are we surrendering any hope of that? Is that why we have to push so hard now for this new bill? Just curious.

Nancy Dubler

Don, thanks for that comment. It seems to me that there's a pattern emerging here in this discussion in Carl's experiences with audiences on this question and with our discussions about signing organ donor cards. The pattern is that people in general don't like to think about the prospect of dying. It seems to me that policy has to take that reluctance into account rather than beating its head against the wall. We have to figure out other ways of sculpting policy that allow people to do the right thing. In this area I think it's the Family Health Care Decisions Act and in the area of organ donation, I believe it's presumed consent with a right of refusal. I think that's the proper way to go because I think the psychological tendencies that we're up against are extremely powerful.

We've been trying for 25 years to get people to sign living wills and proxy forms and they don't do it. We know who does sign these forms. If you go to a very organized medical center for elective surgery and you have a series of meetings with the surgeons who have lots of materials supporting them and they urge you to sign something, you get 50%. But short of that, you get virtually nothing and I think we have to move on.

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Selections from the New York State Task Force on Life and the Law's Twentieth Anniversary Symposium

Keynote Speech: What Bioethics Can Learn from AIDS Relief in Africa

By Mark Barnes

Good morning. I have often been a provocative speaker, and I suppose that this is my role today. I have played the role of provocateur in the state and city health departments, and on many committees and commissions, as many of you here know—so many of you who have been either clients or friends or political opponents, or any combination of the above, at one time or another. I'm originally from a very conservative part of rural Alabama, conservative even by Alabama standards. When I'm down there, I am deeply skeptical of the prevailing attitudes and am viewed as a horrible liberal. Here in New York, I am equally skeptical of the prevailing opinions and am, therefore, viewed as a horrible conservative. My friend, Evan Wolfson, is a leader in the national movement to promote and secure gay marriage rights around the country. When I say things to Evan like, "Evan, do you really think that you should start with gay marriage? Don't you think that equal benefits at the workplace would be a better place to start?" He says, "You are nothing but the right-wing fringe of the lunatic left." And I guess that's exactly where I want to be.

Let me tell you about the recent AIDS treatment work in which I have been involved in Africa and then let me ruminate about lessons learned during the past months since I have been involved with the project there. I'll talk about how what I've learned applies to the debates that go on here in the United States in bioethics and also in public health policy. My work in Africa has been a great and vast learning experience that only ended last Sunday when I returned from what I expect will be my last trip to Botswana. It is all quite fresh in my mind. When Tia asked me to speak here today, I said to her that I could talk about secondary uses of tissue and data, but that it is Africa that is in the front of my mind. She said, "Talk about Africa."

I was called in June by Harvard, which had received about one-quarter of the grant money under President Bush's AIDS in Africa initiative, PEPFAR, the President's Emergency Program For AIDS Relief. I was asked to do a legal risk assessment of the project and to make suggestions as to how it could be best managed. A short meeting to present my findings to the Harvard leadership turned into a lengthy seminar on how to manage such a project in such desperate and difficult circumstances, many thousands of miles away. A few weeks later, on vacation, while lying on the beach in Split, my cell phone rang, and I was told that Harvard had requisitioned me for the next six months from Ropes and Gray and that I was now the interim executive director of the program. So that's how I got started.

I will tell you about what I found in Africa, and its relationship with what has gone on here in New York for most of my adult life, for indeed, the past 25 years. There are similarities between what is happening in Africa and what has happened here. The first thing is relevant to those of you who have worked in AIDS, and who have had some connection to AIDS policy since the disease was first recognized. You will remember, although it is distressingly painful to remember, that up until about the spring of 1995, when the first reports arrived about the success of the protease inhibitors in lengthening life and reducing morbidity, that an AIDS diagnosis was, most often, a death sentence. New York had a pall over it that is worse than the pall that happened after 9/11—at least it seems that way to me. Greenwich Village was deserted. People were dying. You could see them on the subway–emaciated, wasting. They were lined up in emergency rooms, and there was little doctors could do except give Bactrim and aerosolized pentamidine to prevent Pneumocystis pneumonia. Then when the drugs came in 1995, all of a sudden, the phenomenon reminded one of the miracle of Lazarus. People began to get better, even people who had been sick for 10 years and who were, up to that point, barely surviving.

Africa now is like New York City was in 1994. The only thing that doctors really have access to there is Bactrim, and even that is in many places in short supply. There is no aerosolized pentamidine. Doctors can hold people's hands. They can treat symptomatic infections, but they're essentially helpless in almost all African countries. One of the few exceptions is Botswana, where the President of Botswana has taken a

very aggressive role in trying to promote HIV prevention and treatment. Elsewhere little is being done. There is a kind of desperation that one encounters when talking to people with HIV infection—that is, to those who know that they have HIV infection, with the vast majority of the infected not even having been tested. There is, throughout the Africa that I saw, the same desperation that one saw in the faces of AIDS patients, and in the doctors and nurses who treated them in our own country, in the 1980s and up until 1995.

There are other relationships as well, perhaps not as well recognized, between the people who suffer in Africa today and our own national experience. I was essentially raised by two elderly women, one black and one white. There are about as many black people in Alabama as there are white people, and guess where the black people of Alabama came from? They came from Nigeria and Sierra Leone and many parts of West Africa. Many black folks in Alabama, whether they know it or not, had ancestors who were Ibo and Yoruba, from Nigeria or from what is now Benin. There are vast similarities in culture, in the way people behave, in the way they look, in the way they talk, in the English that is spoken and in the way it is spoken. I grew up in rural Alabama in what was, in retrospect, a kind of twilight of the nineteenth century. Perhaps only some few parts of the Mississippi delta were similar to the conditions I saw as a child. There were houses, including those of my great-grandparents, that did not have running water but outhouses instead, and where farmers like my great-grandfather, until I was 12 years old, plowed fields with a mule. This world of kerosene lamps, high feather beds, chamber pots, church twice on Sunday and once on Wednesday evening, and starting each day at 4 AM—it seems, standing in New York City in 2005, like a figment of a boy's imagination. But it was very real. And that world is, in fact, what much of Nigeria is like today. So in seeing it, I was not shocked by the conditions themselves. But when I saw it, I gasped, because it was as though I had gone back in time to a rural Alabama of decades ago.

French and English relief efforts, and those of Germany and Scandinavia, have been very generous toward building health care infrastructure in Africa. But America's relationship to Africa is different. We are lashed to the people of West Africa, and they to us, in a way that is no different from the way that we in New York are lashed as a people to the Jews of Israel or to the Puerto Ricans from Aguadilla or to the working class of Dublin. Those people are our people who live in West Africa and who are suffering from HIV. They are, whether we know it or not, our cousins and family members. They share our religion and our culture. This is different from the relationship that other countries and other peoples who come in as relief workers in Africa have. The French and English came to Africa as imperialist powers, and they still maintain influence there because they have vast commercial interests in their former colonies. There are other countries, like Belgium, Germany, and Italy, whose present relationship to Africa is only tangential and oblique. The imperial history of those countries in Africa is remembered today by historians and diplomats and a few old soldiers in their 90s who fought in the colonial wars. But we in the United States are different, and the people in West Africa, East Africa and South Africa understand that.

"[Americans] are lashed to the people of West Africa, and they to us, in a way that is no different from the way that we in New York are lashed as a people to the Jews of Israel or to the Puerto Ricans from Aguadilla or to the working class of Dublin. Those people are our people who live in West Africa and who are suffering from HIV."

The degree of receptivity that I encountered and that other Americans who worked there encountered, is profound. I visited many hospitals and their staffs in Nigeria, Tanzania, and Botswana. It was a common occurrence that leaders of the medical and nursing staff during formal presentations and introduction would rise and say, "Thank you, and please when you return to the United States, please tell President Bush and your colleagues and the American people how deeply grateful we are because this is the first meaningful relief that allows us to have drugs and equipment and pay doctors' salaries to treat this disease." And so we were viewed, and I think it's quite a wonderful thing, as colleagues and friends, and not as those whose past is tied to imperial ambitions. This view of us that is so prevalent there makes the AIDS problem in Africa all that much closer to home, or at least it should for all of us.

I divided this talk into three segments and I call the segments: "Little Lessons Learned," "No Time to Spare," and finally, "Images of a Floating World." I will take them in that order.

The little lessons learned came up in the course of administering this program. I learned these lessons along with my colleagues at Columbia University,

Catholic Relief Services, and the Elizabeth Glaser Pediatric AIDS Foundation, which are the other primary grantees in the PEPFAR program, and that are working in many of the countries in Africa. Different issues have arisen in these African AIDS relief efforts that closely parallel some of the things that speakers in our program today have addressed: the allocation of scarce resources, as in organ donation, access to basic health care, and family health care decision-making.

One major question that looms over these AIDS relief efforts is that they are, in fact, disease specific. Why have we, as a country, decided to single out this one new disease in Africa for all of this money and attention, when more people in Africa die from other causes like malaria, malnutrition, and yellow fever, than die of AIDS every year? This question was raised when David Axelrod was health commissioner of New York State, when New York adopted its enhanced Medicaid reimbursement rates which paid and still pay, hospitals up to three or four times more for caring for an AIDS patient than they get for caring for a non-AIDS patient with essentially the same diagnoses. The question looms in Africa and is an urgent one. The people are overjoyed there to get the help, but this disparity, this singling out of one disease, creates animosity and jealousy among academic departments at African medical schools and among clinical departments in hospitals in Africa. Why should AIDS and people with AIDS get anything better than people with tuberculosis or other diseases? The best answer I have to that question is what the director of the AIDS Institute, Nick Rango said, and what David Axelrod also repeated many times, when the enhanced Medicaid reimbursement rates were being debated here in New York almost 20 years ago. Dr. Axelrod and Nick responded: it's true that we will be giving better care to people with HIV infection, and that hospitals will have an incentive to do the kind of care that's needed. But first, it's an epidemic that requires a response; second, it's an infectious disease and needs to be controlled, and there is no way to control it without treating it; and third, they said, in moments of painful honesty, would we really prefer that AIDS patients get the same crummy care that most of the regular Medicaid population in New York gets? Why, if we can save somebody, should we not at least make sure that one set of people gets into the lifeboat?

This question of AIDS exceptionalism looms over the long-term as well. Aid from the United States, once it starts, really can't stop. Once people are put on antiretroviral therapy in Africa it would be unethical to interrupt their treatment and unethical for the United States to stop funding the treatment programs. So, once the aid begins, it is a long-term commitment to a disease-specific program. Thus, the ethical dilemmas over the exceptionalism of this program will only become more acute in the years ahead.

The standard of care is another issue. Money, even with the hundreds of millions of dollars going into this program, is not limitless. The standard of care given to people in Africa enrolled in most AIDS treatment programs is not the same standard of care that is given to the average Medicaid patient with AIDS in New York State. There are some countries in which there is no laboratory capacity to do viral loads. In these countries CD4+ cell counts are rationed to one per patient per year instead of one every three or six months, or even one every month in the case of people with rapidly declining CD4+. What are the ethics of our funding and administering a program that provides care at a level and at a quality that is much, much better than anything that they would otherwise get, but that is less than the average AIDS patient gets, less than the Medicaid patient gets in New York State? This is a question that is being asked but really has no answer.

Another interesting question is answered in practice every day. The PEPFAR is limited to about a dozen countries in sub-Saharan African, plus Vietnam and Haiti. Those are the countries in which the PEPFAR grantees are authorized to provide funding and support for local AIDS treatment programs. Within those countries, the demand for services is much greater than even these hundreds of millions of dollars can supply. For example, Mozambique has a general adult seroprevalence rate of roughly 12%, Zimbabwe has an average adult seroprevalence rate of 25%. In Botswana the average seroprevalence among all adults is 37%, in South Africa it is 22%. It goes on and on. The demand for services is much greater than the treatment capacity. It is much greater even if our funds were completely unlimited, as there aren't enough doctors to treat these patients in Africa. Therefore, there is an allocation of treatment slots and there are waiting lists. There are people who stand in queue. It is heartbreaking to go to one of these clinics, even a clinic that is up and operating and has a decent supply of antiretroviral drugs provided by United States funds. In the morning, starting at 5 AM, people line up who don't yet have a treatment slot to see if they can get one that day. That's a normal day at an AIDS clinic in sub-Saharan Africa. And so then we raise the question that is being raised by all of the PEPFAR grantees: how are these treatment slots allocated? How are scarce resources that can truly save lives and make the difference between life and death being allocated? This is not organ allocation, but it is

just as vital, and potentially affects many more thousands, even millions, of people living with HIV infection in Africa every day.

Cultural presumptions are critical in these allocation decisions. For example, when I posed these allocation questions to our colleagues in Africa, I discovered that health care workers there often presume that friends and family of the clinic doctors, nurses and pharmacists should be moved to the front of the queue for treatment. Why? They presume that because in a culture that is not only as poor but also as fragmented as the Nigerian culture, with 300 different tribal and ethnic groups, that the way people deal with one another is inevitably tied to their family, clan and tribal identities. People in Nigeria are accustomed to a hard life, and they pull inward in order to protect their own. It is viewed as entirely appropriate that first preference be given to family members of AIDS clinic staff. (And such a world view is, indeed, similar to that of the Alabama of my youth, when the order of personal accountability and identity ran: family, church, town, county, and state. If there were surplus to share, that surplus was distributed in that order.)

There are questions, of course, about pregnant women. Shouldn't pregnant women get to the head of the line? One would think that everyone would agree on this. However, some say that this is a poor policy because women will get pregnant simply in order to jump the queue. This issue is not resolved, and will not be resolved in our lifetimes. But it is an issue, and the African physicians themselves are talking about it.

Then there is the issue, also relevant to tuberculosis in this country, about what to do with patients who are noncompliant with treatment. Treatment resources and treatment slots are scarce. Some patients don't adhere to their antiretroviral therapy but are continuing to pick up the drugs, which means that someone else is not able to take the same drugs or to occupy the treatment slot. There are tuberculosis doctors around the world who will say to you in private, although few of them will say it in public, that if a patient is truly noncompliant, they prefer, as a public health matter, that the patient not get any treatment at all and just die. If they are going to be noncompliant, they are going to grow a drug-resistant strain and not only kill themselves but also endanger other people. In Africa, perhaps because living is hard and resources are scarce, while we Western liberals anguish over the idea of discharging someone from treatment who is noncompliant, while we talk about how many chances these patients should be given, doctors in Africa have no illusions, and often have no compunction about cutting off drugs to noncompliant patients and giving the slot to the next person in line.

Other ethical issues arise in AIDS research. The PEPFAR program is not research; the whole purpose is to deliver a standard of care. However, many research studies in Africa and other parts of the developing world contain one arm that offers standard care, and another arm that is an experimental treatment. These studies raise a question that applies to all of the universities, hospitals and drug companies that do business in Africa and run or sponsor clinical trials there. The question is whether it is ethical to put a patient in a clinical trial when, in fact, they really don't have a choice. In other words, these patients often have no other treatment source unless they enroll in the clinical trial, hoping that they get assigned to the control arm, but satisfied if they can even get the experimental agent. At least this may offer some hope, as opposed to languishing with no treatment at all.

This is not only an African issue, but also an American one. Nancy Dubler and I have, for the past couple of years, co-chaired a committee within HHS trying to rewrite the prison research regulations under Subpart C of the Common Rule. These regulations are an absolute and total disaster. They make no sense to IRBs or to researchers, and they don't do much in terms of protecting people in correctional custody from research abuses. But when Nancy and I went through this long process, one of the primary debates that has not been settled is this: there are some prison advocates who say, please give us access to clinical trials because our care in prison is so poor. If we don't have clinical trials, we have nothing. We want clinical trials, and we want Subpart C regulations relaxed simply so that we can get some access to treatment, even if the treatment is experimental.

Then of course, as good Western liberals, we ask: how can it be ethical to enroll someone in a clinical trial when they have no choice? How does that preserve autonomy and voluntariness? There is no answer to this question, but the debate over this rages in the American correctional community. It also rages in the African medical communities and within the ministries of health in sub-Saharan Africa. Some think that it would be unethical to allow such studies to be offered to people who have no meaningful access to care. Others assert that research may provide the only meaningful access to treatment for many poor Africans. And lest we think that this issue is only one for the poor of Africa and for the American correctional population, let us remember: with over 40 million Americans uninsured, and many more underinsured or having only meager

Medicaid benefits, is offering these people enrollment in a trial really offering them a meaningful and voluntary choice? If they do not enroll in a trial, will they have access to true standard of care? Our IRB practice in the United States tends to assume that all potential subjects have a standard of care available to them if they decline to enroll. This may often be a convenient fiction that lets us, as IRB members, avert our eyes from the reality of limited health care access.

Perhaps what relief programs funded from the Unites States can do is at least raise these issues as ones that should be spoken about and debated openly, rather than being decided by presumption and default. This openness itself is a major contribution. The debate that has begun in Africa on this and other points is not the elegant and refined process of committee debate and consensus that has characterized the work of the New York State Task Force on Life and the Law. But the discussion is meaningful to people who are AIDS caregivers and care recipients in these countries.

There are no real answers to these questions, but the discussion has been engaged, and that is a beginning.

The second part of this talk is called "No Time to Spare." These are urgent matters. They are urgent because if someone gets on lifesaving therapy on one day as opposed to another, this one day may make a difference in that person's illness. It also is an issue because the implementation of AIDS relief efforts has been severely complicated by miscommunications and lack of program planning, not only by the African ministries of health but also by American government officials who did not anticipate issues like waiting lists and how to procure the massive antiretroviral drug supplies needed to sustain large treatment programs. All of this is tied up in matters of international diplomacy. The American ambassadors in these countries are in the forefront of trying to negotiate with the local ministries of health. There are some countries in which the ministries of health have taken the position that unless they centrally control everything, including drug importation and the allocation of treatment slots, they would prefer treatment programs not begin.

This is unthinkable to those of us in clinical medicine or who advise doctors and hospitals. But for some African governments who perhaps feel they have been taken advantage of, mistreated or ignored in previous aid programs, they don't want anything to happen until everything is planned and pre-approved. There has been a stalemate in some of these countries. So although relief money is sitting in the bank accruing interest, and money is available to purchase the drugs, and doctors have been trained to treat the patients, nothing is happening. There is a stalemate in negotiation between bureaucrats.

One of the major debates concerns the specific issue of how antiretroviral drugs are purchased, shipped into a country and then distributed to clinics. This is important not only because these are lifesaving drugs, but because a one month supply is worth vastly more than the annual salary of most people in that country. Some of the governments in Africa want to control all of this medication centrally, and they would not allow entities, whether American relief organizations or other foreign relief organizations, to purchase drugs. This, even though the money is in the bank, and even though their citizens are dying. In some cases, the United States government supports that preference because our officials also want to make sure that everything is done well and centrally planned, even while Rome burns. The question becomes: what is more important, respecting the governments and political structures of an African country (and our own government officials, who are involved in these decisions as well), or pushing the envelope and being nasty and difficult advocates and saying that the welfare of individual patients must always come before the comfort level of bureaucrats and ministries of health or our own HHS and USAID?

I have no doubt where I stand on this issue. It seems to me that the moral imperative is to ignore the feelings and personal pride of dithering bureaucrats and to use all means possible to assure that patients in need get treated. That may be my bias because I'm surrounded in my own family and my law practice by doctors whom I advise and counsel every day. It just seems to me that it is difficult to defend a practice of waiting to treat until all treatment can be planned, perfected and centrally approved. If this is disrespect for governments and national sovereignty, so be it: at least it gives preference to the suffering patient, which, for physicians, should be the only viable choice.

When I was the Executive Director of the AIDS Action Council in Washington in the mid 1990s, one of the city governments that received (and still receives) millions of dollars in annual funding through the Ryan White CARE Act is the District of Columbia, which has a terrible AIDS problem. In the District of Columbia, the city contracts process was nearly impossible in its intricacies, producing massive delays in getting Ryan White funds out to AIDS service providers. In fact, of all the municipalities when I was at AIDS Action in Washington, D.C., the District government had the very

worst record of failing to spend Ryan White money. Millions of dollars were unused every year because the city contracting process couldn't get the money out to allow agencies and hospitals to care for people living with AIDS. So when the first Ryan White reauthorization bill was being written by Senator Nancy Kassebaum's staff in 1995, knowing that the service providers in Washington were screaming for their funds and the District government could not provide them, I sat late one night with physicians who were on Senator Kassebaum's staff and I thought, let's do something about this. I wrote into the bill that if the District government didn't adhere to a rigid disbursement schedule and get the contracts and money out to the service providers, the Ryan White funds that were unspent would revert to the federal government to give directly to service providers in the District—in other words I proposed to bypass the city government to make sure that funds were given out and care programs started. To me, this was a no-brainer. If you have to choose between respecting the District government and treating people with AIDS, it does not take a genius to decide what one should do. Yet over night, this one little provision seemed to become more controversial than other issues in the reauthorization of the Ryan White CARE Act itself because the District government and many AIDS advocates did not want anybody to intervene in its affairs, much less the federal government. These people preferred respecting District autonomy over assuring care to AIDS patients. If such a preference—to me, unimaginable—is what liberal politics leads us to, then it is time to check our premises, whether we are talking about Africa or about America.

In one African country where these program delays were occurring, I went to the capital city and met with the United States ambassador. I had been advised by many of my colleagues in other relief organizations not to say anything meaningful to the ambassador. There is a logjam, they admitted, but just let it be tolerated and be nice at the meeting. Well, it has just not been my role in life to be nice in situations like that. When I got in his office and sat down, I said, "I've been told not to tell you what's going on, but I'm going to tell you there is no time to spare. Lives are at stake so let's just get down to business." To his credit, he said that he wanted to hear what was really going on so that we could solve this problem. I will tell you today that there is no time to spare in Africa, and there is no time to spare here, as well.

Which leads me to a final war story. In 1993, as most of you know, I was the chief "fixer" within the City health department. In that year, we reached a grim milestone: the 50,000th reported AIDS case in New York City. Peggy Hamburg wanted to give a speech about that, so she and I talked and decided that she would focus on revamping prevention efforts and reorienting prevention messages. The prevention message for HIV that had been used up until that time focused on self-protection. If you have sex or share needles, treat your partners as though both you and they are HIV-infected. The draft of the speech, however, advocated that we reorient our prevention messages so that we instilled a sense of personal responsibility for the epidemic in everyone. The draft said that those who were negative had a moral responsibility to stay that way, that those who were of unknown serostatus had an obligation to find out their serostatus and act accordingly, and that those who were HIV-infected had a moral obligation not to pass on the virus. When we sent the speech around within the department—oh, the outrage that spewed forth! The opposition to that message within the AIDS bureau at the department killed the speech, and it was never given. Ron Bayer later wrote about this shameful episode in the *New England Journal of Medicine*. He protected my identity when he wrote it, but I'll read you what he said:

> How deeply rooted the ideology of self-protection had become and how difficult developing programs that appeal to altruistic feelings might be was starkly revealed in New York City in 1993. To mark the occasion of the city's 50,000th AIDS case, efforts were made to launch a prevention campaign that would focus on protecting others as well as oneself. Those efforts were aborted when AIDS specialists inside the health department denounced the proposal as "victim-blaming."

Now, as most of you know, 25 years into the HIV epidemic, the CDC and state and local health departments have decided that the future of HIV prevention lies in these communitarian, altruistic messages to appeal to people with HIV not to pass on the virus—to "break the chain of infection." Twenty-five years to discern, finally, that people with an infectious disease ought to be asked not to pass it on.

I wish that we in public health and bioethics had taken to heart the message that there is no time to spare. When we debate these bioethical and public health issues, whether it's the New York Family Health Care Decisions Act and the way that families and doctors are put in the position of disobeying the law on medical decision making every day that passes without that long-delayed legislation; whether we talk about

public health efforts to control diseases like HIV and TB; or whether we talk about other issues like the allocation of scarce resources, such as organs and HIV treatment, the fact is that while we talk, people die. There is an urgency to all of our conversations that we should never forget.

Finally, the last part of my talk, is what I call "Images of a Floating World." Images of the Floating World is a loose translation of the Japanese art form called Ukiyo-e, an artistic movement that lasted from about 1650 until about 1850. You have seen examples of it: wonderful woodblock prints that have birds sitting in the snow in stylized ways. Hiroshige portrayed 53 stations of the Tokyo Road, with elderly women hobbling through the snow with parasols protecting them. This art form was both popular and highly sophisticated. It was meant to convey a world that is more beautiful than the world as it really is, a world that is more charming, kinder, more stylized and better than the one in which we live. I call this final part of my talk "Images of a Floating World" because the debate that we are engaged in among the people in this room and also within the New York State Task Force on Life and the Law is a privileged and rarified conversation. God has blessed all of us that we live in a society that has the excess resources and leisure to debate issues like organ donation and the intricacies of medical decision-making within families. Not everyone has this leisure. The fact that we're able to engage in debate while epidemics rage in Africa, while people in New York City die of diseases because they don't have treatment and didn't have appropriate preventive care, is a vast luxury. It is, to me, an image of the floating world. It is better than life itself. That does not mean that we should stop having these conversations. In fact, it makes the conversations that we have that much more important and urgent. These conversations are a beacon to people not only throughout the United States, but throughout the world. I say that because the doctors in Africa, when we tried to talk about things like waiting lists, how to allocate scarce resources, what to do with non-compliant patients, whether to let pregnant women skip the queue, would say to me in private: thank God we are finally having this conversation because we haven't had it before, and it has been long needed.

I will leave you with an African song that captures both the beauty and the sense of sorrow of Africa, a sense raised by both its colonial past and current struggle with AIDS. There are illusions in Africa as there are illusions here, and those illusions can be very useful. There is a town in Tanzania about 50 miles north of Dar es Salaam. In the Kiswahili language, it is called Bagamoyo, which means, "lay down my heart"—*moyo* in Kiswahili means "heart." The explanations for this name vary. This city was the primary shipment point for the slaves who were taken from interior Africa by the Arab slave traders to Zanzibar and then to the Arabian peninsula and to what is now Iraq. Bagamoyo is the end of the great caravan chains, in which ivory and human beings were transported as trade. The slaves would come to Bagamoyo at the end of a 300-mile journey on foot. And when on the slave boats, the slaves would say they lost site of their homeland: that place, that port, is where I laid down my heart.

Bagamoyo, now greatly decayed, was once the capital of German East Africa. It is the site of a battle in the First World War between some forlorn British soldiers and some very distressed Germans. It has a lonely German colonial graveyard, and some 15th century ruins of the homes and mosques of Shirazi refugees from Iran who came to that area of Tanzania. There is a song, loosely translated from the Kiswahili, which was sung by the porters and by those people who were slaves on the way to Bagamoyo, and which represents an image of the floating world for those people, at that time:

> Be happy my soul, let go all worries;
> Soon the place of your yearnings is reached;
> The town of palms, Bagamoyo!
> Far away how my heart was aching
> when I was thinking of you, you pearl,
> You place of happiness, Bagamoyo.
>
> There the women wear their hairs parted;
> You drink palm wine all the year round
> in the gardens of love, in Bagamoyo!
> The dhows arrive with streaming sails
> and take abroad the treasures of Africa
> in the harbor of Bagamoyo!
>
> Oh what delight to see the ngomas
> where the lovely girls are swaying in dance
> at night, in Bagamoyo!
> Be quiet my heart, all worries are gone!
> We are reaching Bagamoyo!

Thank you.

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Comprehensive Institutional Review of Legal, Ethical and Scientific Issues in Human Embryonic Stem Cell Research: ESCROs and Beyond

By Patrick L. Taylor

This article outlines key legal and ethical issues related to stem cell research by research institutions in the United States. It has three goals. One is to help attorneys who are advising clients by identifying essential directions and checkpoints for legal and ethical advice from literature, regulations, and policy statements, including the recent National Academies' recommendations that research institutions establish Embryonic Stem Cell Oversight ("ESCRO") committees. Another goal is to illustrate the remarkable degree to which legal and ethical issues have failed to converge, and the extent to which neither ethical concerns nor scientists' long-term needs for research materials are reflected in legal regulation of stem cell research. The third, most important, goal is to argue that lawyers must take seriously both scientists' long-term needs for ready access to research materials, and also ethicists' profound concerns about how the benefits of stem cell research should be made publicly available. For that reason, this article suggests a method for research institutions to pursue stem cell research that coordinates legal compliance with ethical review and scientists' long-term needs, so that these find a deliberate place in the institutional and corporate conduct of stem cell research.

I. The Ethical Debate Concerning Stem Cell Use

Human embryonic stem cells are the primary cells from which cells in the body ultimately differentiate and develop. Research studies suggest that, if this plasticity and development were closely studied, wholly new forms of therapy could result in which the plasticity and development are channeled into healing. Human embryonic stem cells are, therefore, described by scientific proponents and many patient advocacy groups as leading to a revolution in health care with: careful research promising new insights into how human beings, organs and tissues develop; detailed knowledge of the factors that affect growth and differentiation and how they interact; and dramatic new research and clinical applications, such as autologous repair of tissues and organs that would otherwise require a transplant from a different donor, restoring vital functions at the cellular level, gene therapy through implantation and *in vivo* and *in vitro* growth of genetically "corrected" cells,[1] and rapid, reliable methods of screening new drugs for toxicity and efficacy without prior clinical testing in human beings.[2]

Much academic and public attention has been focused on the extensive deliberations of government advisors concerning the ethics of stem cell derivation. Stem cells are derived from the "inner cell mass" ("ICM") abstracted from a human blastocyst, which is a cluster of cells that has differentiated to the point of dividing into those cells that will go on to form placental and surrounding tissues (the trophoectoderm), and those cells that will later divide into the three basic germ layers from which all organs, tissues and cells of an adult organism will arise. Whether the blastocyst arises from a normally fertilized egg, or from so-called "somatic cell nuclear transfer" ("SCNT")—the transfer of a somatic cell nucleus into an enucleated egg—isolating stem cells necessarily requires the destruction of that blastocyst.

Since 1996, riders to federal appropriations language, generically known as the Dickey Amendment after their key proponent, congressional Representative Jay Dickey (R–Arkansas), have prohibited using federal funds for "the creation of a human embryo or embryos for research purposes" and "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to a risk of injury or death greater than allowed for research on fetuses *in utero*. . . ."[3]

After the famed cloning of Dolly the Sheep announced in 1997, the National Bioethics Advisory Commission, at the request of President Clinton, issued two deeply thoughtful reports. The first report recommended a several year moratorium on reproductive cloning of a human being.[4] The second report was issued after the General Counsel of the Department of Health and Human Services (HHS) opined that the Dickey Amendment did not bar federal funding of stem cell research, as long as the destruction of the embryos involved in obtaining the cells was privately funded.[5] That report recommended that federal funds ought to be available for stem cell research, including derivation of stem cells from excess embryos created for reproduc-

tive purposes and certain cadaveric fetal tissue, if certain conditions were met.[6] These conditions included a ban on buying and selling such embryos, and rigorously separating the process of obtaining donors' informed decision to discard such embryos from asking donors' permission to use discarded embryos for research, on the ground that, "if the decision to discard the embryos precedes the decision to donate them for research purposes, then the research determines only how the destruction occurs, not whether it occurs," treated as a dispositive ethical distinction.[7] The Commission recommended against providing federal funds to create embryos for research or for SCNT at that time.

In 2002, a differently charged and constituted advisory body, President George W. Bush's "President's Bioethics Council," after extraordinarily articulate reflection, again rejected reproductive cloning, but it split on whether SCNT and cloning for research should be encouraged (a minority) or made subject to a four-year, congressionally-enacted moratorium on such research regardless of funding, during which time society could continue to discuss the issue, and comprehensive regulations, outlined in the Council's opinion, would be developed (the majority).[8]

As discussed below, academic literature continues to debate not just the "moral status" of such embryos, but, more fundamentally, how the morality of embryonic derivation should be analyzed.

Some ethicists and scientists argue that one should evaluate the "moral claims" of the embryo based upon its actual human capacities at the time the blastocyst would be destroyed to yield stem cells, while others look to the embryos' theoretical—or actual—potential to develop through infancy. Some condemn any instrumental use of an embryo as intrinsically wrong, or as wrong, because of a perceived slippery slope to unacceptable social or cultural consequences.

