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Health Law Journal

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

Conversations About

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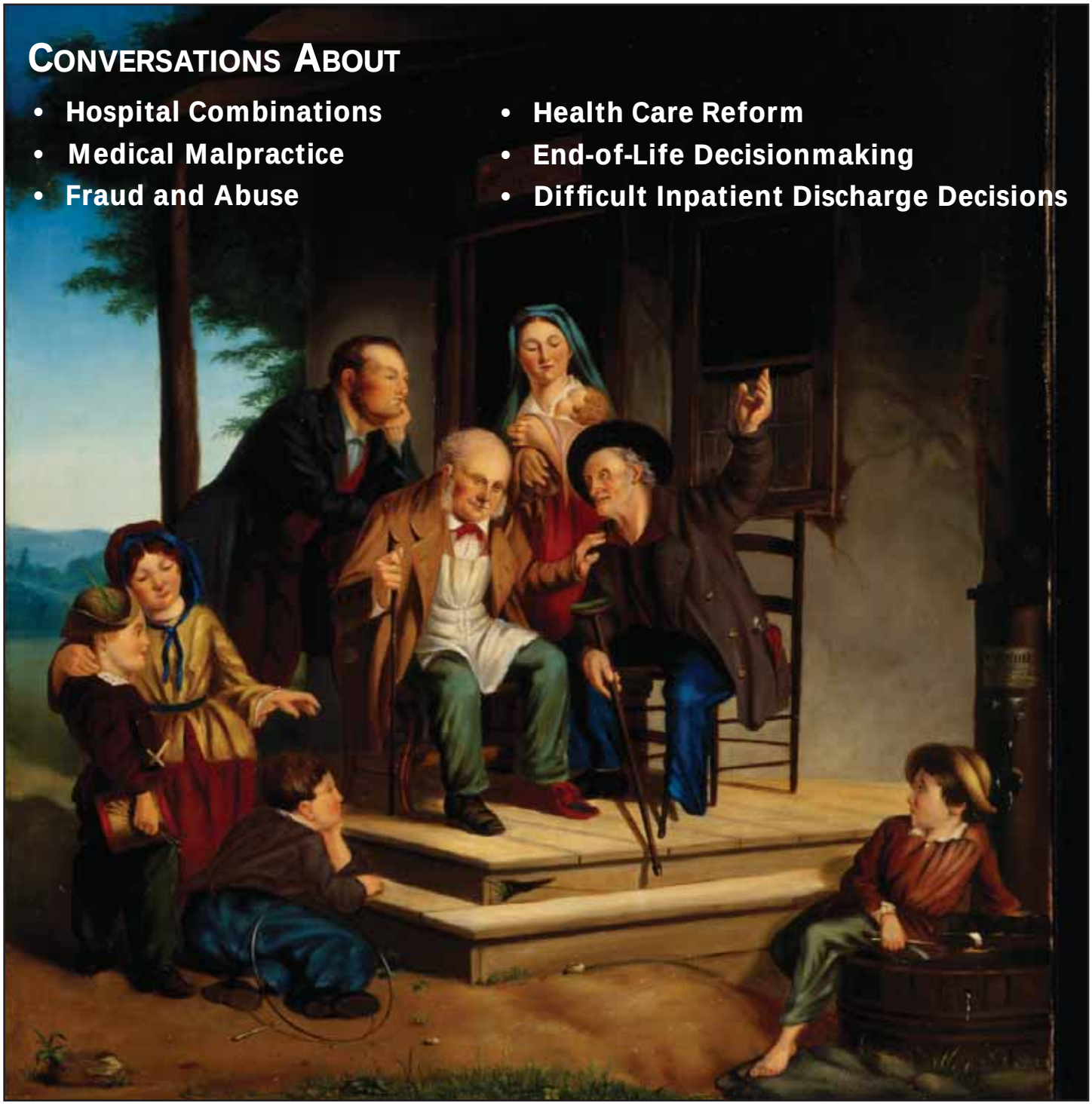

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THE HEALTH LAW SECTION
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Cover artwork:
Billing, Frederick William (1834-1914). *Discussion at the Continental Arms*, 1861

A Message from the Section Chair

It is with much appreciation that I write this column, my first as Chair. The New York State Bar Association *Health Law Journal* has become a resource for health lawyers throughout the country and particularly here in New York. We owe Robert Swidler, our tireless Editor, particular thanks for his remarkable efforts.

This issue comes at a time of potential great change in the health care system. The President has now actively joined an already overheated fray. While the focus falsely has been on "death panels" and government takeovers of health care, there is much in the proposal to provide substantial anxiety, even for a strong supporter of health reform like me. When the President talks about funding a $900 billion program significantly out of reducing waste, I (and many Medicare beneficiaries apparently) "hear" a proposal to cut existing programs. Indeed, the President has made clear that if his potential savings from eliminating waste do not arrive, cuts will be required. Nor is it clear how we are going to raise the funds otherwise. Tax increases, even in return for benefits received by the taxpayer (let alone for benefits to be received by others), are anathema, but will be necessary.

I continue to believe that we are missing a great opportunity to save hundreds of billions of dollars and fundamentally increase patient satisfaction by changing our health care claims adjudication systems. The Attorney General of California recently disclosed that 22% of initially submitted provider claims are rejected by insurance companies. The systemic costs on providers, payers, and beneficiaries when 22% of the claims are initially denied runs to hundreds of billions of dollars. And remarkably, despite this incredible expense, our current system does not eliminate most unnecessary care.

However, my dreams of a reformed claim adjudication system do not appear close to fruition. Any effort to rationalize and centralize that system to make it more efficient will likely be construed, given the recent debate, as a government takeover of the health care system. It is scary to contemplate that reducing costs appears to require more fundamental change to the system than may be feasible politically.

In any event, while contemplating these fundamental changes, I hope that we all remember to help those in the Section who have been hurt by last year's economic meltdown, or otherwise can use a kind word, some encouragement, or perhaps most importantly, a job or client referral. I have always believed that it is the Section's collegiality that makes it special, which we need to reaffirm in these difficult times.

Edward S. Kornreich

In the New York State Courts

By Leonard M. Rosenberg

In 4-3 Decision, Court of Appeals Rules That an Independent Medical Examination Creates a "Limited" Physician-Patient Relationship Such That Allegations of Negligence in the Performance of an IME Is Subject to the 2-1/2 Year Statute of Limitations for Medical Malpractice

Bazakos v. Lewis, 12 N.Y.3d 631, 883 N.Y.S.2d 785 (2009). Plaintiff sued a physician who performed an independent medical examination ("IME") of plaintiff. The IME was performed on behalf of a party adverse to plaintiff in a personal injury action. Plaintiff sought damages for injuries allegedly sustained during the IME. Plaintiff commenced the lawsuit approximately 2 years and 11 months after the IME took place. Defendant IME physician moved to dismiss the suit as untimely under the statute of limitations for medical malpractice actions. The Appellate Division, with two justices dissenting, ruled that because a physician performing an IME does not have a physician-patient relationship with the person being examined, the action is not for medical malpractice and thus is subject to the three-year statute of limitations application to ordinary negligence claims. The Appellate Division then granted leave to appeal to the Court of Appeals.

In a 4-3 decision, the Court of Appeals reversed the Appellate Division and held that plaintiff's claim was a claim for medical malpractice governed by the two-year, six-month statute of limitations for medical malpractice actions pursuant to CPLR 214-a.

Plaintiff alleged that during the IME, defendant "took plaintiff's head in his hands and forcefully rotated it while simultaneously pulling," thereby injuring plaintiff. The Court of Appeals held that such conduct constituted medical treatment by a licensed physician, and the negligent performance of that act was

not ordinary negligence, but a "prototypical act of medical malpractice." Despite plaintiff's contention that there is no physician-patient relationship between the doctor performing an IME and the person undergoing it, the court ruled that "the relationship between a doctor performing an IME and the person he is examining may fairly be called a 'limited physician-patient relationship,'" pointing out that "this language is used in an American Medical Association opinion describing the ethical responsibilities of a doctor performing an IME."

The court further explained that the limited relationship between an examinee and a physician performing an IME imposes a duty on the physician to perform the examination in a manner not to cause physical harm to the examinee. Plaintiff was injured because a doctor failed to perform competently a procedure requiring the doctor's specialized skill. Accordingly, the court ruled that plaintiff's claim that defendant breached his duty of care while performing an IME is a claim for medical malpractice governed by the two-year-and-six-month statute of limitations, and as such, plaintiff's lawsuit was untimely.

Chief Judge Lippman filed a dissenting opinion strongly disagreeing with the majority's decision and rationale, and, in a separate opinion, voted to affirm the Appellate Division's decision in which Judges Pigott and Jones joined.

The dissent pointed out the long-standing rule that "[c]onduct may be deemed malpractice, rather than negligence, when it 'constitutes medical treatment or bears a substantial relationship to the rendition of medical treatment by a licensed physician.'" The dissent reasoned that "bereft of any medical treatment rationale or application, the IME physician's conduct during his examination of plaintiff is not amenable to description as medical malpractice within the meaning of CPLR 214-a." In reaching his conclusion, Judge Lippman explained that although the defendant may have employed medical techniques in his independent medical examination of plaintiff, it is apparent that no medical treatment was intended or provided. Defendant conducted the exam simply for the purpose of providing litigation support services for the benefit of plaintiff's adversary.

The dissent acknowledged that defendant owed plaintiff a limited duty not to harm him in the process of performing the IME; however, the breach of such a duty was ordinary negligence, and not medical malpractice, as defendant had no duty to competently diagnose, inform or, indeed, to treat the plaintiff during the performance of an IME.

Further, the dissent noted that independent medical examinations "are emphatically not occasions for treatment, but are most often utilized to contest the examinee's claimed injury and to dispute the need for any treatment at all." Accordingly, the minimal duty owed to plaintiff by defendant did not arise out of a doctor-patient relationship; rather the duty is one of a general responsibility, frequently enforceable in tort, to refrain from causing foreseeable harm, which is appropriately classified as ordinary negligence.

Judge Lippman asserted that the majority's denomination of such conduct as "medical malpractice" was achieved "only by dint of an exercise in judicial artifice untethered to any law or to the actual nature of the transaction known euphemistically as an 'independent' medical examina-

tion," and thus maintained that the decision of the Appellate Division should be affirmed.

Second Circuit Court of Appeals Holds That Whether Medical Residents Are Exempt from FICA Taxes Is a Question of Fact, Not Law

United States of America v. Memorial Sloan-Kettering Cancer Center, 563 F.3d 19 (2d Cir. 2009). The Second Circuit Court of Appeals decided two cases from the Northern and Southern Districts of New York that both raised the question of whether post-graduate medical residents can invoke the Federal Insurance Contributions Act ("FICA") tax exception for "students." Both District Courts held that medical residency programs at Albany Medical Center ("AMC") and Memorial Sloan-Kettering Cancer Center ("MSKCC"), respectively, are not "schools" and the residents are not "students" under FICA. The Southern District also held that the funds provided to the medical residents of MSKCC were not "scholarships" under the Tax Code, and therefore not exempt from FICA taxes on that basis.

FICA funds Social Security through payroll taxes. However, FICA carves out a "student exception," which excludes from the definition of employment any services performed by a student "in the employ of a school, college, or university[,] … who is enrolled and regularly attending classes at such school, college, or university." 26 U.S.C. § 3121(b)(10). AMC filed a refund application for the FICA taxes it had paid for medical residents from 1995 to 1999. When the IRS failed to act on AMC's application, AMC filed a lawsuit in the Northern District of New York to collect the refund. MSKCC filed for a refund of FICA taxes it paid between 2001 and 2003. The IRS issued a refund to MSKCC, but then later reversed its position and sued MSKCC in the District Court for the Southern District of New York to recover the refund. Both AMC and MSKCC (collectively the "Hospitals") argued that their medical residents are students, and thus eligible for this exception under the plain meaning of the statute. MSKCC also argued that the monies it provided to its medical residents were "scholarships" and not wages under § 3121(a), and therefore were exempt from payroll taxes under FICA.

The government argued that the language of the student exception was ambiguous, and therefore required a review of the legislative history. The District Courts, based on the legislative history, held that Congress did not intend for the student exception to apply to medical residents. Accordingly, the District Courts ruled that medical residents were ineligible for the student exception as a matter of law.

The Court of Appeals, agreeing with decisions of the Sixth, Seventh, and Eleventh Circuits, held that the statute is unambiguous and that whether medical residents are "students" and the Hospitals are "schools" are questions of fact, not questions of law. Further, these "separate factual inquiries depend on the nature of the residency program in which the medical residents participate and the status of the employer."

Accordingly, the Court of Appeals vacated the District Court decisions and remanded the cases for "a particularized review of whether [the Hospitals'] medical residents qualify for the student exclusion." However, the Court affirmed the Southern District's holding that the monies paid by MSKCC to the medical residents are not scholarships, because these payments were conditioned upon services that the residents promised to provide MSKCC.

Court Holds That Limited Non-Medical Information Contained in Medical Record Is Not Privileged Under Statutory Physician-Patient Privilege and HIPAA

Jackson v. Jamaica Hospital Medical Center, 61 A.D.3d 1166, 876 N.Y.S.2d 246 (3d Dep't 2009). After being convicted of murder, Plaintiff brought a fraud action against the hospital where his victim had been transported by ambulance after being shot. Plaintiff alleged that inconsistencies between other official documents and defendant's medical records for the murder victim, which were allegedly fraudulently created by defendants, deprived him of the ability to present a viable defense at his criminal trial. Plaintiff filed a motion to compel discovery of limited non-medical information contained in the victim's medical records. Specifically, Plaintiff sought the time of all calls to the Hospital, the victim's time of arrival at the emergency room, and time of death. Plaintiff requested that all confidential and privileged material be redacted. The trial court granted Plaintiff's motion to compel discovery.

The Appellate Division held that the documents sought by Plaintiff, as redacted, are not privileged under the statutory physician-patient privilege (CPLR 4504(a)) or under Health Insurance Portability and Accountability Act ("HIPAA") (42 U.S.C. § 1320(d), *et seq.*), and must be disclosed. The court found that the defendants, as the party objecting to disclosure, did not show that the material sought is protected from disclosure under state or federal statutory law.

In reaching its decision, the court first analyzed whether the state law physician-patient privilege barred disclosure of the information sought by Plaintiff. The physician-patient privilege prohibits disclosure of any information acquired by a physician in connection with a patient's medical treatment. The court ruled that the very narrow information sought by Plaintiff regarding timing of certain events, as documented in victim's medical records on date of his death, was not information necessary to victim's medical treatment, but merely documented facts regarding time data that would be obvious to a layperson. Thus, the court found that

this information was not privileged under state law.

The court similarly concluded that HIPAA, which regulates disclosure of protected health information, including individually identifiable health information in connection with provision of health care to an individual, did not bar disclosure of the limited information sought by plaintiff. The court reasoned that the information sought by Plaintiff did not constitute protected health information, as it has no apparent connection to the victim's physical condition or medical care.

OPMC Has Authority to Subpoena Confidential HIV-Related Patient Information for Use in Misconduct Investigation; However, Such Disclosure Must Be Limited to That Which Is Necessary for the OPMC's Investigation and Patients Whose Records Are to Be Produced May Submit Objections to the Court and Request Appropriate Redactions

Anonymous v. N.Y.S. Dep't of Health, State Bd. for Prof'l Medical Conduct, 65 A.D.3d 491, 884 N.Y.S.2d 410 (1st Dep't 2009). The petitioner is a licensed physician whose practice focuses on treating patients with HIV and HIV-related conditions. In connection with a professional misconduct investigation, the New York State Office of Professional Medical Conduct ("OPMC") requested the medical and billing records for nine of petitioner's patients during its investigation of petitioner. After petitioner expressed concern about the release of confidential HIV-related patient information, the State Board for Professional Medical Conduct ("Board") issued a subpoena for the records.

The physician notified the patients whose records were subpoenaed, seeking their consent to release the information. None of the patients gave consent. Thereafter, petitioner moved to quash the subpoena and included affidavits from two patients objecting to the production of their records. Petitioner argued that the records sought contained confidential information protected under Public Health Law § 2782(1), which prohibits its disclosure of HIV- or AIDS-related patient information except in limited circumstances, and that the Board was not a party to whom disclosure could be made under one of the statute's limited exceptions.

The Board argued that it was entitled to the disclosure of the medical records under two exceptions. The first exception, § 2782(1)(g), permits disclosure to a health officer when mandated under federal or state law. The second exception, § 2782(6), permits disclosure to federal, state, or local government agencies that have oversight over a provider possessing confidential HIV-related information. In addition, the Board argued that the overarching goal of the Public Health Law protection is to safeguard the privacy of persons seeking treatment for HIV, and not to shield a provider and delay disclosure of information necessary to an investigation into alleged professional medical misconduct. The lower court denied petitioner's motion to quash, finding that the Board was entitled to full disclosure.

The Appellate Division held that under Public Health Law § 2785(2) the Board was acting within its legal authority to issue the subpoena and, based on an in-camera review of the initial complaint against the petitioner, found that the Board had a good-faith basis for seeking the information.

However, the court noted that issues to be determined were the extent of disclosure permitted, and whether patients have standing to challenge the production of their medical records. While § 2785(4) provides that a patient whose confidential HIV-related information is being sought should be given notice of the application and an opportunity to appear for the purpose of providing evidence, the statute provides that service of a subpoena is not subject to that procedure.

Nonetheless, the court held that § 2785(6)(a) does not authorize "blanket and wholesale" disclosure. Rather, § 2785(6)(a) limits the disclosure of confidential HIV-related information to that which is necessary for the Board to conduct a legitimate investigation. Accordingly, the Appellate Division ordered the redaction of materials not necessary to the investigation, and further directed that the patients whose records were sought be given the opportunity to submit any objections to the court, and to request appropriate redactions.

Appellate Division Rules That Parents, as Administrators of Their Son's Estate, Have No Right to Son's Sperm

Speranza v. Repro Lab Inc., 62 A.D.3d 49, 875 N.Y.S.2d 449 (1st Dep't 2009). Parents, as administrators of their son's estate, brought an action against a tissue bank seeking to obtain possession of their deceased son's sperm specimens deposited prior to his death. Plaintiffs also sought a preliminary injunction ordering the tissue bank to preserve the sperm pending the outcome of the action. The motion court denied injunctive relief and, *sua sponte*, dismissed the action due to legal and public policy considerations. The Appellate Division affirmed.

The decedent deposited a number of semen specimens with the tissue bank and completed and signed a form entitled "Ultimate Disposition of Specimens." On this form, the decedent selected an option that authorized and instructed the tissue bank to destroy the semen vials upon his death. Sixth months later, the decedent died and his parents were named administrators of his estate. When the plaintiff administrators contacted the tissue bank to inquire about the samples, the tissue bank informed them that the decedent had deposited the specimens for his use only, and that his specimens were not screened for use by the public. The decedent's mother pleaded with the bank's president not to destroy the

specimens until she could determine her legal options, and that she would continue to pay the annual storage fee. The tissue bank acceded to this request. Plaintiff administrators then began to search for a surrogate mother to be artificially inseminated with the decedent's sperm in the hope of producing a grandchild for them. They later contacted the tissue bank to obtain the specimens, only to be told that the lab could not produce the specimens because the decedent specified that they be destroyed upon his death.

Plaintiffs sought a declaration that the estate is the rightful owner of the specimens. Their theory was that by accepting yearly payments from them after their son's death, the tissue bank breached and terminated their agreement with the decedent, or waived or relinquished any obligation it had to destroy the specimens, and Plaintiff constructively became the rightful and proper owners of the specimens. Plaintiff administrators also sought a preliminary injunction ordering the tissue bank to preserve the specimens pending the outcome of the action. The Supreme Court denied Plaintiffs' motion for a preliminary injunction and then, *sua sponte*, dismissed the action because the specimens had not been tested, and therefore it would violate law and public policy to release the sperm to the Plaintiffs for their own use.

The Appellate Division's main consideration in affirming the lower court's decision was the potential harm to the public that would occur if the sperm were released to the administrators. According to regulations set forth by the New York State Department of Health, semen specimens are only subject to extensive screening and testing for infectious disease when they are produced by a "donor" (a person who provides reproductive tissue for use in procedures performed on recipients other than the donor's regular sexual partner) or a "directed donor" (a person who provides reproductive issue to a surrogate who is not the regular sexual partner of the recipient). In this case, the decedent provided specimens as a "depositor" (a man who deposits reproductive tissue prior to intended or potential use in procedures performed on his regular sexual partner). Therefore, the specimens were not tested at the time they were deposited, and could never be tested subsequent to the decedent's death. Plaintiffs' proposed use of the specimens for a surrogate would violate Department of Health regulations, which continued to apply in these circumstances to protect the public from infectious disease.

The Appellate Division further noted that reformation is only available to correct a mutual mistake to conform an agreement to the original intent of the parties. The agreement here represented the decedent's desire to have the sperm available to him to procreate only if he survived, and did not protect any possibility that his genetic tissue would be used after his death. In fact, the decedent explicitly provided for the destruction of the specimens upon his death. Therefore, the agreement could not be reformed as Plaintiffs suggested because that was not the original intent of the decedent and the tissue bank. Further, the Court held that Defendant's acceptance of storage fees from Plaintiffs did not provide Plaintiffs with a right to an ownership interest over the specimens.

Accordingly, because "the legal obligations with regard to the possession and handling of the semen specimens are dictated solely and completely by the applicable Department of Health regulations"…and "the purpose of the statute is to protect the surrogate mother, and thereby the general public, from disease," the Court held it could not avoid the regulations, "[E]ven though we recognize the joy that ignoring those regulations could bring to Plaintiffs."

Physician's Suit Against U.S. Federation of State Medical Boards for Reporting the Suspension of His Medical License in Britain Dismissed for Lack of Jurisdiction and Failure to State a Claim

Dabiri v. Federation of States Medical Boards of the United States, Inc., et al., No. 08-4718, 2009 WL 803126 (E.D.N.Y. March 25, 2009). Plaintiff-physician brought an action against the Federation of States Medical Boards of the United States, Inc. ("FSMB") and the General Medical Council ("GMC"), a British statutory entity that oversees physicians' fitness to practice medicine. The Plaintiff alleged that GMC deprived him of due process by suspending his medical license in England without notice and hearing, and by providing that information to FSMB, which, in violation of its own rules, included the suspension in its medical disciplinary database in the U.S.

Plaintiff claimed he learned of the suspension seven years later when he requested a copy of FSMB's summary of reported actions related to his medical practice, which summary included a statement that FSMB only considered reports from state boards, federal agencies and federal departments, and that it assumed no responsibility for errors or omissions contained in the report.

After FSMB denied Plaintiff's request to remove the GMC suspension from his record, plaintiff commenced this action seeking equitable relief and damages for loss of income when he could not secure employment, purportedly because of the inclusion of his suspension in the FSMB database.

The court granted GMC's motion to dismiss for lack of subject matter jurisdiction because GMC was an "agency or instrumentality of a foreign state" immune from the court's jurisdiction pursuant to the Foreign Sovereign Immunities Act ("FSIA"). In so holding, the court rejected Plaintiff's contention that GMC fell

under an exception to the immunity rule because GMC was engaged in "commercial activity" when it charged fees for its oversight of physicians and their fitness to practice medicine. Even if true, these activities were insufficient to establish commercial activity to bring GMC within the FSIA exception, particularly because GMC was a public, charitable organization not organized for commercial activity.

As for the claims remaining against FSMB, the court granted its motion to dismiss the complaint for lack of subject matter jurisdiction because Plaintiff failed to allege the amount in controversy against FSMB was in excess of the $75,000.

Further, FSMB's motion to dismiss for lack of personal jurisdiction was granted. The mere collection of information about Plaintiff or other physicians residing in New York, absent any evidence that FSMB actually had contacts within the state, was insufficient to establish personal jurisdiction. Plaintiff did not allege FSMB sent any reports about him to any entity or person in New York, only that FSMB "avail[ed] itself of the opportunity to do business in New York each time it collect[ed] and exchange[d] information with others regarding plaintiff." Without more, the court had no personal jurisdiction over FSMB.

Finally, the court granted FSMB's motion to dismiss for failure to state a claim upon which relief may be granted. The only allegations against FSMB were that it recorded Plaintiff's suspension and disseminated that information in violation of its own rules that it would only distribute information from official reports provided by state boards, federal agencies or departments. These allegations were insufficient to establish a claim of defamation because plaintiff did not dispute the truth of the information reported by FSMB. Moreover, there was no claim that FSMB violated plaintiff's due process rights because FSMB was not a state actor. Finally, Plaintiff did not claim that FSMB had any knowledge of the suspension hearings or any role in the suspension, which would be required to support a claim that FSMB aided and abetted GMC in causing a tort against Plaintiff.

Fourth Department Appellate Division Holds That a Plaintiff Who Sues a Nursing Home Based on Traditional Tort Causes of Action May Also Assert a Claim Under Public Health Law § 2801-d

Kash v. Jewish Home & Infirmary of Rochester, N.Y., Inc., et al., 61 A.D.3d 146, 873 N.Y.S.2d 819 (4th Dep't 2009). Public Health Law § 2801-d provides patients of residential health care facilities with a private right to sue the facility for a failure to meet standards of care that deprives the patient of a right or benefit. The remedies provided by this law "are in addition to and cumulative with any other remedies available to a patient, at law or in equity or by administrative proceedings." The patient is entitled to punitive damages and attorneys' fees, and any damages recovered by the patient are "exempt for purposes of determining initial or continuing eligibility for Medicaid."

Plaintiff, a patient at Defendant nursing home, alleged that she suffered permanent spinal cord injuries due to the home's negligence. Plaintiff sued the home for negligence, and thereafter moved to amend her complaint by adding cause of action under section 2801-d. Plaintiff later admitted that she sought section 2801-d damages to ensure that she could recover compensation for her injuries while retaining Medicaid eligibility to pay for her ongoing care. The Supreme Court denied the motion, relying on two prior decisions.

In *Goldberg v. Plaza Nursing Home Comp*., the court granted the nursing home's summary judgment motion to dismiss the section 2801-d cause of action because the Plaintiff had the right to bring an action predicated upon the defendant's negligence. The *Goldberg* court relied on legislative history in concluding that the "purpose [of the statute] was not to create a new personal injury cause of action based on negligence when that remedy already existed." In *Doe v. Westfall Health Care Ctr.*, the court, by relying on the statute's clear language, permitted the plaintiff to assert the 2801-d cause of action despite the fact that she already asserted traditional torts causes of action. The *Doe* court reasoned that the conduct that formed the basis of the litigation (i.e., patient was raped by an employee of the nursing home) was precisely the sort that the statute was designed to target, but that recovery for such conduct was often barred for plaintiffs who sue at common law. In that case, a negligence cause of action against the facility could have been difficult to establish because of the probable absence of the requisite element of foreseeability, i.e., the facility's lack of prior knowledge of the employee's criminal tendencies.

The majority opinion of the Appellate Division, Fourth Department, embarked on its analysis by first examining the statute's language, which it concluded to be clear and unambiguous in providing remedies in addition to and cumulative with any other remedies. The court then reexamined the precedent decisions, stating that *Goldberg* was the first appellate decision to address section 2801-d, while the *Doe* court modified *Goldberg* to address a particularly heinous set of facts. The court found the *Doe* rule (i.e., one that limits section 2801-d causes of action only to those cases in which recovery under a common-law cause of action would prove difficult or inadequate) unworkable. Under this rule, a court would be required to preliminarily determine the likelihood of recovery under traditional tort causes of action, and *Doe* did not provide criteria for doing so. The court declared that the *Doe* rule creates an ambiguity not present in *Goldberg*, one that will create

the likelihood of inconsistent rulings and unpredictable results. The court was also persuaded by decisions of the First and Third Departments in concluding that a plaintiff is entitled to assert both a cause of action under Public Health Law § 2801-d and traditional causes of action. (Two Justices dissented).

Court Denies Claim for "Wrongful Living" Where Hospital Twice Violated Do-Not-Resuscitate Orders

Cronin v. Jamaica Hospital Medical Center, 60 A.D.3d 803, 875 N.Y.S.2d 222 (2d Dep't 2009). Plaintiff's decedent, Peter F. Cronin, was admitted as a patient to Defendant Jamaica Hospital Medical Center (the "Hospital") with various illnesses. During his hospitalization, the Hospital twice resuscitated Mr. Cronin—thereby prolonging his life—in violation of two Do-Not-Resuscitate orders, which had been issued by the Hospital and executed by decedent's family.

Plaintiff commenced an action against the Hospital asserting a claim for wrongfully prolonging decedent's life. The Appellate Division held that no cause of action exists for "wrongful living," as "the status of being alive does not constitute an injury in New York." Further, Plaintiff failed to raise a triable issue of fact as to whether Mr. Cronin suffered an injury as a result of the resuscitations. Accordingly, the Appellate Division upheld the Supreme Court's determination granting the Hospital's motion for summary judgment dismissal.

Court Holds That Documents Prepared by OPMC During Its Investigation Are Not Subject to Disclosure Under Public Health Law § 230 in the Absence of Any Applicable Exceptions

Hunold v. Community General Hospital of Greater Syracuse, 61 A.D.3d 1331, 876 N.Y.S.2d 828 (4th Dep't 2009). Plaintiff commenced a medical malpractice action against Defendant Community General Hospital of Greater Syracuse (the "Hospital"). During discovery, Plaintiff sought documents from non-party New York State Department of Health, Office of Professional Medical Conduct ("OPMC"), which had investigated the care and treatment of the patient. The Supreme Court ordered the OPMC to produce its investigation documents, including any statements made by Defendants.

Applying Public Health Law § 230(10)(a)(v), the Appellate Division, Fourth Department, reversed the order on the grounds that such materials, which concerned possible instances of professional misconduct, were confidential, and not subject to any applicable exceptions. The Appellate Division further held that, because the Board of Professional Misconduct (the "Board") did not convene to discuss the case, the exception for statements made by parties (here, the Hospital) at a meeting of the Board did not apply under Public Health Law § 230(9). Accordingly, absent any applicable exceptions, the Appellate Division found that the materials sought were not discoverable as a matter of law.

Medicaid IG's Perfunctory Refusal to Reinstate Physician Is Arbitrary and Capricious

Mihailescu v. Sheehan, No. 117072/08, 2009 WL 1799113 (Sup. Ct., N.Y. Co. June 24, 2009). The Office of Professional Conduct ("OPMC") and the Board of Professional Medical Conduct (the "Board") suspended the medical license of petitioner, a psychiatrist, for committing "boundary violations" involving two patients. Petitioner entered into a consent order which provided that if petitioner met certain conditions, after serving a 12-month suspension, she would be permitted to practice in a State-licensed facility (the "Agreement").

OPMC gave notice of the suspension and Agreement to various State and federal agencies, including the State Medicaid Inspector General (the "Medicaid IG" or "IG"), and as a result, petitioner was excluded from the Medicaid program. After serving her 12-month suspension and meeting all other conditions in her consent order, petitioner applied for reinstatement in the Medicaid program; otherwise, as an excluded provider, petitioner would not be permitted to provide services in a facility that received any federal funds. Due to the license suspension, the IG denied petitioner's reinstatement application. Petitioner commenced an Article 78 proceeding to set aside the Medicaid IG's denial of her application for reinstatement.

The IG's discretionary action could only be set aside if the court found the challenged action to be arbitrary and capricious or lacked a rational basis. The court reviewed the IG's authority to make its decision by tracing the history of statutes and regulations relevant to respondents' administrative functions and relationship to the Department of Health (the "DOH"). For the last 40 years, OPMC and the Board have served as the DOH's investigatory and adjudicatory arms concerning allegations of professional misconduct by physicians. In 2006, the Medicaid IG position was removed from the Executive Department and defined as an "independent fraud-fighting entity within the Department of Health." The court pointed to the IG's assumption that he was authorized to assess a physician's participation with Medicaid, even when his determination was conflicting with OPMC and the Board. Ultimately, the court resorted to practical considerations to determine that the IG's authority fell short of his presumption of authority.

The court found that since OPMC and the Board were responsible for determining whether petitioner could care for both non-Medicaid and Medicaid patients, the legislature did not likely intend that the Medicaid IG, a non-doctor, create duplicative Departmental work, especially in light of the IG's lack of investigation and evaluation of the petitioner. The Medicaid IG second-guessed the Department and simply based his determination on the suspension. The prime

avenue of employment contemplated by the Agreement was effectively closed by petitioner's exclusion from participation in the Medicaid program and the Agreement essentially became meaningless.

Instead, the court found that the Medicaid IG is expected to defer to his sister Departmental units for their conclusions. The IG's refusal to reinstate petitioner was found to be arbitrary and capricious as it was baseless and inconsistent with a prior assessment by OPMC and the Board. Accordingly, the court granted Article 78 relief against the IG, directing petitioner's reinstatement to the roster of Medicaid providers.

Appellate Division Affirms Medical License Revocation for Fraudulent Billing, Holding That Physicians Are Ultimately Responsible for the Accuracy of Their Bills

Tsirelman v. Daines, 61 A.D.3d 1128, 876 N.Y.S.2d 237 (3d Dep't 2009). Physician commenced an Article 78 proceeding to challenge a determination of the Hearing Committee of the State Board for Professional Medical Conduct (the "Committee") that he engaged in fraudulent billing, and that his license should be revoked and a fine of $100,000 be imposed. The charges were based upon bills submitted to a no-fault automobile insurer for procedures that were neither medically necessary nor actually performed. Petitioner blamed the billing service for misreading his notes, adding a billing code, and stamping his signature on the bills without his authorization. Citing evasive, fabricated and inconsistent testimony, the Committee found petitioner's claims lacked credibility.

The court applied the standard that physicians are ultimately responsible for the accuracy of the bills that they issue, and found that the Committee could infer that petitioner knew the bills were false and that he willfully intended to mislead and deceive the insurer. The charges of fraudulent medical practice, filing false reports, and moral unfitness were sustained. Further, petitioner failed to establish a deprivation of due process as he did not show that the admission of uncertified and allegedly incomplete patient records unfairly affected the entire proceeding, and submission of additional records would have been redundant, irrelevant, and not exculpatory.

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

In a legislative session likely to be remembered more for its controversy and chaos than its legislative output, a number of bills were nevertheless enacted into law that will have significant impact on New Yorkers. The following summarizes select health-related bills that may have escaped your attention, along with a few bills related to other areas of law and policy that may be relevant to health care clients.

Public Health Legislation:

Organ Donation and Consent for Organ Donations (Chapter 348; A.904-A Gottfried/S.3910-A Duane): This law updates the list of persons who can consent to organ donations by recognizing health care agents, domestic partners as well as disposition-of-remains agents. The bill lists a priority order for consent, but also clarifies that a health care proxy or control-of-remains written instrument may limit the authority of the agent or the designated person who would make a decision about consent. This law takes effect on October 25, 2009. Meanwhile, the long-debated Family Health Care Decision Act (A.7729-C Gottfried / S.3164-A Duane), which would establish procedures for family members, surrogates and others who are close to an incapacitated patient to make health care decisions on behalf of a patient if such person is incapable of doing so, passed the Senate on July 16, 2009 but has not yet passed in the Assembly.

Clarification of Ban on "Valuable Consideration" for Organ Donation (Chapter 362 of 2009; A.4216 Brodsky/S. 4318 Adams): The law clarifies that so-called "paired kidney exchanges" or similarly conditioned organ donations are not characterized as donations for "valuable consideration," which are otherwise subject to criminal prosecution. In a "paired kidney exchange," a kidney donor, who has been determined not to be a good match for a loved one, agrees

to donate the organ when an appropriate matched kidney is identified for their intended recipient, thereby making the organ available for some other person on a waiting list for transplantation. The law took effect on August 26, 2009.

The Breastfeeding Mothers' Bill of Rights (Chapter 292 of 2009; A.789-B Gunther/S.1109-A Krueger): The Breastfeeding Mothers' Bill of Rights codifies existing regulations, best hospital practices and major components of the World Health Organization's Baby Friendly Guidelines as they pertain to the breastfeeding of newborns and infants. The law establishes that it is every woman's right to be informed about the benefits of breastfeeding and provides mothers with basic breastfeeding related rights before, during and after the birth of her baby. The law requires posting of the list of rights in public locations such as maternal health care provider's offices and authorizes the Commissioner of Health to adopt regulations to implement the statute. The law will take effect on May 1, 2010.

Influenza Vaccination for Neonatal Caregivers (Chapter 282 of 2009; S.3911-A Duane/A.876-A Gottfried): This law requires general hospitals with neonatal intensive care units (NICUs) to offer influenza vaccinations to parents of children in the NICU (except those who have already been vaccinated or for whom vaccination would be medically inappropriate) between September 1 and April 1 each year. If parents decline, hospitals are required to provide them with information regarding other locations where they may be vaccinated. Hospitals are required to adopt a formal policy reflecting this requirement and to document each such vaccination. The Commissioner of Health is authorized to waive the requirements of this new law in the event of a vaccine shortage. The law will take effect on November 24, 2009.

Hospital and Nursing Home-Related Legislation:

Hospital Closure Planning Act (A.8461-C Lancman/S.5802-A Huntley): This bill would require the Commissioner of Health, within 30 days of receiving written notice of a general hospital's voluntary closure or of a closure for which notice was not provided, to hold a public hearing concerning the anticipated impact of such closure. Within 30 days of that hearing, the Commissioner would be required to issue a report to the governor and the legislature including his or her findings concerning such impact, the measures to be taken to ameliorate such impact, and any further recommendations to improve health care access in the impacted area. Within 30 days of issuing such report, the Commissioner would be required to hold a public hearing to receive public comment on the report. The bill has passed the Senate and Assembly, but has not yet been delivered to the Governor.

Nursing Care Quality Protection Act (Chapter 422 of 2009; A.1752 Gottfried/S.3527 Duane): This law requires acute care facilities to implement certain direct-care nurse-to-patient ratios in all nursing units; sets minimum staffing requirements; requires every such facility to submit a documented staffing plan to the department on an annual basis and upon application for an operating certificate; requires acute care facilities to maintain staffing records during all shifts; authorizes nurses to refuse work assignments if the assignment exceeds the nurse's abilities or if minimum staffing is not present; requires public access to documented staffing plans; imposes civil penalties for violations of such provisions;

and establishes private right of action for nurses discriminated against for refusing any illegal work assignment. The law will take effect on March 15, 2010.

Safe Patient Handling Demonstration Program Extender (Chapter 153 of 2009; A.8045-B Gunther/S.5786 Maziarz): Chapter 738 of the Laws of 2005 established the Safe Patient Handling Demonstration Program, a two-year demonstration program to collect evidence-based data on the incidence of employee and patient injuries in general hospitals, nursing homes, other long term care facilities and homes served by home health agencies resulting from the use of manual and technology-based techniques in the lifting, transferring, repositioning or moving of patients. This law extends the program until October 18, 2011.

Nursing Home Private Right of Action: Public Health Law § 2801-d provides that nursing homes are liable to residents who have been deprived of any right or benefit unless the nursing home has taken "all care reasonably necessary to prevent and limit" such deprivation or injury. Three bills that would clarify this private right of action were passed by both houses, two of which were signed by the Governor.

- ***Chapter 60 of 2009; A.724 Gottfried/S.3841 Duane:*** This law clarifies that the prohibition against retaliation against complaining patients applies both to residents who have brought an action directly and to residents whose legal representatives have brought such an action. This law took effect on June 9, 2009.
- ***Veto No. 7 of 2009; A.730 Gottfried/S.3834 Duane:*** This bill would have extended the Medicaid exemption for recoveries by a resident's legal representative, including recoveries by a resident's estate. The bill was vetoed by the Governor on June 10, 2009, on the grounds that the purpose of the existing exemption is to prevent the repayment of recovered amounts to nursing homes in which injured residents continue to reside, and that purpose is not served by exempting estate recoveries, which must be repaid to the State under State and Federal law.
- ***Chapter 61 of 2009; A.763 Gottfried/S.3907 Duane:*** This law clarifies that compensable injuries under the statute include physical harm, emotional harm, death and financial loss and that residents may pursue separate tort actions, and that the availability of any other remedy shall not preclude an action under § 2801-d. It also clarifies that the rights in question include not only the rights enumerated in the Nursing Home Patients' Bill of Rights (Public Health Law § 2803-c[3]), but also any other right established by statute, regulation or contract. The Governor issued an approval message noting that it merely clarifies, and does not expand, existing rights under § 2801-d (see ***Approval Message No. 3 of 2009***). The law took effect on June 9, 2009.

Nursing Home Off-Site Therapy Demonstration Project (Chapter 371 of 2009; A.6818-A Morelle/S.939-A Robach): This law establishes a demonstration project allowing up to three nursing homes licensed to offer on-site outpatient services to also offer physical, occupational and speech therapy at off-site facilities. This version corrects deficiencies identified in a previously passed, but vetoed, bill. The law took effect on August 26, 2009, and will expire on June 30, 2012.

Reproductive Health Care-Related Legislation:

Prenatal Care Bill (A.8397 Gottfried/S.3257 Duane): The Department of Health bill would require the Commissioner of Health to develop and update standards for the provision of prenatal care under the Medicaid program. In addition, the law provides that a pregnant woman would be presumed eligible for prenatal care services if her family's income satisfies certain guidelines. All Article 28 facilities that provide prenatal care services are required to make presumptive eligibility determinations, although a facility may apply to the Commissioner for a hardship exemption from the requirement. All other prenatal care providers are required to render prenatal care services to presumptively eligible women. The bill has passed the Senate and Assembly, but has not yet been delivered to the Governor.

Aggravated Interference with Health Care Services (A.8924 Hoyt/S.6112 Parker): The bill would create a new class E felony for causing physical injury to someone who is obtaining, providing or assisting someone to obtain or provide reproductive health services. In addition, the bill would create a new class C felony for causing serious physical injury to someone who is obtaining, providing, or assisting someone to obtain or provide reproductive health services, thereby elevating the more serious assault charge from a class D felony. It also would make certain changes to the law to increase penalties on repeat offenders who interfere with reproductive health care services. For the first time, it makes it a crime to cause such physical injury and serious physical injury to volunteers who are assisting others to obtain reproductive health care services rather than just the actual provider of those services. The bill has passed the Senate and Assembly, but has not yet been delivered to the Governor.