Some of these ethicists and scientists reframe the question, asking whether it is meaningful to make any moral assertion about an embryo that is independent of its physical environment. Such commentators believe that "inherent within the definition of an embryo is an assumption regarding the appropriateness of its environment"[9] as sufficient to sustain growth into a viable fetus or further into an infant. They, therefore, distinguish destruction of *in utero* embryos from destruction of petri dish embryos derived for stem cells. In their view, the abstraction of blastocysts from a uterine environment "causes" them to "take on different meanings depending on the institutional context."[10]

Some ethicists and scientists comment that the transition to human worth is gradual and continuous. Any distinction, therefore, reflects an instrumental choice about how to balance desired outcomes,[11] a view criticized by another as "a deconstruction of the very idea of ethics as anything more than a ratification of the social or political preferences of any group of self-interested people."[12] Others translate developmental continuity into a moral sliding scale that would allow the destruction of early stage embryos in minimal numbers for beneficial purposes if done with a sense of respectful regret at the necessity.[13]

The role of science in deciding these ethical questions is unresolved. Does it matter ethically that at less than 14 days a blastocyst has no neural tissue? On that ground, is derivation of stem cells ethically identical to organ donation on behalf of brain dead donors?[14]

Does it matter ethically whether a blastocyst still retains the potential to undergo complete fission to form an identical twin? As one commentator has put it, since twinning "can occur spontaneously until formation of the primitive streak after 14 days [and] individuality is a *sine qua non* for personhood, it seems safe to consider 14 days of normal embryonic development to be the minimum requirement for a human being to emerge."[15]

Are ethical claims that one must protect the "potential" for human life defeated by scientific assertions that an embryo has no such potential unless it has been implanted in a uterus, or that "both trophoectoderm and ICM cells are required for development of the fetus" so that "a blastocyst or even later embryo lacks the [actual] capacity to develop into a human individual?"[16]

Is there a moral difference between developmentally non-viable embryos, and "pre-viable" embryos?[17] An *in vitro* research embryo will never be implanted. Does that make its destruction ethically identical to preventing pregnancy through intrauterine devices (IUDs), or is the instrumental creation and destruction of an embryo for research ethically different?

Does it matter, ethically, if a human blastocyst created by SCNT, if implanted, would be extremely unlikely to develop into a human being, since "cytoplasmic factors would have to act on an adult nucleus to produce the same patterns of gene activation that are critical for early embryonic development?"[18] For that reason, one view is that SCNT "resemble[s] tissue culture," simply the enhancement of a somatic cell, and does not involve

the creation of independent and protectable human life.[19]

The debate about the role of science is especially important, since so much science remains to be done. This includes: determining the best conditions for culturing and mass production of stem cells; understanding and manipulating the factors that cause their differentiation into specific cell types, and organized and functional tissues and organs; developing methods to avoid tumorgenesis and teratoma formation from implanted cells;[20] defining rigorous standards to evaluate embryonic and adult stem cell plasticity so that their potential therapeutic uses can be accurately compared;[21] and understanding the causes and implications of the genetic and developmental flaws that have emerged in SCNT cases.[22]

Since so much scientific research has yet to be undertaken, arguments that depend on discoveries yet to be made are necessarily premised on some degree of speculation. The argument that the benefit to society from research outweighs embryonic costs depends on health care outcomes that can be demonstrated—or disproved—only if the research is allowed to continue. At the same time, the argument that adult stem cells will produce broadly effective therapies without recourse to embryonic cells is also unestablished[23] and, in effect, shifts the burden of therapeutic uncertainty to the patients who will participate in clinical trials of adult-cell-based therapies.

There is a common core of ethical requirements agreed upon in the literature: informed consent and confidentiality for donors;[24] institutional review board ("IRB") approval;[25] and elimination of financial inducements.[26] Yet other ethicists, on both sides of the derivation question, identify a broader set of ethical issues to be resolved. These include whether informed consent for destruction of embryos should be separated from informed consent for research donation;[27] whether, as in the case of research use of animals, protocols must limit the number of embryos involved to the minimum necessary, and specifically justify that number under a standard of scientific necessity;[28] fair distribution of resulting therapies on affordable terms, and public access to related intellectual property;[29] avoiding the commoditization of human embryos and embryonic stem cells;[30] whether special ethical restrictions should be placed on implantation of SCNT embryos, to avoid organ harvesting from pre-term fetuses;[31] the ethics of allocating resources to stem cells research at the putative expense of improving basic preventative care in underserved populations;[32] the emotional and moral effects on egg donors, recipients, scientists, health care providers and moral culture if stem cell research proceeds or is curtailed; the effects on the "personhood" of a recipient of embryonic stem cells, particularly for neural implantation;[33] and, most broadly, whether the individualistic biotechnically-oriented drive for cellular immortality will supplant traditional, religious and humanist conceptions of human value that find immortality in great works, the life well lived, and "cultural, religious, familial and economic associations" that are the polar opposite of the drive to "self-enhancement."[34]

There is also a potent issue concerning whether human stem cells may ethically be combined with animal cells to make a hybrid for research purposes. While no one favors carrying human-animal chimeras to term, to the extent that diverse human stem cell lines are unavailable it may be scientifically compelling to carry out genetic inquiries with complementary combinations.[35] Finally, ethical issues as well as legal ones arise between companies and investors, and companies and consumers, over how research results are portrayed.

II. Laws Concerning Stem Cell Use

Consistent with this lack of ethical consensus, there is no comprehensive or consistent regulation of stem cell research in the United States. Under the Dickey Amendment, as supplemented by a directive from President George W. Bush, the federal government will not fund stem cell derivation from embryos. It will, however, fund research on certain stem cell lines identified by the National Institutes of Health (NIH) as having been in existence on August 9, 2001.[36] On the other hand, stem cells, their derivation, and their uses are subject to federal patent protection, without regard for the moral questions that whirl around them, or for the federally chartered bodies that exactingly parse the moral status of the embryo. These patents, exploited through exclusive and other commercial licenses, will now be the key basis on which funded progress will depend. Yet naturally enough, they have already produced limitations on accessibility and availability that are directly contrary to the ethical recommendations of some of those who support stem cell research. They are certainly contrary to the sharing standards that govern NIH-funded research tools distributed through the so-called Uniform Biological Materials Transfer Agreements approved by the NIH, which focus on minimizing obstacles to transfer and use of research materials and basic legal protections (such as warrantee disclaimers and limited indemnities), rather than allocating commercial rights between the parties.

Still waiting in the wings are the Food and Drug Administration (FDA) and other regulatory agencies.

The requirements they will impose on stem cell-based diagnostics and therapeutics have yet to be elaborated. One can only guess if, or how, national stem cell politics will affect them.

Divisions among the states, and among other countries, reflect the divisions in American and European thought. California and New Jersey have provided government funding to promote stem cell research, and California has established the California Institute for Regenerative Medicine for the purpose. While some states consider funding measures, other states, including Arkansas, Iowa, Louisiana, Michigan, Nebraska, North Dakota, South Dakota and Virginia, limit such research. As of 2004, in the European Union only one country, the United Kingdom, funded creation of embryos for research purposes, while six countries prohibited creating human embryos for research purposes, either directly or through their ratification of the European Bioethics convention.[37] Five of those six permitted deriving human embryonic stem cells from supernumerary embryos; another six prohibited that.

Laws are evolving, and regulatory structures are mutually inconsistent. Legal and regulatory intuitions honed in one subject area are unreliable guides in others. If one is considering stem cell research, there will be no substitute for coordinated, exacting implementation of issue-specific procedures to ensure compliance.

III. Specific Issues

A. Allocating Federal and Non-Federal Funding

The NIH maintains a registry of stem cell lines eligible for federal funding under President Bush's August 9, 2001, directive.[38] Since federal funds may not be used to support stem cell research on other cell lines, investigators and institutions must segregate and allocate costs of such research so that no federal funds support unallowable charges, as prescribed under OMB Circular A-21.[39]

Not-for-profit academic research institutions are familiar with implementing A-21 for other forms of unallowable cost, so this should not be insuperable, provided that the laboratories and investigators take a disciplined approach to identifying and segregating direct costs involved in such research, and in excluding costs from calculations resulting in the federal share of organized research costs. As a result of a recent change in the cited NIH "FAQs," it appears that such costs may be included in the organized research base, provided that associated indirect costs are appropriately separated and charged to non-federal accounts.

In practice, this means that each laboratory should distinctly fund, identify and track all supplies, materials, space and equipment used on non-federal lines, and should also carefully and separately identify and account for all staff time and effort, and related salary and fringe benefit costs. Ideally, staff, materials and space would be discretely organized and separately funded. Absent that, demonstrable rigor and oversight must ensure that allocations of time, effort, supplies and space are precise and accurate. Time and effort allocations should apply to management and administrative staff as well, if any of their time and effort goes beyond general guidance and oversight. There should be a written policy and precise written procedures. All staff working with stem cells should be trained in these procedures, not just the investigator or department administrator. There should be periodic monitoring and evaluation, and corrective action or quality improvement as necessary.

With rigorous documentation and clear policies, institutions may be able to allocate those costs that the NIH allows to be allocated, like staff effort and space. However, they will still be unable to use or allocate equipment to which the federal government holds title under an NIH grant or contract. Even for equipment for which title has passed to the institution, the institution will need to comply with preferences for federal usage and any limitations in the original grant or contract which led to the purchase. Indeed, some would take a more restrictive view, arguing that equipment purchased with federal funds can never be used for such research, even if title has passed to the sponsored institution after completion of the funded research that allowed its purchase. Under either interpretation, it may be extremely difficult to establish shared facilities for federally and non-federally funded work, even where a rational cost allocation methodology based on usage or relative cost could otherwise be implemented.

Researchers should not assume that they can undertake non-federally funded research on federally approved stem cell lines and their derivatives. For example, derivatives from the federally funded cell lines may be used in non-federally funded research only if their cost (such as the cost of deriving them) is not charged to the federal government under the grant or contract that funded their research use, and it would not violate any other terms of that federal grant or contract. If such a federal grant funded their creation, then supplying them for other purposes (such as incorporating their derivatives into ineligible cell lines) could, in effect, be an impermissible federal subsidy of ineligible research. Tracking these derivatives through a series of

interwoven experiments may become extremely challenging.

B. Human Subject Research Protection and OHRP and FDA Jurisdiction

Title 45 C.F.R. Part 46, Subpart B, extends certain human subject protections to federally funded research concerning the products of human conception "from implantation until delivery." That subpart and other pertinent portions of Part 46 will apply to non-federally funded research as well at institutions whose Federal Wide Assurance or FWA (the mandatory periodic assurance that must be filed with HHS for an institution to be eligible to participate in federally funded research) commits them to apply HHS regulations to all research regardless of funding source.

However, since the inner cell mass is formed prior to implantation, and indeed *in vitro* embryos may never be implanted, Subpart B does not directly govern the separation of the inner cell mass of a human embryo. Nonetheless, 2002 guidance from the Office for Human Research Protections (OHRP) clarifies several ways in which federal human subject protection regulations may be implicated in stem cell research, either because it is federally funded or because of the scope of an FWA.[40]

While stem cells and pre-implantation embryos are not themselves "human subjects" for purposes of these regulations, the donors or treated patients will be "research subjects" if pertinent data is obtained through direct intervention or interaction with them as part of the protocol, or if identifiable private information is linked to them or otherwise can be "readily ascertained."

Thus, a research protocol in which stem cells are derived from the gametes of known donors, differentiated, and transplanted into known subjects, will be subject to the regulations both because of the known identity of the donors and the interaction with the patients. Even *in vitro* research with donor-identifiable stem cells will be "human subject research," unless the investigator's and institution's lack of access to that information is documented by a written agreement that the holder of the identifiers or identifying coding methods will not release that information to them under any circumstances. This is an important compliance point that would be easy to miss. Under OHRP's guidance, such documentation is required, even if the circumstances themselves make identification of donors impossible.

OHRP observes that "all clinical research involving drugs, devices and biological products regulated by the FDA, including cells or test articles regulated as drugs, devices, and biological products, is subject to FDA regulations . . . regardless of the source of support." If applicable, regulations would include the FDA's own requirements for IRB review and informed consent.[41] However, the qualifying phrase "regulated by the FDA" makes this language circular. The specific approach the FDA will take is, as of now, unclear, although it is notable that in a June 2004 discussion of using stem cells in treating heart disease,[42] the FDA used, and cited with approval, its 1997 "Proposed Approach to Regulation of Cellular and Tissue-based Products," which focused on preventing use of contaminated cells and tissues, preventing improper handling, and demonstrating clinical safety and effectiveness.[43] This provides some hint that regulations ultimately proposed will follow the approach suggested in 1997 for cellular products generally, and not delve specifically into ethical issues, apart, of course, from standards generally applicable to IRB review.

Viewed broadly, the FDA's jurisdiction attaches to the marketing of any drug, device or biological product that is intended to be used for preventing, treating, or diagnosing a human disease or condition.[44] While there are no current final regulations aimed explicitly at human embryonic stem cells, there are two areas of existing regulation that have probable impact, in addition to general regulations relating to drugs, devices and biologicals.

First, in 1998, the FDA proposed rules to regulate "manufacturers" of human tissue, manufacturing being broadly defined to include participation in "any or all steps in the recovery, processing, storage, labeling, packaging, distribution, of any human cell or tissue, and the screening or testing of the cell or tissue donor."[45] Proposed and final regulations relate to registration, so-called practices for handling tissue and establishing the suitability of donors.[46] As of this writing (April 2005), there is no final, specific guidance on how these will apply to research institutions engaged in sponsored stem cell research. Second, NIH lines have been grown with bovine serum and on the surface of mouse fibroblasts, cells that generally create connective tissue but which function here as critical "feeder cells," without which those stem cells could not have been maintained in culture. Because of this interdependence with animal tissues and serum, therapies and products derived from those cells, therefore, implicate the FDA's guidelines on preventing animal viruses from infecting patients and the general population.[47]

Detailed discussion of how these regulations could apply to stem cell research is outside the scope of this article, but the reader is referred to the cited materials.

Finally, practitioners should be aware that clinical research involving transplanting cells from human fetal tissue is governed by 42 U.S.C. 289g-2(a), which, among other terms, requires donor informed consent, and prohibits abortions for the purpose of donation.

C. Intellectual Property and Licensing

Numerous patents have been filed relating to human embryonic stem cells. The most fundamental are the so-called "Thomson" patents, which relate to the methods of deriving and maintaining human embryonic stem cells *in vitro*, and the products of those methods.[48] These patents were assigned by the inventors to the Wisconsin Alumni Research Foundation (WARF), which exclusively licensed their commercial applications within certain fields of use to Geron Corporation, a biopharmaceutical company that, among other things, develops and commercializes cell-based therapies. Non-commercial research access to materials, and licenses to practice under the patent rights for research purposes, are available through WiCell, a not-for-profit corporation.[49]

Given *Duke v. Madey*,[50] a 2002 Federal Circuit case that narrowly interpreted the freedom of researchers to conduct basic science research covered by patent claims without fear of infringement, it is reasonably clear that WiCell's consent will be required to continue to conduct any serious, basic exploratory research that falls within the scope of valid patent rights. There is a limited exception under the recently decided *Merck KGa v. Integra Lifesciences I, Ltd., et al.*;[51] for research that is "reasonably related" to "the development and submission of information under . . . Federal law," including submissions to the FDA. However, a "reasonable relationship" to FDA submissions requires that a researcher conduct research with a "reasonable basis for believing that a patented [article] may work, through a particular biological process, to produce a particular physiological effect, and uses the [article] in research that, if successful, would be appropriate to include in a submission to the FDA." While the resulting data need not be included in an FDA submission for the underlying research to be exempt, open-ended basic science research of the sort required to meet the scientific goals described in Part I of this paper will probably not qualify as research towards a clinical application, or meet the Supreme Court's *Integra* standard. For this reason, one must acknowledge that progress in stem cell research will require navigating the growing thicket of intellectual property positions of WiCell and others.

Under agreements among WiCell, HHS, and the various owners of the NIH-approved stem cell lines, certain contractual terms explicitly protecting WiCell's intellectual property rights govern any recipients of federally eligible stem cell lines, since WiCell rights are implicated in their derivation. Comparable restrictive terms will apply to non-federally eligible research.[52] Therefore, conditions and restrictions imposed by WiCell are, in effect, imported broadly into stem cell research.

Although the various agreements with different stem cell line holders state these principles somewhat differently, the principles are the same. Research is restricted. Materials may not be used in commercially sponsored research that grants any "rights" to the sponsor, nor in arrangements that are for the "direct benefit" of any commercial entity, unless the entity has itself directly licensed commercial rights from WiCell on unspecified terms. Such commercial licenses will presumably have to take into account the exclusive commercial license granted to Geron within certain fields of use. They will limit or foreclose therapeutic licenses to other companies that could compete against Geron, regardless of whatever public benefit could arise from such competition.

It is unclear whether the "rights" that may not be granted to a commercial sponsor include only intellectual property rights, or whether this restriction also prohibits any form of research collaboration between academia and a sponsor under which each party necessarily shares data and knowledge with the other to implement the collaboration. This uncertainty may be a serious impediment to any commercial funding of stem cell research. It is very doubtful that such a broad prohibition on basic knowledge sharing is really required to ensure that licenses are implemented on commercial sales of fully developed products.

Materials (including institutionally differentiated cells and unmodified products of such cells, such as DNA and proteins) are also subject to various ethical restrictions on maintenance, implantation and use. Among these are that no materials may be mixed with intact human embryos; materials may not be implanted in a human uterus; and recipients may not use the materials to make whole human embryos by any method.

It is unclear whether the transfer agreements, and any licenses for non-federally funded research, will be subject to exceptions within the patent statute itself, such as the exception for certain therapeutic medical procedures. If not, then the restrictions outlined above, including the potential prohibition on "commercial" uses, and the limitation to teaching and academic uses,

if taken literally, will undermine using stem cells for medical care, at least by for-profit entities (such as classic medical practices) that do not have a license on whatever terms may be demanded.

One may license new inventions to other companies, but subject to a non-exclusive license to WiCell, and as described above, such a license may not have been precommitted or optioned in advance in connection with research sponsorship. Newly created derivative materials may not be transferred to a commercial party unless that party has a license from WiCell. Even a non-commercial transferee of biological materials must have signed a materials transfer agreement containing complementary restrictions.

Despite these limitations, it should be acknowledged that these terms are less restrictive and overbearing than the most shortsighted and confiscatory forms of material transfer agreement that some companies would impose if they could. For example, they do not transfer ownership or an exclusive commercial license to any resulting invention regardless of the relative contribution of materials to the research, nor do they impede publication through confidentiality terms that conceal research results or impose company ownership on all research data. They do at least allow further dissemination of research results and, in a more limited way, materials.

It is also worth emphasizing the generosity and public-spiritedness of WiCell and the other suppliers of federally approved materials in making their rights and materials available at all, and for almost no charge. No law compels them to.

One might also argue that in severely curtailing grants of intellectual property rights in connection with commercial sponsorship of recipients' research, WiCell is also promoting open source-like arrangements and public benefit by prohibiting restrictive arrangements that would exclusively benefit other sponsoring companies (unless of course those companies have procured commercial licenses from WiCell or its assignee).

But the effect of these and similar terms in the current regulatory environment will necessarily be to restrict the exchange of knowledge, collaborations, and commercial funding for stem cell research and, therefore, to restrict research in areas that scientists and the market would perceive as most promising. If philanthropic sources were to follow the government in refusing to fund new stem cell lines, the only significant funding sources for stem cell research on the non-federally eligible lines, aside from commercial funding, would be in those states that had committed research funding from state taxpayer funds. So far, only California has decided to create a substantial pool of such dedicated funds, as a result of last November's ballot initiative. In short, given the current limitations on federal and state funding, commercially sponsored research will be especially important to stem cell research. Yet, given the WiCell patent and license provisions, such commercially sponsored research will be peculiarly dependent on whether WiCell, in its sole discretion, and perhaps Geron, agree to it. In particular, the intellectual property rights that commercial sponsors generally seek to option or license as a vital quid pro quo for sponsorship are squarely within what the WiCell license prohibits.

This basic problem will be aggravated exponentially if other academic research institutions follow suit, and generally license their own stem cell inventions exclusively and on comparable terms. In fact, no law prevents other research institutions from licensing non-federal stem cell inventions to companies on more restrictive (but profitable!) terms, such as terms that bar distribution of new materials or research among academic institutions (except to WiCell and WARF as dictated by their own prior agreements).

Research institutions are capable of being quite inconsistent—complaining about restrictions in documents they receive while profiting from exclusive commercial licenses that foster a burdensome network of similar restrictions.[53] So lawyers who counsel research institutions, and decision-makers at such institutions, have to ask themselves: Will we pursue shortsighted courses that enhance our client's profits, regardless of the aggregate effect? Will we pay attention only to narrow conceptions of legal compliance and obtain the best possible commercial terms regardless of the ongoing ethical and societal debate? What relationship, if any, will we see between the span of ethical issues discussed in the first part of this article, and the course we follow in stem cell research?

Distinguished commentators have questioned the long-term impact of unregulated patenting and licensing on the public interest, and whether it impedes research, sharing of research materials, and development of new therapies because of "a proliferation of fragmented and overlapping intellectual property rights" that is too profound to be resolved simply through market forces.[54] This view was endorsed by the NIH in its statement of Principles and Guidelines on Sharing Biomedical Research Resources: "[I]ntellectual property rights can stifle the broad dissemination of new discoveries and limit future avenues of research and product development."[55] For that reason, the NIH

urged non-exclusive licensing of unique research materials,[56] and commentators have suggested expanding the NIH's discretion to determine what intellectual property protection and licensing requirements should govern government-funded research.[57]

Some argue that the arguments in favor of non-exclusive licensing have specific application to stem cell research. One commentator has observed, "development of technology based upon stem cells is of such fundamental interest that exclusive licenses should not be permitted without any evaluation of the consequence. . . . The combination of patenting and exclusive or unchecked free market licensing can foreclose research and development in a crucial field."[58] Indeed, the WiCell/Geron arrangement was singled out for criticism on exactly this ground by the distinguished legal commentators Rai and Eisenberg, who noted that "[a]lthough embryonic stem cells are precisely the type of broadly applicable enabling technology that, as a general matter, should be licensed nonexclusively in the interest of promoting future research . . . , WARF chose to license exclusively some of the most important commercial rights under the patent."[59]

Whether or not one agrees with the targeted criticism of WARF, it is clear that the NIH Principles and Guidelines for preserving non-exclusive access to primary research materials and rights are not applicable to commercially funded research. They will not protect the public or scientific progress in the profit-driven arena to which federal funding limitations are driving all future research on post-August 2001 lines. If they do not, one must ask what will.

There have been ethical attacks on patenting itself, independent of the scientific aims of the NIH Principles and Guidelines. For example, one author questioned how the national government, since it is opposed to direct federal funding of post-August 2001 lines, can consistently sanction exclusive property rights in such lines, since patents create "indirect research funding" through rewarding market investments.[60]

However, efforts to reinvigorate the moribund "moral utility" doctrine—which permitted the Patent and Trademark Office to reject certain patents as public policy—will collide with the current sense that "everything under the sun" isolated or manipulated by humanity may be patented,[61] and that the patent law is not congressionally intended to displace the police powers of the states with respect to safety, health and morality.[62]

Thus, one of the ethical ironies of the federal position on stem cell funding is that it allows the sensitive ethical questions presented by stem cell research to be decided solely by the marketplace, without any assurance that the marketplace will address those issues in a manner that transcends the most shortsighted implementation of the profit incentive. Our current American approach succeeds in promoting companies' short-term interests in stem cell research, while forgoing any actual federal or other ethical oversight, except as noted above with respect to human subjects.

IV. The National Academies' Proposed Solution: Institutional Oversight Through "ESCRO" Committees

On April 26, 2005, the National Academies released proposed guidelines for institutional review of embryonic stem cell research ("the Guidelines").[63] The Guidelines include substantive ethical principles concerning what sort of research should be permitted and prohibited in research institutions, and procedural recommendations built on the premise that institutions should establish Embryonic Stem Cell Research Oversight ("ESCRO") committees to perform critical functions in reviewing research and providing other forms of oversight. Although the Guidelines describe their functions differently in different contexts, in sum, as stated in the Guidelines, each ESCRO committee is: (1) to provide local oversight of all issues related to derivation and research use of human embryonic stem cell lines; (2) to review and approve the scientific merit of research protocols; (3) to review compliance of in-house human embryonic stem cell research with "all relevant regulations";[64] (4) to "act as a clearinghouse" for research proposals, identifying the form of required review and assisting investigators in understanding what government and other regulations apply; (5) to ensure that the provenance of such cell lines, and its approval by an institutional review board as appropriate, is documented; (6) to facilitate education of investigators involved in human embryonic stem cell research; (7) to maintain a registry of banked human embryonic stem cell lines and associated genetic and medical information with identifiers appropriately protected; (8) to act as the institution's oversight committee on banking of such cells (although from other text it appears that this could also be done through a separate committee); and (9) to "ensur[e] that all applicable regulatory requirements are met."[65]

ESCRO committees must include representatives of the public and persons with expertise in developmental

biology, stem cell research, molecular biology, assisted reproduction, and pertinent ethical and legal issues.

The Guidelines state that ESCRO committees are not intended to displace IRBs, which will review: research protocols and associated informed consent documentation involving procurement and donation of gametes, somatic cells and blastocysts; clinical research uses; and all other matters an IRB must review under federal or state law.

Nonetheless, the recommendations directly affect IRBs. The Guidelines provide that IRBs should never waive consent by any donor of a blastocyst, gamete or somatic cell, nor should they permit compensation for donating IVF blastocysts in excess of clinical need. The Guidelines would prohibit any payments to sperm donors for research-related donations, and limit payments to women undergoing hormonal induction to generate research oocytes to "direct expenses incurred as a result of the procedure." The Guidelines also propose a detailed form of consent that, among other things, specifies research uses; clearly states that embryos will be destroyed; addresses risks, including the extent to which donor identities will be ascertainable; provides assurances concerning best practices; discloses commercial potential and the fact that donors will not financially benefit; and states that donating or declining to donate will not affect future clinical care. These are all matters within the traditional province of an IRB. It is not clear whether an ESCRO committee's function includes assessing or ensuring that an IRB has followed them.

Consistent with substantive ethical principles suggested by the Guidelines, ESCRO committees are to divide research proposals into three categories that determine the form of review required and whether the research is permissible, categorically prohibited, or possibly permissible. To closely paraphrase the Guidelines themselves, these categories are:

1) **Research that is permissible after notification of the research institution's ESCRO committee and completion of the reviews mandated by current requirements.** This includes *in vitro* human embryonic stem cell research with pre-existing coded or anonymous cell lines in general, provided that notice of the research, documentation of the provenance of the cell lines, and evidence of compliance with other institutional requirements is provided to the ESCRO committee. Presumably this would also include research of a type previously approved that did not fall into the prohibited category.

2) **Research that is permissible only after additional review and approval by the ESCRO committee.** This includes all requests to derive new stem cell lines from donated blastocysts, from *in vitro* fertilized oocytes, or by SCNT. As part of this review, the ESCRO committee is to verify that the scientific rationale for doing so is clearly presented, and review the investigator's justification for the number of blastocysts and oocytes. This category also includes research in which personally identifiable information about the donors is "readily ascertainable," as well as all research involving the introduction of human embryonic stem cells into non-human animals at any stage of embryonic, fetal, or postnatal development.

3) **Research that should not be permitted at this time.** Under the Guidelines, an ESCRO committee should not authorize research involving *in vitro* culture of any intact human embryo, regardless of derivation method, for longer than 14 days of development or the manifestation of the primitive streak, whichever occurs first. Nor should it permit research in which human embryonic stem cells are introduced into nonhuman primate blastocysts or in which any embryonic stem cells are introduced into human blastocysts. Finally, an ESCRO committee is to deny approval to research that would involve "breeding" of animals into which human embryonic stem cells have been "introduced at any stage of development."

These recommendations, and the deliberative text that justifies them, are a huge step forward in refining ethical principles, and in implementing them rigorously and thoughtfully. The entire Guidelines Committee report is required reading for anyone seriously interested in stem cell ethics, whether or not one agrees with its specific conclusions.

Nonetheless, the Guideline provisions concerning ESCRO committees have certain limitations. First, taken too literally, having an ESCRO committee oversee regulatory compliance could actually dilute compliance and other functions by providing inappropriate input or control. Should scientist members of an ESCRO committee—perhaps the majority—really be able to vote on how the institution implements federal financial restrictions that they find burdensome? To what extent should attorney members really adjudicate scientific merit? Will institutions fully disclose sensitive compliance issues for resolution if they fear, whether right or

wrong, that confidentiality will be compromised by public members? There is an important distinction between coordinating the actions of responsible managers and officers, and using a committee to effectuate professional and scientific responsibilities. It is also important to ensure that sound organizational mechanisms for compliance oversight are not actually inhibited or decentralized through assignment of such functions to a group whose primary focus is ethical oversight and applying the National Academies principles.

Second, multi-institutional arrangements will be quite challenging if these functions must always occur within a single committee. Institutions may welcome collaborative ethical review but will they participate if the price of collective ethical deliberation is delegation to a new central committee of all oversight of their sensitive compliance functions, including review of confidential information about potential regulatory problems, or violations of state stem cell research laws bearing criminal penalties? Will they be willing to delegate scientific review if the multi-institutional arrangement includes institutions that compete in attracting scientific talent and building their own research programs? There is some argument that institutions ought to be able to participate in multi-institutional ethical review of protocols without necessarily also delegating the responsibility for ensuring legal and regulatory compliance of the whole institutional stem cell research program.

Finally, while ethicists agree that intellectual property issues are ethically material, there is no means within the ESCRO committee structure—nor any emphasis within the Guidelines' ethical principles—for ensuring that institutional policies on intellectual property and public dissemination promote the public interest. Without a means of coordinating institutional positions on intellectual property, an important part of the ethical picture has been omitted.

V. Conclusion: Integrating Legal, Ethical and Scientific Review of Human Embryonic Stem Cell Research

Stem cell research requires an extraordinary degree of coordination among researchers and the various administrative arms of a research institution. For any given research protocol, research institutions need to coordinate institutional ethical review, IRB review, review of ingoing and outgoing material transfer agreements, and review of proposed sponsored research agreements against restrictive license and material transfer agreement terms. Procurement agreements, such as for excess IVF embryos, will need to correspond to, and comply with, ethics committee and IRB rulings.

For research with federally ineligible stem cell lines, institutions will need to provide financial oversight of how labs will appropriately allocate funds for supplies, staff, and other direct costs, and implement procedures for segregating non-federally funded research from federally calculated and supported indirect costs.

Although not previously touched on, they will also need to coordinate meeting import and export restrictions, including any necessary permits for biological materials, in addition to taking into account any state and international restrictions on derivatives of human embryos.

They will also need to review the growing body of state laws and regulations, too numerous to be within the scope of this article, that variously encourage, discourage, or condition embryonic research. Indeed, evolving laws and FDA regulations about tissue banking may soon be accompanied by state laws and regulations that focus on the process of maintaining stem cell banks and the clinical uses of stem cells.

Finally, to the extent ethics committees, IRBs, or other institutional policymakers broaden their ethical focus beyond cell derivation to encompass distributive justice, sharing of research tools, and the other issues previously noted, institutions will have to ensure that licenses, materials transfer agreements, research agreements, and protocols take such concerns into account.

Internal registration, as the Guidelines recommend, is one mechanism for coordinating these functions. Institutions can custom-build a registration application that describes proposed research, and create a process that first provides for ethical and IRB review, and then simultaneously circulates it to pertinent administrative offices that will attend within their responsibilities for coordinating ethical and legal compliance.

Coordinated simultaneous review, such as at periodic meetings involving all administrative offices, would help ensure that all reviewing offices are working from the same set of facts; that review is as rapid as possible; that adjustments required by one office are known to and reflected in actions by the others; and that an investigator can proceed expeditiously with approved research with a guarantee of institutional backing, assuming the research is conducted ethically and as described. It will also help ensure that as law and policy continue to evolve, all offices are equally aware of the complex parameters within which such research must take place.