Managed Care and Health Insurance Coverage Initiatives:

COBRA coverage bills (Chapter 7 of 2009, A.6740 Morelle/S. 3068 Breslin; Chapter 236 of 2009, A.8400 Peoples/S.5471 Breslin; and Chapter 240 of 2009, A.9038 Morelle/S.5030 Duane): Chapter 7 extends the timeframes to elect COBRA coverage and takes advantage of federal stimulus funding to subsidize the cost of pre-

miums for COBRA coverage. Chapter 236 extends COBRA coverage to 36 months in all cases. Chapter 240 permits unmarried dependents to remain on the group coverage through age 29 if the dependent pays the full cost of the coverage.

Managed Care Reforms (Chapter 237 of 2009, A.8042-A Morelle/S.5472-A Breslin): The latest amendments to the "managed care reform" law enacted a series of consumer and provider-protective provisions, including limitations on denials of pre-authorized health care services, strengthened grievance procedures, and tighter timeframes on the utilization review of certain urgent health care services.

Purchase of Family Health Plus Coverage by Voluntary Employee Benefit Associations (Chapter 347 of 2009; A.9033 Gottfried/ S.6024 C. Johnson): In 2007, the State enacted Social Services Law § 369-ff to permit employers and Taft-Hartley funds that offer health coverage to "buy-in" to Family Health Plus, allowing workers to participate in employment-based health coverage. This law extends the ability to "buy-in" to Family Health Plus to a voluntary employee benefit association (VEBA) established in accordance with the requirements of the federal Internal Revenue Code. The law took effect on August 11, 2009.

Medical Malpractice:

Malpractice Rate Freeze (Chapter 216 of 2009; A.9036 Gottfried/S.6026 Rules): In the absence of any substantive changes in the medical malpractice system, the legislature again extended a freeze on malpractice rates for physicians through June 30, 2010. The freeze was first imposed 23 years ago, after the last substantial medical malpractice reform package was enacted, and was intended to delay any dramatic hikes in malpractice insurance rates while those reforms were taking hold. The memorandum in support justifies this freeze on the basis that "the Executive, the Legislature and stakeholders are engaged in discussions to develop long-term solutions to the medical malpractice problem" and that the freeze will provide premium relief in the meantime. Although a malpractice task force had been convened at the outset of the Spitzer Administration, no proposals have yet been advanced as a result of those deliberations and the discussions have largely been discontinued. This law took effect on July 11, 2009.

A number of other bills relating to medical malpractice, most at the behest of the trial lawyers, were considered by the legislature, but were not passed by both houses, including the following:

- **Prohibition on Interviews of Plaintiff's Treating Physician (A.1254 and A.8964 Lancman/S.1514 and S.3203-A DeFrancisco and Klein):** These bills would overturn the Court of Appeals decision in *Arons v. Jutkowitz*, 9 N.Y.3d 393 (2007), which permits malpractice defense attorneys to interview the treating physician of the plaintiff in a malpractice cases, consistent with state law and with the requirements of HIPAA.

- **Revise Statute of Limitations for Malpractice (A.4627-A Weinstein; S.1729 Schneiderman (not same as)):** These bills would modify the existing two-and-a-half year statute of limitations for malpractice cases by measuring the time from when a person knew or should have known of the negligent act or knew or reasonably should have known that the negligent act or omission caused the injury—rather than measuring the time from the act itself.

- **Remove Limits on Contingency Fees (S.2040 DeFrancisco):** The bill would remove limitations on the amount of contingency fees that could be awarded to attorneys in medical malpractice actions. These limitations, which were enacted in the mid-1980s, established a declining percentage of the overall award, ramping down from 30 percent of the first $250,000 to ten percent of an award amount in excess of $1.25 million.

Health-Care Professions Issues:

Surcharge on Professional Registrations (Chapter 396 of 2009; A.8219 Stavisky/S.4200 Glick): This recent law authorizes the State Education Department to collect a 15 percent surcharge on each registration required for the 48 professions licensed pursuant to Education Law Title 8, including physician assistants, dentists, pharmacists, nurses, midwives, podiatrists, optometrists, social workers, mental health practitioners, and respiratory therapists, and many others. This law took effect on August 26, 2009.

Dental Residents Authority (Chapter 436 of 2009; A.6718-B Pheffer/S.4135-A Oppenheimer): This law removes the requirement that a dentist in a residency program obtain a limited permit from the State Education Department in order to practice in New York State. Limited permits are generally required for professionals who comply with the educational qualifications for licensure by the State, but have not yet fulfilled the examination requirement for licensure. The justification for the law is that a dental resident is subject to institutional safeguards that ensure the safety of the public *and* that a similarly situated physician in a residency program is not required to obtain a limited permit. The law also provides that dental residents may fulfill the mandatory three-hour course in dental jurisprudence and ethics during their residency. The law will take effect on January 1, 2010.

Mental Hygiene:

Timothy's Law (Mental Health Parity) Made Permanent (Chapter 181 of 2009, A.8611 Morelle/S.5672 Huntley): When Timothy's Law was

enacted in 2006 to mandate broader coverage of mental illness under health insurance issued in New York, the law had a sunset clause that would have resulted in the expiration of the law at the end of 2009. This law removes the sunset clause, making New York's mental health parity law permanent. The law took effect on July 11, 2009.

Minority Mental Health Act (Veto No. 49; A.5055 P. Rivera/S.4938 Huntley): This legislation would have established the Division of Minority Mental Health within the Office of Mental Health to serve as a liaison and advocate on minority health matters; to establish appropriate program linkages with federal, state and local agencies; to assist in the development of programs to improve the supply of minority mental health personnel; and to review the impact of programs, regulations and reimbursement policies on minority health care service delivery and access. The bill would also have created a Minority Mental Health Council to assist the Commissioner of OMH with these issues and to conduct a study on mental health needs of racial and ethnic minorities. Governor Paterson vetoed this legislation on August 26, 2009, citing a $2 million fiscal impact to the State for the first two years and $770,000 thereafter. In addition, Governor Paterson indicated that this bill would have duplicated work that is already being done by the Bureau of Cultural Competence and a study required by Chapter 119 of 2007.

Economic Development/Energy/ Environmental Issues:

New York City Biotechnology Tax Credit (Chapter 453 of 2009; A.8131 Weprin/S.4845-B Duane): This law authorizes New York City to create a new "Biotechnology [tax] credit" for qualified emerging technology companies in an amount up to $250,000. Eligible expenses will include acquisition of research and development equipment, employee training, and R&D expenses. This tax credit is intended to draw upon the bioscience research expertise available from the City's 26 medical centers and 175 hospitals and is based upon, and complements, the State's Qualified Emerging Technologies Facilities Operations and Training Tax Credit. This law took effect on September 16, 2009.

Medical Waste Disposal Facilities and Zoning Compliance (Chapter 14 of 2009; A.4341-B Perry/S.2581-A Sampson): This law requires a person who submits an application to operate a medical waste treatment, storage and disposal facility to the State Department of Environmental Conservation ("DEC") to certify that such proposed medical waste facility conforms with local zoning laws or ordinances. This law took effect on April 7, 2009.

Green Jobs-Green New York Act of 2009 (A.8901 Silver/S.5888 Aubertine/S.51031 Rules; A.9031 Cahill/S.6032 Aubertine/S.51032 Rules): This bill would use $112 million from the State-sponsored sale of carbon credits to energy utilities to fund low-interest loans for energy efficiency upgrades to existing residential and non-residential structures. The maximum loan would be $26,000 for non-residential projects and $13,000 for residential projects. The fund would also provide financial assistance for energy audits, which would be a precondition to receiving a low-interest loan. Finally, the bill would direct the State to enter into contracts with workforce entities to provide training for individuals to perform energy efficiency upgrades and energy audits, and for the State to provide grants to "constituency-based organizations" for outreach and enrollment of individuals into such training programs. The bill has passed the Senate and Assembly, but has not yet been delivered to the Governor.

In the New York State Agencies

By Frank Serbaroli

Health Department

Approval of Nonclinical Projects

Notice of adoption. The Department of Health amended § 7.10.1(c)(6) of Title 10 N.Y.C.R.R. to substitute prior limited review for administrative CON review of construction projects with costs between $3 million and $10 million. Filing date: January 13, 2009. Effective date: January 28, 2009. *See* N.Y. Register, January 28, 2009.

Fingerprinting and Criminal Background Check Requirements (CBCR) for Unescorted Access to Radioactive Materials

Notice of adoption. The Department of Health added § 16.112 to Title 10 N.Y.C.R.R. to implement fingerprinting and CBCR requirements as issued by the U.S. Nuclear Regulatory Commission for individuals allowed unescorted access to large quantities of radioactive materials. Filing date: June 2, 2009. Effective date: June 17, 2009. *See* N.Y. Register, June 17, 2009.

Criminal History Record Check

Notice of emergency rulemaking. The Department of Health added Part 402 to Title 10 N.Y.C.R.R. to provide for criminal background checks of certain prospective employees of nursing homes, certified home health agencies, licensed home care services agencies and long-term home health care programs. Filing date: September 11, 2009. Effective date: September 11, 2009. *See* N.Y. Register, September 30, 2009.

Notice of revised rulemaking. The Department of Health gave notice of its intent to add Part 402 to Title 10 N.Y.C.R.R. to provide for criminal background checks of certain prospective employees of nursing homes, certified home health agencies, licensed home care services agencies and long-term home health care programs. *See* N.Y. Register, September 30, 2009.

Controlled Substances Data Submissions

Notice of adoption. The Department of Health amended §§ 80.2, 80.23, 80.23, 80.67, 80.68. 80.69, 80.71, 80.73, 80.74, 80.132, and 80.134 of Title 10 N.Y.C.R.R. to govern and control possession, prescribing, manufacturing, dispensing, administering, and distribution of controlled substances within New York. Filing date: February 6, 2009. Effective date: February 25, 2009. *See* N.Y. Register, February 25, 2009.

Payment for FQHC Psychotherapy and Offsite Services

Notice of adoption. The Department of Health amended § 86-4.9 of Title 10 N.Y.C.R.R. to permit psychotherapy by certified social workers in Article 28 Federally Qualified Health Centers as a billable service under certain circumstances. Filing date: March 10, 2009. Effective date: March 25, 2009. *See* N.Y. Register, March 25, 2009.

Practice of Radiologic Technology

Notice of adoption. The Department of Health repealed Part 89 and added a new Part 89 to Title 10 N.Y.C.R.R. to update the register to reflect the current practice of radiologic technology and the administration of the program by DOH. Filing date: February 6, 2009. Effective date: February 25, 2009. *See* N.Y. Register, February 25, 2009.

Chemical Analyses of Blood, Urine, Breath or Saliva for Alcoholic Content

Notice of adoption. The Department of Health amended Part 59 of Title 10 N.Y.C.R.R. to update the conforming products list of breath alcohol testing devices currently approved for use by the NHTSA. Filing date: February 6, 2009. Effective date: February 25, 2009. *See* N.Y. Register, February 25, 2009.

Physical Therapist Assistants and Occupational Therapy Assistants

Notice of adoption. The Department of Health amended § 505.11 of Title 18 N.Y.C.R.R. to allow physical therapist assistants and occupational therapy assistants to provide services to Medicaid recipients. Filing date: March 17, 2009. Effective date: April 1, 2009. *See* N.Y. Register, April 1, 2009.

Service Intensity Weights (SIW) and Average Lengths of Stay

Notice of adoption. The Department of Health amended § 86-1.62 of Title 10 N.Y.C.R.R. to modify the Service Intensity Weights for DRGs. Filing date: May 5, 2009. Effective date: May 20, 2009. *See* N.Y. Register, May 20, 2009.

Initial Purchase of Magnetic Resonance Imagers (MRIs)

Notice of adoption. The Department of Health amended § 710.1(c)(2) and (3) of Title 10 N.Y.C.R.R. to substitute administrative CON review for full CON review of initial purchases of MRIs. Filing date: March 31, 2009. Effective date: April 15, 2009. *See* N.Y. Register, April 15, 2009.

Relocation of Extension Clinics

Notice of adoption. The Department of Health amended § 710.1(c)(3) and (5) of Title 10 N.Y.C.R.R. to substitute prior limited review for administrative CON review of relocations of extension clinics within the same service area. Filing date: March 31, 2009. Effective Date: April 15, 2009. *See* N.Y. Register, April 15, 2009.

Notification and Submission Requirements for Continuing Care Retirement Communities

Notice of adoption. The Department of Health amended § 901.9 of Title 10 N.Y.C.R.R. to revise necessary

approvals required for a continuing care retirement community's extended construction completion date. Filing date: April 14, 2009. Effective date: April 29, 2009. *See* N.Y. Register, April 29, 2009.

Childhood Lead Poisoning Screening and Follow-up

Notice of adoption. The Department of Health amended Subparts 67-1 and 67-3 of Title 10 N.Y.C.R.R. to expand follow-up for children with elevated blood lead levels, and authorize point-of-care laboratory testing and required reporting. Filing date: April 17, 2009. Effective date: June 20, 2009. *See* N.Y. Register, May 6, 2009.

Poison Control Distributions—Rollover of Unexpended Funds

Notice of adoption. The Department of Health repealed § 68.6(e) of Title 10 N.Y.C.R.R. to eliminate the rollover to the subsequent calendar year of unexpended HCRA Resources funds allocated for a given calendar year. Filing date: July 21, 2009. Effective date: August 5, 2009. *See* N.Y. Register, August 5, 2009.

PASRR SCREEN Requirements

Notice of proposed rule making. The Department of Health gave notice of its intent to amend § 400.12 of Title 10 N.Y.C.R.R. to remove outdated language; revise incorrect language; remove SCREEN from regulation text and replace with reference. *See* N.Y. Register, July 15, 2009.

Emergency and Cardiac Services

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend §§ 405.19, 405.22 and 405.29 of Title 10 N.Y.C.R.R. to update the cardiac provisions to reflect current practice. *See* N.Y. Register, July 29, 2009.

Cardiac Services Need Methodology

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend § 709.14 of Title 10 N.Y.C.R.R. to update the need methodology to reflect current practice. *See* N.Y. Register, July 29, 2009.

Certificate of Need Process for Cardiac Services

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend § 710.1 of Title 10 N.Y.C.R.R. to align the certificate of need process in cardiac services. *See* N.Y. Register, July 29, 2009.

Rate Methodology for Non-Public Hospitals to Ensure Access for All Medicaid Patients Requiring Language Assistance

Notice of proposed rulemaking. The Department of Health gave notice of its intent to add § 86-1.11(v) to Title 10 N.Y.C.R.R. to establish a rate methodology for non-public hospitals to ensure access for all Medicaid patients requiring language assistance. *See* N.Y. Register, August 5, 2009.

Physician Board Certification Entities

Notice of adoption. The Department of Health amended § 1000.1(a) of Title 10 N.Y.C.R.R. to remove The College Family Physicians of Canada (CFPC) from the definition of board certified. Filing date: July 23, 2009. Effective date: August 12, 2009. *See* N.Y. Register, August 12, 2009.

Health Care Personnel Influenza Vaccination Requirements

Notice of emergency rulemaking. The Department of Health added Subpart 66-3 and amended §§ 405.3, 751.6, 763.13, 766.11 and 793.5 of Title 10 N.Y.C.R.R. to prevent transmission of influenza disease from health care personnel (HCP) to vulnerable health care facility residents. Filing date: August 13, 2009. Effective date: August 13, 2009. *See* N.Y. Register, September 2, 2009.

Office of Mental Health

Operation of Outpatient Programs

Notice of Adoption. The Office of Mental Health amended Part 587 of Title 14 N.Y.C.R.R. to increase the age of individuals receiving services in day treatment programs for children. Filing date: January 27, 2009. Effective date: February 11, 2009. *See* N.Y. Register, February 11, 2009.

Operation of Residential Programs for Adults

Notice of adoption. The Office of Mental Health amended Part 595 of Title 14 N.Y.C.R.R. to include a new class of community residences for treatment of eating disorders. Filing date: May 5, 2009. Effective date: May 20, 2009. *See* N.Y. Register, May 20, 2009.

Medical Assistance Payments for Community Rehabilitation Services Within Residential Programs for Adults, Children and Adolescents

Notice of adoption. The Office of Mental Health amended Part 593 of Title 14 N.Y.C.R.R. to clarify that services provided by CREDIT programs do not qualify as rehabilitative and are not eligible for Medicaid payments. Filing date: May 5, 2009. Effective date: May 20, 2009. *See* N.Y. Register, May 20, 2009.

Operation of Licensed Housing Programs for Children and Adolescents with Serious Emotional Disturbances

Notice of adoption. The Office of Mental Health amended Part 594 of Title 14 N.Y.C.R.R. to include a new class of community residences for treatment of eating disorders. Filing date: May 5, 2009. Effective date: May 20, 2009. *See* N.Y. Register, May 20, 2009.

Comprehensive Outpatient Programs

Notice of adoption. The Office of Mental Health amended Part 592 of Title 14 N.Y.C.R.R. to adjust the Medicaid reimbursement associated with certain outpatient treatment programs regulated by OMH. Filing date: August 6, 2009. Effective date: August 26, 2009. *See* N.Y. Register, August 26, 2009.

Medical Assistance Payment for Outpatient Programs

Notice of emergency rulemaking. The Office of Mental Health amended Part 588 of Title 14 N.Y.C.R.R. to modify current reimbursement methodology for continuing day treatment programs and restore funding for certain programs. Filing date: June 29, 2009. Effective date: June 29, 2009. *See* N.Y. Register, July 15, 2009.

Medical Assistance Rates of Payment for Residential Treatment Facilities for Children and Youth

Notice of emergency rulemaking. The Office of Mental Health amended § 578.8 of Title 14 N.Y.C.R.R. to reduce the growth rate of Medicaid reimbursement associated with residential treatment facilities for children and youth. Filing date: July 1, 2009. Effective date: July 1, 2009. *See* N.Y. Register, July 22, 2009.

Prior Approval Review for Quality and Appropriateness

Notice of adoption. The Office of Mental Health amended Part 551 of Title 14 N.Y.C.R.R. to streamline the process for agencies to obtain OMH project approval. Filing date: August 12, 2009. Effective date: September 2, 2009. *See* N.Y. Register, September 2, 2009.

Personalized Recovery-Oriented Services (PROS)

Notice of emergency rulemaking. The Office of Mental Health amended Part 512 of Title 14 N.Y.C.R.R. to modify PROS registration, documentation and program standards, and include the methodology for calculating capital add-on. Filing date: September 1, 2009. Effective date: September 1, 2009. *See* N.Y. Register, September 16, 2009.

Office of Medicaid Inspector General

Monetary Penalties

Notice of adoption. The Office of Medicaid Inspector General amended §§ 516.1(c), 516.2, 516.5(a) and added section 516.5(f) and (g) to Title 18 N.Y.C.R.R. to conform to recent statutory changes resulting from the commission of certain proscribed acts in violation of the MA Program. Filing date: February 10, 2009. Effective date: February 25, 2009. *See* N.Y. Register, February 25, 2009.

Compliance Programs for Medical Assistance Provider

Notice of adoption. The Office of Medicaid Inspector General added Part 521 to Title 18 N.Y.C.R.R. to set forth regulations governing compliance programs for medical assistance providers. Filing date: June 9, 2009. Effective date: July 1, 2009. *See* N.Y. Register, June 24, 2009.

Provider Hearings

Notice of proposed rulemaking. The Office of Medicaid Inspector General gave notice of its intent to amend § 519.4(b) and add § 540.6(e)(8) to Title 18 N.Y.C.R.R. to clarify hearing rights and introduce consistency with respect to the recoupment of third party liability overpayments. *See* N.Y. Register, September 30, 2009.

Notice of proposed rulemaking. The Office of Medicaid Inspector General gave notice of its intent to amend §§ 518.1(c) and 518.5(b) of Title 18 N.Y.C.R.R. to clarify hearing rights and introduce consistency with respect to the recoupment of third party liability overpayments. *See* N.Y. Register, September 30, 2009.

Insurance Department

The Processing of Coordination of Benefit (COB) Claims

Notice of adoption. The Insurance Department amended Parts 52 and 217 of Title 11 N.Y.C.R.R. to establish guidelines for processing of health care claims when the person is covered by more than one health insurance policy. Filing date: March 13, 2009. Effective date: July 15, 2009. *See* N.Y. Register, April 1, 2009.

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

Notice of emergency rulemaking. The Insurance Department amended Parts 215 (Regulation 34), 52 (Regulation 62), 360 (Regulation 145), and 361 (Regulation 146); and added Part 58 (Regulation 193) to Title 11 N.Y.C.R.R. to conform the regulations with the requirements of federal law. Filing date: August 10, 2009. Effective date: August 10, 2009. *See* N.Y. Register, August 26, 2009.

Financial Statement Filings and Accounting Practices and Procedures

Notice of emergency rulemaking. The Insurance Department amended Part 83 (Regulation No. 172) of Title 11 N.Y.C.R.R. to update the regulation to conform to NAIC guidelines, statutory amendments, and to clarify existing provisions. Filing date: August 13, 2009. Effective date: August 13, 2009. *See* N.Y. Register, September 2, 2009.