Within their own realms, the various parts of research administration must also take corresponding actions. For example, intellectual property offices (IPOs), made aware of these issues, can take steps in licensing agreements to implement ethical requirements. They can more carefully consider nonexclusive commercial licensing, and reserve from commercial licenses their own rights to distribute materials and to license research-only licenses on terms that do not burden further funded research. Development plans can include terms that promote equitable distribution, for example, by requiring development of products in less profitable markets along with ones anticipated to be profitable. Companies and institutions can jointly agree, in licenses, to establish independent ethical review bodies, a step which Geron evidently took,[66] and which licensees have been willing to undertake in licenses the author has negotiated. They can adhere to the NIH Principles and Guidelines on sharing research materials, whether the research is federally or commercially funded. They can avoid burdening commercial research in the distribution of materials by ensuring that third-party commercial use licenses are required, if at all, only in connection with product sales, not in connection with conduct of research itself by academic or private organizations. They can protect the ability of companies and academic institutions to collaborate by avoiding prohibitions on sharing data and materials between collaborators even where, in some broad sense, those "directly benefit" a commercial entity's research. Finally, whatever licenses may be required for product manufacturers and sellers, IPOs should ensure that doctors and hospitals are not subject to patent infringement lawsuits, or licensing agreement violations, because they are caring for their patients.

Similarly, IRB members and staff can be made aware of, and should review, informed consent documents influenced by ethical requirements specific to stem cell research, including the NAS Guidelines as further articulated through application by the institution's ESCRO committee. In addition, they should review and understand institutional commitments that affect whether the public will really be benefited by proposed research. Since IRBs are charged with weighing risks against both individual and societal benefit from knowledge that may be expected to result from the research,[67] policies that promote or block public dissemination of research materials and results are directly pertinent to their functions. IRBs must, therefore, care about whether institutional commitments—for example, intellectual property commitments—promote or impede fair access to the benefits and results of stem cell research.

The institution must find a method of coordinating these diverse functions with the ESCRO process. For example, for some institutions with established compliance committees, coordination might best be achieved through interlocking membership of key members among separate ESCRO and compliance committees, such as having research administration leadership and some IRB members sit ex officio on the ESCRO committee, and having the ESCRO committee chair be involved in pertinent compliance committee functions. Alternatively, the process could be integrated through structuring meetings of a single stem cell review committee so that meetings focused on ethical debate are staggered with larger meetings that include reporting on overall institutional compliance and the other issues discussed. In some institutions, it may also be sufficient to create strong staff level connections between the ESCRO committee and those responsible for compliance and intellectual property issues, while ESCRO committee members focus on protocol specific issues, monitoring, debating and ratifying general policy judgments relating to the mutual reinforcement of ethical principles and legal compliance.

This coordinating process is all the more important given the remarkable gap between the ethical issues that stem cell research raises and the focus of legal compliance. Simply contrasting the ethical questions outlined at the beginning of this article with the legal issues that follow makes this manifest. We should be troubled when we see the law bear so little relation to the ethical moorings of institutional missions or private businesses' objectives. Companies must establish parameters and mechanisms to integrate broadly ethical thinking and behavior with obligations to shareholders and consumers. Research institutions must moderate and subordinate their own "commercial" desires, and ensure that research discoveries are shared and developed fairly and on reasonable terms that place the public's benefit first. Otherwise, for the public—whether they approve or disapprove of stem cell research—it will be the worst of all worlds.

Other than looking closely at the implications here of *Duke v. Madey*,[68] and the significant impact it yet retains after the *Integra* decision, this is not a problem that legislators can necessarily solve. Given the lack of ethical consensus, it is probably not fair to ask them to resolve it, and in any event the required coordination between ethical and administrative imperatives is inherently institutional and will suffer if fragmented. It is a problem for institutions to resolve, positioned as they necessarily are at the center of these issues.

Of course, for those who are not convinced by appeals to moral principles, there are long-term business issues as well. No company or research institution will ultimately benefit from pretending that there is a fluid and perfect market in patent licensing that readily supports research within the scope of others' patent rights. The only reason that the result in *Duke v. Madey* is not a complete disaster for researchers and the public—and for companies and research institutions—is that companies and institutions have not taken it at its word to cripple research through shortsighted enforcement of theoretical rights. Nor will business and academia thrive if the public's conviction is that they are ethically indifferent. Good business and ethics are aligned here: whatever directions stem cell research continues, whether more or less limited in the future, distribution of its benefits to the public and scientists, and actual, implemented attention to the other ethical issues it raises, ought to be a high priority that is completely integrated in practice with the conduct of stem cell research and commercialization of its results.

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A Pragmatic Approach to the Ethics of Reproductive Human Cloning

By Glenn McGee, Wayne Shelton and Sean Philpott

Human cloning presents a bewitching test of any bioethical method. One can scarcely imagine a worse mess to clean up. Public discussion of human cloning was promulgated by Dolly, a cloned Scottish ewe named after a country music singer, and inflamed by Richard Seed, a Chicago scientist, who played the Jack Kevorkian role of announcing on National Public Radio that he planned to clone himself several times "for fun."[1] Public debate about cloning centered around stopping Seed, cloning pets and livestock, and the likelihood that a despot somewhere in the world would set about the task of breaking what seems to be an international consensus against the reproductive uses of cloning technologies. Virtually every philosopher with an interest in ethics was suddenly called on by television to play Solomon, or at least Nostradamus, to questions like, "is it ethical to clone a recently deceased child?" or, "would a clone have a soul?"[2] Within a year of the birth of Dolly, the odd, marginal, and unlikely problem of human cloning had been elevated to one of the most hotly debated issues in 20th century science and health.

Philosophical debate about cloning has been mounted but along fairly predictable lines, with scant examination of the implications of cloning for human nature, social institutions, or the practice of basic biological science. The question of the day remains narrow and consequential: does anyone have the right to make a clone, and upon whose rights would such a process infringe (McGee 1998c, Roy 1998)? Two recent announcements have made this narrow question seem quite urgent: the news that a clinic in Korea has developed a human embryo from cloned adult DNA, and reports that a team at UMass has inserted human DNA into a cow egg with plans to launch a human-like fetus from that material for transplantation research (McGee 2005e).

Given the hysteria and narrow moral debates, it would seem an odd time to attempt a comprehensive treatment of the philosophical issues in cloning. In fact, that is exactly my intent. I believe that cloning is an ideal test of the usefulness of the uniquely American philosophical strategy called pragmatism. If a pragmatic approach to bioethics is to work anywhere, it is the field of human genetic engineering (McGee 1997, 1998a, 1998b, Saatkamp 1998, Shenk 1997). Genetic research is infused—perhaps more than any other area of natural science—with pragmatic aims (McGee 1997). At bottom and in its implications, genetic science of the 20th century impacts the way we understand our capacity, meaning, and potential. Genetics is intimately tied to procreation, sexuality and reproduction, which are also the foci of our most intimate institutions, such as the family and church. When we make children and when we think of our inheritance, we are building our personal and communal understandings of loyalty, privacy, happiness and growth. And, at the same time, human genetic information is rapidly becoming both a language of medical diagnosis and a commodity for licensure and ownership. Someone *owns* techniques for cloning mammals, including humans. It has become important to make social choices about the institutions that should be entrusted to reconstruct the family in an era of advancing reproduction, genetics and cloning. Pragmatism is uniquely poised to address such questions and also to cope with the fog of current debates about cloning (Moreno 1998).

"Within a year of the birth of Dolly, the odd, marginal, and unlikely problem of human cloning had been elevated to one of the most hotly debated issues in 20th century science and health."

Elsewhere I argue that the most elegant expression of a pragmatic social method is found in Dewey's *Logic: The Theory of Inquiry* (McGee 1994, 1998b).[3] In the *Logic*, Dewey offers a matrix for human inquiry into social problems, which I will use in this article to frame my reflections on the implications of human cloning, science and technology (Dewey 1918). Pragmatic bioethics focuses on the biological, cultural, and common sense dimensions. By selectively emphasizing and analyzing these three dimensions of the context of cloning, rather than rushing to more obviously normative aspects, we will see that human cloning is neither a special moral issue nor a radical step forward. Instead, human cloning is seen to be an element in a set of moral and scientific problems that compel us to reconstruct the enterprise of social thought about the embryo, the fami-

ly and future generations[4] (McGee 1998d, McGee G. & McGee D. 1998).

Biological Dimensions of Human Cloning

While there is an accepted biological definition of cellular cloning, and there are now well-understood (indeed patented) practices for the transfer of nuclei from embryos or somatic cells into enucleated eggs, it is still not possible to define a cloned mammal organism. That this is so has not gone unnoticed in the biological and philosophical literature of the latter part of this century.[5] Yet now that mammalian cloned organisms are among us, and human clones seem imminent, we must ask again what it means to describe an organism, or even an embryo, as a mammalian clone? Must it have all its DNA from a single other creature? Must the donor of a clone's DNA be an adult? Can a clone's egg come from a source other than the DNA source? If the source DNA contains a slight mutation, is the resultant organism still a clone? Must a clone act or sound or seem like its source organism, or perform that organism's role in the community or herd? These questions are unanswered in the current literature of molecular biology despite the use of "clone" as a descriptor for, at last count, more than 400 living mice, sheep, cows, and other mammals.

Received definitions of a human clone come from science fiction, not the lab. Stories of cloning have been used to illustrate the problems of nature vs. nurture, the problem of defining the content of human character, and the problem of preserving our memories in future generations. Captain Kirk's transporter failed, splitting him into two Kirks, one aggressive and domineering, the other intellectual but indecisive. Fictional clones underwent "replicative fading" in *Brave New World*s as they were copied one from another. Mostly, clones of our imagination have carried the memories, feelings, and ambitions of one generation into a next generation. Mostly, clones have been dupes and dopes, only occasionally rising above Frankenstein's guttural longings. When it was announced that Dolly had been constructed with DNA taken from the udder of its progenitor, American fear of cloning was motivated and circumscribed by the clones of a hundred years of imagination. President Clinton penned a letter within hours of the announcement calling his previously unfunded "Presidential bioethics panel" into action to prevent abominations of the family, with exactly these fears in mind.

How one defines a clone seems to depend on to which side of the issue one stands. Those who see no problem with human cloning, such as Princeton geneticist Lee Silver (1998) and Alabama philosopher Greg Pence (1997), matter-of-factly compare any cloned human embryo to a monozygotic twin, who contains the same genetic information as its womb-mate sibling. Twins, it is noted, happen frequently in human life, and it is common today to keep one "sibling" embryo frozen in nitrogen long after the birth of a first. To avoid the pejorative overtone about clones and cloning, Pence suggests a new term: "somatic cell nuclear transfer." By contrast, those who disapprove of human cloning technology point to the centrality of sexual recombination in mammal reproduction, and argue that it would be extremely difficult to predict either the viability or risks associated with gestating or being born a human clone (Kass 1997, Caplan 1997).

Can there be a sober, commensurable definition of a clone? Not in this decade. While the brute techniques required to produce a clone are getting better, embryologists cannot state with certainty the genetic or phenotypic identity of a clone.[6] We think of the identity of mammals, including human beings, more and more in terms of the genetic code they bring into the world.

"Can there be a sober, commensurable definition of a clone? Not in this decade."

A variety of new, urgent and puzzling legal cases force adults to puzzle over the meaning of that code as it bears on parenthood and identity.[7] Biologists and the broader culture would thus like to be able to at least define cloning in terms of something stable: genetic similarity. Cloning, after all, seems to raise the possibility of a wholly new kind of child, one made not from sex or sexual recombination, but rather from the transfer of genetic information from a single progenitor into its offspring. But in reality, while we do not know what sort of a human being a clone would be, neither do we have any real objective purchase on the variety of new kinds of children we make through new reproductive technologies and through new social mechanisms. We may be able to determine the origins of a child's DNA, but that only begins the process of reinventing ideas of relatedness and how relatedness conveys status and responsibility. We have amazing new ways to make children, and think of that process in increasingly design-oriented terms (McGee 1997, Kitcher 1997, Katz Rothman 1997).

That this is so is a function of the biological, political, and economic history of pregnancy and childbearing, which others have discussed in much more detail than I will attempt here (Kitcher 1997, Katz Rothman 1997, Steinbock 1994). Elsewhere I have drawn the conclusion that new genetic technologies and neonatal intensive care, as well as advancing diagnostic science, have changed the nature of the pregnancy experience from one of having, to one of making, babies (McGee, 1997). By this I mean that our best ethnographic and qualitative studies suggest that parents of our time are able to identify with and care for a future child, and that their relationship to future children, including fetuses as well as those not yet conceived, is one that frequently feels like it includes an obligation to prevent future harm. Despite our cultural insistence on the absolute right of a woman to terminate a pregnancy prior to the time a fetus is viable outside the womb, parents and social institutions are increasingly able to think of the fetus as a child for a variety of purposes. Thus, for example, parents who fail to care for their pregnancy, or physicians who fail to diagnose a fetal malady, are subject to sanctions or damages for the tort of harming a being that does not (at the time of pregnancy) have a right to exist *per se*, but seems to nonetheless have a right not to be brought into the world in a way that is harmful to it (Parfit 1984).

The identification of a parental responsibility to future offsping has been long in coming and is tied to a variety of changes in what we mean by childhood and what we expect of children and childbearing. In the course of creating the most recent birth and genetic technologies we have found a way under the hood of pregnancy, radically increasing the ability of adults to take care in choosing the time and manner of pregnancy. We use ultrasound. We conduct amniocentesis. We mix and match genetic parents. We screen for the most healthy embryos all for this purpose.

For example, if my wife's eggs are in some way defective and if I can take a second mortgage or have a free credit card, we will be *treated* for infertility. Why? Because we now say that wholly apart from our need to make love to one another,[8] we feel the separate need to have a biologically similar child; the need to do something to make such a child. The new tool of egg donation implies the possibility we might ameliorate a new kind of need. We want a child. We want it to feel like our child. We want to give birth to it. That need is old. But the need to have a child of such specific parameters is a new one, inspired by our culture's increasing tendency to think of fertility and parenthood as a state of affairs that includes both gestation and genetic relation (McGee & McGee 1998). Our imagination is of a child that is "mostly" ours. But a baby from egg donation, we are told, is not 100% our genetic child. We are not going to be able to completely emulate the "fertile" state. So, electing to use a donated egg, we are under the hood, tinkering with what—for most parents—is just a shiny surprise. Our child is going to require more planning. No more will our sexual encounters be about making babies. Our baby will come from a dish. We control, or at least hope to control, what goes in the petri dish. Put more accurately, parents will feel responsible for what goes in the dish. We won't want to choose a donor who has a dangerous congenital anomaly. If we can choose a donor who is more likely to produce offspring with traits resembling our own (height, eye color), we might spare our child the feeling of being obviously different from us. And if we are under the hood anyway, we might also make sure that one of our children is male, and pay a small amount more for a young, Ivy League donor.

That it is odd to be under the hood is obvious. That it is a different kind of parental decision-making, less subtle and more commodified, seems likely. But the point to be noted here is that our advancing reproductive technologies exacerbate the evolving problem of assigning and enacting parental responsibility. Where the abortion debate focused the attention of the western world on the comparatively simple question of when an *in vivo* fetus takes on moral status, new reproductive technologies raise the problem of what it means to be a parent, and what value that experience has for those involved. In the case above, we will try to compensate for the 50% loss of parental DNA by making wise choices about the donor, choices that will both make us feel responsible and further assert our claim to dominion over the resultant child.

In the case of a cloned embryo, it is not at all obvious who the parents are. The person who donates DNA from a somatic cell is the progenitor, in that the child carries their DNA. But the mammalian parents of the cloned child are the grandparents, if what you mean by parent is that the person contributed 50% of the genes to the recombination process that formed the genome of the person in question. If the egg used to raise the clone comes from another person, as it would in the case of a clone of a male, there is, in addition, an "egg parent," a person who contributes mitochondrial DNA and RNA in the egg wall, the collective role of which on an organism is unknown but perhaps significant. If the progenitor of the clone is itself an embryo or aborted fetus, the parent would not only be a virgin, but also a non-consenting non-person that itself has no legally established

standing apart from the wishes of its own progenitor. Cloning makes acute what is already true in many new technologies and for embryology more generally in our time: we do not know what is in the petri dish, and must make overtly stipulative claims about our relationship to the thing in the dish.

That this problem is acute in cloning results from the complex and engineered nature of that procedure. It is not obvious that a cloned embryo is an embryo. One part of what makes a mammalian embryo, after all, is conception.[9] Sperm and egg fuse, and an embryo is formed. This is not so for a clone. An egg whose nucleus has been removed is starved, then fused with DNA from, for example, a human skin cell. The result is that the egg, in some cases, begins to behave much like an embryo. In the best of cases, that of the cloned mice from Hawaii, successful pregnancies of such embryo-like things result in only about 4% of all attempts. This is, or we believe it to be, much less frequent than pregnancy rates for mice (or humans) attempting to have offspring through sex, though about the same as the rate of pregnancy from human sexual intercourse more generally. Put another way, a cloned mammalian embryo appears to be less viable than a non-cloned embryo. What does it take to call the creature an embryo? Must there be fusion of egg and sperm? Must there be marked potential for gestation? Further, what is the bar for such a creature to count as a restoration of fertility, or as a therapy for infertility?

This last question is the most vexing part of the biological dimension of cloning. The felt need to parent is undeniable in our society, and more than $1 billion is spent annually on the pursuit of biological parenthood through infertility medications and procedures. At one level, we need to know what sort of role individuals should be able to play in designing children; how far under the hood they should be allowed to go by our institutions. There surely are some negative rights against governmental interference in procreative activity (Robertson 1994), and these perhaps include some right to experiment with technologies like cloning (Robertson 1998). But more problematic is what it means to provide care for those who have a need to parent. Elsewhere I have noted that it is a common mistake to assume that it is species-typical for human beings to have children that carry our own genes or are biologically similar to us (McGee & McGee 1998).[10] Thus, while it is fairly easy to establish that infertility includes an inability to contribute gametes or gestation to a child's birth, sequela to some organic dysfunction, the rub is that one cannot always cure the organic dysfunction itself. The therapy for infertility is often a technology aimed at providing as many children as are desired by some parent or parents.[11] But is infertility cured by providing this therapy? Would adoption cure the condition of infertility as well? Does cloning present a cure? It seems clear that the answer requires us to turn to the way that the needs of biology as regards reproduction manifest themselves in our individual and cultural habits.

"The data are fairly clear that tomorrow's children will not be raised in the world of birds and bees. Perhaps the most common model for parenthood in our time is that of the ants and termites, who live in large groups with distributed parental roles."

Culture and Cloning

I was raised in the 1970s with a story about what it meant to be a child. The idea was that parents loved each other, got married, made love, and babies resulted. Parents loved each other so much that they raised those children as their own, and made sure that they could handle the responsibilities of parenting, marriage, and career by organizing life in such a way that only one of the parents would work, while the other raised the children. It is the story of the birds and the bees. Birds and bees, of course, do not live that way. But the story has powerful resonance for many Americans, representing what has taken on the name "traditional family values" in political discourse, despite the fact that such families are increasingly rare. It is a story that links sex, reproduction and family in strict terms. While our technologies for making children have changed quite a bit, most aim at, and are measured against, the story of birds and bees (McGee & Wilmut, 1998). In divorce and adoption, for example, the model of the birds and the bees is used by jurists to measure degrees of variation from the norm, and to aim at restoration of it (ibid).

The data are fairly clear that tomorrow's children will not be raised in the world of birds and bees. Perhaps the most common model for parenthood in our time is that of the ants and termites, who live in large groups with distributed parental roles. We live in a culture in which children are frequently raised by some combination of non-genetic parents, or by those who are not parents at all. More than 40% of those born after 1998, we now believe, will have more than one mother or father by age 18. The majority of American children

are effectively raised in day care, while all three or four of their parents pursue careers. Many in our society have long believed that a critical role one can play in the life of a child is that of godparent, or coach, or foster parent, and many families in many ethnicities have well articulated roles for these mentors.

New technologies will necessitate new stories. Octuplets and septuplets will be the first in our species to hear a story of the dogs and the cats, about being part of a litter. We need a story for a child whose entire first grade class, and soccer team, is comprised of siblings. Children of post-menopausal pregnancy will need a new story more fitting than that of "the accidental" late-born child of yesterday. Children of sperm and egg donors will need a story. While today most parents do not tell their children of the presence of donor DNA, eventually it will not be optional. Perhaps these children will be told a story about the racehorse, bred from chosen samples of stud sperm. Lions represent a story for children who are gestated by one woman, with an egg from another and DNA from a third. As transgenic egg donation from monkeys or cows finds its way into human reproduction, stories for that technology too will be needed.

But what story can one tell a clone? Already we have noted that human cloning is unprecedented in the natural history of mammals. Twins are the closest existing phenomenon, and they are separated by at most a few years. The stories of parental roles in cloning in the media are frightening in almost all cases. One has parents replicating a child who has died early due to an accident. Another has an infertile woman seeking a genetic link to her recently deceased husband through a clone from a tissue sample she happens to have lying around. Still a third has the parent raising a clone of his wife to realize his dream of seeing his wife as a child. The point of discussing children's stories is two-fold. First, it is clear that whatever progress we make in infertility technologies, an important part of realizing the potential of such technology to satisfy the felt needs of adults is an account of what the technology will mean for the child. More, such family relationships are heavily textured by their social and institutional histories. Being tolerant of new kinds of family will have to begin with existing technologies and move out slowly and experimentally toward the margins.

Second, our children's stories—and the lack thereof—evidence the cultural manifestations of methods of satisfying parents' demands for children. The predominance of the story of birds and bees is symptomatic of our cultural and institutional commitments to genetic determinism, which in this case means our social faith that what matters about blood relation and about relatedness itself, is programmed in, and received through, the genes of parents. People get married, make babies, and raise them in ways that seem normal to us because of our history, the habits passed down through the last three or four generations of western families. It is only recently that we could consider the possibility of lesbian or gay reproduction, or ponder the relative value of different kinds of offspring or relatedness. So our efforts to squeeze every case into a standard of deviation from the normal model of birds and bees is merely a kind of collective dissonance with forming new habits about such an intimate matter. Moreover, we struggle in our new technologies to restore the apparent equilibrium of the "classical" family; work to find technologies that give us as much of the birds and bees as is possible. This is one reason why, for example, most couples will use sperm injection rather than donor sperm. It is simply assumed that it is better, more normal to have a child that shares more identity with me. Thinking about and emphasizing the role of children's stories helps to bring these two issues into focus.

Our habits in making our own families are only part of the culture of reproduction. Parenthood is for some purposes at the luxury of the community, and it is more than idle platonic fantasy that children are raised by the state. We have already noted that economics, politics and theology play roles in how infertility is understood and treated. The family is also only one among many institutions that raises children. In fact, when parents fail in a variety of tasks (from immunization to feeding to education), they can lose their parental rights, to be restored only at the discretion of representatives of our democracy. The upstream manifestation of this public concern for the welfare of children is manifest when, for example, it is argued that children in general ought not be born clones, or that research to clone humans is of a comparatively low priority in the existing array of choices for research spending. Even editors of scientific journals and newspapers have a choice about what they will send out for review and in what way they will publish findings about cloning. The goal of examining culture is to square the variety of contexts within which a tool comes to be with the ends it is actually capable of achieving. Dewey calls this the placing of means and ends in strict conjunction, and points to the continuum between means and ends for the purpose of seeing our social methods solve social problems.

Common Sense and Cloning

Common sense is the most misunderstood element of pragmatism. The goal of pragmatism is not to skip the difficult questions and move on to progress. As is already apparent, in the present case pragmatism unpacks the meaning of satisfying the complex and situated demands of a variety of people within a social context. More though, pragmatism shows that ethical evaluation of social problems requires that we take seriously the challenges of science to social thought, and in this respect cloning is clearly a paradigm case. Cloning does not uniquely challenge what it is to make a child, but it has called attention to the vast array of new technologies that make new kinds of families whose parameters and relationships are neither pre-given nor socially sanctioned. It is insufficient to ask, as do most critics of cloning, whether a child of cloning would be deprived of a right to individuality (McGee & Wilmut 1998). No child has an open future, and even our cursory examination of the changing history of parenthood makes clear that it is not individuality but rather correct forms of responsible relation that are our goal.[12]

I have not addressed, in this article, the tough or exceptional cases. Richard Seed wants to make clones. Greg Pence suggests the viability of cloning dead scientists. A Korean clinic may soon make the "first" clone. The tough cases are interesting, and many will ask whether Seed should be stopped or Korea sanctioned. But the pragmatic question is more important: what institutions and arenas are right for situating the debate about human cloning and its ken? Elsewhere I have argued that the adoption procedure is a metaphor for what is possible: regional, localized evaluation of candidates for new procedures, accompanied by education and tolerance of new kinds of families and reproduction (ibid). But other and more experimental methods too may be called for. The claim of this article is that a Deweyan, pragmatic approach to cloning demonstrates the need to reconstruct the entire enterprise of making children in the 21st century as a backdrop for debate about human cloning. Once this is accomplished, we can move beyond exceptional approaches to general problems and develop new institutional and personal habits for making and supporting families in the 21st century.

Endnotes

1. His first son, Richard Seed Jr., had been "lost to him" in a divorce, Seed commented in a public debate (against me) at Northwestern University in 1998. Cloning would make it possible to make more of Richard, and his post-menopausal wife would play Sara to these children.
2. A LEXIS/NEXIS search of newspaper and major television and magazine stories in 1997 containing both the words "clone" and "philosopher" revealed more than 4,500 individual citations, 65% of which occured in March of that year.
3. In this essay I will not explicate the arguments made by classical or contemporary scholars of pragmatism that bear on bioethics, nor will I be starting up some kind of pragmatic machine to solve the problem of cloning. Elsewhere I point out, following a host of others (Hickman, Lachs, McDermott, Moreno), that pragmatism is not "applied" in the ordinary sense of application of acontextual or generic principles to problems (McGee 1994, 1997, 1998b), and that pragmatism neither respects an absolute distinction between facts and values nor posits a need for universal moral norms (McGee, 1998a). I hope that I will be excused too, for failing to give a full account of pragmatic bioethics' history and scope, as my purpose here is only to demonstrate the way in which a Deweyan reflection on cloning manifests itself. It should be noted, as it has elsewhere by other scholars, that contemporary scholars of pragmatism, such as John Lachs, Richard Rorty, Cornell West and others have written about social and medical problems and that each has emphasized different ingredients of the idea of pragmatism. However, each and all of these scholars depend fundamentally on Dewey and James to the extent that they embrace methodical pragmatism. It would be totally insufficient to describe pragmatism without reference to the fundamental work of those two scholars, as I noted elsewhere (McGee 1998f).
4. The argument regarding future generations receives a fuller treatment in my recent essay with Ian Wilmut, "Cloning and the Adoption Model" (McGee G. and Wilmut I. 1998).
5. How one defines a cellular clone is a matter of simple scientific necessity. One must understand the meaning of moving DNA from cell to cell, or species to species, in order to control analysis of conditions and outcomes in the millions of experiments that are conducted in that vein every year.
6. It is impossible even to establish the genetic similarity of Dolly to its progenitor beyond checking a few patches of genetic code in a few cells. Dolly's status as a clone was confirmed in 1998 by analysis of restriction fragment length polymorphisms in Dolly and its dead progenitor ewe. However, the full sheep genome has not yet been sequenced and it is not yet possible to compare the complete genetic information in any two sheep cells. Moreover, Dolly is markedly morphologically different from its progenitor ewe, some 20% larger by Wilmut's own calculations. All this goes to the point that while it is possible to draw inference from our method and the morphological outcome of cloning, it is not possible to confirm what a clone "is" using scientific measurement. This is ironic given how easy it is to make a clone, and emblematic of the degree to which our ability to engineer outstrips our ability to measure the outcome.
7. When two mothers each give part of an egg, are both mothers? If surrogate mothers do not donate DNA, are they mothers? If a couple divorces, what role does each divorcee have in determining the use of frozen embryos they have previously made? If a man dies, can he be a posthumous father? These and more difficult cases have led jurists and legislators to create exceptional new laws about genetic relatedness (McGee 1998d).
8. This, too, is a need we might now use technologies to fulfill, independent of our desire to reproduce.
9. True, a monozygotic twin breaks away from the original conceptus. But the time between the formation of a zygote and the culling away of a twin is so slight as to imply the strong role of fertilization in the twin's origin as well.

10. Toennies noted as early as 1957 that the desire to have sameness in our children is a function of political assumptions about what children are for, rather than some sort of normal human phenomenon. Sociobiologists ignore both the myriad similar species whose members do not all have genetic children, and the extensive evidence that the human choice to reproduce is as much informed by cultural and political drift as anything else.
11. Perhaps octuplets.
12. *See*, for example, Dena Davis, 1997.

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Three Stubborn Misconceptions About the Authority of Health Care Agents

By Kathleen M. Burke, Alice Herb and Robert N. Swidler

New York's Health Care Proxy Law empowers an adult to appoint a health care agent to make treatment decisions for the adult in the event the adult loses the capacity to make such decisions personally.[1] Health care providers and the public now have nearly 15 years' experience with the law, and it appears that the law been very successful, in most respects. The process to create a health care proxy has proven to be simple and easy to accomplish, and largely free of technical requirements that can confuse the public or invalidate the document. Clinical staff members are generally pleased and relieved when patients or family members produce health care proxies, because they clarify both who has decision-making authority and the scope of that person's authority. Finally, there appear to have been very few examples of abuse or misuse in connection with the creation or use of health care proxies.

To be sure, problems occasionally arise relating to the use of health care proxies. Probably the most common problems stem from three misconceptions relating to the authority of health care agents. It is the purpose of this article to refute these three stubborn misconceptions:

> **Misconception 1:** *A health care agent cannot have access to protected health information unless the patient signed a HIPAA-compliant authorization*.—This is wrong.
>
> **Misconception 2**: *A health care agent can consent to the withdrawal or withholding of artificial nutrition and hydration from a patient only if the patient authorized such decision on the proxy form, or left other clear and convincing evidence that he or she would want artificial nutrition and hydration withdrawn or withheld.*—This is wrong.
>
> **Misconception 3**. *A health care agent can override a patient's prior instructions to health care professionals, or a patient's advance directive*.—This is wrong.

1. Unnecessary Evil—Adding a HIPAA Authorization to a Health Care Proxy

The first stubborn misconception is the notion that a HIPAA authorization needs to be added to a health care proxy in order to assure that patient's agent will have access to hospital or physician records.[2] This language, if inserted into the proxy itself, could very well be damaging to the interests of both those who have executed proxies and those who plan to do so.

What can be harmful about adding a simple paragraph about HIPAA to a health care proxy? Briefly stated: At best, the authorization is redundant. At worst, it can potentially delay, if not thwart, implementation of the wishes of the patient and also cause confusion about the validity of other proxies that do not contain HIPAA language. In any event, as explained below, the agent has ample authority to access protected health information without a HIPAA authorization.

The Agent's Authority to Access Information Under the Health Care Proxy Law

Both the New York State Health Care Proxy (HCP) law and federal HIPAA privacy regulations were developed for similar reasons: to protect patients and enhance the exercise of their control—in one instance about medical treatment decisions, in the other about the privacy of their personal health information. Examining the HCP law first, the most striking feature of the statute is its simplicity and clarity. It provides that a person may designate another to make decisions on his or her behalf when and if he or she is unable to do so. The document requirements are few, and the principal (the individual who creates a HCP) may add additional directions to his or her agent if desired. By statute, the agent must have access to all necessary information in order to make an informed decision for the principal. Indeed, Section 2982 of the proxy law, under "Rights and duties of agent," explicitly states:

> 3. Notwithstanding any law to the contrary, the agent shall have the right to receive medical information and medical and clinical records necessary to make informed decisions regarding the principal's health care.[3]

The NYS Department of Health (DOH) provides online a simple HCP form, understandable instructions and commonly asked questions and answers about the statute and the process.[4] In answer to a FAQ, the DOH states:

> All hospitals, nursing homes, doctors and other health care providers are legally required to provide your health care agent with the same information that would be provided to you and to honor

> the decisions by your agent as if they were made by you. . . ."[5]

Moreover, the DOH model HCP form has not been changed to reference the HIPAA regulations even though it has been modified more than once since the promulgation of those regulations. DOH's omission of any HIPAA language in the suggested form—or even in the FAQs material—underscores that in DOH's view no HIPAA language is needed for the agent to have full access.

The Agent's Authority to Access Information Under HIPAA

Although the HCP law does not reference HIPAA privacy regulations, those regulations specifically require the "covered entity" (i.e., the provider) to give the principal access to medical information. Moreover, the regulations go on to mandate that the "personal representative" be treated as if he or she were the individual.[6] With respect to adults and emancipated minors who lack capacity, HIPAA regulations define "personal representative" as follows:

> (2) Implementation specification: adults and emancipated minors. If under applicable law a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.[7]

Accordingly, for purposes of HIPAA an agent is the patient's personal representative.

Furthermore, the Department of Health and Human Services deals directly with this issue in its FAQs. Answers to questions 30 and 95[8] clearly state that the HIPAA Privacy Rule does not affect the way health care representatives are designated nor prevents their access to medical records.[9] In other words, there is no limitation on the authority of the agent other than that specified by the principal. The agent is authorized to obtain all medical information about the principal. The agent "stands in the shoes" of the principal and has authority to make decisions and access all information.

Mougiannis: HIPAA Authorization Unnecessary

In re Mougiannis v. North Shore-Long Island Jewish Health Systems, Inc.[10] is the the only relevant New York State precedent. The court held that HIPAA authorization is *not* necessary to enable a health care agent to have access to the principal's medical information, Judge LaMarca rested his decision on Section 2982(3) stating: ". . . §2982(3) makes the right of a health care agent to medical information clear." The court concluded that the "health care proxy, is deemed a 'qualified person' for the purpose of rquesting access to the subject's health care information."

Proxies with HIPAA Authorizations—An Unnecessary Evil

Since both HIPAA and the HCP law are quite specific about the rights of an agent to access all medical information, the question that remains unanswered is the original one, i.e., how can adding HIPAA authorization language harm the client? But the more appropriate question would be why would attorneys want to append additional language—language that is at once superfluous and can inadvertently sabotage and complicate the process? It should be remembered that HCPs are documents read by non-lawyers—physicians, nurses, etc.—people for whom the familiar form allows them to quickly identify the agent and spot any optional directions. Unnecessary language can confuse, delay or deny the exercise of the principal's rights.[11] Also, what if a change in HIPAA law, regulation or practice affects the acceptable wording of a patient's consent? A HIPAA release form is typically prepared at the time of a patient's visit or hospitalization and, thus, is presumably current with the law. However, an HCP is often prepared years ahead of the time when the principal's illness and incapacity requires its implementation.

The simplicity of the DOH HCP form reflects a compelling public policy goal: to make it easy for anyone, even someone in distress, to execute an HCP, so that in the event of incapacity an authorized agent would be available to make decisions. In fact, the instructions even say that an attorney is not needed. Attempting to "improve" on the form, therefore, is unnecessarily complicating, not protective of the principal. Indeed, it could harm the principal—and defeat the very purpose of the document. If the attorney's rationale for including an authorization is a concern that an uninformed clerk in a record room or in an otherwise non-clinical setting can deny access, pandering to such ignorance only compounds the problem and encourages it. It would be far better to demonstrate with DOH model forms in hand that the agent is entitled to such records and report the refusal to supervisory staff. Attorneys have the obligation to correct a misconception rather than perpetuate it.

For the larger community, it would behoove attorneys to be aware that grafting unnecessary HIPAA language on to an HCP form could lead those unfamiliar with the law

and regulatory interpretation to reject a valid HCP as illegal. Attorneys must avoid creating proxies that become a source of confusion or misinterpretation. Professional ethics demands this.

2. Health Care Agent Decisions Regarding Artificial Nutrition and Hydration

Another stubborn misconception that repeatedly needs to be refuted is the view that a health care agent can consent to the withdrawal or withholding of nutrition and hydration only if the patient provided written authorization for such decision on the proxy form, or if there is clear and convincing evidence that the patient would want artificial nutrition and hydration withdrawn or withheld. This view is inconsistent with the language of the statute, with its legislative history, and with official interpretive guidelines.

The Language of the Statute. PHL § 2982 governs the rights and duties of health care agents. It begins by providing that the agent has the authority to make any decision the principal could make, subject to any express limitations in the health care proxy. It then sets forth the following decision-making standard for agents:

> 2. Decision-making standard. . . . the agent shall make health care decisions: (a) in accordance with the principal's wishes, including the principal's religious and moral beliefs; or (b) if the principal's wishes are not reasonably known and cannot with reasonable diligence be ascertained, in accordance with the principal's best interests; *provided, however, that if the principal's wishes regarding the administration of artificial nutrition and hydration are not reasonably known and cannot with reasonable diligence be ascertained, the agent shall not have the authority to make decisions regarding these measures.*

Elsewhere, the statute sets forth a model health care proxy form which may be used, but is not mandatory. The model form carries this statement:

> NOTE: . . . Unless your agent knows your wishes about artificial nutrition and hydration, your agent will not have the authority to decide about artificial nutrition and hydration. If you choose to state instructions, wishes or limits, please do so below: . . .[12]

Obviously, the statute singles out decisions about artificial nutrition and hydration, and imposes a special restriction on agents with respect to such decisions, i.e.: the agent cannot direct the withdrawal of artificial nutrition and hydration if the principal's wishes "are not reasonably known and cannot with reasonable diligence be ascertained." In other words, the agent cannot base a decision to withdraw artificial nutrition and hydration on the agent's assessment of the principal's best interests. But the agent can make the decision if it is based on patient's wishes that are "reasonably known" or that can "with reasonable diligence be ascertained."

Nothing in the Health Care Proxy Law states that the principal's wishes about artificial nutrition and hydration must be written on the proxy form. The above-mentioned notice in the model form regarding artificial nutrition and hydration is an accurate and helpful statement of the requirement that such wishes must be reasonably known. It is not a cryptic way of warning persons that they must fill in the blank or they will disempower their agent.

Nor does anything in the statute state that there must be "clear and convincing evidence" of the principal's wishes in order for an agent to make a decision about artificial nutrition and hydration. On the contrary, the statute explicitly imposes a lesser evidentiary standard: the principal's wishes need only be "reasonably known" or be ascertainable "with reasonable diligence." The notion that a clear and convincing evidence standard applies to agent decisions about artificial nutrition and hydration presumably is drawn from the Court of Appeals decisions, *In re Storar,*[13] and *In re Westchester County Medical Center [O'Connor].*[14] In those cases, the court held that life-sustaining treatment can be withdrawn or withheld from patients who lack capacity only if there is clear and convincing evidence that the patient would want the treatment withdrawn or withheld under the circumstances. Indeed, that principle still applies, except where, and to the extent the legislature has supplanted it with a different standard—as it did in the Health Care Proxy Law.

Thus, if the Health Care Proxy Law had simply provided that health care agents do not have authority to make decisions about artificial nutrition and hydration, then the *Storar/O'Connor* clear and convincing evidence standard would apply to such decisions. But the Health Care Proxy Law did not do that. Rather, it provided: (1) that agents have the authority to make any decision the principal could make—including decisions about artificial nutrition and hydration; (2) that in general, health care decisions by an agent must be based on the principal's reasonably known or ascertainable wishes or, absent such wishes, on the principal's best interest; but (3) that decisions to withdraw artificial nutrition and hydration can be made by an agent only if based on the principal's reasonably known or ascertainable wishes.

The Legislative History

It should not be necessary to review the legislative history of the Health Care Proxy Law's decision-making standard; its meaning is clear from its plain language. In any event, the legislative history firmly supports the authority of an agent to make decisions about artificial nutrition and hydration based on the patient's wishes, without the need for authorization in the form, and without clear and convincing evidence.

The Health Care Proxy Law is based on a 1987 proposal by the New York State Task Force on Life and the Law.[15] The Task Force's proposal, and the initial governor's program bill based on the proposal, included a decision-making standard for agents that did not single out decisions about artificial nutrition and hydration for special treatment.[16]

However, the Senate was reluctant to pass the bill unless it was revised to address concerns identified by the NYS Catholic Conference, an influential advocacy organization. The Conference, then represented by its Executive Director J. Alan Davitt, expressed general reservations about empowering agents to authorize the withdrawal of artificial nutrition. But the Conference was particularly critical of the notion that the withdrawal of artificial nutrition and hydration could ever be in a patient's "best interests." Discussions toward the end-of-session in 1990 between officials from the governor's office, the NYS Health Department and the Conference led to a proposed compromise: to eliminate the authority of agents to base such decisions on the patient's best interests. That compromise proposal did not include any amendment to the evidentiary standard applicable to decisions based on patient wishes; the general "reasonably known" standard would remain applicable to all such decisions.[17]

The Senate and Assembly sponsors made the proposed change, and reintroduced the bill. On July 22, 1990, the legislature passed the bill. The governor's approval message addressed the artificial nutrition and hydration decision-making standard, stating as follows:

> Special safeguards apply to decisions about artificial nutrition and hydration: A health care agent can decide against the provision of such measures only when the decision reflects the patient's reasonably known wishes.[18]

The Health Care Proxy Law became effective January 18, 1991.

Post-Enactment Guidelines

Official guidelines and other authoritative materials confirm that an agent does not need written instructions on the proxy form, or other clear and convincing evidence of a patient's wishes in order to direct the withdrawal of artificial nutrition and hydration.

- ***The Health Care Proxy Form and Instructions:***[19] The NYS Department of Health Web site carries a model health care proxy form and instructions that provides this information about the decisions relating to nutrition and hydration:

  > **About the Health Care Proxy Form**: . . . Unless your agent *reasonably knows* your wishes about artificial nutrition and hydration (nourishment and water provided by a feeding tube or intravenous line) he or she will not be allowed to refuse or consent to those measures for you . . . [20]
  >
  > **Frequently Asked Questions** . . . What decision can my agent make? . . . [Y]our agent can only make decisions about artificial nutrition and hydration (nourishment and water provided by feeding tube or intravenous line) if he or she *knows your wishes from what you have said or what you have written* . . .[21]
  >
  > **Health Care Proxy**: . . . In order for your agent to make health care decisions for you about artificial nutrition and hydration (nourishment and water provided by feeding tube or intravenous line), your agent must *reasonably know* your wishes. You can either tell your agent what your wishes are or include them in this section. See instructions for sample language that you could use if you choose to include your wishes on this form, including your wishes about artificial nutrition and hydration.[22]

- ***The Health Care Proxy Law: A Guideline For Professionals*** (January 1991)—This is a guidebook prepared by the New York State Department of Health and the New York State Task Force on Life and the Law, in consultation with various health care organizations. It provides these two relevant Q & A's:

  > Q: Must the agent have "clear and convincing evidence" of the patient's wishes in order to consent to withdraw or withhold life-sustaining treatment?
  >
  > A: No. Reasonable knowledge of the patient's wishes is sufficient. In addition, if no such evidence is available, the agent can consent to forgo life-sustaining treatment if he or she makes a good faith judgment that forgoing treatment is in the patient's best interests, except for a decision about artificial nutrition and hydration. To decide about artificial

nutrition and hydration, the agent must have reasonable knowledge of the patient's wishes.

Q: Must evidence of the patient's wishes about artificial nutrition and hydration be written on the proxy form?

A: No. There is no requirement that this evidence be written on the proxy form or elsewhere. The agent's knowledge can be based on prior oral statements by the patient and knowledge of the patient's religious, moral and personal belief about health care.[23]

- ***Miller Analysis.*** Shortly after the law's enactment, Tracy E. Miller, who was Executive Director of the Task Force on Life and the Law and was closely involved in both the law's development and enactment, wrote a comprehensive analysis of the law for the *New York Law Journal*.[24] She explained:

> An agent can only decide about artificial nutrition and hydration based on knowledge of the patient's wishes. Clear and convincing evidence is not required; the law expressly displaces that standard by allowing decisions based on reasonable knowledge of the patient's wishes. The patient's wishes about artificial nutrition and hydration may, but need not, be set forth in writing.

Relevant Case Law

There appears to be only one lower court decision that specifically addresses the evidentiary standard for an agent's decision to withdraw artificial nutrition and hydration. In *Berenstein v. Simonson*,[25] the daughter and health care agent of an 86-year-old woman with advanced heart disease and advanced Alzheimer's Disease, directed hospital staff not to surgically insert a feeding tube into her mother's stomach. The patient's sister petitioned the court to override the daughter/health care agent's decision, alleging that the daughter's decision was contrary to her mother's orthodox Jewish beliefs. After an emergency hearing, the court granted the petition. On the evidentiary point, it stated:

> Mrs. Kahan left no written instructions in said Health Care Proxy regarding the administration of artificial nutrition and hydration, and it is conceded that her wishes in that regard are not reasonably known and cannot with reasonable diligence be ascertained. There is surely no "clear and convincing" evidence on this specific issue. (see *In the Matter of Westchester County Med.Center [O'Connor], supra*). Under these circumstances, the Court finds that, pursuant to Public Health Law Section 2982(2)(b), respondent Joan Simonson, is without authority to make decisions about artificial nutrition and hydration for her mother, Lee Kahan.

The decision is troubling in a number of respects. Once the court found that the patient's wishes were not reasonably known and could not with reasonable diligence be ascertained, that finding provided a legally sufficient basis to cancel the agent's decision. Unfortunately, the court contributed to confusion about the applicable standard by referring to the absence of a writing and, especially, by alluding to the absence of clear and convincing evidence of the patient's wishes. Certainly attorneys should not conclude from the lower court's dicta and superfluous findings that an agent's decision regarding nutrition and hydration requires a writing or clear and convincing evidence.[26]

3. The Authority of Agents to Override the Decisions of Principals

The third misconception is that a health care agent can override a principal's prior instructions to health care professionals, or a principal's advance directive. An agent cannot do so.

N.Y. PHL § 2982 (Rights and duties of agent) gives the agent the authority to make "any and all health care decisions on the principal's behalf that the principal could make." However, it immediately thereafter provides that:

> [T]he agent shall make health care decisions . . . in accordance with the principal's wishes, including the principal's religious and moral beliefs.[26]

This provision reflects the core purpose of creating a health care proxy: to extend patient autonomy beyond the loss of decision-making capacity. Health care agents are appointed to advance the wishes and values of the patient; not to disregard them and substitute their own wishes and values.

Accordingly, in a situation where the principal, prior to losing capacity issued explicit instructions regarding a treatment decision, and there are no exceptional factors (such as those discussed further below) the agent who seeks to override the principal's decision is violating the law's decision-making standard.

Moreover, Section 2989.2 confirms that the principal's prior decision is paramount:

> 2989.2. Nothing in this article creates, expands, diminishes, impairs or supersedes any authority that a principal may have under law to make or express decisions, wishes or instructions regarding health care, including decisions about life-sustaining treatment, whether or not expressed in a health care proxy.

The clause confirms that a patient who, while competent, issued unequivocal instructions regarding treatment has already provided legally sufficient consent to the provision or to the withdrawal/withholding of treatment. Under such circumstances, there is no need, from a purely legal standpoint, to seek a redundant second decision from the health care agent.

Of course, medical staff routinely and understandably consult with, and even seek consent from health care agents, even when the staff may already possess the patient's specific prior decision. That practice is respectful, considerate, and usually advisable from a risk management and customer service perspective. But the fact is, a definitive prior decision by the patient is a sufficient legal basis for staff to act.

Accordingly, where the patient has made an unequivocal prior decision, it is not legally necessary to seek the agent's subsequent, redundant decision. But if it is sought, or if the agent unilaterally makes such treatment decision, the agent is required by law to make the decision that reflects the principal's wishes, namely, the prior decision.

For example, consider a hospital patient with decisional capacity who firmly tells his physician, "I do not want any more dialysis, even if it means I will die." If and when the patient loses capacity, the agent will acquire the authority to make decisions for the patient. Even so, the hospital need not seek a decision by the agent regarding withholding dialysis—it already has the patient's instructions, and absent exceptional circumstances, the hospital is bound to honor those instructions. But in the event the hospital did seek a decision from the agent regarding dialysis, or in the event the agent asserted a decision-making role, the agent would be obligated to make such decision "in accordance with the principal's wishes, including the principal's religious and moral beliefs." In this example, that would necessarily mean a decision to withhold dialysis.

A similar analysis applies where the principal left an unequivocal written advance directive, e.g., "in the event I lose decisional capacity and my physician determines that there is no reasonable hope that I will recover it, I direct that my physician discontinue my dialysis treatments, even if it means I will die." Later, if the patient loses capacity and the physician makes the required determination, the hospital does not need to seek the agent's decision to discontinue dialysis. If it did seek a decision, the agent would be obligated to consent to discontinuing dialysis.

A variety of exceptional circumstances would change this analysis. For example, the physician and hospital might accept an agent's decision that was contrary to the patient's prior instructions if there was evidence that:

- the patient never actually made the statement, or wrote the document, that he or she was alleged to have stated or written;
- the patient lacked capacity at the time he or she gave the prior instructions;
- the patient's instructions were vague or ambiguous;
- the patient's instructions were made so long ago, or under such different circumstances, as to call into question their currency or applicability;
- the patient issued subsequent instructions that superseded the earlier instructions; or
- the patient subsequently revoked his or her prior instructions.

If a health care agent alleges any of the foregoing exceptional circumstances, the hospital would need to examine such allegations carefully and see if they provide a basis to set aside the patient's instructions, or to refer the matter to court. The provider should not allow a health care agent to override a patient's firm, clear decision based on allegations that are patently pretext or fabricated.

In instances where it is clear that the agent is violating his or her obligation to speak for the patient, the hospital and physician still face a complex question of legal procedure with significant ethical overtones: can the provider simply disregard the agent's *ultra vires* decision and carry out the patient's decision—leaving it to the agent to go to court for injunctive relief if he or she feels so motivated? Or must the provider bear the burden of seeking a court decision before defying the agent?

The Health Care Proxy Law has three provisions that are pertinent here. Section 2984 Provider Obligations, subsection 2, provides that:

> A health care provider shall comply with health care decisions made by an agent in good faith under a health care proxy to the same extent as if such decisions had been made by the principal, subject to any limitations in the health care proxy

> and pursuant to the provisions of [§ 2983.5].[28]

Section 2986—Immunity provides that:

> No health care provider or employee thereof shall be subjected to criminal or civil liability, or be deemed to have engaged in unprofessional conduct, for honoring in good faith a health care decision by an agent, or for other actions taken in good faith pursuant to this article.

Finally, section 2992 authorizes the provider or others to commence a special court proceeding to, among other issues:

> override the agent's decision about health care treatment on the grounds that (a) the decision was made in bad faith or (b) the decision is not in accordance with the standards set forth in [PHL § 2982—the decision-making standard].

Viewed together, these provisions indicate that a provider, faced with a decision by an agent that is contrary to a patient's decision, could commence a special proceeding to override the decision, and abide by whatever the court decides.[29] But that is an option, not a mandate.

On the other hand, it is less clear that the provider could simply comply with the agent's decision pursuant to section 2984 and still expect the immunity under section 2986. The provider's duty and immunity only extend to complying with decisions made by the agent "in good faith." If the provider knows that the agent is violating the decision-making standard, and informs the agent regarding his or her obligations, there is a strong case that the agent's insistence upon a decision in defiance of the standard is not a decision made by the agent "in good faith."

A third option for the provider is to inform the agent that it intends to carry out the patient's decision, and leave it to the agent to commence a proceeding if the agent so wishes. The provider who takes this course assumes some risk that a court or regulator will find that it has violated the provider's obligation to comply with an agent's decision under section 2984. In a case where it is clear that the provider is disregarding the agent's decision in order to give effect to the patient's paramount decision, the provider should avoid civil or regulatory liability. In fact, it should even be able to avail itself of immunity under section 2986, which gives it immunity for "actions taken in good faith pursuant to this article."

Of course, shifting the burden of commencing a court proceeding to the agent could impose a substantial hardship on the agent—the party that is probably less able to bear that burden, both from a cost and knowledge/experience standpoint. Moreover, in a situation where the provider intends to carry out the patient's wish to withdraw or withhold treatment, its action may be irrevocable before the agent can place the matter before the court.

Accordingly, providers faced with an agent who is seeking to override a patient's unequivocal prior decision must consider various factors in deciding whether to commence a proceeding or simply disregard the agent and implement the patient's decision. On one end of the spectrum is the case where the patient's decision was recent, absolutely clear and unequivocal, and reasonable under the circumstances; where the agent's rationale for overriding the patient's decision is basically "because I say so"; and where the agent will have sufficient time to seek a court order to restrain the provider's action if he or she decides to do so (for example, where a feeding tube is withdrawn). In such case, the provider should feel secure in notifying the agent that it intends to disregard his or her decision and carry out the patient's decision.

However, as those elements weaken—e.g., in a case where the patient's decision is less recent or clear; where the agent's rationale is more plausible ("Dad told me he changed his mind"); and where the provider's action might become irrevocable before the agent could contest it (for example, where mechanical ventilation is discontinued)—it becomes more advisable and prudent for the provider to commence the court proceeding.

Another article in this edition addresses other legal, clinical, and institutional concerns that arise when family members attempt to override the clear decisions of patients.[30]

Endnotes

1. N.Y. Public Health Law (PHL) Article 29-C, L.1990, Ch. 752. Under the statute, the term "health care proxy" refers to the document; the term "health care agent" refers to the person appointed. PHL § 2980.5, § 2980.9.
2. HIPAA privacy regulations provide, in general, that covered entities may not use or disclose protected health information except (i) to the individual or the individual's personal representative; (ii) for treatment, payment and health care operations purposes; (iii) to others, pursuant to a HIPAA-compliant authorization from the individual; or (iv) for other limited and specified purposes. 45 CFR § 164.502(a).
3. PHL § 2982.3.
4. NYS Department of Health, *Health Care Proxy: Appointing Your Health Care Agent in New York State* (2005), *available at* http://www.health.state.ny.us/nysdoh/hospital/healthcareproxy/1430.pdf.

5. *Id.* (emphasis added).
6. 45 C.F.R. § 164.502(g)(1).
7. *Id.*, § 502(g)(2).
8. http://healthprivacy.answers.hhs.gov/cgi-bin/hipaa.cfg/php/enduser/prnt_adp.php?p_faqid=220&p_created =1040315553&p_sid=-n4ZuaLh
9. *See* 45 CFR § 164.524. HIPAA provides for two exceptions to treating a "personal representative" as the "individual." Neither is relevant to the typical proxy situation. One involves unemancipated minors (45 CFR 164.502(3)(i)) and the other involves suspicion that the person claiming to be the personal representative is responsible for domestic violence, abuse or neglect of the individual and treating him or her as such would endanger the individual. (45 CFR 164.502(5)).
10. N.Y.L.J., Volume 231, May 19, 2004 (LaMarca, J.).
11. Another article in this edition, and one in a recent edition, of the *NYSBA Health Law Journal* further discuss how clinical staff are susceptible to "HIPAA scare," and become anxious about disclosing information even in permissible situations. See C. Levine, *Family Caregivers Out in the Cold: HIPAA's Chilling Effect on Communication*, NYSBA Health Law J., 10(3):71-74 (Summer/Fall 2005); R. Senska, *Mitigating the 'HIPAA Scare': A closer look at provider disclosures to patient representatives under the Health Portability and Accountability Act (HIPAA)*, NYSBA Health Law J., 10(1):38-47 (Spring 2004).
12. PHL § 29815(d).
13. 52 N.Y.2d 363 (1981).
14. 72 N.Y.2d 517 (1986).
15. *NYS Task Force on Life and the Law, Life-Sustaining Treatment: Making Decisions and Appointing a Health Care Agent* (July 1987). Task Force reports are available from the NYS Department of Health, *available at* http://www.health.state.ny.us/nysdoh/taskfce/inforpts.htm.
16. *Id.*; S.6967 (1988), A.8955 (1988).
17. One of the authors, Robert N. Swidler, was Assistant Counsel to Governor Cuomo at the time, and represented the governor in discussions on this provision. This paragraph is based on his personal knowledge and recollection.
18. *Approval Message of Governor Mario M. Cuomo*, Ch. 752, L. 1990 (July 22, 1990).
19. NYS Department of Health, *Health Care Proxy: Appointing Your Health Care Agent in New York State* (2005), *available at* http://www.health.state.ny.us/nysdoh/hospital/healthcareproxy/1430.pdf.
20. *Id.* at 2, emphasis added.
21. *Id.* at 3, emphasis added.
22. *Id.* at 7, emphasis added.
23. NYS Dept. of Health, NYS Task Force on Life and the Law, *The Health Care Proxy Law: A Guidebook for Health Care Professionals* (January 1991) at 17.
24. T.E. Miller, *New York State's Health Care Proxy Law*, N.Y.L.J., August 16, 1990, at 1.
25. N.Y.L.J., April 12, 2005.
26. The court's opinion is troubling in other respects as well: first, the court wrote its decision after an emergency hearing at which the daughter appeared *pro se* and by telephone, so the court did not have the benefit of legal analysis and advocacy in support of the daughter's case, or even the ability to assess the daughter's sincerity. Second, the opinion sets forth a history of the Health Care Proxy Law which, in important respects, is incomplete and misleading—such as its incorrect view that the provision on artificial nutrition and hydration stemmed from criticisms of the law by the Health Care Facilities Association.

    Most problematic, however, is that the opinion includes a lengthy discourse on Orthodox Jewish law (Halacha) with the rationale that the patient would have wanted whatever treatment decision Halacha commanded. That course of reasoning compelled the court to wade deeply and inappropriately into ascertaining religious tenets and resolving internal religious doctrinal debates. Moreover, the court started down that troubling path based on a faulty assumption: that because the patient allegedly was an Orthodox Jew, she would accept Halacha teachings, whatever they may be. Ultimately, that exercise in determining a patient's wishes by studying religious doctrines seems far less likely to arrive at an accurate indication of what the patient would have wanted than simply relying upon her daughter/health care agent's judgment.
27. PHL § 2982(2)(a). If the patient's wishes are not known, and cannot with reasonable diligence be ascertained, the agent must base a decision on his or her assessment of the patient's best interests. *Id.*, § 2982(2)(b).
28. PHL § 2984.2. The section referred to therein, PHL § 2983.5, is not directly applicable here: it relates to the priority of a principal's decision if the principal actually expresses his or her objection to determination of incapacity or to an agent's decision. This article analyzes situations where the principal is not able to express his or her objection to the agent's decision. The section does, however, confirm again the law's premise that the principal's decision is paramount.
29. PHL § 2992.3(b).
30. R. Swidler, *When a Patient's Prior Decision to Forgo Treatment Conflicts With a Family's Current Decision to Provide Treatment*, NYSBA Health Law J., 10(3):75-82 (Summer/Fall 2005).

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Family Caregivers Out in the Cold: HIPAA's Chilling Effect on Communication

By Carol Levine

The Health Insurance Portability and Accountability Act (Pub. L. No. 104-191) (HIPAA) seems to be working well enough—unless you are one of the nation's 27 million or more family caregivers who provide unpaid care to elderly, ill, or disabled friends or relatives. Here are some examples, culled and anonymized from personal communications:

- *In Florida, Ms. A. left her infirm husband with Alzheimer's disease in the care of friends and neighbors when she went away for a few days. Mr. A managed to slip away, drove 80 miles to an estranged daughter's home, and demanded she take him in. The daughter had him "Baker-Acted" (the Florida term for involuntary commitment). When Ms. A. arrived on the scene, the facility holding her husband refused to give her any information about his condition. Yet they willingly discharged him to her care after the term of the Baker Act ran out.*
- *Ms. B's mother, who suffers from dementia, is in a nursing home in Delaware. Mother's primary care physician left the area but she did not remember who replaced him. When Ms. B. asked the staff about her mother's medications, she was told that HIPAA prevented them from telling her the name of the new physician.*
- *Ms. C, from Virginia, tried to facilitate her mother-in-law's adjustment to nursing home placement by asking staff which residents would be most likely to welcome her into their tightly closed meal groupings. The staff refused to discuss lunch seating because it would, they said, violate HIPAA.*
- *In upstate New York, Mr. D, a case manager in a social service agency, provided critical information to a hospital about a client with Parkinson's disease who had been brought there in an emergency. Yet when he called the next day to find out about his client's condition, he was told that he had no right to know.*

Two and a half years after its implementation, HIPAA appears to have fallen off the major list of complaints about health care regulation. Intended to protect the privacy of health records from marketers, employers, the media, and nosy strangers, and to facilitate communication among health care providers with legitimate needs for patient information, HIPAA has been integrated—slowly and at times grudgingly—into routine medical practice.[1]

Assuming that they understand their rights under HIPAA, which is by no means certain given the legalistic language in which most notices are written, patients have benefited from the law.[2] They can get a free report once a year on when and why their health information was shared and ask to be reached somewhere other than home and by a mailed envelope rather than a postcard. They can file a complaint if they believe their information was used or shared in a prohibited way. Probably the most important benefit has come from the general increase in staff awareness about protecting confidentiality, including the common breaches that occur in casual conversation.

"[F]or family caregivers HIPAA continues to be nothing but trouble. It fits into the unhappy category of a Law of Unintended Consequences."

However, for family caregivers HIPAA continues to be nothing but trouble. It fits into the unhappy category of a Law of Unintended Consequences. As a result of flawed interpretation of the Privacy Rule (45 C.F.R. 164.510[b]), which implements HIPAA, many family caregivers cannot get information about their relative's condition and care from health care providers without encountering rebuffs and resistance. Yet these caregivers provide 80 to 90% of all the long-term care in the country and are increasingly responsible for complex home medical management, including all forms of medication administration, equipment monitoring, and pain and symptom control.[3] Patient advocates who are trying to help the ill person access and coordinate services are experiencing the same problem. "I can't tell you because of HIPAA," is a typical response to any inquiry, no matter how ordinary. Even in situations in which it is important to inform the family about aspects of the client's care or condition, such as Alzheimer's disease in which competence is diminished, staff believe that HIPAA requires the client's permission to contact family caregivers.

This is both a misreading of the law and a serious threat to quality care. As interpreted by the Department of Health and Human Services' Office of Civil Rights (OCR), the compliance agency for HIPAA, "**HIPAA does not cut off all communications between providers and the families and friends of patients"** (bold in original).[4] This May 2004 "Dear Health Care Provider letter" says that, "Doctors and other providers covered by HIPAA can share needed information with family, friends—or even with anyone a patient identifies as involved in his or her care—as long as the patient does not object. . . . Even if the patient is incapacitated, a provider can share appropriate information . . . if he believes it is in the best interests of the patient." The letter refers providers to the OCR Web site for more information.[5]

Misunderstanding persists, however, as the General Accountability Office (GAO) found in its September 2004 review of the first year's experience with HIPPA by health care plans, providers and staff ("covered entities" in HIPAA-speak). The GAO found that although implementation had gone "more smoothly than expected," difficulties remain for public health monitoring, research, and patient advocacy.[6] The GAO found that, "Providers and health plans that are uncertain or misinformed about their privacy responsibilities have often responded with an overly guarded approach to disclosing information, resulting in *procedures that may be more protective of the organization than necessary to ensure compliance with the Privacy Rule*" (italics added).[7]

The report specifically mentioned problems reported by organizations representing families and patient advocates. "Where the rule permits discretion, some covered entities have taken a strict approach to patient authorization requirements, requiring any adult calling on behalf of another adult to obtain an authorization form signed by the patient." According to the report, one health plan required 10,000 separate authorizations in a year.[8]

How widespread is this problem? Unfortunately, there has been no systematic survey of family caregivers and patient advocates on this issue, and they are not likely to report their individual difficulties to OCR. It is not even clear if the agency's complaint form, intended to document unauthorized sharing of patients' health information, would accommodate caregivers' grievances about unjustified withholding of information. But the OCR letter, the GAO report, along with anecdotal accounts[9] indicates that further inquiry and some corrective actions are warranted.