Minimum Standards for the Form, Content and Sale of Health Insurance, Including Standards of Full and Fair Disclosure

Notice of proposed rulemaking. The Insurance Department gave notice of its intent to amend § 52.70(e)(2) of Title 11 N.Y.C.R.R. to comply with N.Y. Ins. Law 3234(b), pursuant to *Benesowitz v. Metropolitan Life Insurance Company*. *See* N.Y. Register, September 9, 2009.

Compiled by Francis J. Serbaroli. Mr. Serbaroli is a shareholder in the Health & FDA Business department of Greenberg Traurig's New York office. He is a member 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. The assistance of Ms. Whitney M. Phelps and Mr. Benjamin M. Friedman, associates at Greenberg Traurig in the Health and FDA Business group, in compiling this summary is gratefully acknowledged.

In the Journals

AHLA Journal of Health & Life Sciences Law, Vol. 2, No. 3 (April 2009)

- *The Legacy of Jay Katz: The Abiding Relevance of the "Obligation for Conversation" in The Physician-Patient Relationship*
- *Healthcare Reform: A Discussion with Thomas A. Daschle and Thomas A. Scully*
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Compiled by the Editor.

For Your Information

By Claudia O. Torrey

There is an old adage—**IF IT ISN'T BROKE, DON'T FIX IT!** Many of us would agree that our health care system is broken in some ways, but how to fix it has become THE hot topic of the last few months. Thus, both economists and health law professionals are in a position to EDUCATE the public (which also includes Congress) on this subject so that our citizenry is as informed as possible. Medicare? Single Payer? Medicaid? Comparative Effectiveness? Public Option? COBRA? Health Care Cooperatives? These terms and others have been sliced, diced, misused, and abused; ironically, as this column is being written the news media have just announced that health care's "champion of champions" has just died—Sen. Edward M. Kennedy of Massachusetts. For over four decades Sen. Kennedy was involved in international affairs and fought for civil rights, women's rights, and accessible quality health care for all; he envisioned health care as a *right* and not a privilege! Known for successfully reaching out "across the aisle" to get legislation passed, this uncanny ability reminds us that working together to find common ground is very important. Just as the rain pours and the sun shines on rich and poor alike, access to quality health care should be available without regard to one's social status, employment status, racial / ethnic background, or geographic location.

Irrespective of one's "political stripe," this author believes common ground can be found on such topics as:

1. **Health Care Costs**—According to an August 23, 2009 article in the *San Francisco Chronicle*[1] by Mr. Joe Nation, "…health care spending in 2009 will be 17 percent of our gross domestic product, nearly double its level in 1980. Projections suggest it will hit close to 20 percent in 2017." How to rein in costs (for example, taxing employer-provided health care benefits; making changes in the provider payment system; etc.) will surely be at the heart of any intelligent discussion of health care reform; this very issue of the *Health Law Journal* contains a Summary Report[2] on Health Care Costs. A project combining members of the Health Law Section's Public Health & Policy Committee, along with members from the Health Law Committee of the Association of the Bar of the City of New York, the principal author is the Chair of the Section's Public Health & Policy Committee—Attorney Margaret J. Davino. The Summary Report can also be viewed at www.nysba.org/HLSHealthcareCostsReport.

2. **Access to Quality Health Care and Having Health Insurance Are Mutually Exclusive Concepts**—The one thing we all know is that at some point in time we will **all** be patients. While neither the United States Constitution nor common law recognizes an explicit right to health care,[3] the range of social and environmental factors that affect health are often as or more important than medical care.[4] Though a right to health care is not to be misunderstood as a right to be healthy (which cannot be guaranteed), perhaps our current Congress will include looking at Article 12 of the International Covenant on Economic, Social and Cultural Rights.[5] Article 12 expounds upon three duties: to *respect* individual human rights and personal freedoms; to *protect* people from harm due to external sources or third parties; and to *fulfill* the health needs of the population.[6]

3. **A Government Plan**—Just saying these words lately seems to turn an otherwise civil acting group of human beings into an angry insensitive mob. Public or private, universal coverage or not, the Health Care Bar can play an important role in educating the public on what they have in their "proverbial pocket." Entities such as Medicaid, Medicare, Veterans Affairs, and Indian Affairs are examples of government oriented health care. Moreover, Medicare **is a single payer!** Americans can disagree on how to improve these entities, but the Health Care Bar can make sure that the public is knowledgeable about **what** they are discussing. A look at how other countries are tackling health care could prove useful (i.e., Taiwan, France, the Netherlands, Sweden, Germany, or Japan)—increase the number of quality primary care physicians and have a strong health information technology system.[7]

Perhaps the past is prologue! It was in 1945 when President Truman first proposed the idea of a national health insurance that eventually evolved into Medicare in 1965 under President Johnson (20 years later President Johnson had President Truman return to Washington D.C. to "sign in" as the first Medicare recipient). While the health care town hall meetings held during the Summer of 2009 might politely be called "the summer of our discontent," we certainly do not want to see a continuation of what gave the appearance of a

"fact-free zone." To quote an anonymous source—"[e]very worthwhile accomplishment, big or little, has its stages of drudgery and triumph; a beginning, a struggle, and a victory."

Endnotes

1. Joe Nation, *Health care debate misses issue of costs*, San Francisco Chronicle, p. E-5 (August 23, 2009), http://sfgate.com/cgi-bin/article.cgi/f=/c/a/2009/08/22/INDR19B11F.DTL.
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4. Wendy K. Mariner, *Toward an Architecture of Health Law*, 35(1) Am. J. of Law & Medicine 67, 77 (2009).
5. *Id.* at 72-73.
6. *Id.* at 73-77.
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Introduction

By Peter Millock, Special Edition Editor and Robert N. Swidler, *Journal* Editor

SWIDLER: Instead of an actual introduction for this special edition on "Conversations" we decided to have a conversation. I'll start by noting how this edition came about. And in fact, it resulted from a conversation. As I recall, Peter, last Spring you and I were at a meeting at the Bar Center in Albany, and as we were getting ready to leave you said you had an idea for a *Journal* edition. What was the original idea again?

MILLOCK: The idea was to record and transcribe a conversation among lawyers on a particular health law subject.

SWIDLER: I thought that was a great idea. And in talking it over, we started to consider devoting an entire edition to those conversations. Then we discussed what topics the conversations should cover, and who should host them. And then we went back to our offices. But afterward, largely through your efforts, this started to take shape. So now, what do you think about the end result? Is this edition what you had in mind?

MILLOCK: I was amazed then and am more amazed now! Initially, I thought we would do one discussion on the theme of a particular *Journal* issue. This is far grander. It is a refreshing change, covers a broad range of timely subjects and is full of provocative comments by people we all respect.

SWIDLER: I agree. But you and I now know that this was far more challenging, and far more work, than either of us expected. It certainly took far longer than we expected. But it turned out to be a unique, memorable and really valuable edition. Peter, the *Journal*, its readers and I owe you our thanks for coming up with this idea and for seeing it through. Please convey our appreciation to your firm, Nixon Peabody LLP as well for its invaluable support. And of course, we need to say a special thank-you to Kathy Deyo of Nixon Peabody, who worked so hard on organizing the conversations and editing the transcripts.

MILLOCK: Thank you on behalf of the firm and Kathy Deyo (although Kathy has asked not to be involved in the implementation of our next idea!). I also want to thank the moderators (Ed Kornreich, Jim Lytle, Marty Bienstock, Alicia Ouelette and you) for assembling the panels, organizing the questions, conducting the discussions and editing the transcripts. That took a lot of work. And I want to thank the twenty-seven (!) participants who each spent several hours offering their thoughts and correcting the transcripts.

SWIDLER: I second that. We also need to thank the Health Law Section for picking up the videotaping and transcription costs. And you know what? We really ought to thank in advance Lyn Curtis and Wendy Harbour of NYSBA's hardworking publications staff, who at this point have no idea of the massive and unusual *Journal* content we are about to send to them.

So Peter, now what's you idea for the next edition?

MILLOCK: We learned a lot from this exercise about how to record and transcribe a discussion. It is simpler and better to have everyone in one room with a stenographer. The next person who organizes a panel discussion should be able to do the job much more efficiently. If we can do it more efficiently, we can make a panel discussion a regular part of each *Journal* issue. The panel could include, but not be limited to, the contributors to the issue. The moderator could be the issue editor. As always, Robert, it was a pleasure to work with you.

SWIDLER: Thanks, Peter. When I asked about your proposal for the next edition, I half-expected to hear an expletive that I'd have to delete. But that was actually some very useful advice. And it was a pleasure working with you, too.

A Conversation About Hospital Combinations

Moderator: Peter J. Millock
Partner, Nixon Peabody, LLP
Albany, NY

Participants: Robert Hall Iseman
Partner
Iseman, Cunningham, Riester & Hyde
Albany, NY

Richard M. Cook
Deputy Commissioner
Office of Health Systems Management
New York State Department of Health
Albany, NY

John F. (Jack) Gleason
Partner
Epstein Becker & Green
New York, NY

Robert Wild
Managing Partner
Garfunkel, Wild & Travis
Great Neck, NY

June 24, 2009

MILLOCK: My first question is how each of you would define "hospital combinations."

ISEMAN: Hospital combinations can take any of the forms that we're all familiar with, such as mergers, consolidations, asset purchases, and the traditional holding company model based on membership rights, as those membership rights are defined under the Not-For-Profit Corporation Law. The holding company model has a number of permutations. One is the active parent model, and another is the passive parent model.

There also are a variety of combinations based on joint venture relationships. These contractual combinations are sometimes called joint operating agreements. They often meet the legal definition of "joint ventures" and may well present significant risks, including antitrust risks.

Some joint ventures may be "clinically integrated" under Statements 8 and 9 of the Department of Justice and Federal Trade Commission Joint Statements of Antitrust Enforcement Policy in Healthcare published in 1996. An example of a successful clinically integrated joint venture among hospitals is found in the Long Island Health Network, which I believe is the only clinically integrated hospital network in the United States. The uniqueness of LIHN is that it is a clinically integrated hospital network formed under the policy considerations found in Statement 8, which refer to physician networks, not hospital networks.

And then finally there is a model of combination that is formed for the limited purpose of obligated group financing. This requires Public Health Council approval because hospitals must be jointly established in order to share their credit with one another. It also should be noted that New York only permits intrastate, as compared to interstate, obligated groups.

Just a word or two about active and passive parent models. Over the last 10 years I have found that most of the holding company models have gravitated toward active parent models. As someone who negotiated the passive/active parent rules in 1988-89 with Peter Millock when he was counsel to the Department of Health and who was committed to the passive parent model, I never thought I would hear myself say that I would recommend an active parent model rather than a passive parent model, but for the last 10, 15 years I've done exactly that except in unusual circumstances.

While the goals and objectives of the client always drive the model of combination, I have always had a real concern about successor liability and have tried to use models and strategies that not only limit successor liability, but maintain the greatest amount of flexibility in the event of future financial problems. This is accomplished by maintaining the corporate separateness of the component entities within the combination. We certainly have used the member model and the holding company model most frequently.

MILLOCK: What factors push parties to one model or another?

WILD: I think the factors are both practical and legal. As Bob Iseman pointed out, you start whether or not you want to go with a full asset merger, can the parties tolerate the assumption of all the liabilities in the resulting entity or the surviving entity? That is a critical factor which tends to militate against full asset mergers more often than not.

Another factor is, are we dealing with a bankruptcy situation. There have unfortunately been a large number of hospital bankruptcies in New York and some of the combinations have been either as a result of the bankruptcy or where the bankruptcy is planned as part of the strategy.

You also have to deal with existing financing. If one hospital has a certain type of tax-exempt financing and

the second hospital has different type of financing then the liens against the assets, of course, would be different. Then there is the question of whether or not you can actually come together. The model that you use to come together can be dictated in part by the fact that you have different secured interests in the assets.

There are nonlegal issues such as what the boards can accept, the political, the traditional. There are offshoot models of what Bob described. For example, the common board approach which is utilized in some models in New York State. The corporations remain separate, there is a holding company, but the boards of all the participating hospitals in the network are identical with one board sitting over anywhere from two, three, four, or perhaps even a dozen health care institutions. That model is utilized in the Albany area; it is utilized in part on Long Island as well.

Culture and the history to some extent dictate the model. The physicians on the medical staff, if it is an employed medical staff, a hybrid between employees and voluntary physicians, or an all volunteer medical staff (in a community hospital).

And then the last point, I think, and there probably are others, is affiliations. If you have a hospital that's tied to a medical school, that may dictate what the outcome is going to be. Because that affiliation may have certain requirements as opposed to a hospital that is not tied to a medical school.

And today we are even dealing with municipal hospitals or quasi-municipal hospitals such as the situation in Buffalo, the Erie County Medical Center and the Kaleida Health System which were dictated by "Berger" to come together. That raised a host of issues because the Erie County Medical Center is a Public Benefit Corporation, with municipal unions versus nonmunicipal unions. The labor issues themselves when they're in that setting or in other settings also may dictate what you can or cannot do by virtue of the legacy liabilities that you have in some of the union settings, municipal hospital settings and so forth.

GLEASON: Rather than starting out with a specific model and looking at combinations, in my view form follows function; what is it that we're trying to achieve via the combination? Is it a combination that affects governance, does it just affect management, does it affect specific programs, is it a combination to do planning or negotiating? Agreement on the objectives for the combination would dictate what model should be employed.

I also want to point out that it's very different working with an organization that is relatively sophisticated in terms of having done combinations because they probably have a preferred model or models that they've employed in the past. It is more difficult starting *de novo* with entities that haven't experienced a combination, where you're basically setting up a new model based on the very unique circumstances of those organizations.

MILLOCK: Rick, from the Health Department's perspective, do you see differences in the motivation of the hospitals that present proposals to you?

COOK: The Department's critical issue will be to understand the purpose of the merger and what the hospitals seek to accomplish. Will it benefit the community? We try not to be prescriptive concerning the model.

From the Health Department perspective, the issue we will examine is whether the facility is really needed? Is it such a critical player within a community that without its presence there would be a significant problem for that community in accessing care?

The model must meet current rules and law, but we are not the experts to decide which model is best. The parties involved need to address this issue.

Our mission must be to assure that the community—and all populations within that community—are not adversely affected by the merger. Today, more than ever, our focus is access to primary care. The whole reimbursement system is moving away from institutional care, so our goal is to assure the merger serves the community, not just the individual institution.

MILLOCK: Why have certain arrangements succeeded and others not succeeded in recent years? We have seen combinations in New York City fall apart. There are obviously some Berger-mandated changes that could have happened but didn't. Why do some combinations succeed and others fail?

WILD: I think at least as to some of the systems, and we won't use the names, I think the looser affiliations, the ones that do not have real governance structure, tend to be the ones that collapse more frequently. The ones that are more integrated, if you will, where there is some financial interdependence, clinical interdependence, tend to last more.

For example, the North Shore Health System is highly integrated, so I think it tends to be more successful than some of the other somewhat looser affiliations. There was, of course, I guess in the mid- to late 90s, into the early part of the current century, somewhat of a frenzy for hospitals to associate with each other in one form or

another and I think Jack's point about form following structure is valid. To some extent, they were not necessarily well planned out.

I think some of the financial issues ended up taking hold. We've had some bankruptcies and some closures within some systems. I think for the most part the finances and the lack of a true integrated structure which take into account the different cultures, and trying to put hospitals together that may not have belonged together in the first place, created failures. That's at least been some of my experience. There are others, I'm sure.

GLEASON: Yes, in my view there are some typical causes for failure which would include lack of a common vision and lack of unified leadership. There are organizations that I've been involved with that attempted a combination without having developed an integrated view of the future. Lack of single leadership is also problematic. There are organizations that avoid making tough decisions in order to "get the deal done that can get done." That occasionally means there is no cohesive leader at the top of the enterprise, often resulting in "leadership by committee." Without a common vision and unified leadership, many of those potential combinations are condemned to failure from the beginning.

Another critical element is physician support which varies depending on the community of physicians and the nature of the organization. Dealing with an academic medical center and a medical school with a physician organization or faculty practice plan, adds a level of complexity to a combination. Soliciting physician input in the early stages is critically important. Often organizations have failed attempts at combinations because of lack of physician participation and support.

ISEMAN: I agree with everything that Robert and Jack have said. I would just add that apart from the lack of a common vision and the level of integration which are certainly the key factors, there is sometimes a lack of a realistic appreciation and understanding of the roles that each of the component entities have in the new enterprise and what the consequences of the affiliation will be in such important areas as the culture of the organization and the siting of clinical services. There's an opportunity during the due diligence process to not only address the usual legal and financial issues, but to also review and understand cultural and sponsorship issues and to gain a realistic understanding of what life will be like under the new enterprise. Conducting due diligence in these areas is critically important.

Further, the parties should be asking themselves how they will achieve the efficiencies that must be shown under many circumstances under the horizontal merger guidelines. Where will clinical services be sited? What services will be consolidated or eliminated? What effect will this have on sponsorship, hospital culture, community perception, and organizational leadership?

I remember one transaction where the spark point that contributed to the failure of the combination was the issue of how the efficiencies would be realized through the closing and / or relocating of some clinical services, including acute care services in an inner city location, and then relocating some of them in the suburbs. The combination came unraveled largely because of that issue. While there was a recognition before the deal was consummated that certain clinical services would be restructured and relocated, I'm not sure the stakeholders fully prepared themselves for the reality and consequences of the necessary change. This is a particularly difficult issue because the siting of services is usually not agreed to until the combination is formed, even if subject to contingencies.

The lesson is that planning and board education are key to governance acceptance, management commitment, and community and medical staff buy-in. I am not suggesting that you have to be able to foresee where the entire combination is going to go in every last detail before you close the arrangement, but there needs to be a realistic assessment of what the consequences will be and what the respective institutional roles are going to be and not be once the organization is created.

MILLOCK: Rick, can you tell from your first meeting with hospitals proposing a combination that the combination will fail or succeed?

COOK: I think one of the clear signs is the financial situations of the facilities, including the debt capacity or debt legacy that Bob talked about. If you've got two facilities coming in and one has an outstanding liability of $50 million and it has a $30 million operating budget, there are very few systems that can take over that debt. Therefore, it is unlikely such a merger can succeed unless the State or some other entity is going to buy and / or restructure that debt.

If there's an old physical plant that requires significant investment by one party, that too can discourage the merger. We saw this in Queens where two hospitals closed due to financial failures. There was significant interest in one or both of those two hospitals by other systems to take over the facilities and operations and to restructure services, but the outstanding debt and the state of the physical plant discourage real interest.

Another critical success factor is who comes to the table to discuss the merger. Are the boards part of the meeting? From my practical experience, having spent 12 years

at Albany Med where we had discussions with other systems, it is important to understand if the Board is really committed to the merger discussion.

Hospitals don't want to lose their identity. They feel they're a critical element in a community. They've been there for years and they are looking somehow, even in the worst financial times, to maintain that identity. The ultimate merger will result in one system losing its identity.

We saw that in Schenectady with Bellevue. Most believed that Bellevue could not sustain itself. It had a limited product line, it had significant debt, it had an old physical plant. It could not negotiate with the payers and yet it was hanging on. It probably would not have closed without the Berger Commission. It did not want to close and lose its identity—the Board and the CEO fought the closure at every step. So, if the board and senior management are not in agreement and at the merger discussion, success is unlikely.

WILD: It gets back to Robert's observation about integration. I think it's absolutely right and I think the question is: once the strong integration happens what are the reactions of the governance stakeholders, the management stakeholders, the community stakeholders, and how will they adjust to a different point of view after years of having been in the position that Rick describes (of being an important identifiable part of the community) with a particular heritage and culture and now it's been taken and integrated into something new that hopefully is better but nevertheless is different?

GLEASON: Most combinations can be categorized either as a strong system taking over a weaker institution or a "merger of equals." Even if the organizations aren't exactly equal it's frequently characterized that way in the initial negotiations, so there's not the early perception of a winner and a loser. It's a lot easier to do the former deal than the latter deal, meaning that integrating a weaker organization into a stronger system that's done it before, where there are guidelines and clear leadership is more straightforward. Putting together two organizations which are coming together as equals and where every decision needs to be negotiated is much more difficult.

Kingston was a more complicated situation because Catholic and secular entities and values were brought together. Regarding the board role, those organizations' boards became actively involved in the management of the organizations in transition. That was quite different from my typical experience where the board wants to stay as removed as possible from day-to-day management.

A problem when boards are not adequately engaged is that they see success as the signing of an agreement to combine. "Pop open the champagne, we've gotten the deal done"—when in essence we all know that the success of a combination is really in the implementation. It's not the wedding ceremony, it's the eventual marriage that will determine whether the combination is successful.

In the case of Kingston/Benedictine, the boards recognized that for the combination to be successful, trustee leadership needed to remain involved during the implementation phase. Despite some bumps in the road that approach was very successful.

MILLOCK: What was the impact of Berger? What is the continuing impact of Berger and HEAL money?

WILD: As Jack was talking about, there's no question in my mind that the coming together of equals tends to be a more fragile relationship than where there is a stronger system or stronger hospital and a weaker one, I think for almost the obvious reasons.

There are some systems today which are made up of equals, but I don't think they necessarily achieve the level of integration. They may from a legal perspective, but from a more practical operating perspective I think they may not. In some instances you end up with a situation where you have hospitals coming together in a regional-type system where they are part of the same system (they have a parent)—usually a parent/subsidiary model but—to some extent they're still competing with each other and that creates some of its own problems, although there are systems that nevertheless persist.