None of the official communications give any specifics about what family caregivers are actually experiencing. The examples cited earlier were culled from an admittedly nonscientific and informal survey of conference attendees, phone inquiries, and e-mails. These lapses from good clinical practice do not protect patients from unwarranted invasions of privacy. They do jeopardize good patient care and make family caregivers' jobs harder. Family caregivers need information and support, not a cold shoulder.[10]

From a nursing perspective, Kumekawa asserts, "When individuals or institutions are afraid to rely on common sense, experience, and good judgment because they may be fined or jailed for an 'incorrect' response, or when they 'play by the rules' so rigidly that the purpose of their mission is forgotten, the outcome can be distressing."[11] Describing this perspective from a legal viewpoint, Senska says, "Health care administrators and lawyers have coined the term 'HIPAA Scare.'"[12] "The HIPAA Scare has prompted covered entities to engage in behaviors that thwart the ability of people to care for their loved ones. . . . If providers possessed a more thorough understanding of the Privacy Rule, surely they would not fear sharing information with people intimately involved with and legitimately interested in the patient's care and overall health." Fear of legal liability is at the root of much of this behavior, but Senska says, "Despite the overarching privacy thrust of the HIPAA regulations, a provider has a great deal of latitude when determining disclosures to patient representatives, and as long as such disclosures are made with reasonable professional judgment and in the patient's best interests, there should be no resulting liability."[13]

Part of the problem stems from a misreading of HIPAA but part of it stems from the law itself. HIPAA envisions an adult patient in complete control of decision-making, not an elderly patient who is confused or demented. Jeffrey Nichols, a New York geriatrician, believes that, "basically HIPAA runs in direct contradiction to all the principles of good geriatric care, which attempt to see disease in the context of the whole patient." In his practice he tells patients who he will be sharing information with and allows them to object; so far, no one ever has (personal communication, February 5, 2005).

Why has HIPAA been so zealously embraced? Partly, it seems, because the extensive training that preceded its introduction focused heavily on compliance and the stiff fines and criminal penalties for violations. Many health care providers now apparently feel it is

simply safer to say "no" or "prove it" than to use the professional judgment that the law provides. With the institution's interests uppermost in their minds, many attorneys have reinforced this fear. Certainly there are rare situations, memorable for their unpleasantness, when squabbling siblings, vengeful ex-spouses, or greedy relatives seek information without justification. There are also cases, for example, in psychiatric and dementia care, where patients are reluctant to share information with their families. These require clinical discretion and negotiation.[14] Dilemmas also arise when a sexual partner is reluctant to disclose his or her sexually transmitted disease to others who may be at risk. If unresolvable, this situation becomes a matter for public health authorities. The majority of family caregivers, however, are just trying—under difficult circumstances—to take care of their relative or friend who needs their care and who has no objection—indeed, who affirmatively wants—information shared with them.

Another reason for HIPAA's misuse is that it fits neatly into an already well established pattern of keeping family caregivers at arm's length.[15] From the viewpoint of many providers, families cause trouble. They are emotional and not "objective." A law that limits sharing information offers a convenient rationale. Providers sometimes claim that only "next of kin" are entitled to information. This term has no legal standing and does not fit many of today's multicultural and multilayered family structures. Some states do have priority lists of relatives who can make end-of-life decisions for an incompetent patient; others, such as New York, do not. Even where these lists exist, they should be only a starting point for determining who best knows the patient and can best represent his or her interests. They are not intended to govern ordinary, day-to-day conversations about a patient's care. When they are used in court proceedings, as in the Schiavo case, it is generally a sign that irreconcilable conflict exists.

Janlori Goldman, director of the Health Privacy Project, which advocated for a strong HIPAA law, said, "The law sets the basic standard of presuming that health care providers can communicate with a patient's family unless the patient objects. If a hospital or nursing home has more restrictive policies, it should not be pointing to the HIPAA Privacy Rule" (personal communication, January 26, 2005). "Unless the patient objects" is often turned into "unless the patient consents," requiring the patient to take an affirmative action. While recognizing that family members whose relative is undergoing surgery experience anxiety, a study of waiting room practices concludes, "To satisfy HIPAA privacy regulations, the staff and physicians talking to family members in the waiting room will need to know if the patient has agreed to the release of information."[16] Presumably, if the patient has not done so, the family will not be given any information.

Family caregivers who have discussed how to share information with the patient's regular providers have generally found a workable arrangement. But very ill people often have many providers and new ones frequently come and go. Getting a written authorization from the patient for each encounter is an unwieldy and burdensome requirement, especially when there is more than one caregiver and many providers. Some advocates are urging clients to add a privacy authorization clause to their health care proxy, even though it is not legally required. The Alzheimer's Association of New York City, for example, recommends the following to be added to the New York State proxy form: "I also grant authority and power to my agent(s) to serve as personal representatives for all purposes of . . . (HIPAA). My agent is authorized to execute any and all releases and other documents necessary in order to obtain disclosure of my patient records and other medical information subject to and protected by HIPAA" (J. Levine, personal communication, January 5, 2005).

Even if the consequences of HIPAA were unintended, they are no less serious. Given the lack of data, some systematic research is needed to determine when HIPAA is invoked, by whom, under what conditions, and with what consequences.

Some reeducation of health care providers is in order, especially with administrative and front-line staff who are often the gatekeepers to information and access to physicians. A more balanced view of HIPAA and family caregivers should be a topic on conference and workshop agendas to balance the fear of liability that was induced in earlier trainings. Providers who have negotiated a balance between protecting patient privacy and sharing needed information with family caregivers should be encouraged to present their experiences in journals and professional settings, such as grand rounds.

Privacy and communication are both important values, and sometimes they do come into conflict. But they should not be forced into opposition where no conflict exists.

Endnotes

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When a Patient's Prior Decision to Forgo Treatment Conflicts with a Family's Current Insistence that Treatment Be Provided

By Robert N. Swidler

In hospitals and nursing homes, variations of this uncomfortable situation arise from time to time:

> *Patient is a 79-year-old man who was brought to the hospital by ambulance after a massive, second heart attack. He was stabilized, placed on a ventilator and admitted. The patient, a smoker, had several co-morbidities, including emphysema, diabetes and, in a new development, partial kidney failure. It quickly became clear to his attending physician and staff that he was dying. Still, as of Day 2 he was lucid and had decisional capacity.*
>
> *On Day 2, the attending physician discussed with the patient his condition and his prognosis, including the prospect of his heart stopping again, and the likelihood that resuscitation efforts would not be successful. With a nurse present, the patient requested a do-not-resuscitate order (DNR), which the physician wrote and placed in the chart. The patient also stated to the attending physician and the nurse that he did not want to be on the ventilator indefinitely, and that he would want it shut off, "if I lose capacity and it's clear I'm never going to get off this machine." That night the patient lost consciousness; he would remain unconscious or semiconscious from that point on.*
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> *The patient's wife and two adult children (a son and daughter) were at the hospital much of the time since his admission. On the afternoon of Day 3, when all three were present, the attending physician explained to them the patient's poor prognosis—that he was in fact dying—and he told them about the DNR order. Moreover, he said, "we're also going to need to decide soon whether it's time to stop the ventilator."*
>
> *The patient's son was visibly upset, and demanded the DNR order be removed and the ventilator continued. He said, "Dad's been through this before and you have to give him every chance to get through it this time." He accused the physician and the hospital of "giving up" on his father. He made comments that if the order was not removed, he would demand to see the CEO of the hospital, and that he would contact a lawyer, his state senator (who he knows) and "Channel 6 News." The patient's wife and daughter were less adamant but deferred to the son.*
>
> *The physician, shaken by the son's strong opposition, directed staff to remove the DNR order. The nursing staff was distressed at the prospect of performing resuscitation efforts that, in their view, were both futile and contrary to the patient's express instructions. The director of nursing phoned the hospital counsel for advice. She pointed out, "you know, he could code any minute."*

Assuming there are no other relevant facts, this case is not especially difficult to analyze from a strictly legal standpoint. As explained below, the legal obligation of the hospital and the physician is to give effect to the patient's decision. That is, legal principles support keeping the DNR order in place, and discontinuing the ventilator once there is reasonable certainty that the patient will not recover decisional capacity or respiratory function.

Nor does this case present a vexing ethical dilemma. Under broadly accepted principles of medical ethics, the ethical value of patient autonomy would prevail in this case, compelling the provider to comply with the patient's directive.[1]

Nonetheless, the case is enormously challenging in many respects. A hospital that recognizes its legal and ethical obligation to honor the patient's wishes must still struggle to enlist a liability-adverse attending physician to its point of view; decide upon procedural and ethical issues regarding when to implement the

patient's decision; defuse a potentially wrenching battle with the family; avoid a public relations disaster; and—these days—avoid becoming a new battleground in the culture wars.

This article reviews the relevant law, identifies exceptional circumstances that might affect the hospitals' obligation, and provides some suggestions for hospitals for meeting the challenges presented by this case.

"What many family members—even health care professionals—do not realize is that in New York, there is no statute that generally empowers family members to consent to treatment on behalf of patients who lack capacity."

Decisions by Patients

In New York, adult patients have a very broad right to make decisions about their own medical treatment. The Court of Appeals has repeatedly affirmed "the basic right of a competent adult to refuse treatment, even when the treatment may be necessary to preserve the person's life."[2] Accordingly, doctors and hospital staff have a legal, ethical and professional obligation to honor that right, and not to treat a patient who has expressly decided to forgo treatment, even life-sustaining treatment, absent some compelling countervailing interest.[3]

A patient does not lose the right to forgo treatment when he or she loses capacity. Rather, the Court of Appeals has upheld a rule "requiring the doctors and hospitals to respect the right even when the patient becomes incompetent if, while competent, the patient had clearly stated a desire to decline life-sustaining treatment under specified circumstances."[4]

There are no specific legal requirements about how a patient must express his or her wish to forgo treatment before that expression becomes binding upon a provider (except with respect to decisions about resuscitation).[5] Courts have required only that the evidence of the patient's decision must be "clear and convincing,"[6] which means it must reflect the patient's "firm and settled commitment to the termination of life supports" under the circumstances like those presented.[7]

Some patients may create a document, such as a "living will" to express their treatment wishes. Others may discuss their wishes with a friend or relative, who relays that information to the provider. But it would seem that the most reliable evidence would be the type of statement made under the circumstances described in the hypothetical: where the capable patient sat up in the hospital bed and, after a full explanation of the specific circumstances, personally informed the provider and a witness what he did not want done.[8] In such instance, the provider's obligation would be to carry out the patient's clear instructions.

Moreover, with respect to decisions about resuscitation, the obligation to carry out the patient's decision to forgo that procedure is expressly set forth in New York's DNR statute. That law provides that when a decisionally capable hospitalized patient consents to a DNR order, either orally or in writing, the attending physician must either (i) issue the DNR order—either promptly, or at such time as the conditions, if any, specified in the patient's consent are met; (ii) or transfer the care of the patient to someone who will issue the order; or (iii) commence a dispute mediation process.[9] He or she may not simply veto or refuse to enter the order. Thus, in our hypothetical, once the hospitalized patient consented to a DNR order, the provider became bound by law to write the order, transfer the patient to another provider who would write the order, or commence dispute resolution.

Decisions by Family Members

When a patient lacks capacity and did not leave clear prior instructions, the doctor and hospital staff generally turn to family members for guidance regarding treatment decisions.[10] Indeed, it is common and customary for hospitals to accept consent for treatment from family members on behalf of patients who lack capacity and who did not previously provide such consent.

What many family members—even health care professionals—do not realize is that in New York, there is no statute that generally empowers family members to consent to treatment on behalf of patients who lack capacity.[11] To be sure, even absent such statute, it is generally safe for a provider to render medically necessary, noncontroversial treatment based on the consent of the incapable patient's closest available relative. But the principal legal support for such practice is New York's informed consent law.[12] That law generally requires that the provider secure the patient's informed consent before commencing a significant treatment, but then identifies exceptions, among them: when obtaining the patient's consent was not reasonably possible because of incapacity, and emergency treatment.[13] The law then does not empower family members to give consent;

rather it excuses providers from getting consent directly from the patient.

The point here is that the closest relative does not, by virtue of being the closest relative, possess authority to make health care decisions for an incapable patient, much less the authority to override the patient's clear prior decision.

Indeed, where the patient has made a clear prior decision, the provider has no legal obligation even to seek a second, redundant decision from a family member since the decision had already been made by a higher authority, the patient.[14] But in those situations where, for whatever reason, the provider asks a family member to decide the same question, or where the family member on his or her own initiates purports to decide the question, it must be noted that the family member has no general power to override the patient's prior decision.

There are, indeed, instances where a family member may have or secure specific statutory or regulatory authority to make decisions for an incapable adult patient. The three principal statutes authorizing surrogate decisions for incapable patients are the Health Care Proxy Law, the DNR Law and MHL Article 81 Guardians.[15] But all of those statutes obligate the surrogate to make health care decisions in accordance with the patient's wishes, if such wishes are known, and, therefore, make it clear that the surrogate decision-maker does not have the authority to override a clear prior decision by the patient:

- ***Health Care Agents.*** A health care agent, appointed by the patient pursuant to the Health Care Proxy Law, can make health care decisions for the decisionally-incapable patient, including life-sustaining treatment decisions.[16] However, the agent is obligated to make health care decisions "in accordance with the principal's wishes, including the principal's religious and moral beliefs. . . ."[17] Accordingly, a health care agent cannot override the clearly stated prior wishes of the patient.[18]
- ***DNR Law Surrogates.*** A surrogate decision-maker, identified pursuant to New York's DNR Law, may consent to the entry of a DNR order on behalf of a decisionally-incapable patient.[19] However, the surrogate is required to make such decision "on the basis of the adult patient's wishes, including a consideration of the patient's religious and moral beliefs. . . . "[20] Accordingly, the DNR Law surrogate cannot override the unequivocally stated prior wishes of the patient.[21]
- ***Article 81 Guardians for Personal Needs.*** A guardian of the person appointed pursuant to Mental Hygiene Law Article 81 can make health care decisions for the decisionally-incapable patient, other than life-sustaining treatment decisions.[22] However, the guardian is obligated to make such decisions "in accordance with the patient's wishes, including the patient's wishes and moral beliefs. . . . "[23] Accordingly, an Article 81 guardian cannot override the unequivocally stated prior wishes of the patient.

"Indeed, where the patient has made a clear prior decision, the provider has no legal obligation even to seek a second, redundant decision from a family member since the decision had already been made by a higher authority, the patient."

In our hypothetical, the patient stated his wishes clearly and unequivocally. As a result, the decision-maker, whether he or she is a health care agent, a surrogate under the DNR Law, or an Article 81 guardian, would be legally obligated to make his or her decision consistent with those instructions.

In sum, providers are obligated to give effect to a clear, unequivocal decision by a patient to forgo life-sustaining treatment (except in the unusual case where there is a contrary compelling state interest). Providers who have such a clear decision from the patient have no obligation, if the patient later loses capacity, to seek another decision from a relative. Indeed, close relatives have no general authority to make decisions for incapable patients, much less authority to override the patient's clear prior decision. Indeed, even family members who are health care agents, DNR surrogates and Article 81 guardians are obligated to make decisions that reflect the patient's wishes.

Exceptional Circumstances

Notwithstanding the principles stated so far, there are a number of exceptional circumstances that, if substantiated, would support overriding the patient's decision to forgo treatment. For example, there might be evidence that:

- the patient never actually made the statement that he was alleged to have made, or the patient

never wrote the document he was alleged to have written;

- the patient lacked capacity at the time he or she gave the prior instructions;
- the attending physician or another person exerted undue pressure upon the patient to agree to the decision;
- the patient's instructions were vague or ambiguous;
- the patient's instructions were made so long ago, or under such different circumstances, as to call into question their currency or applicability;
- the patient issued subsequent instructions that superseded the earlier instructions; or
- the patient subsequently revoked his or her prior instructions.

Any of these allegations, if true, would call into question the basic premise that the patient would want treatment withdrawn or withheld under the current circumstances. Accordingly, if such allegation is made, it is incumbent upon the provider to look into the matter and determine if the allegation is credible or specious. If the allegation appears at all credible, it would be prudent for the provider to defer the withdrawal or withholding of treatment and refer the matter to an ethics committee for guidance, or to court for a legal determination.

On the other hand, the provider should not allow clearly unbelievable allegations of exceptional circumstances by a relative, or purely personal opposition by a relative, to lead it to disregard the patient's prior instructions. Accordingly, when a relative demands that the provider provide life-sustaining treatment despite the patient's prior instructions, the provider must listen carefully to the relative's rationale: "Because I said so" is not a basis to provide treatment; "Because dad said so," may be.

Practice Tips for Providers

As noted at the outset, cases like the hypothetical at the outset of this article may be easy to resolve as a matter of legal and ethical analysis, but are still quite problematic for providers. Indeed, an assessment of the case from a pure risk management standpoint would lead a provider to conclude that he or she should follow the demands of a healthy, litigious relative rather than the prior instructions of an incapable dying patient. But that course would violate the provider's legal and ethical obligations.

Accordingly, the provider's goal should be to meet his or her obligation to the patient while trying to defuse the dispute with the insistent relative. While there is no sure way to accomplish both of those conflicting goals, these approaches merit consideration:

- ***Explain that it's the patient's decision that counts.*** A staff member who has the best rapport with the relative, or whom the relative respects, should remind the relative, in a non-adversarial manner, that the core question is "What would the patient want?" It is not, "What do you family members want?" or "What do we the providers think is best?"
- ***Buy time.*** If possible, the provider should give the family member some time to adjust to the situation. It is very difficult for a family member to make a well-considered decision, or accept advice, when they are absorbing tragic news. Thus, the decision about discontinuing a ventilator might be deferred a few days to allow the relative time to think, to grieve, and to understand that it's the patient's decision that counts. Unfortunately, the DNR decision might have to be made more promptly. But even that can often be put off, at least for a few hours or overnight.[24]
- ***Offer the ethics committee's guidance.*** If the hospital has a clinical ethics committee, the relative should be offered the opportunity to discuss the matter with that committee and get the benefit of its guidance. However, the relative must be assured that the committee is not controlled by the institution and obligated to affirm the institution's decision. If that is done, perhaps the committee can make the relative accept the appropriateness of complying with the patient's decision.
- ***Use an educational brochure.*** At Northeast Health, we are in the process of introducing a brochure that specifically addresses the issue of family members attempting to override patient decisions. It was our view that the use of such brochure would:
  - — provide a clear, consistent explanation to family members of their limited authority, and of the provider's legal obligation to comply with the patient's wishes;

— help family members realize that the provider did not single them out for an ad hoc decision rejecting their instructions. Rather the provider is implementing a consistent policy of honoring patient wishes;

— help take pressure off of staff to justify the decision, and deflect anger from them;

— inform family members about the facts that would constitute legitimate grounds for overriding a patient's prior decision, and the arguments that would not do so; and

— also serve as an educational tool for hospital staff, including the medical staff.

The brochure we developed is set forth as an Appendix to this article.

- ***Document, document, document.*** This is, of course, the health lawyer's mantra. Obviously, the provider that clearly documents the patient's expression of his or her wishes will be better able to prevail in a lawsuit, if it comes to that. But beyond that advantage, solid documentation of the patient's wishes will help the provider convince the family to defer to the patient's wishes. It will also help the provider avoid regulatory liability and respond to political and media inquiries.
- ***Reassure physicians and staff.*** The attending physician and hospital clinical staff understandably will be concerned about civil liability and threats to their licenses for withdrawing or withholding treatment from a patient over the objection of a family member. It would be helpful to reassure them that, notwithstanding family member threats, applicable law supports honoring the patient's wishes. This article, and the attached brochure, may be useful tools in that effort.

Finally, even when it is clear that the provider must honor the patient's wish to forgo treatment, and not the family's insistence upon the provision of treatment, the provider must consider, as an independent question, whether to seek court approval of its impending withdrawal or withholding of treatment, or act without such approval. Attorneys who are focused strictly on minimizing provider liability exposure would likely advise seeking court approval before withdrawing or withholding treatment whenever the matter is disputed. However, that approach could result in subjecting dying patients to treatments and procedures they may have pleaded to avoid.

Another article in this edition, in the course of discussing decisions by health care agents that are contrary to the prior decision of principal, describes factors that provider's counsel should consider in determining whether to seek the protection of a court order before following the principal's decision:

> On one end of the spectrum is the case where the patient's decision was recent, absolutely clear and unequivocal, and reasonable under the circumstances; where the agent's rationale for overriding the patient's decision is basically "because I say so"; and where the agent will have sufficient time to seek a court order to restrain the provider's action if he or she decides to do so (for example, where a feeding tube is withdrawn). In such case, the provider should feel secure in notifying the agent that it intends to disregard his or her decision and carry out the patient's decision.
>
> However, as those elements weaken—e.g., in a case where the patient's decision is less recent or clear; where the agent's rationale is more plausible ("he told me he changed his mind"); and where the provider's action might become irrevocable before the agent could contest it (for example, where mechanical ventilation is discontinued), it becomes more advisable and prudent for the provider to commence the court proceeding.

That advice seems equally applicable here.[25]

Endnotes

1. *See generally*, T. Beauchamp, J. Childress, *Principles of Biomedical Ethics, 5th ed*. (Oxford 2001); A. Jonsen, M. Siegler, W. Winslade, *Clinical Ethics: A Practical Approach to Ethical Decisions in Clinical Medicine* (McGraw-Hill (2002)). Indeed, the decision would be consistent with the core ethical values of beneficence and fairness as well. *Id.* Note—This article will use the generic term "provider" when referring to the attending physician and hospital collectively.
2. *Fosmire v. Nicoleau*, 75 NY.2d 218 at 226, citing *In re Storar*, 52 N.Y.2d 363, *Rivers v. Katz*, 67 N.Y.2d 485 and *In re Westchester County Medical Center [O'Connor]*, 72 N.Y.2d 517.
3. *Fosmire v. Nicoleau*, 75 N.Y.2d 218. One of the few examples of a state interest that overrides a capable patient's right to refuse treatment is the state's interest in preventing suicide. *See Vacco v. Quill*, 521 U.S. 793 (1997).
4. *Fosmire*, *supra* at 228, citing *In re Eichner v. Dillon*, 52 N.Y.2d 363.

5. New York's DNR law specifies the manner in which a capable patient may express a decision about resuscitation. N.Y. Public Health Law § 2964.2 (PHL).
6. *In re Storar*, 52 N.Y.2d 363.
7. *O'Connor*, *supra* at 531.
8. To be sure, even in the case described there could be extraneous factors that might undermine reliance upon the patient decision. See discussion *infra*, at pp 77-78.
9. PHL § 2964(2)(c). If the physician opts for dispute mediation but the dispute cannot be resolved within 72 hours, the physician must either enter the order or transfer the patient to another physician or hospital. PHL § 2972.4.
10. See NYS Task Force on Life and the Law, *When Others Must Choose: Deciding for Patients Who Lack Capacity* (1992) at 37.
11. The proposed Family Health Care Decisions Act would accomplish this. *Id. See* S.5807/A.5405-A (2005).
12. PHL § 2805-d.
13. PHL § 2805-d(4).
14. See R.N. Swidler and N.M. Daratsos, "Informed Consent and Decisions for Patients Who Lack Capacity, " in R. Abrams and D. Moy, eds., *Legal Manuel for New York Physicians* (NYSBA and Medical Society of the State of New York 2003) § 20.7 at 323.
15. Other statutes or regulations authorize family members or others to make health care decisions for persons with mental illness or developmental disabilities. E.g., N.Y. Mental Hygiene Law art. 80 (Surrogate Decision-making Committees and Panels); Surrogate's Court Procedure Act § 1750-B (Health Care Decisions for Mentally Retarded Persons). 10 N.Y.C.R.R. § 27.9(b) (Family consent to treatment for patients of mental health facilities). Those provisions are less deferential to the prior expressed wishes of patients, given the greater likelihood that the patients had diminished capacity at the time they expressed such wishes.
16. PHL art. 29-C.
17. PHL § 2982.2. This issue is discussed in greater detail elsewhere in this edition. See K. Burke, A. Herb and R. Swidler, *Three Stubborn Misconceptions About the Authority of Health Care Agents*, NYSBA Health Law Journal, vol. 10, No. 3, at 63 (Summer/Fall 2005).
18. This issue is discussed in greater detail elsewhere in this edition of the *NYSBA Health Law Journal*. See K. Burke, A. Herb and R. Swidler, *Three Stubborn Misconceptions About the Authority of Health Care Agents*, NYSBA Health Law Journal, vol. 10, no. 3, at 63 (Summer/Fall 2005).
19. PHL art. 29-B.
20. PHL § 2965.3(a).
21. Moreover, the DNR expressly directs the attending physician to honor the decision a patient made when capable, and authorizes the surrogate to revoke only a DNR order that the surrogate consented to, not a DNR order that the patient consented to. PHL § 2969.
22. N.Y. Mental Hygiene Law art. 81. (MHL).
23. MHL § 81.22(a)(8).
24. A particularly difficult problem arises when, as in the hypothetical, the DNR order must be addressed immediately because the patient "could code any minute." In that circumstance every option is bad: keeping the DNR order in place will appall and enrage the family, and induce them to take the most drastic adversarial steps. Suspending the order could result in staff performing futile and burdensome CPR on a patient who expressly sought to avoid it. Other options like instituting a "slow code," "show code," or covert DNR order are deceitful and unacceptable both legally and ethically. In this author's view, the least-worst option is to keep the DNR order in place provisionally (because the provider has a legal and ethical duty to honor the patient's decision), but promptly inform the family of their right to submit the matter to the hospital's dispute mediation system. See PHL § 2972. If they opt to do so, the order will be suspended until (a) the dispute is resolved or (b) 72 hours elapse, whichever occurs first. *Id.*, § 2972.3. After that time if the issue has not been resolved, and if it is still clear that patient unequivocally wanted to avoid resuscitation, in this author's view the provider should reissue the order unless a court enjoins it from doing so.
25. K. Burke, A. Herb and R. Swidler, *Three Stubborn Misconceptions About the Authority of Health Care Agents*, NYSBA Health Law Journal, vol. 10, no. 3, at 63 (Summer/Fall 2005).

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When a Patient's Prior Decision To Forgo Treatment Conflicts With a Family's Current Decision To Provide Treatment

Guidance for Family Members

Northeast Health

Introduction

Usually, when an important treatment decision must be made, such as whether or not to perform a medical procedure, the doctor will discuss the decision with the patient, and the patient will make the decision personally. But sometimes, patients who are very seriously ill lack the ability to make treatment decisions personally at the time the need for the decision arises.

In those situations, sometimes a patient will have given prior written or verbal instructions about his or her wishes. Often family members are available and provide their direction as well. Sometimes those instructions conflict.

This pamphlet addresses the role of prior decisions by the patient and current decisions by family members -- and the obligations of medical staff when those directives conflict.

As explained below, in general the legal, ethical and professional obligation of the doctor and the hospital, is to follow the decision the patient previously made - if the patient had capacity at the time he or she made the decision, and if the decision clearly applies to the circumstances.

Decisions by Patients

In New York, adult patients have a very broad right to make decisions about their own medical treatment - that is, whether to consent to medical treatment, or choose to forgo treatment - even life-sustaining treatment. And in general, doctors and hospital staff have a legal, ethical and professional obligation to follow the treatment decisions of their patients.

When a patient lacks "capacity" - the mental ability to make a reasoned decision - then the next best guidance staff have is the prior decision the patient made, provided the patient had capacity when he or she made the decision.

Court decisions in New York establish that if a patient leaves clear instructions that he or she would not want treatment under specific circumstances, those wishes must be honored later, when the patient no longer has the capacity to state his or her wishes directly.

There are no specific legal requirements about how a patient must express his or her wishes - except that they must be clear. Some patients may create a document such as a "living will" to

express treatment wishes. Others may simply tell their doctor or the hospital staff what they would want under certain circumstances. In either case, if the patient, when capable, makes his or her decision about treatment clearly known, it generally must be honored, even after the patient loses capacity.

For example, if a patient tells her doctor, or writes in a living will, that she does not want resuscitation in the event her heart stops, in general staff will honor those instructions. More specifically, the physician will write a "do-not-resuscitate order (DNR)" on the patient's medical chart, to reflect that decision.

Decisions by Family Members

When a patient lacks capacity and did not leave clear prior instructions, the doctor and hospital staff will generally turn to family members for guidance regarding treatment decision. Indeed, it is common for hospitals to accept consent for treatment from family members on behalf of patients who lack capacity and who did not previously provide such consent.

But as a result of laws and court decisions, some special rules apply to decisions to forgo life-sustaining treatment:

- If there is a clear prior decision by the patient, that should be honored;
- If there is no clear prior decision by the patient, in general family members have no authority to authorize the withdrawal or withholding of life-sustaining treatment - but there are two exceptions noted below:
- New York's "DNR Law" law allows family members to authorize the entry of a DNR order in certain circumstances.
- New York's "Health Care Proxy Law" enables adults to appoint someone - a "health care agent," who could make health care decisions - including life-sustaining treatment decisions - on behalf of the adult, if the adult loses the capacity to make those decision personally.

Significantly, under both the DNR Law and the Health Care Proxy Law, the decisionmaker's obligation is to make the decision the patient would make, if known.

Conflicts

It is rare for there to be a situation in which a now-incapable patient's prior decision is in clear conflict with a family's current instructions about withdrawal of life-sustaining treatment. But it does occur.

When it occurs, it is important for the family and the patient's doctor to discuss the issue thoroughly, and make sure all involved understand the important facts, including: the patient's medical condition, the benefits and burdens of the proposed treatment, the evidence of patient's decision, the reason for the family's conflicting decision. Usually, conflicts can be resolved simply after a complete discussion of these matters.

But when the conflict persists, the family must try to understand that in each case, the core question is "What would the patient want?" It is not "What do family members want?"

Accordingly, when the patient's decision is clear, it is the legal, ethical and professional responsibility of the doctor and staff to give effect to that decision. Family members cannot

override, revoke or rescind a clear prior decision by the patient.

This principle applies both when the patient opts for treatment, and when the patient opts to forgo treatment.

DNR Decisions

NY's DNR Law reflects the principle that the patient's decision controls. Although family members, under certain circumstances, can consent to the entry of a DNR order and then revoke their own consent, they cannot override the prior consent to a DNR order by the patient.

Health Care Agents

New York's Health Care Proxy Law also reflects the principle that the patient's decision controls. The law gives health care agents broad authority to make decisions for incapable patients. But it specifies that the health care agent must make the decision that the patient would make, if known. Accordingly, when the patient previously made a clear decision, the agent is bound by that. In sum, the health care agent's role is to give effect to the patient's wishes, not to override them.

Valid Reasons for Overriding a Patient's Decision

Even though the general principle is that the patient's decision controls, there may be valid reasons for overriding a patient's decision, for example:

- If there is evidence that the patient lacked capacity at the time he or she made his or her decision
- If there is evidence that the patient changed his or her mind at some point after making his or her decision.
- If the decision previously expressed by the patient does not clearly apply to the current circumstances.

Because these reasons would call into question whether the patient made a clear prior decision, the doctor and hospital staff will have to evaluate them carefully.

On the other hand, a family's opposition to a patient's decision that is based on the family's personal beliefs or preferences is not a valid reason for overriding the patient's clear prior decision.

Northeast Health Ethics Consult Service

Northeast Health offers an Ethics Consult Service that is available to discuss and provide advice to family member in ethically difficult cases. For more information, ask staff for the pamphlet "Northeast Health Ethics Consult Service."

Reconciling Legal and Medical Ethics in a Hospital Setting: A Hospital's Experience Implementing JCAHO's Rule on Medication Orders

By David N. Hoffman

Making improvements in the system of health care delivery is a lot like changing a flat tire on a moving bus.

It is a clear sign of the progress that medical ethics has made in influencing the delivery of health care that hospital lawyers are thinking and sounding more like doctors when discussing patient rights and institutional responsibility. It is also true, in my opinion, unfortunately, that doctors are thinking and sounding more like lawyers. This is a function of lawyers' increasing immersion in the culture of medicine and the growing sophistication of physicians, due to their administrative responsibilities and medical malpractice litigation experiences.

This emerging reality was on display recently when I took my usual spot in the corner of the hospital board room for a regularly scheduled meeting of the Medical Board. Among the many items on the agenda was a presentation by our Quality Management department on implementation of one of the new Joint Commission Patient Safety Goals. The freshly minted policy and procedure was the one implementing Joint Commission standards 3.10 and 3.20 which require that all medication orders be accompanied by an entry in the chart describing the condition indication or diagnosis (CID) for which the medication was being prescribed.

This appeared to be a straightforward proposal directed at further reducing the already small possibility of a medication error due to misinterpretation of the prescribed medication or the route and dosage to be administered. The theory, of course, is that if the pharmacist and/or allied health professional who is preparing or administering the physician's ordered medication knows the condition or the basis upon which the physician chose that particular medication, then he or she will be more likely to recognize if the medicine being drawn is not appropriate for the condition being treated, or that the dosage is out of proportion to the patient's condition. For example, a medication order for Inderol (a heart medication) to treat a post-operative inflammation or swelling is not likely to get past either a pharmacist, technician or a nurse.

The policy and procedure that was presented for consideration further required that the individual filling the medication order contact the prescriber to verify his or her medical intention if no CID was provided. This is a necessary feature because it would be unacceptable for the person administering the medication to assume that the doctor's scribble, which appeared to read Inderol, was actually Indocin (an anti-inflammatory) because even patients with pain and inflammation can suffer from heart conditions.

"It is a clear sign of the progress that medical ethics has made in influencing the delivery of health care that hospital lawyers are thinking and sounding more like doctors when discussing patient rights and institutional responsibility. It is also true . . . that doctors are thinking and sounding more like lawyers."

Our approach to implementation of the Joint Commission's medication management standards called for the CID to be documented directly on the medication order sheet. This enables the individual receiving the order from the floor to avoid having to refer back to the progress notes in the medical record to verify that the medication and dosage was appropriate for the patient's complaints.

Notwithstanding the reality that the number of medication errors, as measured against the total number of patient dosages administered, is very small, the potential severity of an adverse event certainly warrants substantial additional effort on the part of practitioners.

Given that these quality assurance measures are not without their costs, in time, money and unintended consequences, a substantial amount of discussion and debate is necessary before implementing any particular Q/A measure.

Although the proposal to require charting of CID seemed warranted on its face, I anticipated a significant degree of debate over the cost/benefit justification. What I clearly did not anticipate, as the debate flowered, was the argument raised by members of the medical staff that orders written without the requisite CID on the order sheet should be filled anyway, to ensure timely provision of treatment. They proposed that the lapse in implementation of this new patient safety protocol should be dealt with subsequently through educational or disciplinary action.

This position triggered the entirely predictable response from the quality assurance staff, that if physicians were permitted to get orders filled without providing the requisite CID, the objective of changing physician behavior would likely never be accomplished. The truly disturbing aspect of the discussion was the response from members of the medical staff who insisted that orders had to be carried out immediately lest they and the hospital be subject to tort actions for failure to provide timely treatment. At that moment, as is so often the case, eyes turned in my direction for a legal determination of the hospital's obligation.

It is specifically in these situations that we, as hospital attorneys, have to first acknowledge and then confront the natural tension that exists between our obligation to insulate our institutions from liability and our obligation to promote and advance the hospital's patient care and patient safety missions. The position being advanced by the medical staff was that while it was all well and good to require documentation of CID, it would be dangerous and, therefore, irresponsible to actually hold a medication order in order to obtain that information. The Quality Assurance staff, long experienced in trying to change physician behavior in an institutional setting, argued for strict enforcement of the proposed new rule. They asserted that orders should be held until the responsible physician or other practitioner could be contacted, and the appropriate CID noted into the order.

In my often conflicted roles as hospital counsel and director of the Bio-Ethics Consultation Service, I immediately saw liability and safety issues on both sides of the argument. If we accepted the medical staff's position and filled orders without the necessary CID, we would be acting in explicit violation of the hospital's new policy and procedure. Our QA staff asserted that if such a patient were to then have an adverse reaction because the patient received the wrong medication (based on a misunderstanding of the physician's order and lack of confirming CID), liability would clearly attach. The proof of the violation of the standard of care would be the hospital's own policy and procedure. Carrying out the physician's order without the CID creates the very risk that the patient safety goal of charting CID was designed to prevent.

The arguments offered by the medical staff, however, were equally compelling on both liability and patient safety grounds. If we enforced the more stringent policy requiring charting of CID, and then delayed administering the ordered medication while waiting for the ordering physician to be identified, and obtaining his or her CID to justify the medication, patient safety would be compromised if, during that interval, the patient were to suffer harm due to the delay in administering the prescribed treatment.

An animated discussion ensued, and as is inevitably the case, it turned toward what many believed was the easiest and, therefore, arguably the best solution, "to make no change in our policy at all." The advocates of this position espoused that, by requiring that a CID be charted, we were exposing the hospital to liability whether we enforced the policy or not. Therefore, the safest course of action was to do nothing. In support of this view, several participants in the meeting cited back to me an argument that I had advanced on many occasions. The standard of care to which we are most strictly held is the one that we have created ourselves, where we have raised the bar to a higher level than is generally expected in the medical community. Nonetheless, for the reasons set forth below the "do nothing approach" was summarily rejected on medical-ethical grounds.

Hospital lawyers who divorce themselves from the fiduciary responsibility of promoting patient safety may find comfort in leaving the task of advancing the standard of care to others. But this is directly contrary to the legal-ethical obligation of an attorney who engages himself or herself in the representation of health care providers and institutions. The legal/ethical standard to which health lawyers must be held is to advance the medical and ethical obligations of their clients. It can be asserted, therefore, by extension, that a hospital lawyer's legal-ethical obligation incorporates—by reference—the medical-ethical obligations of his or her physician and institutional clients. While it may be true that in a strictly commercial setting a lawyer has an obligation to prioritze avoidance of liability over other ethical obligations of his commercial client, the same cannot be said for legal practitioners in the for-profit, or not-for-profit, health care sector. It is in this respect that representing health care providers and institutions fun-

damentally changes the legal-ethical obligations of hospital lawyers. If the medical standard of care requires the health care practitioner to strive to improve the quality of care and enhance patient safety, then the health care lawyer's legal-ethical obligation to promote and facilitate that objective must take priority over the historical obligation of lawyers to insulate their clients from legal liability.

With this legal-ethical framework in mind, I rejected the assertion made by members of my medical staff that we could simply forgo the proposed improvement in the medical standard of care or that we could implement the change in policy and procedure, but not enforce it. The "legal" advice I provided to the Medical Board was that, having identified a risk of medication errors, due to the absence of documentation of a CID, as a patient safety concern, the hospital was obligated to both implement the proposed change in practice and to enforce it at the time of the breach of that standard. From an ethical perspective this must be the case, even though such a course might expose the hospital to tort liability if treatment was delayed while the responsible physician was contacted to properly complete his or her order.

Our discussion then turned to the question of what resources and efforts would have to be incorporated into the new policy and procedure to ensure that any failure by a physician to write a proper order was corrected as soon as possible. The procedure was, therefore, further expanded at additional cost in terms of time and resources in order to insure that incomplete medication orders were identified and corrected immediately upon their discovery.

As with most changes in practice in medicine, the window of vulnerability should be small because the constant flow of new medical interns and residents provides many opportunities to establish good habits in the first instance. The medical staff agreed to closely monitor physician compliance through daily review of pharmacy records of prescriber practice. Our experience to date has been excellent. The medical staff has adopted this change in practice patterns as they have so many others; with some suspicion, but willingness, nonetheless, to do what is best for the patient in the long run.

This change is not so different, of course, from the numerous accommodations we as lawyers have demanded from them in the reimbursement and compliance arenas. No doctor in practice today would expect to be paid for the care she/he provides without proper documentation of medical necessity or preauthorization. This was not the case as recently as a decade ago.

Conclusion

It is incumbent upon health care lawyers to acknowledge both to themselves and to their institutional clients that the practice of health care, as well as the practice of law, in the representation of health care clients, is a fundamentally different enterprise than that carried out by legal practitioners in non-health care settings. What distinguishes health care from all other human endeavors is that the process cannot be stopped in order to study and analyze the effects of quality improvement initiatives. The patients keep coming and, unlike a car or computer, you can not turn them off. To make peace with this responsibility you must resign yourself to the fact that stopping the bus is simply not an option.

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Public Health Emergencies in New York: Are We Legally Ready?

By Joshua Lipsman

I. Introduction

In the first years of this new century, New Yorkers have become acutely aware of the great hazards that the world can bring. From intentional tragedies, such as the destruction of the World Trade Center towers on September 11, 2001, and the bioterrorism of the anthrax attacks that fall, to accidents and naturally occurring disasters, such as the blackout of August 2003, and the outbreak of SARS that winter, residents of New York now are all too familiar with large-scale emergencies. Even as this article is written, the specter looms of a global pandemic of avian influenza.

"[H]ow is New York legally prepared to respond to a public health emergency, and what, if anything, should be done to improve the response capacity of New York's governments?"

All of those occurrences were either threatened or actual public health emergencies, in that they have the potential to affect the health of large numbers of people and it is in large part the responsibility of government entities to respond to them. In New York, government entities include municipal, county, and state governments, all of which may have roles to play in a public health emergency. Law, politics, and custom determine the respective responsibilities and formal relationships of the various levels of government in a public health emergency.

This article focuses on legal aspects of the responses by New York's government entities to public health emergencies. The questions asked are: how is New York legally prepared to respond to a public health emergency, and what, if anything, should be done to improve the response capacity of New York's governments? These questions are not only timely but also address some of the most significant tensions inherent in government's assumption of increased powers in a public health emergency: those arising from its need to prevent the spread of disease through the control and protection of persons, and the use, regulation and seizure of property.

Such tensions arise because the federal and state constitutions give us rights that can be infringed upon by government only in extraordinary circumstances. The United States Constitution assures that, "[n]o person shall be . . . deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation."[1] The Fourteenth Amendment applies the rights of due process and equal protection to state actions.[2] The New York State Constitution promises that, "[n]o person shall be deprived of life, liberty or property without due process of law[3] [and p]rivate property shall not be taken for public use without just compensation."[4] This article premises its analyses on these constitutionally guaranteed liberties.

Part II of the article focuses on the law in New York for dealing with public health emergencies. Part III considers the Model State Emergency Health Powers Act ("the MSEHPA"),[5] model legislation prepared by the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities. Part IV offers assessments of the law in New York and a proposed New York version of the MSEHPA. Part V concludes with some steps to enhance legal preparedness for public health emergencies in New York.

II. The Law in New York for Responding to Public Health Emergencies

Statutory law relating to civil liberties issues in public health emergency situations is limited. Some federal authority with regard to the control of communicable diseases is vested in the Surgeon General,[6] but for the most part states have this responsibility. In New York, relevant law is found in several places. The Public Health Law has no specific section on public health emergencies, but applicable provisions are found in sections on nuisances[7] and control of acute communicable diseases,[8] complemented by the State Sanitary Code.[9] Relevant Public Health Law statutes are few and no regulations other than the Sanitary Code pertain.

The Defense Emergency Act of 1951[10] is the most comprehensive legislation to address mass emergencies, including public health emergencies. It has no associated pertinent administrative rules and regulations other than a recent Executive Order that implicates no consti-

tutional issues.[11] State and Local Natural and Man-Made Disaster Preparedness legislation[12] passed in 1978 adds administrative detail to the state's planning and response authority; it has no associated regulations.

Dispositive case law relating to the control of persons or property in a public health emergency situation also is limited.

A. Basic New York Public Health Law

Under New York Public Health Law for the regulation of nuisances, the State Health Commissioner has "all necessary powers to make investigations and examinations into nuisances, or questions affecting the security of life and health in any locality."[13] This authority may be delegated to local health officers,[14] who, under the direction of the "local board of health, shall order the suppression and removal of all nuisances and conditions detrimental to life and health found to exist within the health district."[15]

New York Public Health Law for the control of acute communicable diseases declares that "[e]very local board of health and every health officer shall guard against the introduction of such communicable diseases as are designated in the sanitary code, by the exercise of proper and vigilant medical inspection and control of all persons and things infected with or exposed to such diseases."[16] Boards of health and health officers are authorized to "provide for care and isolation of cases of communicable disease in a hospital or elsewhere when necessary for protection of the public health."[17] The law does not have any generic provisions for vaccination or treatment although there are provisions for specific immunizations of students to attend educational institutions.[18]

Any "person having knowledge of an individual affected with any disease presumably communicable, [has the duty] to report immediately the name and address of such person to the . . . health officer."[19] The local health officer must investigate the circumstances surrounding reports that an individual is sick or infected with a communicable disease "and is unable or unwilling to conduct himself and to live in such a manner as not to expose members of his family or household or other persons . . . to danger of infection."[20] If the health officer finds that "a person so afflicted is a menace to others,"[21] he must bring the person before a magistrate who, after notice and hearing, "if satisfied that . . . the afflicted person is a source of danger to others, may commit the said person to [a] hospital or institution."[22]

Health officials have a right of entrance and inspection "to any house, building, vessel, or other premises . . . in the discharge of [their] official duties."[23] A health officer may direct that rooms and effects be cleansed and disinfected; articles that cannot be disinfected may be destroyed.[24]

The foregoing provisions are the only ones that apply to prevention and response to communicable diseases generally, and even those provisions require that a new disease be added to the State Sanitary Code either before or shortly after the law is enforced.[25] Public Health Law provisions for the control of specific diseases would not apply in the event of a public health emergency caused by a different microorganism.[26]

B. The New York State Defense Emergency Act

In 1951, the New York State Legislature declared that "there exists a serious danger that this state will be subjected to enemy attack, including attack by atomic bombs or other radiological weapons."[27] In passing the New York State Defense Emergency Act ("the Act") in response to perceived nuclear threats, the legislature declared that, "[i]t is the purpose of this legislation to meet these dangers and problems with the least possible interference with the existing division of the powers of the government and the least possible infringement of the liberties of the people, including the freedom of speech, press and assembly."[28]

The Act "established a broad coordinated civil defense program."[29] One of the Act's key provisions is the creation of the State Civil Defense Commission in the governor's office.[30] The Commission has extensive powers and duties, including authority to plan and promulgate wide-ranging regulations.[31]

During an attack, defined as "[a]ny attack, actual or imminent . . . by an enemy or a foreign nation . . . causing, or which may cause, substantial damage or injury to civilian property or persons . . . by the use of bombs, shellfire, or nuclear, radiological, chemical, bacteriological, or biological means,"[32] the Civil Defense Commission has even broader power, to commandeer personnel and materiel, both public and private.[33] Also during an attack that "jeopardizes the safety or the health of the people," the Act allows the Commission to permit counties and cities, to "compel the evacuation" of people in the name of safety; "control all pedestrian and vehicular traffic, transportation and communication facilities and public utilities; [and] take, use or destroy real or personal property and impress persons into service for" the Act's civil defense purposes.[34]

The Act also allows counties and the cities within counties to form consolidated offices of civil defense[35] and permits "two or more political subdivisions of the state [to] enter into mutual aid agreements [in which s]tate agencies [also] may participate."[36]

The Act permits the governor to "designate any area in the state . . . as an emergency health and sanitation area and fix the boundaries thereof" whenever "an emergency exists as the result of attack, or[if,] as a result of conditions created directly or indirectly by the defense effort, insufficient or inadequate medical or health personnel or facilities are available in any area."[37] After such a designation,

> it shall be the duty of the local board . . . of health . . . to make and enforce rules and regulations consistent with the provisions of the public health law (a) to prevent or limit the introduction or spread of any contagious or infectious disease and (b) to protect the public health within the area.[38]

The Act does not explain what "consistent with the provisions of the public health law" means, leaving open the possibility of both varied and contested applications of the Public Health Law in an attack situation.

The Act confers broad immunity from liability on the state and state actors acting in good faith, even in the event of death, personal injury or property damage.[39]

C. State and Local Natural and Man-Made Disaster Preparedness Legislation

In 1978, the New York State Legislature enacted State and Local Natural and Man-Made Disaster Preparedness legislation ("the legislation").[40] The legislature noted that, "the state must give leadership and direction to this important task of establishing an emergency disaster preparedness program, [but also found] that without local disaster planning, no state disaster program can be fully effective,"[41] since local governments are "the first line of defense in times of disaster."[42] The legislature further indicated that the purpose of the legislation was to empower local chief executives to "develop . . . and implement . . . disaster preparedness programs"[43] and to coordinate "state and local natural disaster and emergency response functions."[44]

The legislation creates "a disaster preparedness commission"[45] in the executive branch composed of high-level public and private officials that meets twice a year[46] to "prepare state disaster preparedness plans" that are to be reviewed and reported upon to the governor annually.[47] The Disaster Preparedness Commission serves in an executive capacity and must "coordinate" and "integrate" its work with that of the more administrative Civil Defense Commission.[48]

State disaster preparedness plans must include provisions for "disaster prevention[,] response[, and] recovery."[49] The legislation also authorizes counties to prepare "local disaster preparedness plans" with similar provisions.[50] In contrast with the Defense Emergency Act, the legislation contains no language authorizing any disaster preparedness plans to provide for exercising control over persons or private property.

"[F]ollowing the declaration of a state disaster emergency" the Disaster Preparedness Commission is to "direct state disaster operations and coordinate state [with local] disaster operations"[51] and is authorized to create "a temporary organization in the disaster area to provide for integration and coordination of efforts among the various federal, state, municipal and private agencies involved."[52] The Commission "may, with the approval of the governor, direct the temporary organization to assume direction of the local disaster operations of [a] municipality . . . unable to manage [its own] local disaster operations."[53]

The legislation allows the governor[54] or a local chief executive to declare a local state of emergency, during which the legislation grants the chief executive many of the powers conferred by the Defense Emergency Act, although the legislation offers more specifics and detail.[55] In a declared emergency, only the governor is authorized to request federal assistance.[56] During such an emergency, the governor may suspend state and local laws, subject to the state and federal constitutions and specified restrictions.[57]

D. Case Law

Federal and state case law regarding the control of persons and property applies in New York, although case law applicable to civil liberties issues in public health emergency situations generally is limited.[58] A particularly important federal case from a century ago, *Jacobson v. Massachusetts*,[59] is known for its confirmation of the reasonable use of state police power to protect public health and safety. The *Jacobson* plaintiff challenged his compulsory participation in the state's smallpox vaccination program as unreasonable, arbitrary and oppressive.[60] Affirming the Massachusetts Supreme Judicial Court holding that the program was constitutional, the Supreme Court held that:

> the liberty secured by the Constitution . . . does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. [I]t is a fundamental principle that "persons and property are subjected to all kinds of [reasonable] restraints and burdens, in order to secure the general comfort, health, and prosperity of the State. . . ."[61]

A contemporaneous New York case relied on by the *Jacobson* court, *Viemeister v. White*,[62] upheld mandatory smallpox vaccination for school entry. Plaintiff father appealed a lower court's denial of an order for the school to admit his unvaccinated child, which conflicted with school board regulations. Noting that "[w]hen the sole object and general tendency of legislation is to promote the public health, there is no invasion of the Constitution, even if the enforcement of the law interferes to some extent with liberty or property,"[63] the Court of Appeals held that "[i]f vaccination strongly tends to prevent the transmission or spread of this disease, it logically follows that children may be refused admission to the public schools until they have been vaccinated."[64]

In *In re Smith*,[65] plaintiffs challenged their involuntary quarantine during an outbreak of smallpox in Brooklyn. The *Smith* plaintiffs had a business carrying furniture and household effects in the city's "worst infected district."[66] The City of Brooklyn Health Commissioner asserted that they were "unusually exposed to . . . contagion" and required vaccination.[67] When plaintiffs refused, the commissioner ordered them quarantined in their house without judgment by a court, allegedly pursuant to local ordinance and state law.[68]

In proceedings ultimately reviewed by the Court of Appeals, plaintiffs alleged that they were imprisoned against their will and "they had been exposed to no contagion and were not afflicted with any disease, contagious or otherwise."[69] Agreeing with them, the court held that when persons are to be quarantined, they must be "either . . . infected with the contagious disease, or . . . exposed to it."[70] There was no mandatory vaccination law and the court held that the commissioner could not simply declare that:

> "wherever any person shall refuse to be vaccinated, such person shall be immediately quarantined and continued in quarantine until he consents to such vaccination." [To] give to [the Commissioner] the right to compel the vaccination of every citizen . . . if he would escape quarantine, seems . . . unnecessary and . . . an unwarrantable inference.[71]

Discharging the plaintiffs from the commissioner's custody, the court held "that an 'isolation of all persons and things' is only permitted when they are 'infected with or exposed to' contagious and infectious diseases [which] means, when speaking of persons and things 'exposed' to disease, the actual fact and not a mere possibility."[72]

A century later, during a resurgence of tuberculosis in New York City, challenges to quarantine resurfaced. A tuberculosis patient contested an order continuing her detention in a hospital until she completed her course of medication or became more reliable in taking it. She "argue[d] that her multi-drug resistant tuberculosis [could] be treated, and the public health protected, by means less restrictive than detention in a hospital" for the projected 18 to 24 month period.[73] In a succinct opinion, the Supreme Court, Appellate Division, disagreed, holding that the New York City Health Department had shown by clear and convincing evidence that appellant was unable to comply voluntarily with her treatment in a less restrictive environment. In another case from the Supreme Court of Queens County a year later, a petitioner requested to be released from detention in a hospital for treatment of tuberculosis after failing three times to complete her treatment as an outpatient. The court held that the City Health Commissioner "demonstrated through clear and convincing evidence [petitioner's] inability to comply with a prescribed course of medication in a less restrictive environment," and upheld the commissioner's detention order.[74]

The appropriate standard of proof was considered explicitly in a case of first impression following a consent order for involuntary hospital commitment for treatment of communicable tuberculosis.[75] The Supreme Court of Suffolk County clarified that the burden of proof standard for a state actor is clear and convincing evidence "when the 'denial of personal or liberty rights' is at issue or when 'particularly important personal interests are at stake.'"[76] The court applied the clear and convincing standard, which is intermediate between "the 'fair preponderance of the evidence' standard [of] civil cases and the 'beyond a reasonable doubt' standard [of] criminal cases, [because t]he party bearing the burden of establishing a fact by clear and convincing evidence must satisfy the trier of fact that what he claims is actually so."[77] The court held that:

> [a]lthough there is no mention of [the appropriate] standard in [the] Public Health Law, this situation is analogous to situations where, because of mental infirmity, a person is sought to be detained in a mental facility against his will pursuant to Mental Hygiene Law. In such situations, where the petitioner is a governmental agency, it must sustain its petition calling for involuntary detention of a person by clear and convincing evidence. Accordingly, this standard shall also govern here. . . .[78]

The court's reliance on the Mental Hygiene Law standard reflects the federal case law standard for civil commitment.[79]

With regard to property, there are two ways in which government may deprive an owner of property. Property may be physically seized or its value may be diminished by regulation. Any such deprivation is compensable if it is a "taking" under the Fifth Amendment. In general, most physical seizures of property are considered compensable takings.[80] Thus, seizures in a public health emergency of, e.g., a hospital or one of its operating rooms to treat victims, a drive-through restaurant for mass dispensing of antibiotics, or cell phone channels in order to maintain open lines for communication, potentially would be compensable since they would be physical confiscations of private property by the government. However, the Supreme Court has held that emergency governmental seizures of property are not always takings,[81] leaving open the question whether property seizures in a public health emergency would be deemed compensable.

The court considered regulatory takings in *Lucas v. S.C. Coastal Council*.[82] It reiterated the two categories of compensable takings (without regard to the legitimacy of any state interest) as either any "physical 'invasion' of . . . property [for which] (at least with regard to permanent invasions), we have required compensation [or when] all economically beneficial or productive use of land" is denied.[83] The *Lucas* court held that in some instances a total regulatory taking that denies an owner all economically viable use of property might not be compensable but that a regulatory taking not under established nuisance or property law must be compensated. This analysis could pose problems during a novel public health emergency in that, "it forces health officers to rely on often vague and outdated concepts of what constitutes a public health threat"[84] and does not allow them to designate new nuisances if they wish to avoid compensation.

However, the *Lucas* dissent argued that when there is a sufficiently important state interest, total deprivations of property are not takings and are not compensable,[85] citing Supreme Court precedents in which total property deprivations in situations of compelling state interest were not held to be compensable takings.[86] Such a perspective adds uncertainty as to how courts might apply *Lucas* in a public health emergency and whether total regulatory deprivations in such a situation would be takings.

A public health emergency that is a bioterrorist event also could be an act of war. In *United States v. Caltex (Philippines), Inc.*,[87] the court denied compensation claims for overseas oil terminal facilities that had been destroyed by the United States Army to prevent them from falling into enemy hands at the height of World War II. The court first considered prior century wartime takings of equipment by the Army for its own use, for which despite "[e]xtraordinary and unforeseen occasions [such as] in time of war or of immediate and impending public danger [nevertheless] the government is bound to make full compensation to the owner."[88] The court contrasted such situations with the matter at bar in which property was not "appropriated for subsequent use"[89] but destroyed to prevent its falling into enemy hands. Such destruction was not a compensable taking.[90]

In addition to compensation, the regulation and seizure of property are also subject to due process. Courts have held that substantive due process is not violated when legislatures regulate in areas of public health concern.[91] There are no definitive procedural due process requirements concerning property interests in public health emergencies, but the Supreme Court's consideration of procedural due process in the social welfare arena is instructive. Weighing the balance between the interests of an individual and the interests of government in challenges by recipients to terminations of their benefits, the court upheld a requirement for a pre-termination hearing when welfare benefits were at stake[92] but denied the right to a pre-termination hearing for disability benefits.[93] The *Eldridge* court explained the distinction between the due process required for termination from the two programs by reference to the public and private interests at stake and to "the risk of an erroneous deprivation of [the individual's] interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards."[94] The risk of hardship to the individual was less with the termination of disability benefits than with welfare benefits.

These holdings suggest that in a public health emergency, authorities should strive to comply with due process but that in some situations, courts will not always find that the interests of an individual sufficiently outweigh those of the government to require a hearing prior to depriving an individual of a property interest.

III. The Model State Emergency Health Powers Act (MSEHPA)

A. The MSEHPA

Declaring after the tragedy of September 11, 2001, that public officials must have "the ability to prevent, detect, manage, and contain emergency health threats without unduly interfering with civil rights and liberties,"[95] the Center for Law and the Public's Health at

Georgetown and Johns Hopkins Universities prepared the Model State Emergency Health Powers Act ("the MSEHPA").[96] The MSEHPA consists of eight articles dealing with planning for, detecting, tracking, and declaring a public health emergency; and with managing property, protecting persons, and providing public information during such an emergency. Almost all of the MSEHPA has been adapted from various state and federal statutory provisions.[97]

The MSEHPA is intended to be a template for states to better prepare themselves—through their laws—to respond to public health emergencies, such as bioterrorist attacks and massive disease epidemics "and, at the same time, [to] protect individual rights and freedoms."[98] It is "an attempted best synthesis of advice, recommendations, and dialogue regarding the purpose of emergency public health law, its proper reach, and the protection of civil liberties and private property."[99]

In New York, an edited version of the MSEHPA ("A.3207/S.185") has been introduced into the New York Legislature to enhance legal preparedness for bioterrorism. It consists of additions to section 29 of the Executive Law (adding measures for planning for, and declaring a public health emergency) and a new article 10 of the Public Health Law (adding measures for managing property, protecting persons, and providing public information during a public health emergency).[100] A hearing on the predecessor bills to A.3207/S.105 was held, although the bills were not adopted into law.[101]

Of note, the MSEHPA defines a public health emergency as being caused by bioterrorism or a naturally occurring event.[102] In contrast, A.3207/S.185 identifies only bioterrorism as the cause of a public health emergency, narrowing its scope and utility since its provisions would not be applicable in the event of a naturally occurring biological disaster.[103] Another significant modification from the MSEHPA in A.3207/S.185 is the exclusion of the MSEHPA provisions for detecting and tracking public health emergencies. This is perhaps because detecting and tracking provisions would be applicable to a variety of public health purposes, and it would not make sense to propose such innovations only for bioterrorism surveillance. However, exclusion of the provisions potentially limits opportunities to enhance the state's surveillance and monitoring capacities. The legislative record is silent as to the motivations for these and other variances from the text of the MSEHPA.

B. Reactions to the MSEHPA and Its New York Version

The MSEHPA is controversial for several reasons.[104] The very appropriateness of enhancing state power to respond to bioterrorism rather than strengthening federal response capabilities has been questioned in light of the anthrax attacks of 2001.[105] Given that bioterrorist acts and their effects can cross state borders rapidly and that in addition to being public health events, bioterrorist acts also are crimes or even acts of war, George Annas, a major critic of the MSEHPA, calls bioterrorism "an inherently federal matter."[106] Another critic has argued for "state regionalization" as the "optimal plan for the United States . . . for the initial response to a bioterrorist attack,"[107] given the "speed with which disease spreads in the twenty-first century, coupled with gaping differences between funding, staffing, and resource levels of state and local public health departments"[108] and the need for "some level of uniformity"[109] of response.

The MSEHPA also appears to favor comprehensive public health interventions too heavily at the expense of civil liberties,[110] despite the belief of one of its authors that the MSEHPA maintains "the delicate balance between public health and civil liberties in a constitutional democracy."[111] One commentator asserts that the MSEHPA "provides a strong basis . . . to reconsider [state] public health laws and update them as necessary but that [it] must be altered so as to bolster privacy and civil liberty protections that are unjustifiably weakened to an unnecessary degree."[112]

Annas has leveled other criticisms against the MSEHPA. These include the arguments that: it is difficult to assess the value of the MSEHPA because it is proposed as a remedy to an unspecified problem;[113] it is inappropriate to give public health authorities primacy in response to bioterrorism, given the equally important role to be played by physicians and hospitals;[114] it is unreasonable and unnecessary to compel participation by the medical community and the public in response to bioterrorism when the September 11, 2001, experience demonstrated their willingness to cooperate voluntarily[115] as did the 2003 SARS outbreak experience in Toronto;[116] if public health authorities compel cooperation, it "would . . . engender distrust [and perhaps active non-cooperation], because it would suggest that [they] could not provide valid reasons for their actions";[117] a large-scale involuntary quarantine is logistically impossible in today's world of the Internet, "televised news 24 hours a day, cell phones, and automobiles" (and in fact there has been no large scale quarantine in the United States for more than eighty years);[118] and state governors already have sufficient emergency powers,[119] although Annas also agrees that "many state public health laws are outdated and perhaps inadequate. . . ."[120]

Daniel Reich, another critic of the MSEHPA, has pointed out that the definitions of "quarantine" and

"isolation" in the MSEHPA may be overly broad and inconsistent with standard definitions of the terms.[121] Generally, quarantine is when individuals who have been, or are reasonably likely to have been, exposed to a communicable infection are restricted in their movement to a specified location, often the home, to allow time to see if they develop disease.[122] Isolation refers to the separation of a known or reasonably likely to be infected individual from others to prevent further transmission.[123] However, A.3207/S.185 defines quarantine as:

> the physical separation and confinement of an individual or groups of individuals, who are or *may have been* exposed to a contagious *or possibly contagious* disease and who do not show signs or symptoms of a contagious disease, from non-quarantined individuals, to prevent or limit the transmission of the disease to non-quarantined individuals.[124]

It defines isolation as "the physical separation and confinement of an individual or groups of individuals who are infected or reasonably believed to be infected with a contagious or *possibly contagious* disease from non-isolated individuals, to prevent or limit the transmission of the disease to non-isolated individuals."[125]

The inclusion of individuals who "may have been exposed" to a contagious disease without specification of a standard for the required degree of exposure potentially allows too broad of a group to be swept up.[126] It conflicts with the New York Court of Appeals *In re Smith*, holding that when persons are to be quarantined, they must be "either . . . infected with the contagious disease, or . . . exposed to it."[127] Permitting quarantine after exposure to, and isolation for infection with, a "possibly contagious disease" permits decisions to be made arbitrarily and in the absence of a "scientific basis for this determination."[128] Since A.3207/S.185 does not specify a standard for determining the likelihood of contagiousness of a disease, it gives considerable leeway to the discretion of the public health authority by allowing for quarantine and isolation based on popular professional suppositions that appear reasonable but have no scientific basis.