Moving away from that to your question, "Berger" obviously presented something that we'd never seen before which, for lack of a better term, it produced some shotgun weddings. So you have to some extent hospitals coming together who, left to their own devices, would not have bothered to do so and I think the Department, and I know Rick can speak to this, was faced with issues where the language of Berger called for, say, a merger, and yet the merger as we lawyers know it, a full asset merger under the statute, was really not something that could be achieved because of labor issues, because of financing issues, because of cultural issues.

So you had hospitals, in some instances, coming together because they were required to do so. You have a law, State law, so models were put together to satisfy State requirements where unlike everything that we've been talking about—what Jack, Bob and Rick were talking about—about planning, about bringing the parties together, you really had the opposite situation.

You had parties come together where they had no choice. Now some—you know, you talked about the Kingston / Benedictine System and I think it looks like it's a success but it's also quite young. You have the three East End hospitals, the east end of Long Island, the East End Health Alliance, who have come together mandated by Berger, active parent, and they're working to achieve—now that they're together, now they're really trying to achieve the integration that—not necessarily what Berger was talking about, but that would be practical and allow them to function as a real system.

HEAL, at least HEAL 11, is somewhat in the same vein except there it's voluntary. If you wanted the money, especially under HEAL 11, which is not the only grant obviously, but if you wanted the money you had to show an integrated structure. There are hospitals that clearly wanted the money, that needed the money in order to carry out programs that they want to do on an integrated basis, but now they're in a sense, to get the money over here you first have to create the integration necessary over there. In the prior HEAL grants, I think, and Rick can speak to this, and no criticism intended, I think HEAL to some extent created expectations of enough money to cover certain aspects of integration and then as the grants started to be given out and the contracts were signed, not all those expectations were met. A problem I know I'm facing with some of my clients, and I think Jack and Bob will be in the same boat, there are clients that actually want to carry out the requirements of the earlier HEAL grants in order to get the money necessary, but HEAL basically requires an expenditure prior to the grant being given and there are hospitals that can't get the financing necessary to do so. So there's a willingness to carry out some of the integration called for under the various HEAL grants. There is a true desire to do so. There is a cooperation among participating hospitals and an inability to effectuate it because of the inability to get the financing necessary to qualify to get the HEAL grant.

ISEMAN: Regardless of whether you viewed the Berger recommendations favorably or unfavorably, it made a huge impact, and it has a significant legacy and important residual effect on the marketplace. An important result of the Berger Commission is the energy, awareness and mindset it created in the marketplace. There are now frequent discussions about Berger look-alikes and HEAL money that's available for the kind of integrated approaches that Robert was describing. In conjunction with the current financial climate, the need to control health care costs, and the recognition of the need for fewer acute care beds, Berger created a real sponsor- and governance-driven interest in hospital combinations to effect the goals that the Berger Commission identified. This post-Berger environment is very healthy because it has changed the thinking of board members as a matter of their fiduciary duty and their responsibility to the community to think about efficiencies and what the future is going to bring for their institution in a way they have never thought about it before. A local example is the St. Peter's Health Care System, Northeast Health, Seton Health System affiliation in the Capital District. This is a governance- and management-driven combination in pursuit of efficiency and enhanced service to the community. The affiliation results from the commitment of the boards and management to seek and realize many of the goals identified by the Berger Commission.

We talked about the commitment of sponsorship, governance and management and how important it is to the success of combinations and affiliations. If you truly have a combination that results from the foresight and commitment of governance, it's a huge advantage and Berger has helped to accomplish that.

COOK: I think there's an interesting issue about Berger. I was in the private sector at Albany Medical Center when Berger was going on and if you asked me whether or not hospitals would be closed as a result of Berger, I would have said no—it will not be capable of closing hospitals. I would have said I really believed that, and I think the interesting thing was how quickly the recommendations were endorsed by Eliot Spitzer.

When Spitzer comes in, he's an extraordinarily powerful Governor. He's won by a landslide, he endorses Berger, he takes on the hospitals. As Bob stated, the mindset was changed. The Department was given extraordinary authority to make changes and, you know, it resulted in some 2,000 beds being taken out through mergers and closures.

But Berger went beyond closing facilities. It also recommended changing the reimbursement system with more emphasis on community planning, more investment in primary and preventive services.

These other recommendations have really been pushed over the last two years. The hospital reimbursement system has been changed, much to the chagrin of many of the hospitals. There's $600 million that's been invested for primary care services and for physicians' fees. This push to community planning and primary services is an important lesson for a hospital board. They need to ask: What do the next 10 years look like for my facility, because I will tell you that when CEOs, in my experience, and boards get together and they look at a strategic plan, the first thing they're looking at is how do I attract more docs, how do I get more volumes and how do I get more high-end specialists, and all those things cannot work in

every hospital and they don't reflect State and Federal reforms.

Every year a hospital's budget needs to grow probably 7 to 10 percent just for it to hold where it is, 4 to 6 percent in labor costs, probably another 3 to 4 percent in basic capital investment. I'm not talking major investments. I'm just talking making sure the roof doesn't leak.

So where's that money going come from for hospitals? If you're a board director and you really are honest with yourself, and the status of your facility, ask how are you serving the community? Berger starts to raise these issues and now boards and CEOs need to ask themselves if they really are critical to a community or are they better off by merging or restructuring?

MILLOCK: Apart from Berger and HEAL, what other legal developments do we see affecting combinations?

WILD: I think—actually from the antitrust point of view, I don't think there are new developments that are making a substantial impact on the ability of hospitals to come together, if they are indeed trying to come together. I think the traditional antitrust rules, putting aside Berger which would create State action issues, I think the traditional antitrust rules tend to apply. You have to deal with Hart, Scott, Rodino filings where appropriate. You have to deal with both the State Attorney General's Antitrust Bureau and the Feds, but I don't think the rules have changed so dramatically regarding hospital combinations.

I think probably the biggest single impact is in part what Rick was saying—that obviously everybody can't increase market share as well as the practicality of being able to meet the ever-increasing costs and seemingly constant reductions in reimbursement, and especially the unknowns at the Federal level with the President's proposed health care plan and the State budget, the recession and so forth.

I think the technical legal issues have actually not changed all that much in terms of corporate law, the Attorney General, Charities Bureau, Antitrust Bureau. I don't see significant changes there. I think the changes are more on the practical side, the economics, the cultural—I think one other change again, which is not really legal, is that there has been, at least in my experience, an enormous change on the physician side.

You've got physicians who are—at one end of the spectrum—pulling more and more services into their offices, office-based surgery, ambulatory surgery centers, ancillary services in their office because of the drop in their reimbursement which, of course, has potentially a negative effect on the hospitals. You're seeing more and more hospitals moving to a hospitalist model which has a cost to the hospital and it has the attending physicians spending less and less time inside the hospitals, and you're seeing at least—since this is a New York State issue we're talking about -- you're seeing an out-migration. Physicians leaving the state for the simple reason that the cost of practice in this state, with malpractice, the cost of housing, the general cost of living, is getting out of hand. I give you a statistic.

My daughter-in-law is an obstetrician, ob/gyn, graduated several years ago and according to what she has told me—it may have changed a little bit—she graduated from a major medical center residency program here in the New York area and not one of the members of her graduating class sought a position in the State of New York. Some may have ended up here, but not one sought such a position. They all sought out-of-state positions.

When you go for the more rural or at least suburban hospitals, their ability to get certain subspecialists, ob/gyns, neurosurgeons, even orthopods, on a practical level is forcing hospitals to look at their neighbors and see what they can work out. I see the practical issues, economic issues, being far more significant than any real changes on the legal side.

MILLOCK: How do physicians affect the prospects for combinations?

GLEASON: I think it varies by geography. There are certain regions in the state that have seen a lot more physician consolidation; physicians forming larger and larger multi-specialty group practices and becoming major economic enterprises. Local hospitals are obviously very fearful. Physicians in those communities who don't belong to the mega-medical group are also concerned.

I think this phenomenon is going to lead to closer cooperation and more combinations of hospitals in the future. A hospital's primary competitor may not be the hospital a mile away, but the major multi-specialty physician group that's pulling out all their ancillary business.

WILD: I was just going to add one sentence to what Jack was saying. I'm seeing more and more pressure on the hospitals that we represent for the doctors to have a direct economic relationship with the hospital because they see their income dropping, such as payment for on-call, such as direct salary relationships. Where the physicians are starting to move toward retirement age and because of the New York State problem of the cost of doing business, practices are having trouble attracting young associates to fill in as the senior physicians start to get older. That's putting a lot of pressure on the hospitals themselves, both on volume, on increasing volume, as Rick points out, but

even on maintaining volume for the simple reason that, as the doctor goes, so goes the volume.

ISEMAN: I was just going to comment on one of the legal factors bearing on hospital combinations.

Right now there is no antitrust safe harbor applicable to clinical integration among hospitals. Statement 8 of the 1996 DOJ/FTC guidelines speaks of clinical integration in physician networks. Statement 9 addresses multi-provider networks but doesn't give the more specific guidance found in Statement 8. Sometimes PHOs have succeeded in applying by analogy the Statement 8 rules on clinical integration to multi-provider networks under Statement 9.

There are only a few clinically integrated physician networks nationally, one of which, Greater Rochester Independent Practice Association, is located in Rochester. There is now increasing interest in trying to push for a similar enforcement statement for clinically integrated hospitals. The idea is to replicate the clinical integration concept for physician networks but apply it to hospitals.

If hospitals receive that kind of safe harbor treatment, it would open up a whole new area for hospitals to come together in a way that is entirely different from the consolidations, mergers, holding companies that we've used in the past; truly a joint venture type of relationship. As I mentioned earlier, the only clinically integrated hospital network in the United States is the Long Island Health Network, which succeeded in applying Statement 8 on physician networks by analogy to hospitals.

All of this must also be viewed against the backdrop of the Obama Administration and the likelihood of a more aggressive look by the FTC and DOJ at merger activities and exactly how they are going to look at and apply the horizontal merger guidelines in these difficult economic times.

Other political considerations are also important. On the legal side of the analysis, efficiencies are the cornerstone for making a successful case under the horizontal merger guidelines, but from a political perspective some efficiencies, such as workforce reductions, may not be palatable to either the public or the regulators. How much efficiency will be expected or "tolerated" in the area of workforce reduction at a time of high unemployment and recession?

And so the two wild cards in the antitrust deck as it relates to hospital combinations are whether the regulators will challenge more combinations than they have in the past and whether clinical integration will be applied to hospital networks.

There also is an interesting point based on the possible connection between state and federal grant money and the application of the state action exemption. The *Health Law Journal* article by Marty Bienstock raised the question of how the State Action Exemption fits in to Berger-type combinations and whether certain combinations would have enough State supervision to result in the State Action Exemption being available based on the controls and conditions imposed by a state or federal grant. I don't think the case law supports the application of the State Action Exemption based on conditions found in government grants, but this is another very interesting area that may open up to give antitrust relief if you were willing to subject yourself to the kind of pervasive and continuing supervision that the State Action Exemption requires.

MILLOCK: Bob, do you see the Evanston, Illinois review as leading to further retrospective reviews of mergers that have already been approved?

ISEMAN: Probably, but it's too early to say. We have seen examples of situations where there is an interesting, if not helpful, retrospective look so that you can actually quantify the effect on the market without just relying on the prediction of the experts. Most of the challenges come before the merger is implemented. An example in New York is the North Shore-Long Island Jewish case that was decided in 1997, which presented disputes about the definition of the market and the predicted effect on that particular market of the combination. In one sense it would be interesting to see how the expert testimony then squares with the reality today. There's a real temptation to retrospectively determine whether a particular combination has had an adverse effect on the public and competition. I think we're going to get more retrospective looks than we've had in the past, understanding that once a combination has been in place for a number of years, it becomes difficult to unscramble the egg.

MILLOCK: Do you see that as part of the Health Department's responsibilities?

COOK: It's a difficult question from a resource standpoint. From a practical perspective the simple answer is yes. It's something that we need to do. But there's a practical resource issue for the Department and other State agencies to be able to dedicate resources and go back and look at what's happened. Clearly, the trend is for a more transparent process whereby we can bring more groups into the evaluation of the health care system.

What do I mean by that? If you look at what we did in Rochester and the proposal by three Rochester hospitals all coming in to rebuild, or build or add several hundred beds, we went in and we looked at something called preventive quality indicators. In other words, admissions

to those facilities that could have been treated on the outside if there was sufficient capacity.

Our role going forward is to evaluate what's going on within the current system, trying to push hospitals to be more focused on the community and not their own individual need.

I say that from a very pragmatic perspective, not that we shouldn't do it, not that it's not important to do it but, the resource issue is a real challenge. We really need to go back and look at what's happened with Berger in a year or two, and evaluate whether or not the investments for the closings have produced the efficiencies that we thought, because an extraordinary amount of money has been spent.

There was an extraordinary amount of resources and personnel that were engaged and, at the end of the day, you want to know what was accomplished. We clearly closed hospitals, but is the system more efficient or have we really just dealt with the edges of the system?

I think a driving factor in health care, whether it's national or state, is cost and a driving factor of those costs are the hospitals with 30 percent of the bill. Whether it's the Obama health plan, whether it's the Medicaid budget, everyone is looking at ways to reduce inappropriate utilization, to cut costs and to have a more efficient system.

I think those are the things that are going to drive the evaluation and I think it's going to be harder to really go back and do so. There's too much on the current agenda.

MILLOCK: I think the government has a tough time evaluating its own programs.

COOK: It has a very tough time.

MILLOCK: It takes so much energy to get a program going and there often isn't much left to look back and see whether the program worked or not. You have to look outside of government for those evaluations.

COOK: Or a separate entity. But, the industry has to challenge itself. The industry, I believe, is still operating under a perspective that it can win political battles, continue to build hospitals and continue to be a dominant player. I don't think they're challenging themselves the way they should be and asking what does the community need.

MILLOCK: Who's out there other than the government to do this? Who is going to push two hospitals in one town together other than the State Health Department?

COOK: I agree that government is the likely candidate, but I think there has to be an extraordinary political push to take that on. It clearly was reflected in Berger. We spent the last two years implementing Berger, pushing further changes. I really think the reimbursement changes that are coming down from us, from the Feds, will challenge hospitals to change.

Government can push the industry, but the industry is very good at stopping fundamental change.

ISEMAN: I don't think we should sell the boards short. I don't think government is necessary to force these changes. I go back to the situation in the Capital District. The affiliation that is now being pursued is one that is governance- and management-driven. I referred to what is happening in the wake of Berger and the different mindset and I think that the boards, not only in Albany but across the state, are thinking hard about the future and considering not only the results of the Berger Commission but also the external forces that Rick talks about. The boards we deal with are ready, willing and able to break out of the parochial mold and do what is best for the broader community.

I have great hope that is going to happen. I've seen it happen. There still may be instances of protecting turf and trying to do business as usual, but we have an environment where the external forces are pushing responsible people to think about where their organization will be 10 years from now and how they should address these dynamic and challenging factors on behalf of the communities they serve.

MILLOCK: One subject that interests me is Catholic/secular combinations. Any thoughts?

GLEASON: There's been a pretty dramatic change in Catholic hospitals in New York State over the past 10 or 15 years. Part of the change has to do with Catholic entities re-evaluating whether they need to operate acute care hospitals to support and sustain their missions. Historically, many Catholic organizations were located in poorer communities, established in an era where there was a real need for hospitals to serve immigrant and indigent populations. By and large times have changed; there are other hospitals available which serve those populations today and many Catholic hospitals in New York City have closed or are financially distressed. This has led the remaining Catholic hospitals to think about potential ways to cooperate with their secular counterparts without abandoning their mission.

Anyone working with Catholic hospitals knows, while there are overarching rules embodied in the Ethical and Religious Directives, it's frequently the interpretation of those rules by the local bishop that dictates how Catholic hospitals in a particular region act.

There is also the added complexity that Catholic hospitals are not all of the same flavor, meaning there are Catholic hospitals that are run by the local diocese where the bishop has approval power over virtually everything that they do. In contrast there are Catholic organizations that are sponsored by religious orders, and although the local bishop has a strong voice in how those organizations are run, he doesn't have direct approval power.

A combination of these elements has created more opportunities for Catholic hospitals to combine not only with other Catholic organizations, but in some cases with secular organizations as well. There are specific guidelines in the ERDs that apply to Catholic hospitals combining with secular organizations. That's not to suggest that Catholic principles can be negotiated away, but I think that there is a far more open environment now for combinations and we have several precedents now in the State.

WILD: We have worked on a couple of these transactions. I think the main point in some instances is that the Catholic hospital insists on maintaining its catholicity. We have seen situations where the hospital, together with the Diocese in which it is located, has decided that the greater good for the patient is the ability to provide care as opposed to being a Catholic hospital, and although some elements are retained and we have specific examples in New York, the actual jurisdiction, if you will, of the Diocese over the hospital is given up in exchange for the maintenance of the facility in combination with a non-Catholic hospital. Of course, Montefiore and Our Lady of Mercy are classic examples of that.

I think the issues start with, at least in my personal experience, as to what was the position of the Diocese or, as Jack pointed out, the decision of the Order that may be running the hospital and being an Order to reporting directly to Rome rather than reporting directly to the local ordinary, and that may dictate in the first instance whether or not you're really combining a Catholic hospital as opposed to a hospital with Catholic traditions with a non-Catholic facility.

It is relatively easy in our experience to limit what can and cannot be done in the particular facility that is or was a Catholic facility in accordance with the Ethical and Religious Directives. Another bigger issue is the participation of those who are in the governance of the Catholic hospitals in an overarching organization over both the Catholic and non-Catholic facility where the non-Catholic facility is performing procedures not consistent with the Ethical or Religious Directives. That seems to be one of the driving issues and it varies.

In the City of New York there is only one Catholic hospital left, which is St. Vincent's in Greenwich Village. There are no more Catholic hospitals in the outer boroughs. There are no longer any Catholic hospitals in Westchester County, there's one in Rockland and one in Dutchess, so the-the participation of the Church in Catholic hospitals and the maintenance of Catholic hospitals as true Catholic institutions in New York State, the lower part of New York State, has diminished dramatically.

ISEMAN: As Jack alluded to, it's really a function of how the diocesan bishop interprets and applies the ERDs in the context of a particular transaction—a matter that is entirely within the Bishop's discretion.

I think we all are aware of the fact that the ERDs have not always been interpreted and applied the same way from diocese to diocese. That is true not only in the State of New York, but across the country. One of the variables is the way the bishop and his advisers view and apply, if at all, the concept of "duress"—the idea that external forces are requiring certain accommodations in order to enable the religious sponsor to achieve the greatest good. One of the first things that you need to do when you are talking about a Catholic and other than Catholic relationship or combination is to make sure that you understand the position of the local bishop, talk to him and his advisers, so that you understand right at the beginning what's possible and what is not possible.

Just one further comment about religiously sponsored hospitals. Faith-based institutions meet a very important element of community need. We will lose something significant in our health care delivery system if we lose the tradition of faith-based health care providers, be they Catholic, Jewish, Baptist, what have you.

COOK: I think the Health Department's been pretty clear that we are supportive of mergers and affiliations between religious, faith-based organizations and non-religious organizations. I think the rules that we apply are what's the impact to the community, are there particular services that are going to be restricted or no longer available and, if that's the case, then we have to make sure those issues are addressed.

The challenge from a political perspective, as Bob mentioned, is there have been various interpretations of the ERDs and various experiences, not just in New York, but in other states. The advocates will use those variations as a way to block or alter policy. Quite simply, a deal today will change with new leadership—but we cannot prevent future changes—the best we can do is make sure the deal meets the community's needs.

For each proposal we want to see the impact to the community. I believe at the end of the day there needs to be more integration and more linkages within the

communities, regardless of whether you're faith-based or not.

GLEASON: If I may, I want to ask Rick a question regarding the State's point of view on combinations of New York State hospitals with out-of-state entities for example, a Catholic organization that is headquartered out of the State of New York with a Catholic hospital within the State.

COOK: Decisions are never made in a vacuum and there are political, geographical and other forces that can intercede.

For out-of-state proposals, we try to apply the same type of tests, but I can't deny that there are strong geographical and political forces that come in and how they play out is very difficult to predict.

ISEMAN: My experience has been that there have been no impediments to interstate linkages of providers so long as the passive parent model is used.

Where we have had frustration is in the area of obligated group financing where the Department has permitted intrastate obligated group financing but for all practical purposes prohibits New York hospitals from joining interstate obligated groups. This is particularly frustrating because it usually is the New York facility that needs the credit enhancement and would receive a disproportionate benefit from joining the obligated group.

And so I'm a little concerned, after listening to Jack's question and Rick's response, about whether there is any position the Department is thinking of or developing that is different from what I've just articulated and I understand to be the history over the last 25 years.

MILLOCK: Jack, what were you thinking about when you posed the question to Rick? Were you thinking about obligated groups or were you thinking about combinations with an active parent outside of the state?

GLEASON: I was thinking about it in the broadest possible sense. I just wanted to understand if the State had a particular perspective in terms of a combination involving an out-of-state organization.

COOK: We don't have a preconceived position—but there are regulatory and political challenges.

GLEASON: I'm also considering State largesse as in distribution of HEAL funds and the like, whether there be a built-in bias towards intrastate combinations as opposed to interstate combinations, potentially that could be supported under future HEAL grants. Was that something that the State would review in an unbiased fashion?

COOK: I am just not sure of the statute and whether there are any legal impediments.

MILLOCK: If some lawyer approached you and said he or she was beginning to get involved in a combination and had limited experience in the area, what would be the first thing that you'd want that lawyer to consider?

WILD: In a sense, that's tongue in cheek, but not entirely. Moving around the room, excluding Rick for a second because he's not a lawyer but looking at the other four people, Peter, Bob, Jack, I mean we've developed expertise, the four of us combined, of well over 100 years.

This field is not a field you can dabble in. Sure, there are lawyers that can handle corporate transactions and not-for-profit corporate transactions, but unless you have real facility with the antitrust piece of it, the health care antitrust piece, the health care regulatory piece, the health care financial piece, I have had calls like this not only on the hospital-to-hospital level, sometimes doctor groups, sometimes smaller practices and so forth and my real advice is, you know, stay involved, counselor, if you want to but you really need somebody who knows what they're doing.

And so without—and again not tongue in cheek and not saying give the work to me or to one of my good friends here on this program—you really need to bring in somebody who knows what they're doing. You need somebody with CON expertise, you need somebody with expertise in all the other fields I would want counsel to have.

Lawyers who are good business lawyers with no health care experience really shouldn't be undertaking it because sooner or later they're going to miss something important.

MILLOCK: If you yourself were getting into a transaction on behalf of a hospital that was considering a combination, what would be the first thing that you would consider?

GLEASON: Understanding the deal breakers early on. What are the hot button issues on both sides.

WILD: My answer would have been what is it that the client wants to accomplish? Who do you want to do business with? What do you want to accomplish? Are you looking to merge, to affiliate? Are you trying to meet a Berger mandate, a HEAL mandate? Are you trying to deal with the fact that you can't compete in the marketplace the way you'd like to?

I mean I think the earlier part of this whole discussion centered about what does the client want? It's almost an obvious question and then try to guide the client how to get there in a reasonable fashion or be honest enough to say you can't get what you want. Maybe there's some alternative.

ISEMAN: Certainly the client's objectives are the most important thing to understand. The other thing I would try to understand is what is motivating the client. What are the external forces that are causing the client to identify this objective? Is it the shotgun wedding that Robert described in regard to the Berger Commission? Is it truly a spontaneous evaluation by governance and management that this is the best thing to do for the community? Is it because one of the organizations is a failing organization? It is the combination of understanding the client's objective and understanding the factors that are pushing that objective that is the place to start.

MILLOCK: And Rick, in your hospital work before going to the Department when you were advising a CEO on combinations and outside activities, what would you have asked him if he had asked you to get involved in some potential transaction?

COOK: It really goes to the objective of what you're trying to accomplish. Are you just trying to build market share or to build presence, that's kind of a simple issue. You've got to be in control.

But the other thing I would raise—and again I keep coming back to this—is where do you need to be in the next five or 10 years. How does the merger fit with the external environment? And the other thing I would say is, sooner rather than later, don't presume you know what the Health Department will think. Meet with the Department. Because the worst thing that you can do to a regulatory agency is to either mislead them or to surprise them.

The biggest lesson I have learned was most people in the industry are absolutely unaware of the culture and the decision-making process within government. They come with presumptions that do not reflect how policy and politics really work

The Department can be a friend or at least not a barrier—I was always amazed at how fearful and how misunderstood the regulatory body was when I was on the outside.

Your first step is don't presume you know where the Department is. Meet with them, get advice and then factor that advice into your discussions.

GLEASON: I want to go back to something that Robert and Bob said regarding understanding the client's objectives and expectations. I think for a lawyer just starting out in one of these assignments, understanding that the client does not always speak with one voice and understanding what the clients' objectives are in the plural sense, are important.

Too frequently we view the client through the perspective of the CEO and as all of us have learned through our experience, the CEO's objectives are not always the same objectives as the leadership of the Board and/or leadership of the medical staff and in the case of religious organizations, the sponsor. Understanding the client's motivations, including the various constituents of the client, is very important for a rookie starting out on these combinations.

ISEMAN: Picking up on that, one thing that I left out before is the perspective from which you are evaluating a particular arrangement. For example, there's an entirely different relational dynamic that applies if you are "counsel to the deal" rather than representing a particular client.

WILD: One last comment. Jack phrased it in an interesting way. He talked about indoctrinating a rookie client—a rookie lawyer, I'm sorry, as opposed to an experienced lawyer who comes to a deal like this without necessarily having health care experience. Whenever I have orientation of a board that I represent, I remind them of a couple of things which really makes our business unique.

The obvious one is the degree to which health care is regulated in New York State, but not quite as obvious, although it should be, is the fact that we have a dichotomy in the health care world that you don't find in any other business, which is that the customer is not the payer to a large extent and the payer is not the customer. It's not the same as merging two major companies in the United States. That dichotomy often impacts the transactions to a much greater extent than you would see in the ordinary world of non-health care.

And the second thing is in New York State, which is not true in the rest of the country, in the acute care side we have basically and exclusively a not-for-profit system, which is not true of the hospital world outside of New York State.

Those are unique factors we have here and I think unless you're in the business to some extent or take the trouble to learn the business, that can be lost on people once they start working on these transactions.

ISEMAN: Peter, one other issue is the challenge of using consultants. When do you engage the consultants, how are they used most effectively, and how do you prevent the situation where the boards of various organizations engage a consultant and the consultant suddenly is driving the bus rather than being a resource to the client? Also, how and when do you involve the medical staff? Hospital combinations can rise or fall based on the manner and timing of medical staff involvement.

GLEASON: Thank you. Having practiced as a consultant for more years than having practiced as a lawyer, I will tell you that when I was introduced to a transaction I would often say something to the client like—"you're going to find this strange to hear from me, but as a lawyer and a partner in an accounting firm, the first persons to bring in to the proposed transactions should not be your accountants or your lawyers."

While perhaps self-serving for me as a consultant, the point is that bringing in the accountants or the lawyers early on frequently polarized the discussions. I think the appropriate role of the consultant is representing the transaction, gaining consensus and developing a meaningful process around how to implement the transaction.

WILD: Perhaps to my surprise, I actually agree with Jack quite a bit. Notwithstanding how I earn a living, I think the deal should be made to the greatest extent possible by the clients. I think they should be bringing the deal to the lawyer as opposed to the lawyer structuring the deal while talking about combining health care facilities, and it's not the same as merging two major companies in the United States.

It's a very different set of circumstances. I encourage the hospitals, if you're talking principally about hospitals, if you want to hire a consultant, try to agree on a single consultant and let that consultant act as a facilitator. You should be directing the consultant, rather than the other way around, and try and put together the elements of a deal before you bring in your lawyers. You may bring in your accountants somewhat earlier just to have the financial information in front of you but you are, generally speaking, making deals of this type (putting aside government mandates such as Berger). Even then you still have to have the client guide the specifics.

I think it's the client that should be making the deal as much as possible and I encourage the clients to always talk among themselves. We're not dealing with a litigation issue where you might say you must speak through your attorney. We're dealing with people presumably who want a positive outcome and a combination that will work when the lawyers have gone home, so I think Jack is right on the money on that one. I agree a hundred percent.

MILLOCK: I want to thank all of you. The last hour-and-a-half with the four of you has been a learning experience for me. We could probably go on for another three hours.

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A Conversation About Medical Malpractice

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I. Introduction

BIENSTOCK: We've convened today a panel of experts to discuss reforming the New York State medical malpractice system. Our panel is meeting at a fascinating time. Congress is home on recess, and members are holding regular town hall meetings to discuss the prospect of wide-ranging reforms to the health care system. At the same time, more locally, New York State medical malpractice insurance companies are facing significant financial strains, due in part to increases in the size of medical malpractice awards.

While physician rates have been frozen, hospitals are facing significant rate increases or, for the self-insured, significant payouts. And despite the rate freeze, physicians in some areas and some specialties pay extremely high medical malpractice insurance premiums.

For that reason, one issue that some would like to see on the reform agenda at the state or the national level is the issue of medical malpractice. Medical malpractice reform raises a number of important policy issues, and I'd like to touch on them a little first before we head into our panel discussion.

On the one hand, medical malpractice liability payments impose a significant direct cost on the health care system, as money that might otherwise be spent on providing treatment is instead paid out to medical malpractice claimants or toward supporting the overhead of the system. Those direct costs are swamped, some say, by the indirect costs of the medical malpractice system, as physicians engage in defensive medicine and order costly and unnecessary tests and treatments. All of these costs might otherwise be directed to improving coverage.

Now, on the other hand, hundreds of years of common law support the underlying principles of the current system. Physicians and hospitals owe their patients a duty of care. And when they breach that duty and injure their patients, they should be made responsible to make them whole. Not only do the injured patients themselves benefit from the medical malpractice system, but the system itself, the health care delivery system itself, is better off.

What some deride as defensive medicine others praise as ensuring that the duty of care is provided. These people argue that physicians should take the steps necessary to ensure that they do not injure their patients, and the threat of a malpractice suit is necessary to make sure that they comply with this duty.

Not only that, the medical malpractice system can provide an impetus to comprehensive reform of medical practices. At the least, the lawsuits themselves help identify the flaws in the individual systems. Sometimes lawsuits can help drive reform across an entire industry. The poster child for this type of reform is in the practice of anesthesia, which in response to a medical malpractice crisis reengineered entirely the way that it does business and drastically reduced the incidence of bad outcomes.

Of course, no one is proposing here to abolish the medical malpractice system. The reforms under discussion today will address some aspects of the system, and each has its own advantages and disadvantages. Of necessity, though, one's views on these reforms will be colored to some extent by the prism through which you view the entire system.

II. Health Courts (and Clinical Guidelines)

WALTMAN: There have been many discussions about the need to improve the dispute-resolution process for medical malpractice cases. I recognize that when we start to talk about that issue, it often leads to a very explosive conversation. In my view, that very result proves the need to improve the process: when key stakeholders are unable to even talk about the need for change or how well the system works, I think it demonstrates the amount of acrimony that the system breeds.

I'm a big supporter, actually I'm a very big supporter, of the judicial system and how it works in the United States. But when you look, factually, at aspects of the way the medical malpractice system works—or doesn't work—today, I believe it militates in favor of an improved process for resolving these claims.

First, there are many barriers to entry into the court system. A lot of people, meaning a lot of potential plaintiffs, are unable to enter the court system today because it is so costly and because it is often difficult to find attorneys to take cases, not just because of the complexity or acrimony of the process itself, but again because of the costs associated with navigating it.

Second, the cases themselves take a very long time to wend their way through the judicial system. There are two sides to that story, I recognize. But one way or the other, a tremendous amount of costs are consumed by the medical malpractice dispute-resolution process. Indeed, studies indicate that an amount equal to 54 percent of the compensation paid to plaintiffs goes toward the administrative costs of the system.

Third, the system is very costly for providers. I will run through those costs quickly.

We project that more than $1.6 billion or more than 3 percent of New York State hospitals' operating costs is spent on medical malpractice coverage. If you look at those costs in relation to hospitals' total non-personnel costs, it translates to more than 8 percent of hospitals' non-personnel costs going toward medical malpractice dispute resolution.

That's a lot of money. I know that sometimes people will say that medical malpractice costs aren't really that high. But for our member hospitals, an extraordinary amount of money goes into covering the costs of the medical malpractice dispute resolution process.

There is also, as you note, Marty, the larger cost of defensive medicine, with experts projecting its cost being anywhere from $25 billion a year to $190 billion, which is quite a large range, I recognize. Some people will say that not all "defensive medicine" stems from providers worrying about lawsuits, and I am willing to accept that. But there is still a large amount of resources being devoted to the medical malpractice system and the related practice of defensive medicine.

With that background in mind, I will move to my initial set of recommendations. I strongly urge, particularly in the midst of a discussion about health reform, that we look at meaningful ways to improve the way we resolve medical malpractice disputes. I therefore put forward the notion of health courts. I recognize that some people object to the idea of health courts in their purest sense, meaning they do not support establishing administrative systems for resolving disputes. But I do think that we need a system, whether it's judicial or administrative in nature, that recognizes the special nature of these kinds of claims, their cost to society at large, and the problems that arise from them. Therefore, I strongly recommend the establishment of health courts that would use specially trained judges; neutral experts, as needed; clinical practice guidelines, both to facilitate the dispute resolution process as well as to protect those who follow them; and, finally, general guidelines for compensation, particularly noneconomic damages—not necessarily caps, but guidelines. Taken together, these features would help improve the dispute resolution tremendously.

As part of the federal reform discussions, we have actually suggested creating special federal courts, or actually federal health courts, similar to bankruptcy or patent courts.

Regardless of the approach, I do hope, for the benefit of plaintiffs, providers, and society at large, that we can identify a better way to handle these disputes.

BIENSTOCK: So, Susan, are the highlights of your proposal specially trained judges, neutral experts, guidelines for compensation—and was there a fourth?

WALTMAN: Yes, the fourth feature is using clinical practice guidelines that can frame and inform the court's deliberations.

I think clinical practice guidelines can do two things. They can help shape and drive the delivery of better health care on the part of providers outside the courtroom, and they can also be used by providers to demonstrate that they have not been negligent in the delivery of care when they must respond to a claim in the courtroom.

BIENSTOCK: Would you propose that juries be permitted in these courts, or are you doing away with the juries?

WALTMAN: I have not taken a specific position on that point. I think the purest, most efficacious way would be to have just a judge. But I recognize that's a flash point.

I have purposely laid out considerations that I think will improve the process from the standpoint of all of the parties involved and have tried to minimize the flash points as much as possible.

CLARK: Let me respond. Let's look at what has happened in medical malpractice law in recent years. The statute of limitations was reduced from 3 years to 2 1/2 for adults and from 21 to 10 years for children. The fee for

plaintiffs' attorneys has been reduced from one-third to a sliding scale that goes down to 10%. Then the medical malpractice panel was introduced. And that was a panel in which there was a doctor, a lawyer, and a judge. And if they were unanimous in their findings of either liability or non-liability, that could be mentioned to the jury.

We found that the findings of juries tended to be almost diametrically opposite from the findings of the panel.

The panels also ended up in delaying malpractice cases, the resolution, for years, sometimes seven or eight years, because they were waiting for a panel. In Suffolk County, one law firm represented most of the doctors, and it was impossible to get a panel that did not have any kind of connection with that law firm.

So that was another reason why the panels did not work and where special malpractice courts, as it were, in microcosm was not a functional system.

As a practical matter, right now we do have malpractice courts. If you go to New York County—and in almost every county—there's a select group of judges who are the brightest, the most experienced judges, who have experience and who are qualified, who are assigned the malpractice cases. Malpractice cases don't go to the new judges, the uninitiated, or the judges who don't know what the law is. So we do have malpractice cases being tried in malpractice courts by judges who are competent.

Most plaintiff's attorneys will not bring cases in the federal court because, while it might be a few months less processing time, to bring a case in the federal court results in probably twice the expense it takes to bring in the state court. Moreover, each federal judge has her own case load, including criminal cases. It is not uncommon for a federal judge to give a "rigid" schedule for the prosecution of the case with a definite trial date, only to have the judge start a two- month criminal trial the week before the malpractice case is to be commenced. It is also very rare to find a federal judge who had any experience with medical malpractice cases before ascending to the bench or who has presided over medical malpractice cases as a judge.

Clinical practice guidelines, that's what medical malpractice is. If a doctor departs from the accepted standards of medical practice in treating a patient, that is malpractice. Negligence in medical malpractice is a departure from the accepted standard or departure from the practice guidelines. Regularly in the trial of these cases we'll look at the standards of the American College of Obstetricians or the published standards of other specialties as guidance. Paradoxically, an expert witness, on direct examination, cannot support her testimony by referring to a publication, be it a standard published by the specialty board or a learned treatise or article in a medical publication. The expert can, however, on cross examination be confronted with those publications in an attempt to impeach the expert's testimony on direct examination. The federal courts allow publications to be admitted into evidence. In my opinion, the state practice is more likely to result in a better verdict. As far as I am concerned, the system ain't broke and it doesn't need fixing.

AMSLER: Can I chime in here? Especially as to that last point, I think we need to take a look back and ask: Is the system broken? Is the system working? There's no question it is broken. Is it working to serve society? Is it working to serve those who are truly injured as a result of malpractice? I submit to you that it doesn't work.

We have a system here which, if you wanted to have a yardstick to judge it by, you'd measure whether it is efficient, equitable, and predictable. Well, it's none of those in terms of goals.

It's not efficient. It spends more money in its process than it does in payments to truly injured patients. As Susan pointed out, over 50 percent of the money goes to the costs of litigation. That's not just plaintiff's attorneys, I don't mean it that way; I mean it's plaintiff's attorneys, it's defense attorneys, it's expert reviews, it's costs associated with the litigation.

And yet in our insurance company, which is a mutual insurance company owned by the physicians and hospitals, we closed, last year, close to 70 percent of our cases without payment. So, if you're closing all of these cases without payment, a major driving force behind it is the cost of defending these cases and the cost of litigation that's involved in it.

Is it predictable? It's wholly unpredictable. Same person with the same injury: Different juries, different location, different geography, different result. Depending upon expert testimony, sympathy for the plaintiff, experience of the litigator, venue—all of those elements go into making it an unpredictable system.

So it has always been my opinion that I don't think the system is serving society well at this point. And I think it's antiquated in terms of the needs of society and both patients and physicians and hospitals in that regard.

To analogize the old medical malpractice panel system to a medical court I don't think serves any of us well, because in the old panel system, remember, had a doctor, a judge, and an attorney. And one of the major problems with that was there was never any unanimity. There would always be a split panel, delays involved—and I agree with Mr. Clark completely, there were delays

involved in it. And it wasn't efficient, because even after long delays in getting those panels done, 90 percent of the time they were split panels and they became nonentities, as they weren't admitted into evidence.

I think that we need to take a fresh look at this with those people who truly have an interest in the injured patients.

Are they being compensated effectively?

There are cases that we try to a conclusion which result in defendants' verdicts which others may disagree that it should have been a defendant's verdict and the exact opposite occurs, because there is no predictability under it. I know parameters have been tried in Maine, to a degree, and I think that there is a presumption of non-negligence in certain specialties if they adhere to certain practice parameters.

It's the same story with many of these proposals: the devil exists in the details. You don't know how effective practice parameters will be. I know a lot of physicians are concerned that it will result in "cookbook medicine," if a patient comes in with a certain clinical presentation they'd be required to render care in a cookbook fashion in order to obtain a presumption of no negligence.

So I know there is some objection to it on that basis, and the parameters are the types of things that you have to analyze. Although I must say that practice parameters would give predictability to the system, which we currently don't have.

And the thought that currently the system is really dealing with parameters I don't think is accurate, because the parameters really are dependent upon the expert who testifies, both for the plaintiff and for the defendant. And if we did not have a dispute between those experts, we wouldn't be having a trial. Hence the parameters certainly aren't in agreement between plaintiffs and defendants, and that's what's generating litigation.

BIENSTOCK: Isn't it the case, though, that any kind of dispute-resolution mechanism is going to be messy? And the one that we've arrived at is the one that we as a society think is best. So in the example of, for instance, neutral experts, we don't use neutral experts in litigation. That's not where we've gone. There's an assumption that the adversarial process will produce a better source of truth than would a different system. They may use a different system in France or on the European continent. We use the adversary system.

And so why would it be that you think these types of disputes are especially amenable to specialized judges, neutral experts, compensation guidelines, which are usually the province of the jury in our system?

WALTMAN: I believe there is a strong case to be made that health care is a special area. Not only, as some argue, because it's beyond the knowledge of certain judges or juries, but because health care, in general, is so costly and because medical malpractice costs, together with the cost of defensive medicine, represent such a significant portion of health care costs. Quite simply, as the nation undertakes health reform, it should also look at fair and effective ways to reduce medical malpractice costs as well. I assume Mr. Clark may talk about other ways to reduce those costs, such as reducing adverse outcomes, and I subscribe to those ways to reduce costs as well. That is exactly what GNYHA is doing with its member hospitals, namely, trying to assist them in reducing adverse events, reducing costs, and improving the efficiency and effectiveness of the care that they deliver.

I would suggest, however, that because health care consumes such a large portion of our nation's resources and because medical malpractice costs in particular represent and / or drive such a large portion of our health care costs, medical malpractice claims deserve special treatment within our judicial system.

I emphasize that I do not want to undermine the rights of the parties to medical malpractice disputes. Our country was founded on a commitment to certain rights, and I don't mean to throw those rights to the winds. But I believe it is important to look at ways to improve the dispute resolution process so that more people can enter the system and cases can move more quickly and be disposed of more fairly.

In the end, I would hope that whether you represent plaintiffs or defendants, you would agree that there are improvements that can be made in the processing of claims.

On clinical practice guidelines in particular, yes, there are a lot of guidelines that are available. I am suggesting, however, that someone such as the Secretary of Health and Human Services bring together professional societies, provider and consumer groups, and other stakeholders, and that they would, by consensus, identify clinical practice guidelines particularly in certain high-risk areas. Without that consensus approach, what occurs is too often a battle of the experts as to what guidelines should control. I was recently looking through some of the health reform proposals, and there are many, many provisions that discuss best practices, quality measurements, and comparative effectiveness and that's exactly why we have battles of the experts in the courtroom today. Perhaps some might say that having the right to put forward the guidelines that serve your purpose is what the United States is founded upon, but it's a shame that so much

time, energy, and resources go into the litigation of medical malpractice cases.