Annas finds many deficiencies in the article of the MSEHPA having to do with "protection of persons."[129] A.3207/S.185 permits the public health authority to isolate or quarantine "any person whose refusal of medical examination or testing results in uncertainty regarding whether such person has been exposed to or is infected with a contagious or possibly contagious disease, or otherwise poses a danger to public health."[130] Annas cautions that this is the equivalent of no standard at all since a refusal will result almost always in uncertainty, and the section thus allows too broad a discretion to isolate and quarantine.[131] A.3207/S.185 also permits the health authority to isolate or quarantine any person who has "not been vaccinated, treated, tested or examined,"[132] again allowing too broad a power, since such persons could include, among others, those who have not yet been processed merely because of public health staffing shortages.

A.3207/S.185 allows for compulsory vaccination without exception,[133] as the MSEHPA has, for a vaccine "reasonably likely to result in serious harm to the affected individual,"[134] whereas an exception is allowed in both A.3207/S.185 and the MSEHPA for treatment "reasonably likely to result in serious harm to the affected individual."[135] Those individuals refusing vaccination or treatment "for reasons of health, religion or conscience" may be quarantined or isolated.[136] Annas is critical of the latter provision, observing that "[t]oday, all adults have the constitutional right to refuse examination and treatment, and such a refusal should not result in involuntary confinement simply on the whim of a public health official."[137] The right to refuse treatment has been articulated by both the Supreme Court and the New York Court of Appeals.[138]

A.3207/S.185 allows the health authority up to 10 days to obtain a court order to continue isolation or quarantine that has been imposed upon individuals or groups of people,[139] and allows the court up to five days to hold a hearing, with a 10-day continuance allowed "in extraordinary circumstances and for good cause shown."[140] This means up to 25 days may pass before individuals or groups of people are afforded an opportunity to be heard. Hearings need not be individual; under certain circumstances the court may consolidate individual claims into a group.[141] A group hearing, though perhaps expedient in an emergency, nevertheless is worrisome from a civil liberties perspective.

Annas notes that, "the standard for a continued quarantine appears to be the finding that the person would 'significantly jeopardize the public health authority's ability to prevent or limit the transmission of a contagious or possibly contagious disease to others,'"[142] which wrongly shifts what should be an emphasis on an individual's status and its risk to the public's health to the prerogatives of government bureaucracy.[143] Of note, A.3207/S.185 states that the standard of proof for granting a health authority's petition for isolation or quarantine is a preponderance of the evidence,[144] which is counter to New York precedent that the standard is one of clear and convincing evidence.[145]

A.3207/S.185 has provisions regarding participation of medical and emergency health care providers within

the state that Annas finds "especially troublesome."[146] During a public health emergency due to bioterrorism, health personnel may be required "to assist" the public health authority "as a condition of continued licensure [or as a condition of] the ability to continue to function as a health care provider in this state,"[147] introducing an element of coercion that could work at cross-purposes to fostering an effective response capacity. Also, as a condition of licensure or functioning in the state, health care facilities may be required to provide services or the use of facilities "includ[ing] transferring the management and supervision of the health care facility to the public health authority for a limited or unlimited period of time."[148]

A.3207/S.185 has compensation provisions for lawful takings of private property for temporary or permanent use by public health officials during a declared bioterrorism emergency,[149] though not for destruction of property reasonably believed to endanger public health.[150] To destroy property, public health officials must institute civil proceedings "to the extent practicable."[151]

A.3207/S.185 offers health personnel immunity from civil liability, even in the case of death, personal injury or property damage, except for gross negligence or willful misconduct.[152] Interestingly this appears to be a greater degree of legal exposure than provided for in the Defense Emergency Act, which confers total immunity from liability.[153] A.3207/S.185 also extends the same degree of immunity from civil liability to the governor, the public health authority, participating state and local officials,[154] and "any private person, firm or corporation, and the[ir] employees and agents" either under contract with,[155] or "who renders assistance or advice" at the request of the government.[156] Out-of-state emergency health care providers are granted greater immunity, being held liable only for "reckless disregard for . . . life or health."[157]

The degree of immunity for so broad a spectrum of state actors in the face of arguably vague standards for the protection of persons appears to be a final, if not fatal, flaw in A.3207/S.185, by tipping the balance to favor sweeping, far-reaching public health interventions at the expense of civil liberties. The critical defect is inadequate accountability. "Citizens should never be treated against their will by their government, but if they ever are, they should be fully compensated for injuries suffered as a result."[158]

IV. The Law in New York and the Proposed Law: An Assessment

Although in disparate parts, New York's legal capability to respond to a public health emergency is robust. The New York State Defense Emergency Act enables the State Civil Defense Commission to plan and promulgate regulations regarding most conceivable aspects of a response to an actual or imminent attack.[159] In addition to state-level authority, localities may consolidate their own civil defense efforts and form mutual aid agreements.[160]

In the event of an attack, broadly defined, the State Civil Defense Commission has the power to take any state assets and any and all real or personal property.[161] The Commission also has the power during an attack to appropriate civil defense powers from counties and cities, and may have the power to give counties and cities far-reaching authority to compel evacuation, take or destroy property, and draft people into service.[162]

The governor may designate any part of the state as an emergency health and sanitation area, which confers authority on the local board of health to take and enforce necessary measures to protect public health.[163] State actors, including designated private individuals and entities, enjoy absolute immunity for good faith, civil defense-related actions even if they result in death or property damage.[164]

Both the State and Local Natural and Man-Made Disaster Preparedness legislation and the Defense Emergency Act enable a state disaster preparedness planning capacity although the legislation gives additional detail not in the Act. As well, the legislation applies in the event of a disaster, as the Act does not. The legislation also includes explicit authority after the declaration of a state of emergency for the imposition of a qualified form of martial law by the governor or a local chief executive.[165]

The Public Health Law, through its nuisance and communicable disease provisions and the State Sanitary Code, gives state and local public health authorities powers of surveillance and control of nuisances and of persons and things infected or exposed to a long list of communicable diseases, including broad powers of quarantine and isolation with notice and hearing.[166] However, there are no provisions to mandate vaccination or treatment other than for students. Public health authorities may seize or destroy articles hazardous to the public health and may regulate public health nuisances.[167] All persons have a duty to report known or suspected cases of communicable disease to public health authorities.[168]

Federal case law upholds the reasonable use of state police power to protect public health and safety.[169] New York precedents have clarified the Public Health Law by upholding mandatory vaccination of school children to promote the public good,[170] proscribing vaccination in the clear absence of infection or exposure to contagious disease,[171] setting a standard of proof of the need

for quarantine of clear and convincing evidence,[172] and mandating the least restrictive quarantine environment.[173]

The Constitution requires compensation for physical or regulatory takings, though for the latter only if all value is lost and the taking is not under established nuisance or property law.[174] In a public health emergency or wartime, certain physical takings may not be compensable.[175] Substantive due process is not violated by regulations that bear some rational relationship to a legitimate legislative purpose in a public health emergency.[176] The requirements of due process in a public health emergency might be determined by a balancing of private and public interests and the risk of hardship to an individual with the "value . . . of additional or substitute procedural safeguards."[177]

A.3207/S.185, introduced this year in the New York Legislature, contains a number of provisions that are non-controversial and that could add meaningful elements to New York law.[178] However, A.3207/S.185 also has controversial aspects, raising cautionary signals about enactment. First, it is unclear whether it is appropriate to strengthen state rather than federal power given the potential for widespread diffusion and the criminal nature of bioterrorism. As well, the extent to which A.3207/S.185 tips the balance away from civil liberties and toward public health control of persons and property should be clarified, made explicit and discussed as a matter of public policy before any law is passed. Even the premise in A.3207/S.185 that a mass quarantine could be imposed effectively in today's world of instant electronic communications is uncertain. By the time a state bureaucracy has mobilized itself, significant numbers of people will have heard of impending plans in an e-mail or a cell phone call and fled. Part of the problem with A.3207/S.185 is that conceptualizations of possible bioterrorist events are so varied that a "one size fits all," stand-alone statute may be meaningless.

Among the controversial provisions of A.3207/S.185 are: the degree to which it gives primary responsibility for responding to bioterrorism to public health authorities rather than equally including physicians and hospitals; the compelling of health care professionals and facilities to assist in the event of bioterrorism even if compensated; the broad discretion granted to public health officials to decide who and when to examine, vaccinate, treat, quarantine and isolate; the perception of inadequacy in the due process afforded those contesting quarantine or isolation;[179] and its immunity provisions.

V. Next Steps

Ultimately, the primary benefit of the MSEHPA may be "the extent [to which] it encourages states to review their emergency laws."[180] It may be worthwhile also to review New York Public Health Law to improve it rather than adopting A.3207/S.185 in its entirety. One valuable source for such a review is the Turning Point Model State Public Health Act,[181] the goal of which is "to assist state and local governments to assess their existing public health laws and update laws to effectively address a range of modern public health issues."[182] The Turning Point Model State Public Health Act includes, *inter alia,* a section and other relevant provisions on public health emergencies derived from the MSEHPA[183] and explicit provisions that address criticisms of the MSEHPA.[184]

Philosophic and ethical issues raised by A.3207/S.185 and the MSEHPA[185] should be considered and resolved explicitly in the legislature before enactment of any of its provisions. Provisions of A.3207/S.185, the MSEHPA, and other sources merit selective incorporation into New York law, allowing meritorious and relevant passages to be included while avoiding controversy and redundancy. Any adopted provisions should be appropriately amended for consistency. For example, A.3207/S.185 does not include a role for local governments in public health emergency response. Local involvement is an important component of public health practice in New York, a reality that is reflected in statutory language. As well, inconsistencies in the proposed law with prevailing standards of liability, immunity and proof should be resolved.

The sections on detection and tracking of the MSEHPA should be considered for enactment in New York. Surveillance is a bedrock public health function. Prior to, and during, potential contemporary public health emergencies "public health officers may need additional authorities beyond [conventional] surveillance and disease reporting."[186] Given the explosion of methods for information gathering and of types of information available since surveillance laws were last enacted, the enhancement of state and local detection and tracking capabilities would be an invaluable addition to public health.

With regard to measures for the control or protection of persons, standards for decision-making in the Public Health Law should be made more explicit and reflect civil libertarian values that were not considered when the laws were initially drafted. Non-disease-specific provisions for examination, vaccination and treatment should be incorporated. Their development should be informed by a recognition of the tension between (a) the need for public health officials to compel certain outcomes in order to optimize the response to a rapidly evolving, mass public health emergency; and (b) the potential for mandates to foment reactions that range from public mistrust of authorities to overt civil disobedience. Provisions for the control of proper-

ty in New York law should be updated to reflect principles of compensation and due process.

The last four years have witnessed a veritable renaissance of interest in public health and its role, particularly in public health emergencies. A crucial aspect of public health is its legal underpinnings. The introduction of A.3207/S.185 in New York represents a valuable opportunity to improve legal preparedness that should be exploited.

Endnotes

1. U.S. Const. amend. V.
2. U.S. Const. amend. XIV, § 1.
3. N.Y. Const. art. I, § 6.
4. N.Y. Const. art. I, § 7(a).
5. Lawrence O. Gostin, *Model State Emergency Health Powers Act, December 21, 2001* (MSEHPA), *available at* http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf (last visited Mar. 25, 2005).
6. *See* 42 U.S.C. § 264 (2005).
7. N.Y. Pub. Health Law art. 13 (Consol. 2004) (PHL).
8. *Id.* art. 21.
9. N.Y. Comp. Codes R. & Regs. tit. 10, ch. I (2005) (N.Y.C.R.R.).
10. New York State Defense Emergency Act, N.Y. Unconsol. Law ch. 131 (Consol. 2004).
11. 9 N.Y.C.R.R., § 5.132 (2005) (Designating the State Prevention and Preparedness Council; Establishing the Positions of Senior Advisor to the Governor for Counter-Terrorism and Senior Advisor to the Governor for Disaster Preparedness and Response; and Revoking Certain Executive Orders.).
12. N.Y. Exec. Law art. 2-B (Consol. 2004). The legislation does not have a formal title.
13. PHL § 1300(1) (Consol. 2004).
14. *Id.* § 206(9).
15. *Id.* § 1303(3).
16. *Id.* § 2100(1) (Consol. 2004).
17. *Id.* § 2100(2)(a).
18. *Id.* §§ 2164 (against polio, mumps, measles, diphtheria, German measles, chickenpox, Haemophilus influenza type b, whooping cough, tetanus, and Hepatitis B), 2165 (against measles, mumps and German measles), 2176 (against meningococcal meningitis).
19. 10 N.Y.C.R.R., § 2.12 (2005).
20. PHL § 2120(1) (Consol. 2004).
21. *Id.* § 2120(2).
22. *Id.* § 2120(3).
23. 10 N.Y.C.R.R., § 1.11 (2005).
24. PHL § 2100(2)(b) (Consol. 2004); 10 N.Y.C.R.R., § 2.53 (2005).
25. 10 N.Y.C.R.R., § 2.1(a) (2005).
26. *See*, *e.g.*, PHL §§ 2130-39 (HIV), 2140-46 (rabies), 2220-30 (tuberculosis), 2300-11 (STDs), 2780–87 (HIV) (Consol. 2005).
27. New York State Defense Emergency Act, N.Y. Unconsol. Law ch. 131 § 2 (Consol. 2004).
28. *Id.* § 2.
29. *Id* § 2-a.
30. *Id.* § 20.
31. These include provisions for "[m]edical treatment, food, clothing and shelter[,] materials and facilities[;] training and information [for] the public [and] municipal agencies[; e]vacuation of certain persons in the event of or anticipation of attack, including the establishment of temporary housing and schools and other emergency facilities[; c]ontinuity of [g]overnment[; p]ublic order[, including the c]ontrol of pedestrian and vehicular traffic, transportation and communication facilities, public utilities and the conduct of persons other than members of the armed services or military forces in the event of an attack, during drills and tests and immediately prior and subsequent thereto." *Id.* § 21 (Consol. 2004).
32. *Id.* § 3(2).
33. The commission has authority to "(a) assume direct operational control of any or all civil defense forces; (b) order, direct, require and use the personnel, materials, facilities and services of any agency, public officer, or political subdivision of the state, . . . (d) take, use or destroy any and all real or personal property, or any interest therein, necessary or proper for the purposes of civil defense; (e) execute any or all of the civil defense powers and duties of any county or city after notifying the chief executive officer of such county or city if such notification is possible." New York State Defense Emergency Act, N.Y. Unconsol. Law ch. 131 § 25(1) (Consol. 2004).
34. *Id.* § 25(2). The Act states that the permitting of counties and cities to execute the aforementioned powers is subject not only to the "plans, regulations and orders" of the commission, but also to a "State Defense Council" created by the Act. *Id.* § 25(2). The existence of the State Defense Council is terminated by the Act at the termination of the then national emergency. *Id.* § 3(13). This likely was in the early 1950s. If the permitting of expanded powers to counties and cities during an attack requires action by both the Civil Defense Commission and a State Defense Council that no longer exists, it is uncertain whether the Commission alone could confer such permission. Thus, it is unclear if the Act's authorization of the delegation of control over the movements of persons and property to counties and cities remains lawful.
35. *Id.* § 27.
36. *Id.* § 28.
37. *Id.* § 43.
38. *Id*.
39. "The state, any political subdivision, municipal or volunteer agency, . . . or any individual, partnership, corporation, association, . . . in good faith carrying out, complying with or attempting to comply with any law, any rule, regulation or order duly promulgated or issued pursuant to this act . . . in preparation for anticipated attack, during attack, or following attack or false warning thereof, or in connection with an authorized drill or test, shall not be liable for any injury or death to persons or damage to property as the result thereof." New York State Defense Emergency Act, N.Y. Unconsol. Law ch. 131 § 113 (Consol. 2004).
40. N.Y. Exec. Law art. 2-B (Consol. 2004). As justification, the Legislature asserted "that it must provide for preparations to prevent, meet, defend against and recover from, dangers and problems arising from . . . a wide variety of disasters, often caused or compounded by mankind's own acts . . . with the least possible interference with the existing division of the powers of the government." 1978 N.Y. Laws ch. 640, § 1 (cited at N.Y. Exec. Law § 20 (Consol. 2004)).
41. 1978 N.Y. Laws ch. 640, § 1 (cited at N.Y. Exec. Law § 20 (Consol. 2004)).
42. N.Y. Exec. Law § 20(1)(a) (Consol. 2004).

43. *Id.* § 20(1)(b).
44. *Id.* § 20(1)(c).
45. *Id.* § 21(1).
46. *Id.* § 21(2).
47. *Id.* § 21(3)(c).
48. N.Y. Exec. Law § 21(3)(j) (Consol. 2004). Powers of the civil defense commission are enumerated in the Defense Emergency Act, N.Y. Unconsol. Law ch. 131 (Consol. 2004).
49. N.Y. Exec. Law § 22(3) (Consol. 2004).
50. *Id.* § 23(1).
51. *Id.* § 21(3)(e).
52. *Id.* § 21(3)(f).
53. *Id.* § 21(3)(f).
54. *Id.* § 28(1).
55. The chief executive "may promulgate local emergency orders to protect life and property or to bring the emergency situation under control . . . . Such orders may . . . provide for . . .the establishment of a curfew and the prohibition and control of pedestrian and vehicular traffic; . . . the designation of specific zones within which the occupancy and use of buildings and the ingress and egress of vehicles and persons may be prohibited or regulated; . . . the regulation and closing of places of amusement and assembly; . . . the suspension or limitation of the sale, dispensing, use or transportation of alcoholic beverages, firearms, explosives, and flammable materials and liquids; . . . the prohibition and control of the presence of persons on public streets and places; . . . the suspension within any part or all of its territorial limits of any of its local laws, ordinances or regulations, or parts thereof subject to federal and state constitutional, statutory and regulatory limitations [and also] subject to . . . standards and limits [as described in the legislation]." N.Y. Exec. Law § 24(1) (Consol. 2004).
56. *Id.* § 28(4).
57. *Id.* § 29-a.
58. Note that litigation has been limited to the Public Health Law and its antecedents. There are no civil liberties cases under the Defense Emergency Act or the State and Local Natural and Man-Made Disaster Preparedness legislation.
59. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).
60. *Id.* at 26.
61. *Id*.
62. *Viemeister v. White*, 72 N.E. 97 (N.Y. 1904).
63. *Id*.
64. *Id*.
65. *In re Smith*, 40 N.E. 497 (N.Y. 1895).
66. *Id*.
67. *Id*.
68. *Id.* at 498.
69. *Id*.
70. *Id*.
71. 40 N.E. at 498.
72. *Id.* at 498-99.
73. *City of New York v. Doe*, 614 N.Y.S.2d 8, 9 (App. Div. 1994).
74. *City of New York v. Antoinette R.*, 630 N.Y.S.2d 1008, 1011 (Sup. Ct., Queens Co. 1995).
75. *Radley v. Crowell*, 694 N.Y.S.2d 617 (Sup. Ct., Suffolk Co. 1999).
76. *Id.* at 618 (citation omitted).
77. *Id*.
78. *Id.* (citation omitted).
79. *See Addington v. Texas*, 441 U.S. 418 (1979) (holding in a challenge to a state civil commitment proceeding that the standard of proof was clear and convincing evidence).
80. James J. Misrahi et al., *Legal Authorities for Interventions During Public Health Emergencies*, *in* Law in Public Health Practice 195, 203 (Richard A. Goodman et al. eds., 2002).
81. *See*, *e.g.*, *Miller v. Schoene*, 276 U.S. 272 (1928) (holding in a suit challenging a Virginia statute requiring certain trees to be cut when trees of much greater economic value were threatened by infection that the exercise of police power is characterized by the state's choosing to favor the public interest over a private property interest and that no compensation need be paid (plaintiff was left with the salvage value of the cut wood)).
82. *Lucas v. S.C. Coastal Council*, 505 U.S. 1003 (1992).
83. *Id.* at 1015 (holding in a challenge to a regulation prohibiting construction of habitable structures on beachfront property that there was a compensable taking unless the regulated use was prohibited under "background principles of nuisance and property law," *id.* at 1031, and remanding).
84. Misrahi, *supra* note 80, at 203.
85. "This Court repeatedly has recognized the ability of government . . . to prohibit uses of property injurious to public health, safety, or welfare without paying compensation." *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1047 (1992) (Blackmun, J., dissenting).
86. "[I]n *Keystone Bituminous Coal*, the Court summarized over 100 years of precedent: 'The Court has repeatedly upheld regulations that destroy or adversely affect real property interests.'" *Id.* at 1049 (quoting *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 489, n.18 (1987)).
87. *United States v. Caltex (Philippines), Inc.*, 344 U.S. 149 (1952).
88. *Id.* at 152, n.2.
89. *Id.* at 155.
90. *See also United States v. Central Eureka Mining Co.*, 357 U.S. 155 (1958) (denying compensation for mandated wartime conservation of mining resources and holding that the court has "treated the issue as to whether a particular governmental restriction amounted to a constitutional taking as being a question properly turning upon the particular circumstances of each case[.] In the context of war, we have been reluctant to find that . . . regulation [depriving an owner of the most profitable use of property] requires compensation to be paid for resulting losses of income[. The effect of such regulation is] insignificant when compared to the widespread uncompensated loss of life and freedom of action which war traditionally demands." *Id.* at 168).
91. *See*, *e.g.*, *Beattie v. City of New York*, 123 F.3d 707 (2d Cir. 1997) (holding in an unsuccessful challenge to a New York City regulation prohibiting indoor smoking that a "rational relationship between the legislation and a legitimate legislative purpose," *id.* at 711, was sufficient for substantive due process and that the burden of disproving such a relationship was on the challenger); *New York City Friends of Ferrets v. City of New York*, 879 F. Supp. 529 (S.D. N.Y. 1995) (holding in an unsuccessful challenge to New York City regulation of ferrets that "deprivation of private property pursuant to an exercise of police power is constitutionally permissible where the challenged legislative enactment bears a rational relationship to legitimate legislative goal or purpose," *id.* at 534).
92. *Goldberg v. Kelly*, 397 U.S. 254 (1970).
93. *Mathews v. Eldridge*, 424 U.S. 319 (1976).

94. 424 U.S. at 335.

95. Gostin, *supra* note 5, § 103(g).

96. Gostin, *supra* note 5.

97. New York law is minimally used as a source. The MSEHPA "definition for 'organized militia' was adapted from NY CLS Military § 1 (2001)," Gostin, *supra* note 5, at 12, "[s]ection 302, the main text under 'Tracking' was adapted from . . . N.Y. Comp. Codes R. & Regs. tit. 10, § 2.6 (LEXIS through Oct. 12, 2001)," *id.* at 17, and "[s]ection 602 [Medical examination and testing] was adapted from . . . N.Y. Comp. Codes R. & Regs. tit. 10, § 2.5 (LEXIS through Oct. 12, 2001)," *id.* at 26.

98. Lawrence O. Gostin et al., *The Model State Emergency Health Powers Act: Planning for and Response to Bioterrorism and Naturally Occurring Infectious Diseases*, 288 JAMA 622 (2002).

99. *Id.* at 625.

100. The legislation has been introduced in three of the last four legislative sessions, most recently as A.3207, 2004-2005 Assem., Reg. Sess. (N.Y. 2005)/S.185, 2004-2005 S., Reg. Sess. (N.Y. 2005) (hereinafter A.3207/S.185).

101. *Public Health Emergency Planning and Response and the Model Emergency State Health Powers Act: Hearing on A.9508-A Before the Assem. Comms. on Health, Codes, Gov't Operations*, 2001-2002 Assem., Reg. Sess. (N.Y. 2002).

102. A natural event occurs with "the appearance of a novel or previously controlled or eradicated infectious agent or biological toxin." Gostin, *supra* note 5, § 104(m)(1)(ii).

103. A.3207/S.185, PHL § 1003(13) (proposed). The legislation consists of four sections. The first section is a statement of legislative intent. The second section is the proposed additions to § 29 of the Executive Law. The third section is the proposed art. 10 of the PHL. The fourth section is the stated effective date. References to A.3207/S.185 cite to the proposed sections of the Executive Law and the Public Health Law within sections two and three, rather than to the four sections of the legislation itself.

104. I will consider only those sections of the MSEHPA that are included in A.3207/S.185, as those are the ones potentially applicable in New York. Also, as a convention, I will refer to "the MSEHPA" when considering commentary made exclusively with respect to the MSEHPA (even though it applies to A.3207/S.185) and to "A.3207/S.185" when discussing A.3207/S.185.

105. George J. Annas, *Bioterrorism, Public Health, and Civil Liberties*, 346 New Eng. J. Med. 1337 (2002).

106. *Id*.

107. Matthew E. Brown, *Reconsidering the Model State Emergency Health Powers Act: Toward State Regionalization in Bioterrorism Response*, 14 Ann. Health L. 95, 97 (2005).

108. *Id.* at 100-01.

109. *Id.* at 120.

110. Annas, *supra* note 105, at 1341.

111. Gostin, *supra* note 98, at 623.

112. Daniel S. Reich, *Modernizing Local Responses to Public Health Emergencies: Bioterrorism, Epidemics, and the Model State Emergency Health Powers Act*, 19 J. Contemp. Health L. & Pol'y 379, 382 (2003).

113. Annas, *supra* note 105, at 1338.

114. *Id.* at 1339.

115. *Id*.

116. Lawrence O. Gostin et al., *Concurrent Session: Building Emergency Legal Preparedness: Quarantine: Voluntary or Not?*, 32 J.L. Med. & Ethics 83 (2004).

117. Annas, *supra* note 105, at 1340.

118. *Id*.

119. *Id*.

120. *Id.* at 1337-38.

121. Reich, *supra* note 112, at 408-10.

122. *See* Dorland's Illustrated Medical Dictionary (26th ed. 1985).

123. *Id*.

124. A.3207/S.185 § 1003(15) (emphasis added).

125. *Id.* § 1003(8) (emphasis added).

126. *See* Reich, *supra* note 112, at 408-410.

127. *In re Smith*, 40 N.E. 497, 498 (N.Y. 1895).

128. Reich, *supra* note 112, at 408-410.

129. A.3207/S.185 §§ 1020-27.

130. *Id.* § 1021(3).

131. Annas, *supra* note 105, at 1341.

132. A.3207/S.185 § 1023(1).

133. *Id.* § 1022(1) (perhaps this is an error in transcription).

134. Gostin, *supra* note 5, § 603(a)(2).

135. A.3207/S.185 § 1022(2)(b).

136. *Id.* §§ 1022(1)(b), (2)(c).

137. Annas, *supra* note 105, at 1340.

138. *See, e.g.*, *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261 (1990) (holding in a challenge to an order to withdraw artificial nutrition devices that patients generally have the right to refuse treatment); *Rivers v. Katz*, 495 N.E.2d 337 (N.Y. 1986) (holding in a challenge by institutionalized patients to the involuntary administration of antipsychotic medication "that every individual 'of adult years and sound mind has a right to determine what shall be done with his own body' and to control the course of his medical treatment," *id.* at 341 (citation omitted)).

139. A.3207/S.185 § 1024(1)(d).

140. *Id.* § 1024(2)(d).

141. *Id.* § 1024(5)(b).

142. Annas, *supra* note 105, at 1341 (quoting Gostin, *supra* note 5, § 605(a)(1) (also found at A.3207/S.185 § 1024(1)(a))).

143. The standard seems to be the degree to which release from quarantine hampers the on-going emergency work of the public health authority, instead of the determination that an individual or a group is not infected and consequently no longer an actual or a potential risk to the public's health. One can conceive of a situation in which large numbers of people are continued in quarantine for convenience' sake merely to avoid adding to massive chaos that has arisen during a bioterror event, rather than justifying the continued quarantine with a "true" public health reason.

144. A.3207/S.185 § 1024(2)(e).

145. *Bradley v. Crowell*, 694 N.Y.S.2d 617 (Sup. Ct. 1999).

146. Annas, *supra* note 105, at 1341.

147. A.3207/S.185 § 1027(1).

148. *Id.* § 1011(2).

149. *Id.* § 1044(1).

150. "Just compensation [shall be paid] to the owner of any facility or material that is lawfully taken or appropriated by the public health authority for its temporary or permanent use [though payment] shall not be provided for facilities or materials that are closed, evacuated, decontaminated or destroyed when there is

reasonable cause to believe that they may endanger the public health. . . ." *Id.* § 1015. A.3207/S.185 also has a provision for determining the amount of any compensation. *Id.* § 1044(3).

151. *Id.* § 1016.
152. *Id.* § 1043(2)(c). The legislation is silent as to any criminal liability.
153. N.Y. Unconsol. Law ch. 131 § 113 (Consol. 2004).
154. A.3207/S.185 § 1043(1).
155. *Id.* § 1043(2)(b).
156. *Id.* § 1043(2)(c).
157. *Id.* § 1027(2)(c).
158. Annas, *supra* note 105, at 1341.
159. New York State Defense Emergency Act, N.Y. Unconsol. Law ch. 131 § 21 (Consol. 2004).
160. *Id.* §§ 27-28.
161. *Id.* §§ 3, 25.
162. *Id.* § 25.
163. *Id.* § 43.
164. *Id.* § 113.
165. N.Y. Exec. Law §§ 24(1), 29(a) (Consol. 2004).
166. PHL §§ 1303(3), 2100(1)-(2)(a), 2120(1)-(3) (Consol. 2004).
167. *Id.* § 2100(2)(b) (Consol. 2004); 10 N.Y.C.R.R., § 2.53 (2005)
168. 10 N.Y.C.R.R., § 2.12 (2005).
169. *Jacobson v. Massachusetts,* 197 U.S. 11 (1905).
170. *Viemeister v. White*, 72 N.E. 97 (N.Y. 1904).
171. *In re Smith*, 40 N.E. 497 (N.Y. 1895).
172. *Bradley v. Crowell*, 694 N.Y.S.2d 617 (Sup. Ct., Suffolk Co. 1999).
173. *City of New York v. Doe*, 614 N.Y.S.2d 8 (App. Div. 1994); *City of New York v. Antoinette R.*, 630 N.Y.S.2d 1008 (Sup. Ct., Queens Co. 1995).
174. *Lucas v. S.C. Coastal Council*, 505 U.S. 1003 (1992).
175. *Miller v. Schoene*, 276 U.S. 272 (1928); *United States v. Caltex (Philippines), Inc.*, 344 U.S. 149 (1952).
176. *Beattie v. City of New York*, 123 F.3d 707 (2d Cir. 1997).
177. *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976).
178. Full consideration of all such elements is beyond the scope of this article.
179. The minimal due process provisions of A.3207/S.185 contrast starkly with the extensive safeguards afforded the mentally ill when committed involuntarily to a mental hospital in N.Y. under art. 9 of the Mental Hygiene Law.
180. Annas, *supra* note 105, at 1338.
181. Turning Point, Model State Public Health Act (2003), *available at* http://www.turningpointprogram.org/Pages/MSPHAfinal.pdf (last visited May 4, 2005).
182. *Id.* at 1.
183. *See id.* arts. V (Public Health Authorities/Powers), VI (Public Health Emergencies), VIII (Administrative Procedures, Civil and Criminal Enforcement, and Immunities).
184. *See, e.g., id.* §§ 5-108(b) (defining conditions and principles for quarantine and isolation, including requirements for the least restrictive means necessary, regular monitoring of individuals, immediate termination when an individual no longer poses a risk), (d)-(f) (elaborating procedures for isolation and quarantine with and without notice and hearing, and relief therefrom), 5-109(h) (listing four exceptions to required vaccination), 6-105(b) (providing for immunity for non-state actors assisting the state from civil liability for death or personal injury except for gross negligence or willful misconduct), 8-104 (specifying criminal penalties to which state actors are subject), 8-105 (specifying civil remedies available against state actors), 8-107(a) (providing for immunity for state actors from liability for death or personal injury except for gross negligence or willful misconduct).
185. Listed *supra* in text of paragraph following n.178.
186. Misrahi, *supra* note 80, at 201.