CLARK: Could I tell you a little bit about what happens in my office? I probably get inquiries of about 200 cases a year. Before I spend any money, I will meet with the client, I will speak with the client or an attorney in my office will speak with the client, and we'll winnow those 200 cases down to maybe 50 that sound like they have merit.

Then of those 50 I will gather records and we'll investigate them ourselves, we'll evaluate them. And then from the 50 we'll take about 20 that we will proceed with, and there we will hire the best-qualified experts we can have to analyze and tell us if we have a case. And ultimately we come down to, out of the 200 cases, maybe we've taken 10 or 12 cases a year, and we work them very hard.

But I have spent, in the course of preparing these cases, tens upon thousands of dollars, which you're not paying and which the health care system is not paying. So I am winnowing down the cases and restricting the cases that I commence to the ones I feel are merited. Basically, the doctors, the courts and the medical system are not troubled by cases that are insignificant. The system has evolved to provide a day in court for those with serious injuries.

And I can't afford to take bad cases. I can't afford to take phony cases. Because I'm going to spend 20, 30, 50, sometimes $80,000 to prosecute a case. And if the client is a phony or the injury is a phony, Mr. Amsler's people are going to kill me, and I'm going to be out 20, 30, $50,000. Sometimes he'll kill me on the good cases.

AMSLER: We can but hope. [laughing]

I just want to make a point that I think of when we look at reforming the system—and I think Bruce very cogently makes the point—there are a lot of cases out there that don't see compensation yet really involve malpractice, and the reason they don't is because they don't have the financial impact that would drive an attorney to take the case. So I think when you reform the system, you are going to open up the funnel of the system to smaller cases and increase costs on that basis.

Now, I'm not saying that reform of this system is going to be less costly, ultimately, because, as you point out, it's very difficult for a competent plaintiff's counsel to accept a case that only has minimal financial value because of the costs involved in bringing the litigation. That is the hurdle over which they have to go in order to commence the case. So aside from the negligence itself, it's also the potential financial return.

So one of the problems with our current system is that it precludes these cases that have absolute liability in them but don't have significant enough damages for counsel to take them.

WALTMAN: Bruce, I respect how you handle your cases. And that's always the problem of having these kinds of debates; we should not be painting everyone on the other side with the same brush.

But do you have a comment about the fact that Ed's insurance company closes 70 percent of the claims with no payment? Why is that occurring?

CLARK: What happens is there are attorneys who handle automobile cases, and in the course of handling an automobile case maybe the patient, after the initial impact, has an adverse result. And they will say, "Oh, this sounds like a great medical malpractice case." They'll get involved, they'll spend the $10,000 or $20,000 to prepare the case, and then they'll lose it. They'll be one of those 70 percent of the cases.

And then the next time they get a case in, they're still smarting from the expense of the first one, they'll send it out to somebody who is a specialist.

BIENSTOCK: Let me offer a different explanation, which is that the system is designed, you know, so that you can file a complaint without knowing much about the facts of the case and you often don't really learn much about the facts of the case until you've had a chance to sit down with experts and maybe to depose the doctors and the nurses and to find out what happened.

And, you know, certainly my professor friends say there's an argument in favor of that process, because without it you can't necessarily identify what really happened. Certainly there should be an interview process up-front to weed out the cases where you're going to waste your money. But even then I suspect you're still going to get plaintiffs who come in through the door, sound like they've got a good case, something bad happened that shouldn't have happened, and it isn't until you've done some discovery that you can figure out that maybe no, there isn't any case here.

CLARK: That's right. And you will have that same discovery process if you open the whole process up to every claim where somebody says "I had my appendix taken out and now I have a scar on my abdomen." That type case, maybe there was negligence that resulted in a little bit larger scar than you would expect. But in all those cases, in all those compensation-type situations, if you're going to let everybody recover, that's not going to save any money.

WALTMAN: I believe that both Ed and I acknowledge that making improvements to the system may mean more claims may come into the system. But if you could start afresh and focus on what could make the system work better, you would hope that, in the process, more people could appropriately enter the system and yet have the system cost less overall. Currently, however, there is a considerable access problem, and yet the system costs so much.

I don't want to open the floodgates necessarily either, but I think that the current system is unnecessarily expensive, perhaps not the way you approach it, Bruce, but overall, it's an exceptionally expensive system. But how would you go about improving the dispute-resolution process in order to allow more of the money to either go to the plaintiffs or stay in the health care system?

AMSLER: Marty asked the question as to the efficacy of the advocacy process: equally competent counsel on both sides in front of a jury, and it will render truth. I was trained in that and still practice it, and believe in it.

But society progresses. And just because we have done the same thing over all these years doesn't make it necessarily right. And if we still had that process, we'd be having employees suing employers and we wouldn't have a Workers' Compensation system.

The provision of health care in this country has become such a monumental issue at this time, as well as the costs associated with it. As lawyers, I think we need to take a hard look at whether this is the best way to be addressing this problem. Are there more efficient methods? We've seen arbitration, for example, come about in all forms of litigation, commercial litigation, because people recognize the efficacy of binding arbitration in those actions. But we refuse to recognize it in this area.

So I think we need to put different lenses on and take a broader look at it, as opposed to relying on what we've always done.

III. Expert Identity and Deposition

AMSLER: Let's talk about procedure, if we can, for a moment. I've always been concerned that here in New York State, we don't have the capacity to both identify and depose experts on both sides. We have what is classically known as "trial by ambush."

And I've been in the courtrooms where you sit there and you've got your associates sitting next to you and you've got them running outside trying to dig up transcripts on the name who you've just found out or, in current practice, trying to discern who the expert would be based upon the identification that you've received pursuant to the CPLR, which excludes the name.

And to me, it's antiquated and it's almost irresponsible at this point for our system to do that. Every other state has at least identification of experts. And under federal rules, you have depositions. And why is that good? I think it's good for several reasons. One, it's good for both sides to understand what the theory is upon which the litigation is founded.

With a lot of counsel, a lot of plaintiff's counsel nowadays—and we're doing a lot more mediation than we ever did in the past, and we've found that experienced plaintiff's counsel nowadays are not disinclined to give us the name of the expert and what the theory is, because they feel they've got a solid case and this is their theory.

And what that tells us is that, okay, here's the theory. Do we agree? And, we have a physician-owned company, and the physicians review it. They say: "Well, here's the plaintiff's theory. Is this right? And if this is right, maybe we ought to get out the checkbook, as opposed to spending three weeks in trial."

If you had discovery and you had depositions, you have an opportunity to understand the opinion, the basis for the opinion, the effectiveness of the opinion, and the causal relationship between any departure and any damages that are there. What it does is it limits the scope of the case so that you really know what the issues are.

Every other state has it. The old argument 10 years ago, 20 years ago used to be that there's this "conspiracy of silence" out there, and if we tell you who the name is, nobody will come in and testify. As Mr. Clark points out, he goes out and gets the most experienced experts to review these files. I don't know that any plaintiff's counsel has difficulty getting experts to review these files, nor is there a conspiracy of silence in the current milieu in which we practice.

So I think it's time to bring this into the 21st century and have discovery of identity. And it's going to increase the defendant's costs, obviously. I mean, we're going to spend money to depose experts, and that's going to cost a great deal of money to the insurance carriers. But the net effect of that is going to be faster resolution, because you're going to know the theory, you're going to settle the case earlier. And if you think the plaintiff has a solid theory, you can define the causation in it.

So you're going to have to balance that increased cost against earlier resolution of these cases. Earlier resolution, I think, is of benefit to both the system and to society as a whole. So I think it's time we moved in that direction.

CLARK: As a practical matter, Ed refers to Civil Practice Law and Rules 3101(d), which requires you to disclose the qualifications and the summary of your expert's position.

We have computer programs, both the defense and the plaintiff's bar, by which we can put in the doctor's medical school, his internship, his residency, and the computer will spit out five names that have those three correlates, and then from those we can usually figure out which one is going to be the expert for the other side. And the defendants do that also.

And I have had many trials where the defendant has a porter come in carrying boxes of transcripts of testimony of my expert, and they know what he's said and where he's testified before.

And we are also precluded from asking the expert questions if we don't disclose what his position is. And we have to disclose that beforehand. So they are getting practically everything they need. And if they don't get enough in my 3101(d) statement, they go to the court and they say, "We either want to preclude him from offering anything else, or we want more information."

And there are cases now where you have to provide every publication that the person has ever given. So as a practical matter, they are getting all those things. And I agree with Ed that there should be earlier resolution. And that's one of my positions, that with earlier resolution everybody will save money.

BIENSTOCK: Bruce, what about depositions? What about expert depositions?

CLARK: The depositions are expensive. They delay the case. They require extra preparation. And we all know what they're going to testify to anyway.

I don't think it's a big secret when, you know, if a child is dropped on his head in the delivery room or the nurse ignores the patient when the patient says the baby is beginning to have seizures or something like that. So I think it rarely would benefit.

AMSLER: You know, I think it's almost silly, it's just like playing cards and saying, "I have a card that's somewhere between a 4 and a 6, and you've got to guess what it is."

Now, if everybody knows what it is, what are we really doing here as lawyers, as rational beings? Is this really what we want to be doing? If everybody is using computer programs to guess who the other expert is, why don't we just say, "This is my expert"?

CLARK: That's what I do.

AMSLER: So why don't we have a law that says you've got to do that?

And the value of taking depositions is not just a theory on liability, but it's also on damages. In many of these cases—in fact, the vast majority of these cases—patients don't go to physicians or hospitals because they're healthy. Most of them go there because they have a problem and there is an underlying problem or a preexisting condition that we're dealing with. And differentiating what the difference is between the alleged act of negligence in terms of damage caused versus what the underlying condition caused is oftentimes a determining element in the value of the case, so you determine whether the case is worth X number of dollars or Y number of dollars.

Now, if you have an expert who testifies and renders an opinion as to what the causal relationship between the alleged negligence is and the damages, then the defendant is put in a posture of evaluating if it's related to all of these damages so it has X value or it has Y value because it is only related to more limited damages.

Otherwise, it's playing a game of "I'll tell you at the trial," and the expert will come in and testify then, and it's subjected to cross-examination where you can whittle down the causal relationships. Well, by that time, the lines in the sand have been drawn and it's very hard to settle cases. You can settle cases years in advance if you can define what the damage elements are.

WALTMAN: Marty, you know that I don't do medical malpractice litigation, but rather I approach the area from a policy and advocacy position. I have to say that I found it fascinating to learn that, in the State of New York, you don't have the right to know the name of the opposing party's experts and you don't have the right to take their depositions. It is a very "interesting" phenomenon in our State's civil procedure.

Our hospital members will say to us—and I note that I rely heavily on individuals in our hospitals who are strong claims managers, all of whom also care deeply about the quality of the care that is provided to their patients—"if I could take the expert's deposition and learn more about the theory of the case, I would be in a better position to settle more quickly."

They describe the ability to depose experts as a way to understand the claims better and settle them more quickly.

CLARK: I do disclose what the theory of my case is. I don't dare not disclose it. Because if I have not disclosed it in the 3101 and the bill of particulars, when we get to trial the defendant's attorney stands up and he says, "This is

a complete surprise. Mr. Clark should be precluded from proving this theory of liability."

And I've seen it happen. If you have not given adequate notice of what your theory of liability is, the defendant wins his motion to preclude you.

And as I said, as a practical matter, everybody knows who the expert is going to be. So we don't need new law for that. The law has been evolving. Initially, in the *Jasopersaud* case, you were protected from disclosing anything that would lead to the identity of the expert. Now there's an *Alleyne* case which says you have to disclose every writing that your expert has ever done. So if you disclose 10 articles and they all have one person in common, there's the expert. And if the computer program doesn't work, then you do it the other way.

So you really don't need that at this point. It would just delay things more. It would make things more cumbersome.

WALTMAN: I have sat through this discussion before, and I appreciate the fact that you can glean what the arguments and theories are and that the plaintiff can be penalized if he or she doesn't put those theories forward. It is just an "interesting" aspect of the State's judicial system that you cannot take the deposition of the other party's expert in order to learn more about the theories behind a claim.

BIENSTOCK: Bruce, Ed says that the original purpose of this was to protect the physician, the testifying expert physician from retaliation on the part of his peers, and that that's long gone because the identity is there. Is that your sense as well, that that idea of protecting the doctor from being viewed as a rat is no longer operative?

CLARK: I don't think it's no longer operative. And the way I overcome that is I try to get experts who are invulnerable to pressure. I don't ask for a doctor who's just completed his residency and is in his first position after he's become a specialist, because nobody is going to go to him. Or I don't go to the doctor who relies on referrals from people like the doctor I'm suing.

I have experienced it bitterly where my expert has been reached or intimidated from testifying. It's happened enough that I have developed defensive postures against it.

So there is a reason to do that, but we get around it by getting people who are very well qualified or who are retired and who cannot have their position taken away from them, who will not have the chief of their department come up to them and say, "Did I hear that you're testifying against Dr. So-and-So? You know, that's not going to be very good for your career."

I've seen that happen many times, and that's the underside of trial law, that people get intimidated and people get threatened. Sometimes it works.

WALTMAN: I will say again, for all the discussion that takes place about wanting to maintain the judicial system and respecting the tenets of the judicial system, it remains amazing to me that you can't take the deposition of the other party's experts.

IV. Reducing Cost Associated with Physician's Authority to Consent to Settlement

CLARK: Well, I think leading into from what we've said, one of the reasons that medical malpractice is as expensive as it is—and I will not grant that it's as expensive as Susan says. I think that we don't have complete disclosure of what the real finances are of the field. And I would like to know how much profit the Medical Liability Mutual Company is making, or—

AMSLER: I'd love to answer that one (laughing). The answer is zero. Absolutely zero.

In fact, recently, with the rate freeze and everything else, our surplus, which is the money that we need beyond the reserves that we have to pay claims—a surplus is a rainy-day fund by which the industry judges the financial security of insurance companies—has been diminished from $1.5 billion down to $275 million, as the net result of reserve increases, assessments put on by the state, and the failure of the state to permit adequate rate increases.

So the fact of the matter is Medical Liability Mutual is a mutual insurance company owned by its insureds. If they ever made a profit, it goes back to them via dividends. They are not making any profit, and they're not designed to make a profit. Every rate request that's put into the Insurance Department is put in on the basis of the ultimate claim's costs minus the investment income that's intended to be derived during the course that the money is held.

Medical Liability Mutual is not a profit-making company. There are no large profit-making companies, no commercial carriers which write that business in this state. And there's a reason for that. It's because it's not a profit-making business. You don't have AIG, you don't have Aetna. You don't have profit-making companies in this state because historically profit can't be made in it.

So, I'm glad to respond to that. I think that any argument that this is a profitable business is fallacious on its face and it shouldn't be discussed, in terms of dealing with this problem and this issue.

WALTMAN: I find that often when we have the debate about the costs of the medical malpractice system, people

will say, let's look hard at what the insurance companies are doing, maybe they're making too much money.

However, most hospitals in New York State are not covered by commercial insurance because it isn't available to them at any reasonable price or perhaps not available at all. They therefore have established self-insured trusts or captive insurance companies. Under those arrangements, and similar to what Ed described with respect to his company, if there is any extra money, it would go back to the hospitals. So, the concern that insurance companies are somehow making too much money or requiring excess reserves shouldn't arise in New York State.

CLARK: Well, we've been talking about costs of litigation, and litigation is expensive for both sides. The way the malpractice law is structured in New York State at this time is if a doctor settles or loses any combination of two cases, this goes onto the data bank, and patients can access what the doctor's record has been.

So the doctor—and in many of the cases, in most of the cases, my understanding is the doctor has the right to refuse to consent to a settlement. So what happens is the doctor says, "If I settle this case, my name is going to go onto a data bank, and it's going to hit me in the wallet because patients are not going to come to me when they see I've had three lawsuits against me that I've settled."

So I think what would expedite cases infinitely would be to eliminate that provision of the law that says doctors have to report and doctors' names go into a data bank if they settle cases. Let it be if they lose cases.

I have cases—right now I've been dealing with a client who has a potential multimillion-dollar case, and his house is being foreclosed on right now. I can't call you up and say, "Ed, you know, you're going to owe a lot of money on this case." My experience is you just don't pay until you've had all the disclosure, and then the doctor is going to say, "I'm not going to do that, I want the hospital to pay."

So this case that you could probably settle for half the value at this point, you will not be able to because the doctor will not consent at this point. So I will then take the case to trial, and instead of settling it for a million dollars now, I'll get a $3 million verdict. And just because of the exigencies of the doctors having to disclose and be reported on cases that he or she has lost.

AMSLER: I think Bruce makes a valid point to an extent. I think one of the unintended consequences of these levels of transparency of malpractice litigation—and they include, at the national level, the National Practitioner Data Bank. And then there's the state level where there are also reporting functions. And it's also at HMOs and for hospital privileges. All of these organizations have to be reported to if you've had a malpractice case, a malpractice settlement, or a malpractice judgment.

So it's not just the National Practitioner Data Bank, it's this transparency across the board. Basically driven by consumer interests: they want to know: "has my physician been sued?" Consumers, or those who establish these laws, assume a correlation between malpractice litigation and bad medical practice, this may not necessarily be the case, but that's the correlation which patients often draw, and that's what drives this sort of legislation.

The unintended consequences of that is a reluctance by physicians and hospitals to consent to settle these cases. But on the other hand, you have to look at it from their perspective. These are professionals who have trained for years. And they truly believe—and they're often in actions wherein they truly believe they did nothing wrong.

Now, that doesn't mean they may not ultimately lose the case, because it's a jury system. But they truly believe they did nothing wrong, and they want their day in court. And they've paid their premiums to have that day in court, and they want that day in court. Just as your clients, the injured patients, want their day in court, the defendant wants their day in court.

And I think that in many cases—in our situation, we're a physician-owned company, you're in a position where if the company feels that it's a case to settle, usually the physicians will understand why ultimately that the case should be settled. Because, the physicians will reason with one another.

I think that the genesis of the no-consent requirement was really from commercial carriers who were doing it for expediency's sake and economics' sake. Which, you know, even with large litigation, that's not usually the case, and that's not part of the claims philosophy of our company. You pay on cases that have liability and the cases that indicate departures from standard of care with causation.

So it's put us through a great deal more effort and an educational process with our insureds. But it is one of the side effects of the National Practitioner Data Bank and all of these levels of transparency. And the chances of changing that are slim and none, because they're in so many levels of government, from what I see.

WALTMAN: Ed, my understanding is that you offer policies that provide a slight discount in premiums

for physicians willing to waive the right to consent to settlement.

AMSLER: Yes, a few percentage points to waive the consent.

We were required to offer that by the Insurance Department. There's never been any actuarial showing that waiving a consent-to-settle provision in a policy saves any money, but we were required to do that by the Insurance Department many years ago.

Very few doctors will accept that policy because they want to be able to control their litigation.

WALTMAN: One of the corollary questions is how deep would the discount need to be to get doctors to waive their right to consent to settlement.

AMSLER: Well, the difficulty with that, I think there's no question, you could say there may be a 90 percent discount—but that's not really the answer, because the discount has to be related to some actuarial savings that you could document as a result. And nobody has been able to document savings as a result of it.

I mean, the discount which is offered now is just arbitrarily set by the Department in an attempt, many years ago, to incentivize its use and it requires all carriers who write this business inside the state to have it.

WALTMAN: I note that Greater New York Hospital Association offers a program to its hospitals that trains individual health-care workers how to talk with patients who have experienced an adverse outcome in order to provide full disclosure regarding the event, a meaningful apology, and an early offer of compensation, where appropriate.

CLARK: Right. The offer and disclosure policy that if you go to a patient and say, "We've made a mistake, you were injured, we would like to give you X dollars." More often than not, the patient will accept that and will not go to an attorney afterwards.

WALTMAN: Yes, it's sooner in the process than the claim stage. So it may eliminate the need for patients to ever name a physician.

A lot of hospitals are working on this approach and see the value as it relates to adverse events in general.

BIENSTOCK: It sounds to me like one common theme that I'm hearing is the market mechanisms on the insurance side aren't necessarily working the way that they should. So that physicians, for instance, face no penalty for refusing to settle, when, if the money was coming out-of-pocket, you know, they'd be settling on Day 1 or on Day 30.

Instead, the limited hit they get, the limited hit to their reputation is all that they feel, so there's no harm in going to trial and losing. There may be some harm; I'm exaggerating. But they're not feeling the costs—those are passed through the insurance company—and so they can be less reasonable than they ordinarily would be in deciding whether to settle a medical malpractice claim.

And that cycles through further, in that their very premiums aren't related to any kind of market mechanisms. The insurance companies are kind of state-sponsored or mutuals that there's no profit margin in. The rates are set by the state. The physician's practices don't affect his insurance rate.

So there isn't the kind of push-back onto doctors that you might ordinarily see from the insurance companies that said, "Look, if you don't straighten out XYZ, we're going to increase your rate by 20 percent." Or, "If you do ABC, you'll get a 40 percent cut." None of those mechanisms seem to be working in a way where the insurance companies look to save costs by pushing back onto the doctors.