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Editor's Note—This article was prepared before the occurrence of Hurricane Katrina. It will be discussed at an upcoming symposium hosted by Pace Law School, the New York State Judicial Institute and the Westchester County Department, "Public Health and the Law: Responding to Terrorism and Other Public Health Emergencies in New York," to be held in White Plains, NY, on November 30, 2005. For more information, contact jbrand@law.pace.edu or visit www.law.pace.edu.

The Barry Gold Memorial Health Law Student Writing Competition is named after the founding Chair of the Health Law Section, who died in 2002.

EDITOR'S SELECTED COURT DECISION

In the Matter of M.B., 2003-10271 (2d Dep't 2005)
In the Matter of M.B. (Anonymous) Mental Hygiene Legal Service, appellant; Staten Island Developmental Disabilities Services Office, et al., respondents.

(File No. 33/02). 2003-10271.
Appellate Division of the Supreme Court of New York, Second Department.
Decided June 13, 2005.

APPEAL by the Mental Hygiene Legal Service, in a proceeding pursuant to SCPA article 17-A to determine that the guardian of M.B. did not have the authority to withhold or withdraw life-sustaining treatment pursuant to SCPA 1750 and 1750-b, effective March 16, 2003, on the ground that those provisions are not to be applied retroactively to guardians appointed prior to the effective date, from so much of an order of the Surrogate's Court (John Fusco, S.), dated October 31, 2003, and entered in Richmond County, as denied its petition.

Mental Hygiene Legal Service, Mineola, N.Y. (Sidney Hirschfeld, Lisa Volpe, and Dennis B. Feld of counsel), appellant pro se.

Eliot Spitzer, Attorney General, New York, N.Y. (Michael S. Belohlavek and Jean Lin of counsel), for respondent Staten Island Developmental Disabilities Services Office.

NYSARC, Inc., Delmar, N.Y. (Tania F. Seaburg and John F. Von Ahn of counsel), amicus curiae.

Before: HOWARD MILLER, J.P., THOMAS A. ADAMS, GLORIA GOLDSTEIN, ROBERT A. SPOLZINO, JJ.

OPINION & ORDER

GOLDSTEIN, J.

By amended decree of the Surrogate's Court, Richmond County, dated January 24, 2003, M.B.'s brother, R.B., was appointed "guardian of the person only" of M.B. The amended decree made no mention of any powers to make health care decisions. Thereafter, M.B. was admitted to Staten Island University Hospital suffering from pneumonia, hypertension, and hypoxia. In early October 2003, he was placed on a respirator for breathing and a nasal-gastric tube for feeding and hydration. On or about October 14, 2003, R.B., as guardian of the person of M.B., requested pursuant to SCPA 1750-b that life-sustaining treatment be withdrawn and withheld from M.B.

SCPA 1750-b is part of the "Health Care Decisions Act for Persons with Mental Retardation" (L 2002, ch 500), effective March 16, 2003. This act of the Legislature also amended SCPA 1750 relating to the appointment of guardians for mentally-retarded persons. SCPA 1750-b(1) provides that "[u]nless specifically prohibited by the court" the guardian for a mentally-retarded person appointed pursuant to SCPA 1750 has the authority to make health care decisions on behalf of the mentally-retarded person which "may include decisions to withhold or withdraw life-sustaining treatment" as defined in Mental Hygiene Law § 81.29(e). Mental Hygiene Law § 81.29(e) defines life-sustaining treatment as "medical treatment" including "artificial nutrition and hydration" that "is sustaining life functions and without which, according to reasonable medical judgment, that patient will die within a relatively short time period."

The appellant Mental Hygiene Legal Service (hereinafter MHLS) commenced the instant proceeding to determine that R.B. did not have the authority to withhold or withdraw life-sustaining treatment pursuant to SCPA 1750 and 1750-b on the ground that those provisions are not to be applied retroactively to guardians appointed prior to their effective date. MHLS contended that R.B., as guardian of the person of M.B., could "only exercise authority under SCPA 1750-b if his authority is specifically expanded by the Surrogate." The order appealed from (see *Matter of MB*, 2 Misc 3d 328, 331), held that the Health Care Decisions Act for Persons with Mental Retardation "applies to all guardians, whether appointed before or after its effective date."

At the outset, we note that the issue of the powers of the guardian for M.B. is now academic, since M.B. died within hours of the termination of life-sustaining treatment. However, in view of a likelihood of the repetition of this issue in the future, the fact that the issue could tend to evade review, and that the questions raised by this appeal are substantial, an exception to the mootness doctrine applies (see *Matter of Hearst Corp. v. Clyne*, 50 NY2d 707, 714-715).

The constitutionality of the Health Care Decisions Act for Persons with Mental Retardation is in no way contested on this appeal. The only question before this court is whether its provisions are to be applied retroactively.

In determining whether the amendments should be applied retroactively, one must examine the legislative intent. "[T]he clearest indicator of legislative intent is the statutory text" (*Majewski v. Broadalbin-Perth*, 91

NY2d 577, 583). The retroactive application of statutes is not favored (see *Majewski v. Broadalbin-Perth*, supra at 594). Substantive statutes which create new rights are generally not applied retroactively; indeed, even statutes which are remedial in nature are not applied retroactively if vested rights would be impaired (see *Matter of Marino S.*, 100 NY2d 361, 371, cert denied 540 US 1059; *Alliance of Am. Insurers v. Chu*, 77 NY2d 573, 586; McKinney's Cons Laws of NY, Book 1, Statutes, § 51, pp 98-100).

The amendments were enacted to address a problem discussed in the relevant case law. New York case law holds that a competent adult has the right to refuse life-saving medical treatment (see *Matter of Fosmire v. Nicoleau*, 75 NY2d 182). When the patient is not competent, a decision to withhold or withdraw life-sustaining treatment may be made if there is clear and convincing evidence that the patient, when competent, did not wish to have his or her life prolonged by medical means with no hope of recovery (see *Matter of Storar*, 52 NY2d 363, cert denied 454 US 858). Such a determination can only be made if the patient "had been competent and capable of expressing" his or her wishes at some point (*Matter of O'Connor*, 72 NY2d 517, 529). In the case of Storar, who was profoundly retarded and was never able to competently express his wishes, the Court of Appeals held that the guardian could not withhold or withdraw life-sustaining treatment (see *Matter of Storar*, supra).

Like all individuals, mentally-retarded persons are not all the same. The levels of mental retardation have been classified as (1) mildly retarded with IQ of 50 to 70, (2) moderately retarded with an IQ of 35 to 50, (3) severely retarded with an IQ of 20 to 35, and (4) profoundly retarded with an IQ below 20 (*Matter of Baby Boy W.*, 3 Misc 3d 656, 666). Mentally-retarded persons can be competent to make their own medical decisions (see *Matter of Baby Boy W.*, supra at 666; *Matter of B.*, 190 Misc 2d 581 [retarded person with IQ of 62 can give informed consent to sterilization]) and can be capable of pursuing their legal rights without the aid of a guardian (see *Matter of an Individual with a Disability for Leave to Change Her Name*, 195 Misc 2d 497).

The new SCPA 1750(2) properly recognizes that there are mentally-retarded persons who are capable of making their own health care decisions. Every certification by two physicians or a physician and a psychologist that the mentally-retarded person is incapable of managing his or her affairs "shall include a specific determination . . . as to whether the mentally retarded person has the capacity to make health care decisions." A determination by the examining physicians and/or psychologist that the mentally-retarded person is capable of making health care decisions "shall not preclude the appointment of a guardian pursuant to this section to make *other* decisions on behalf of the mentally retarded person" (emphasis supplied).

With respect to guardians appointed prior to the effective date of the new provisions, SCPA 1750(2) provides that the absence of a determination as to whether the mentally-retarded person has the capacity to make health care decisions "shall not preclude such guardians from making health care decisions." Further, SCPA 1750-b states:

> 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 seventeen hundred fifty of this article, the guardian of such person appointed pursuant to section seventeen hundred fifty of this article shall have the authority to make any and all health care decisions, as defined by subdivision six of section twenty-nine hundred eighty of the public health law, 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 (emphasis supplied).

In reaching the conclusion that the new provisions should be applied retroactively, the Surrogate relied upon this statutory text. It held that the use of the term "if any" in SCPA 1750-b "contemplates a situation where a guardian would have health care decision-making authority, even in the absence of the SCPA 1750 determination" of whether the mentally-retarded person has the capacity to make his or her own health care decisions (*Matter of MB*, supra at 330).

In enacting the Heath Care Decisions Act for Persons with Mental Retardation, the Legislature intended to eliminate discrimination against mentally-retarded persons who could never express their wishes with respect to life-sustaining treatment, to afford them "the same choices afforded to competent or formerly-competent patients" to refuse life-sustaining treatment (Mem of Senator Hannon, L 2002, ch 500, 2002 NY Legis Ann, at 280). The "overarching motive" of the Legislature was:

> (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 (i.e. where patients are profoundly ill and *never had the ability to*

make such decisions for themselves), (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 (emphasis supplied) (Mem of Senator Hannon, L 2002, ch 500, 2002 NY Legis Ann, at 280).

A retroactive application of the new SCPA 1750 and 1750-b would serve the contrary purpose of depriving mentally-retarded persons with guardians appointed prior to March 16, 2003, of their statutory right under the new SCPA 1750(2) to a determination of their capacity to make their own health care decisions.

The former statutory scheme also provided protections which will be lost with the retroactive application of the amendments. Guardians for mentally-retarded persons appointed pursuant to SCPA former 1750 were appointed based upon a certification that the mentally retarded person was "incapable to manage him or herself and/or his or her affairs by reason of mental retardation." No certification was made of the mentally-retarded person's capacity to make his or her own health care decisions. However, guardians appointed pursuant to SCPA former 1750 had similar powers as guardians appointed pursuant to Mental Hygiene Law article 81 (see *Matter of B.*, 190 Misc 2d 581, 585). Mental Hygiene Law § 81.29(e) authorizes the court to specifically grant or deny a guardian the power to give consent to the withdrawing of life-sustaining treatment. Such a determination is generally made based upon clear and convincing evidence of the patient's wishes (see *Wickel v. Spellman*, 159 AD2d 576; *Matter of Barsky*, 165 Misc 2d 175).

The provision in the new SCPA 1750-b(4) which states that "[i]n the event that a guardian makes a decision to withdraw or withhold life-sustaining treatment from a mentally-retarded person" the attending physician must confirm that the mentally-retarded person lacks the capacity to make health care decisions (see SCPA 1750-b[4][a]) provides no protection. This certification occurs when the decision to terminate life-sustaining treatment is made. Generally such a decision is made when a patient who may have been competent when well is unconscious or too sick to make health care decisions. By its terms, it would not protect mentally-retarded persons formerly competent to make health care decisions. Nor would it ensure any mentally-retarded person of an opportunity to be heard at a meaningful time and in a meaningful manner as to whether the guardian should have the power to withdraw or withhold life-sustaining treatment (see *Matter of Chantel R.*, 6 Misc 3d 695).

Under the new statutory scheme, the Surrogate must expressly deny a guardian the power to withhold or withdraw life-sustaining treatment if the Surrogate deems such a limitation appropriate (see SCPA 1750-b[1]). However, with respect to guardians appointed prior to the effective date of SCPA 1750-b, no such limitation was necessary since the guardian would have had to affirmatively seek the authority to withhold or withdraw life-sustaining treatment from the court, based upon clear and convincing evidence of the patient's wishes and/or the best interests of the mentally-retarded person. The retroactive application of SCPA 1750-b to guardians appointed pursuant to SCPA former 1750 would expand their powers without any consideration by the court as to whether such an expansion of authority would be appropriate.

The amicus curiae NYSARC, Inc., notes that "[u]nless the Court in this case finds that guardians appointed prior to March 16, 2003, the effective date of the Act, have the authority to make end-of-life decisions on behalf of their wards, thousands of guardians will be forced to expend both their own and judicial resources by seeking to have guardianship decrees and other related documents amended." However, each life is precious. A requirement of judicial intervention is not a waste of resources to insure that mentally-retarded persons are treated fairly and in accordance with all their rights.

Accordingly, we hold that SCPA 1750-b shall not apply to guardians appointed prior to its effective date, without a judicial determination specifically granting such guardians powers pursuant to SCPA 1750-b in accordance with the statutory safeguards set forth in SCPA 1750(2). The order is reversed insofar as appealed from, on the law, without costs or disbursements, and the petition is granted.

H. MILLER, J.P., and ADAMS, JJ., concur.

SPOLZINO, J., dissents and votes to affirm the order insofar as appealed from with the following memorandum:

I share the serious concerns that prompt my colleagues to hold that the Health Care Decisions Act for Persons with Mental Retardation does not apply retroactively so as to authorize a guardian appointed prior to the adoption of that law to make health care decisions, including the decision to refuse medical treatment, for a mentally-retarded ward. Nevertheless, the Legislature has, in my view, resolved the limited issue presented on this appeal by providing clearly and unambiguously in the statute itself for its retroactive application. As I see it, in the absence of a constitutional challenge to such application, the Legislature has thus put the issue beyond our purview. Since the petitioner

has declined to make that challenge here, I would affirm the order of the Surrogate and therefore, I dissent, respectfully.

The Health Care Decisions Act for Persons with Mental Retardation (L 2002, ch 500) (hereinafter the 2002 amendments) significantly amended the statutory provisions for the guardianship of mentally-retarded persons that had been established in article 17-A of the SCPA, adopted in 1969 (L 1969, ch 1143) and subsequently amended in 1989 (L 1989, ch 675). Pursuant to the 2002 amendments, every medical certification made in support of the appointment of a guardian for a mentally-retarded person is now required to include "a specific determination . . . as to whether the mentally retarded person has the capacity to make health care decisions" for himself or herself (SCPA 1750[2]). It is then incumbent upon the appointing court to consider the medical determination and, upon such consideration, to withhold from the guardian the authority to make health care decisions for the mentally-retarded person if it is appropriate to do so (see SCPA 1750-b). In the absence of an express judicial determination to withhold the authority to make health care decisions, however, such authority is conferred upon the guardian (see SCPA 1750-b[1]).

Despite the breadth of the authority that may be granted pursuant to the statute, the guardian's power to decline life-sustaining treatment for the mentally-retarded person is, nevertheless, circumscribed in several significant ways. The statute establishes specific substantive standards to which the guardian must adhere in making such a determination (see SCPA 1750-b[2]). In addition, there are specific procedures that must be followed. Among the procedural necessities are medical determinations that the mentally-retarded person does not have the capacity to make the decision for himself or herself and that he or she is in such condition that a determination to withdraw life-sustaining treatment is medically appropriate (see SCPA 1750-b[4][a],[b]). The statute also sets forth specific requirements with respect to giving notice of the decision to family members and other interested parties identified in the statute and provides for timely judicial review of the decision in the event of an objection by such parties (see SCPA 1750-b[4][e]; [5],[6]).

These provisions constitute a sharp break with prior decisional law. Although the New York courts have long recognized that a competent person may make life-ending medical decisions for himself or herself, based upon the right recognized at common law to be free from unwanted medical treatment (see *Schloendorff v. Society of NY Hosp.*, 211 NY 125, 129), such decisions may be made by a guardian only where the patient's intent with respect to such issues when competent can be established by clear and convincing evidence (see *Matter of Storar*, 52 NY2d 363, 379, cert denied 454 US 858). Where that intent cannot be so established, necessary medical treatment may not be declined by a guardian or other surrogate decision-maker (see *Matter of Westchester County Med. Ctr.*, 72 NY2d 517, 528, 530-531). Thus, in the absence of statutory authority, the guardian of a mentally-retarded person who was never competent to make a reasoned decision about medical treatment is without power to withhold or withdraw life-sustaining treatment (see *Matter of Storar*, supra).

Recognizing the serious policy implications of its decision in *Storar*, the Court of Appeals expressly invited the Legislature to address the issue of surrogate decision-making for the mentally impaired (see *Storar*, supra at 382-383). Before 2002 however, the Legislature did not accept the court's invitation. SCPA article 17-A did not address the issue of health care decision-making. Article 81 of the Mental Hygiene Law, enacted in 1993 to govern the guardianship of persons alleged to be incompetent, similarly left in place the common law rules as defined by the Court of Appeals (see Mental Hygiene Law § 81.29[e]). The Legislature ultimately turned to the matter, however, in 2002, filling the gap in the law identified in *Storar* (see Turano, 2002 Supplementary Practice Commentaries to SCPA § 1750-b, at 38-39), by adopting the amendments in issue, following a well-publicized controversy with respect to the unfortunate circumstances of Sheila Pouliot, a mentally-retarded person whose guardian was determined not to have the requisite authority based upon the Attorney-General's reading of *Storar* (see *Blouin v. Spitzer*, 213 F Supp 2d 184, 186-187, affd 356 F3d 348, 352-356; *Chantel R.*, 6 Misc 3d 693, 696).

Like Ms. Pouliot, M.B. was a mentally-retarded person for whom a guardian, R.B., had been appointed pursuant to SCPA article 17-A. As the majority correctly notes, this proceeding was commenced by Mental Hygiene Legal Services for a determination that SCPA 1750-b did not apply to R.B. on the ground that he had been appointed as M.B.'s guardian prior to the effective date of the 2002 amendments. The pleadings do not challenge the constitutionality of the retroactive application of the statute and no notice of a constitutional claim was ever provided to the Attorney-General, as required by CPLR 1012(b) and Executive Law § 71. The issue before us, therefore, is simply one of statutory construction.

"Amendments are presumed to have prospective application unless the Legislature's preference for retroactivity is explicitly stated or clearly indicated" (*Gleason*, 96 NY2d 117, 122; see *Marino S.,* 100 NY2d 361, 370, cert denied sub nom *Marino S. v. Angel Guardian Children and Family Servs.*, 540 US 1059). The issue of the retroactive application of a statute is thus, as the majori-

ty correctly notes, a question of the Legislature's intent (see *Majewski v. Broadalbin-Perth*, 91 NY2d 577, 583). It is axiomatic that the Legislature's intent is determined, in the first instance, on the basis of the language that the Legislature has employed (see *Patrolmen's Benevolent Assn. v. City of New York*, 41 NY2d 205, 208). It is also hornbook law that where the statutory language is clear and unambiguous, the court must construe that language so as to give effect to the plain meaning of the words used (see *New Amsterdam Cas. Co. v. Stecker*, 3 NY2d 1; *Bender v. Jamaica Hosp.*, 40 NY2d 560; *Meltzer v. Koenigsberg*, 302 NY 523). Here, in my view, the language employed by the Legislature leads clearly and unambiguously to the conclusion that the Legislature intended for the authority to make health care decisions for mentally-retarded persons, as granted by the 2002 amendments, to be applied to all guardians, even those appointed prior to the effective date of those amendments.

SCPA 1750-b(1) provides that the authority to make health care decisions is within the general grant of authority to the guardian, "unless specifically prohibited by the court." Critically, the statute provides that the court must make that decision after considering the medical determination with respect to the capacity of the mentally-retarded person, "if any," that is now a required part of the guardianship petition (see SCPA 1750-b[1]). Thus, health care decision-making authority can be granted in the absence of the medical determination as to capacity. Reading these two provisions together, the authority to make health care decisions is thus included within the grant to the guardian, in the absence of a judicial decision to the contrary, even in those cases where there has been no medical determination with respect to competency.

Moreover, since the statute now mandates that such a medical determination be made in all proceedings under article 17-A, after the effective date of the 2002 amendments, the language addressing the absence of such a determination is meaningless unless it applies to those situations where the guardian was appointed prior to the amendments. If we are to read the statute so as to give effect to all of its provisions, as we must (see *Rangolan v. County of Nassau*, 96 NY2d 42, 48; McKinney's Cons Laws of NY, Book 1, Statutes § 97), this provision thus requires that the statute apply retroactively.

The Legislature's intent that previously-appointed guardians have the authority granted by the amendments to make health care decisions is also apparent from the manner in which it defined the effective date of the statute. Although the amendments generally became effective 180 days after they became law, the provisions requiring the certification of capacity to make health care decisions were treated differently, becoming effective only with respect to those determinations made on or after the effective date of the statute (L 2002, ch 500, § 4). Had the Legislature intended that no guardian should have the power to make health care decisions without having been so authorized under the newly-established process, as the majority contends, it could simply have avoided any reference to SCPA 1750 in the general clause providing for the effective date of the amendments. The fact that it did not do so is telling.

If these provisions were not, by themselves, sufficient to establish the Legislature's intent, however, the Legislature was even more direct. The statutory provision that mandates the medical determination specifically provides that "[t]he 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]). Since the term "health care decisions," defined by reference to section 2980(3) of the Public Health Law, includes the authority to refuse medical treatment (Public Health Law § 2980[6]), the authority of the previously-appointed guardian is clear.

Despite this language, my colleagues in the majority would decline to apply the 2002 amendments to previously-appointed guardians. In so doing, they read the legislative history to find that retroactive application of the amendments would be inconsistent with the Legislature's "overarching motive" of allowing end-of-life decisions to be made for mentally-retarded persons who "never had the ability to make such decisions for themselves" only after a judicial determination as to their prior capacity. As a result, my colleagues find that by the retroactive application of the 2002 amendments, a mentally-retarded person for whom a guardian was previously appointed, would be deprived of the right provided thereunder to determination of his or her medical decision-making capacity before such authority may be exercised by a guardian. In my view, however, the legislative memorandum upon which my colleagues rely to reach their conclusion is not quite as clear as they read it to be in expressing the intent they find.

Initially, the memorandum upon which the majority relies expressly states that "the absence of such a determination [as to capacity to make health care decisions] in the case of guardians appointed prior to this act shall not preclude their making such decisions" (2002 McKinney's Session Laws of NY, at 2002). Even were we to ignore this express statement with regard to the issue of retroactivity, the memorandum expressly asserts that the discrimination with which the statute is concerned is not discrimination against mentally-retarded persons by denying them the common law right to personal autonomy that is recognized for competent persons, but rather, is discrimination against mentally-retarded per-

sons by refusing to allow their guardians to make the same health care decisions that can be made by competent persons. Referring to the common-law rule that life-sustaining treatment cannot be withheld in the absence of "clear and convincing evidence" that to do so would be consistent with the patient's intent when competent (*Westchester County Med. Ctr.*, supra at 528, 530-531; see *Storar*, supra at 379), the legislative memorandum states:

> This clear and convincing evidence rule has been applied to thwart decisions even by court-appointed guardians, who in almost every other respect step into the shoes of their wards, and can make any decisions their wards could have made if competent.
>
> In precluding the withholding or withdrawal of life sustaining treatment from mentally retarded persons, the clear and convincing evidence rule clearly discriminates against this particularly vulnerable segment of the population by denying them the same choices afforded to competent or formerly-competent patients (2002 McKinney's Session Laws of NY, at 2003-2004 [internal quotation marks omitted]).

Finally, if the intent as to the retroactive application of the 2002 amendments was not sufficiently expressed already, the memorandum states that this bill "clarifies that guardians of mentally retarded persons have the authority to make the full range of health care decisions for them" (2002 McKinney's Session Laws of NY, at 2004 [emphasis supplied]).

I thus differ with my colleagues in my reading of the legislative memorandum as supporting the retroactive application of the 2002 amendments. But legislative history, however one reads it, is not statutory text. While contemporaneous legislative statements are instructive in establishing the Legislature's intent with respect to ambiguous provisions (see *Rankin v. Shanker*, 23 NY2d 111; see also McKinney's Cons Laws of NY, Book 1, Statutes § 92[b]), they do not overcome the language that the Legislature actually adopted and the Governor actually approved. Here, that language is, in my view, clear, for the reasons I have stated above. In the absence of a countervailing legal basis for doing so, we are not at liberty to disregard that clear and unambiguous expression of the Legislature's intent and we must give effect to the plain meaning of the statute (see *Raritan Dev. Corp. v. Silva*, 91 NY2d 98; *Patrolmen's Benevolent Assn. v. City of New York*, supra; *Tompkins v. Hunter*, 149 NY 117, 122-123).

The concerns raised by the majority would clearly be implicated, in a manner cognizable by the courts, in a constitutional challenge to the retroactive application of the statute. There is no doubt that it can be seriously, and perhaps successfully, argued that granting to a guardian the authority to make potentially life-ending medical decisions for a mentally-impaired person without first ascertaining through a judicial process whether that person, when capable, would have made that choice deprives the impaired person of life without due process of law or denies to him or her the equal protection of the laws. However, since the petitioner chose not to raise such a claim in this proceeding, that issue is not presented in this case.

Thus, despite the importance of the constitutional issues that may be raised in some future case, I would decide this case on the basis of the issue that has been presented, which is whether the Legislature intended that SCPA 1750-b apply retroactively. Although I disagree with the majority, I join my colleagues in recognizing that there are few issues presented in the law as serious and as difficult as defining the circumstances under which life-sustaining medical treatment may be refused. The issue of when one person may be authorized to make medical decisions that will likely result in the death of another is exponentially more complicated, as witnessed by recent national developments (see *Schiavo ex rel. Schindler v. Schiavo*, 404 F3d 1282; see also *Cruzan v. Director, Missouri Department of Health*, 497 US 261; *Conroy*, 98 NJ 321, 486 A2d 1209; *Superintendent of Belchertown State School v. Saikewicz*, 373 Mass 728, 370 NE2d 417; *Quinlan*, 70 NJ 10, 355 A2d 647, cert denied sub nom. *Garger v. New Jersey*, 429 US 922).

In the absence of the statute, I would concur that we should err on the side of life, as *Storar* (supra) requires. Were I a legislator, I might be persuaded by the majority of the wisdom of applying the statutory amendments prospectively only. As a judge, however, I am not free to make that determination in the face of statutory language to the contrary. Since I believe that the Legislature unequivocally expressed in the legislation itself its intent that the statutory amendments in issue here apply retroactively, I would affirm the order of the Surrogate insofar as appealed from.

ORDERED that order is reversed insofar as appealed from, on the law, without costs or disbursements, and the petition is granted.

Upcoming Programs

- *The New Medicaid Fraud and Overpayment Initiative: Representing Health Care Providers in Medicaid Audits* (October 28-29). This timely program will be the centerpiece of the Section Fall Retreat at the beautiful Sagamore Hotel on Lake George. The Health Law Section has assembled an experienced faculty, including key government officials, to present an intensive program designed to assist practitioners in the representation of clients facing Medicaid payment investigations and audits by the New York State Department of Health and the Attorney General's Medicaid Fraud Control Unit. The program will provide guidance in the defense of Medicaid payment investigations, audits, hearings and recoupments, covering the fundamentals of Medicaid payment investigations and audits and highlighting some of the key issues in the field. The program was organized by former Section Chair Jim Lytle of Manatt, Phelps & Phillips. For more information, go to nysba.org/health.

  The fall retreat at The Sagamore will also include ample time for socializing, networking, and exploring beautiful Lake George and Lake George Village. Bring your family.

- *When Your Client's Health Problems Become Your Own / Meet the AUSA's* (September 23). This seminar will discuss circumstances under which a lawyer or other consultant can incur civil or criminal liability from his or her relationship with a client who violates fraud laws. It also features a panel discussion by all four of the Assistant U.S. Attorneys in charge of the criminal fraud units in the Southern and Eastern District of N.Y. on enforcement of federal health care fraud and abuse laws. It concludes with a luncheon presentation by the U.S. Attorney for the Eastern District of N.Y., Roslyn R. Mauskopf. The program was planned by Robert P. Borsody, Esq., of Phillips Nizer LLP, New York City.

- *Mental Health Courts; Better Outcomes from the Legal and Mental Health Systems* (November 4, 2005). This program, which will be held in NYC, is being organized by David Seay of the National Alliance for the Mentally Ill (Albany), and Henry A. Dlugaz of NYC.

- *After the Flood: Legal Issues in Public Health Emergencies* (January 26, 2006). This timely program, offered in connection with the NYSBA Annual Meeting, is being organized by Margaret Davino of Kaufman, Borgeest & Ryan.

- *Representing Agencies Funded by the New York State Department of Mental Hygiene* (February 24, 2006 in NYC; March 3, 2006 in Albany). This program, co-sponsored with the Committee on Disabilities, is being organized by Hermes Fernandez of Bond, Schoeneck & King, Albany, Chair of the Section's Committee on Mental Retardation/ Developmental Disabilities.

- *Representing Physicians and Dentists in the Disciplinary Process* (April 7 in Long Island; April 28 in NYC; May 5 in Albany; and May 19 in Rochester). This program is being organized by Professional Discipline Committee Co-Chairs Ken Larywon of Martin, Clearwater & Bell, LLP, NYC, and Carolyn Shearer of Bond, Schoeneck & King, PLLC, Albany.

- *Long-Term Care and the Law: Issues and Skills* (May 12 in Rochester; May 12 in NYC; and May 19 in Albany). Ari Markenson, of Epstein, Becker & Green, P.C., is organizing this program.

Upcoming *Journal* Editions

- The next edition of the NYSBA *Health Law Journal* (Winter 2006) will focus on "Legal Issues in Long-Term Care." Ari Markenson, of Epstein, Becker & Green, P.C., will be the Special Edition Editor.

- The Spring 2006 edition of the NYSBA *Health Law Journal* will focus on "Legal Issues in Mental Health Care." The Special Edition Editors are David Seay, of the National Alliance for the Mentally Ill (Albany), and Henry A. Dlugaz of NYC.

  Persons wishing to submit articles for either of these special editions should contact the special edition editors.

Other Section Activities

- Toward the end of the state legislative session, four members of the Section's Executive Committee went to the Capitol to lobby in support of the Family Health Care Decisions Act. Section Chair Lynn Stansel, Former Chair Jim Lytle, Ethics Committee Chair Kathleen Burke, and *Journal* Editor Robert Swidler, along with representatives from several other organizations, met with legislators and legislative staff to urge them to pass the FHCDA. The Act would empower family members to make decisions, including life-sustaining treatment decisions, on behalf of incapable patients, subject to clear standards and safeguards. The legislature adjourned without passing the Act, but great progress was made in resolving outstanding issues and building support for passage next session.

New Executive Committee Members

Section Chair Lynn Stansel recently appointed several new Committee Chairs, who will also become members of the Section's Executive Committee:

- Margaret Davino, of Kaufman, Borgeest & Ryan, NYC, was appointed Chair of the Public Health Committee. Ms. Davino formerly was General Counsel to St. Vincent's Hospital in NYC.
- Edward Case, Associate General Counsel to University of Rochester Medical Center, was appointed Chair of the In-House Counsel Committee.
- Erik Ramanathan, General Counsel to Imclone Systems, Inc., was appointed Chair of the Biotechnology Committee.
- Mark P. Scherzer, of the Law Offices of Mark P. Scherzer, will be the new Co-Chair of the Consumer Rights Committee, along with Randy Redkin.
- Steve Chananie, of Garfunkel, Wild & Travis (Great Neck), will co-chair the Fraud, Abuse and Compliance Committee, along with Marcia Smith.
- Frank Serbaroli, of Cadwalder, Wickersham & Taft, will chair the Provider Committee.

Two New Committees

Two new committee have been formed, and Chairs appointed to them:

- Esther Widowski, of Widowski & Steinhart, NYC, will chair the newly-created Special Committee on Insurance & Liability Issues.
- Jim Lytle, of Manatt, Phelps & Phillips, will chair the new Legislative Issues Committee.

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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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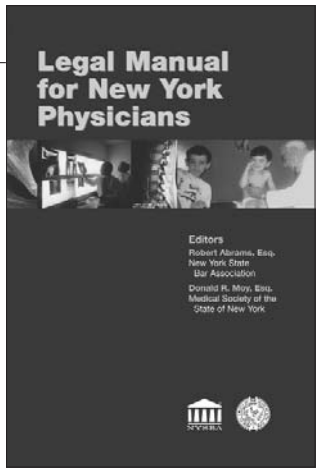

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