Is that observation accurate?

AMSLER: Marty, let me—to an extent, perhaps. But let me give you some examples so that you'll understand how the system works.

We write physicians who practice good medicine, and we have peer review. If we have an insured that has multiple claims, for example, and we bring that physician in, we may find that he practices in a high-risk specialty in a high-risk position in a high-risk hospital. In which case we continue to insure that individual at normal rates. The view of this mutual has always been a broader view than just a commercial carrier.

On the other hand, if we bring a physician in that has multiple cases and we find that his standards of practice or her standards of practice are all below what we consider good medical practice, we will non-renew that physician. We can't cancel them, under state regulation, we have to non-renew. Which means the next common anniversary date, which is July 1 of a given year, that physician is non-renewed.

If that physician cannot find cover in the voluntary market—in other words, by going to one of the other insurers—they have to be insured with the Medical Malpractice Pool. Now, the Medical Malpractice Pool, ironically, is comprised of a pool of all the insurance carriers who write this risk inside the State of New York, and their exposure is based upon their market share.

So we have approximately, let's say, 50 percent of the market inside New York. If we decline to write a given

physician because of that physician's standards of practice and that physician goes into the pool, we are exposed to 50 percent of the exposure for that physician. That's the irony of it.

The reality, however, is that in terms of cost, the medical malpractice pool rates are approximately 300 percent higher than are the rates that are established by the Superintendent of Insurance for the regular voluntary market.

And the other aspect of it is that the voluntary market is burdened not only with those exposures but with exposures that they don't write. For example, we don't write adult-care facilities, but adult-care facilities can get insured in the medical malpractice insurance pool and we are exposed to that as well.

So, we have a lot of exposures out there which are dictated by regulation and by statute which are not voluntary exposures that the company takes on.

So yes, physicians who have been canceled can get insurance through the Medical Malpractice Pool, and the Medical Malpractice Pool is obligated to write them. They cannot turn them down. So the cover is there, but it is much more expensive.

CLARK: This is a wonderful example of how bad medical practice results in disciplining doctors, getting them out of the field. If the doctor has to pay 300 percent of his premium, he's going to be encouraged to leave the practice of medicine or go take a job someplace else.

AMSLER: You know, I tend to agree. But the reality of it is that we're doing indirectly what we should be doing directly.

I don't think that we should be using medical malpractice insurance or professional liability insurance to determine the competence of physicians. I think that's a job for somebody who has the experience, capability and capacity to make those determinations for the health care of the people in this state, not the malpractice insurance industry.

WALTMAN: I'd like to make a comment related to your point that the requirement to report settlements actually deters physicians from the desired goal settling. That is absolutely true in some cases. But I'd like to point out how the system as a whole acts as a deterrent to improving provider behavior.

One of the goals of the medical malpractice system, as well as the judicial system at large, is to deter unsafe conduct.

Yet, patient safety experts say that a culture of blame undermines the ability of providers to improve care. Thus, there is a disconnect between the judicial system, which by definition determines and assigns fault or blame, and what safety experts say it takes to create a culture of safety within a health care setting so that people will come forward and discuss errors and systems and behavior can be improved.

That was the underpinning of the Institute of Medicine's 1999 report: in order to improve patient safety, providers should create a culture of safety in which individuals don't get blamed for their actions. The judicial system does exactly the opposite. I recognize that the assignment of blame is at the core of the current judicial system, but that approach undermines some of the efforts of hospitals to improve care. Similarly, as you suggest, the requirement that physicians report settlements to the data bank can undermine the ability to enter early settlements.

CLARK: Well, the larger question is how can medical care be improved across the board. And we're addressing that right now with the health care legislation that's going on in Washington.

One of the major areas is medical fraud that doesn't involve patients or plaintiff's lawyers but the doctors themselves who own the MRI facility or who own the hospital or who own the clinic or who own the sonogram machine and who are billing—doing these procedures in a hundred percent of their patients and overcharging. And the *New England Journal of Medicine* has documented how much fraud there is within the medical field.

On June 9th in *The New Yorker*, Dr. Atul Gawande writes a wonderful article about how medical costs in McAllen, Texas, are twice what they are at the Mayo Clinic because the doctors own all the facilities.

I just wanted to respond to something that Susan had said, or make an observation about Susan's focus on improving quality of care as a means of reducing medical malpractice and medical malpractice costs, which I think is a special focus of hers.

BIENSTOCK: And just to make the observation that hospitals are the one area where the two kind of come together in a financial and practical way. The hospitals are paying for their medical malpractice costs and they're providing care.

Certainly the physicians are in hospitals too, and the hospitals don't necessarily control the action of the physicians. But when you've got that commonality where you're actually providing the care and you're paying for the costs of the malpractice, you're immediately focused

and incentivized to provide care in a way that doesn't increase malpractice costs.

Whereas on the physician side, there's a very strong disconnect between the costs of malpractice and their actual practice. That's not to say physicians aren't doing their best to provide the top quality of care. But there's a very strong disconnect.

If a physician gets sued, it's very annoying, but he's not paying out that $1.3 million; it's MLMIC that's doing it. And there's a lag, a very long lag between those practices and their bottom line. And, you know, I think that there's a kind of market disconnect within that insurance market that doesn't exist for the hospitals.

I think it would be much better if hospitals could get commercial insurance and would have access to that. But it is forcing the hospitals to say, "Hey, guys, wait a minute, we need to do our stuff better and improve quality and not do the things that get us sued for medical malpractice, because we can't afford it."

And that's, I think, a good dynamic that we've got, but it only covers the hospital side of the equation. And it's a complicated interplay, because the physicians are the ones who are providing the treatment.

So I just thought that was very interesting.

AMSLER: To comment on that, Marty, if I can, I think it's an error to look at this totally in terms of financial incentives and in terms of what the physician—how much his malpractice insurance costs as it relates to the care and treatment that he renders or she renders.

Representing physicians over the years and even seeing them now in this capacity as an insurance company, these physicians out there, when they get sued, it's a sleepless-night event for them.

The relationship of physician / patient is not only a quasi-fiduciary relationship, it's one of trust and confidence. And there's a degree of pride and professionalism that they have. They don't decide what to do for a patient or what not to do for a patient on the basis of their malpractice premiums or their financials.

I recognize Bruce's point about that, but most of our malpractice cases aren't driven by unnecessary tests or ordering of tests to inure to the doctor's financial benefit.

And these good physicians who get sued and they go through trial—and even when they win the case, they haven't won anything. They just go back to practice the next day, after the Sturm und Drang of an entire six-or-seven-year period of being a defendant in a malpractice. If you've ever been cross-examined by somebody like Bruce, you know what that feels like after two days on the stand. It is not a pleasant experience to have your entire professional capacity come into question. And anybody who's been through that once does not want to go through it twice.

So I think the physicians that I deal with and I see, very rarely do I see a financial motivation for their determination as to whether to settle a case or not to settle a case or how to proceed in terms of their practice of medicine.

BIENSTOCK: I would agree with you. And I think physicians are doing their best.

But there is that distinction. It's personal, it's not just business. And in a certain way, personal is more important. But when you think of it as business, there's much more money involved and there are more institutional reforms that might go on.

So, you know, Susan is sitting there thinking about how do we make hospitals as institutions more responsive to medical malpractice problems. And she sits there and I assume she's got, I know she's got access to people at the hospitals who sit there and worry about this day in, day out, because it goes directly to their bottom lines.

And it's a very different worry than the physician who can't sleep at night, and it affects you in different ways. But I think the drive that comes from the bottom line sometimes produces different results—maybe better results—than even sleepless nights do.

V. No-Fault Insurance for Neurologically Impaired Newborns

WALTMAN: As we have looked at the costs that are being incurred by hospitals in particular, we have focused heavily on the fact that approximately 35 to 50 percent of the costs of our medical malpractice coverage relates to coverage of obstetric services, a percentage that includes both coverage costs and the direct costs of certain settlements or awards. I bother to reference the direct costs of settlements and recoveries because, while many of our members carry forms of coverage, for some of our members, the cost of a settlement or recovery falls directly to their bottom line, particularly in the case of very large recoveries and settlements.

As stated, we have found that 35 to 50 percent of hospitals' medical malpractice costs relate to coverage of their obstetrics services and more particularly to cases involving neurologically impaired newborns and the costs associated with the care that they require.

At the same time, our members point to studies that demonstrate that many of the adverse outcomes

involving neurologically impaired newborns are not sensitive to medical interventions that exist today, citing articles, for example, that have been written by Karin Nelson at the National Institutes for Health.

Those facts have led us to take the position that there should be a better, fairer way to address the costs of caring for these individuals, beginning with the creation of a no-fault compensation fund. Under that model, payments would be made without needing to determine negligence or perhaps even causation. Instead, individuals with certain defined injuries would be qualified for coverage by the fund. We would thus be eliminating from the system what former Superintendent of Insurance Dinallo calls "frictional" or litigation costs and potentially providing compensation to a broader array of individuals with injuries.

The no-fault approach reduces the costs of medical malpractice coverage in two ways. First, as stated, it eliminates the frictional costs from the system. Second, depending on how it's financed, it also can spread the cost of caring for individuals with qualifying injuries across a broader portion of society as opposed to imposing those costs only on the providers delivering obstetrical care. The latter point, namely, sharing the costs of care, is important in light of the studies that indicate that providers are not able to change most of the adverse outcomes involving neurological impairment.

Having said that, I firmly believe that what must go hand in hand with a no-fault fund approach is a very concentrated effort on the part of providers to reduce those adverse events that are subject to intervention. In this regard, GNYHA, together with the United Hospital Fund, is in the midst of a very large perinatal safety collaborative involving many of its member hospitals, which focuses on developing clinical guidelines as well as structures within our institutions that support perinatal safety—both because it's the right thing to do and because the area drives a great deal of our medical malpractice costs.

I recognize that some people react negatively to the idea of a no-fault approach. We therefore also support a variation of a neurologically impaired newborn fund that allows cases to go through the judicial system. However, once there is a determination of responsibility through a settlement or an award, payments for the individual's future medical care would be made from a medical indemnity fund rather than by the provider's medical malpractice coverage.

Thus, there are two variations of funds that can address these enormous costs that are currently borne only by the health care system. We would prefer the no-fault approach in order to eliminate the unnecessary costs of litigation. In addition, we underscore that the no-fault approach will compensate injured individuals more quickly and with more certainty. And, as stated, it should go hand in hand with our trying to address all of the adverse events that we can.

AMSLER: I would comment that I agree with Susan, neurologically impaired infants are a significant cost driver of our system. And it's an area where there's "thin medicine" associating many of these cases with hypoxia or anoxia or intrapartum events and/or prematurity.

And as we should look at these infants, we say: What kind of a job are we doing as a society in terms of compensating them, in terms of taking care of them? On one hand we might have an infant that has a genetic defect or is premature without any negligence and has the same disabilities as someone who has a claim that goes before a jury, and we say society compensates them at X. And then we have the one that goes through the jury system and fault is found, and society compensates them at Y because of the funding that's available—ultimately from hospitals, mainly.

And you have to question whether or not that is the best way to be compensating these infants. Is that the way we want to be doing it, to be associating fault for some of them and no fault for others and compensating them at different levels?

And, once again, are we being efficient and timely in terms of compensation to these infants? They are a huge driver of our losses, and yet at the same time most obstetricians will tell us that, although—admittedly, we don't have this problem down to an irreducible minimum. It's the efforts by Susan and the hospitals and physicians and obstetricians who are attempting to get all of these cases down to an irreducible minimum.

But even when you get it down to an irreducible minimum, we will still have neurologically impaired infants for which we will have a contest of experts where one says there's fault and one says there's not. Very difficult cases to win as a defendant, as you might imagine. The sympathy for these infants is monumental inside a courtroom and before the jury. And the damages awarded for future medical, future expenses are again horrendous.

And see what it does to the system. It causes a collateral exposure factor where you not only have the obstetrician sued, but you have the obstetrician's group sued, you have his or her partners sued, you have anesthesiologists sued, you have the neonatologists sued. And beyond that, we go into the hospital, which becomes a deep pocket for this exposure.

Because when you have the Appellate Division sustaining $8 million, $9 million for neurologically impaired infants in terms of damages, most obstetricians carry $1.3 million in primary coverage and maybe a million dollars in excess, and so that's all that's available. So you have this bleed over into codefendants, into hospitals as a deep pocket.

And the parents of these infants who go through this process that takes years and years and years, even after the awards are determined and the money is paid, one has to ask: has that infant's life appreciably changed as a result of the monetary award? Sure, there's some change. But could it have been done in a more equitable fashion: more infants on a broader scale and in a more timely fashion? You have to ask that question.

CLARK: Very often the awards are commensurate with the horrible practice that results in the child's injury. And I feel sorry for the anesthesiologists and the other doctors who get sued, but I see it from the point of view of the child and her family, how not only is the child imprisoned in a useless body for the rest of her life, but the family is imprisoned because that child has the disability. And everybody's life, from the parents to the grandparents to the siblings to the descendants of the siblings, are all affected. And it just cries out for a large compensation if there has been negligence.

I just settled a case where the father had a video camera running for the entire period, 45 minutes after the child was born up until the child essentially died on the mother's breast, and after the mother had said to the nurse, "He seems to be twitching." The child was seizing, and the nurse left for 11 minutes.

When you see a situation like that, which is so egregious, it just cries out for some sort of punishment and compensation. And I know we don't allow for punitive damages, but what has happened to this child demands compensation. And he needs benefits for the rest of his life that other kids won't have.

Our country is 16th in the world in infant mortality. We're behind Third World countries in protecting the health of our newborns, and that shouldn't be. Let's eliminate the medical malpractice by eliminating bad malpractice.

AMSLER: Well, if I thought that the medical malpractice system in which we practice, in which our physicians practice, was truly resulting in better care for patients, I would agree with Mr. Clark.

But for as long I've been involved in this, over 30 years, I've heard that this is a great deterrent, our system is a great deterrent for bad medical practice and improves medical practice. And yet at the same time I've seen nothing but increases in frequency and increases in severity of claims. So obviously it's not working.

If this system truly is a deterrent to bad medical practice, it assumes that physicians are going to practice bad medicine unless there is a malpractice system to deter it. I don't think empirically we can demonstrate that.

And it's not so much the abandonment of the patient. How many times have we seen these cases evolve from two different experts disagreeing as to what a fetal heart monitor strip reads? And when you have an expert for a plaintiff and the sympathy factor involved in front of a jury over that, it's very, very difficult to win a neurologically impaired infant case.

And yet it's not a case of absolute black-and-white negligence where the patient's been abandoned, the infant's been abandoned on the mother's breast. These are cases where we have rational beings disagreeing about what a medical test reads, and we leave it up to a jury to make a determination as to whether or not there was negligence.

I submit to you that if you had a system where you could compensate these people, as Susan points out, these infants, no matter what that fetal heart strip read, whether you agree with this expert or you agree with that expert, I think that infant is better served under that system.

CLARK: Well, hopefully we're going to have universal healthcare so that these infants, along with everybody else in our society, or at least all other infants, will get good medical care for the rest of their lives.

You can't expect the medical malpractice system to be a cure-all for the entire system when you've got places like this McAllen, Texas, that Dr. Gawande writes about, where malpractice is not an issue. There is no malpractice litigation in Texas, and yet they have the highest medical costs in the country and probably in the world because the doctors are benefiting, they are profiting from factors that don't necessarily result in benefits to the patient.

He gives an example of one doctor who takes out every gallbladder even though the gallbladders don't need, in most of the cases, to be removed. But he gets $1,500 or whatever it is per operation. And it's not to the patient's benefit.

WALTMAN: I'd like to go back to the fact that such a large portion of the medical malpractice costs are related to OB services. I emphasize that it is absolutely our position that individuals with neurological impairments should be compensated or covered in some way; we are very interested in ensuring that their needs are met.

But given what we understand regarding the science and limits of medicine today, provider behavior during the labor and delivery process is not the reason for the impairment in most of the cases. There's no question that, as a society, we need to improve prenatal care and learn as much as we can about how to improve birth outcomes. But the point is to look at this as an area that's driving nearly half of providers' medical malpractice costs, yet the injuries involved are not, in most cases, caused by the negligence of those providers. We therefore must look at a broader, more equitable way to fund the care that neurologically impaired individuals need.

I note that, as we looked at this area as part of the State's Medical Malpractice Task Force review process, we realized that the State's Medicaid program was already paying for the initial care—and sometimes the continuing care--of many of these individuals while they were waiting for their lawsuits to wend their way through the judicial system. We also learned that, following the resolution of the case, the local social service districts were not uniformly recouping the outlay of Medicaid dollars under the required third party recovery process. Thus, in some cases, plaintiffs experienced double recoveries for their injuries—once from the State's Medicaid program and again from the defendants. My point is that perhaps creating a funding mechanism that builds upon the Medicaid payments and benefits that have already been devoted to caring for some of these patients might be a strong start in terms of developing alternative coverage for their care.

I emphasize that I absolutely support that there be coverage for these individuals. But, we must focus on the fact that the costs of these very large cases—and it's the severity of cases that drives our medical malpractice costs, not the frequency of claims--directly affect hospital bottom lines. When it comes to big awards, studies indicate that one of the best predictors of whether there's a large recovery in a case is the degree of disability suffered by the plaintiff, not whether there is negligence. Nowhere is that more true than in the area of neurologically impaired newborns.

I therefore think that, as we look at ways to reduce the costs of the medical malpractice system, how to fairly and properly fund the care needed by neurologically impaired newborns should be at the top of the list.

CLARK: You know, what happens in cases that go to verdict is that after the jury makes a determination, a motion is made to the trial judge saying this verdict is excessive. The defendants make a motion, if the plaintiffs win, saying the verdict is excessive and there are legal errors that should throw out the entire thing. That trial judge may reduce the verdict.

CLARK: What happens is that first there's a decision by the judge. And one of the earliest cases I had, the trial judge reduced a $900,000 verdict to $750,000. Then the case was appealed, and the appellate court reduced the $750,000 to $300, 000.

I've had dozens of multimillion-dollar verdicts, and I can think of one that was not reduced when it got before the Appellate Division. So there is a control that is asserted.

VI. Caps on Damages for Pain and Suffering

AMSLER: You know, caps have been bandied about for years. In 1975, during one of our early malpractice crises in this country, one of the few states that approved a cap on pain and suffering was California. And they had a cap at $250,000 as part of their MICRA bill and have had that cap since that time.

And now there are about 30 states now that have caps in one form or another: overall caps, pain and suffering caps, whatever. These are parameters which damage awards are not allowed to exceed.

And I think it's important that we discuss that, and I think it's important for this reason. The major elements of damage in most of these cases nowadays are not pain and suffering, I think they're financial damages. They're future medical costs, they're future loss of earnings. When you look at a neurologically impaired infant, that's the case.

But yet we have the aspect of "pain and suffering" which is, you know, truly in the eyes of the jury—as controlled by the Appellate Division and the trial judge, admittedly—but it's been ever-increasing. In other words, that amount which is sustainable for pain and suffering.

And so when you say a cap on pain and suffering, let's say for argument's sake we have a cap of $250,000 as in California. The rates for malpractice insurance are less than half of what they are in New York in California now. Certainly the trends in terms of tort exposure and tort liability in California are probably more liberal than they are here in New York.

So what has kept those rates down? You can't make the argument that medical care is better in California. And really we have pretty much all of the tort reforms here in New York that MICRA has, with the exception of the cap on pain and suffering.

So why is it that I think that a cap on pain and suffering really would have such a beneficial effect in terms of severity of claim? And I think California documents—all the studies that document it indicate that it would reduce premiums. A study by Milliman indicates it's a 24, 25 percent reduction in premiums for physicians inside New

York. That's really pretty much a reduction in claims costs. That's what they're saying, that claims costs are much less.

I think a cap on pain and suffering has a synergistic effect on moving cases which is analogous to the structured settlement effect. One of the great things that came about for both plaintiffs and defendants was this whole idea of being able to purchase an annuity to provide for future costs for truly injured patients. If you knew what the life expectancy was, you purchased an annuity from a life carrier and they took the risk on the life expectancy.

Any plaintiff's attorney will argue a normal life expectancy for a damaged plaintiff, and the defendant is put in the position of arguing a less-than-normal life expectancy. But by purchasing an annuity, the life carrier takes that risk and they age that plaintiff and price the annuity accordingly.

And you can argue with plaintiff's counsel over the value of the future economic loss, the value of the future medical costs. But in reality, usually with experienced counsel you come to a conclusion as to what those values are. And they are available on a present-day value by purchasing an annuity through a life carrier who then assumes the risk of the life expectancy.

So that's a predictable loss. And I think that's a valuable tool to getting these cases settled and having a predictable loss.

Plaintiff's counsel love it for a lot of good reasons. One, it prevents the spendthrift plaintiff from going out and spending the money on frivolous items and not protecting their future. And it protects their counsel in terms of their advice they give them and secures an income stream for the rest of their lives.

Insurance companies love it for the obvious reason that it permits them to pay present-day values with someone else assuming the risk of a life.

So if you can eliminate that aspect from the damages, the only thing that's remaining is pain and suffering. And that's really what the jury is going to evaluate and it's unpredictable.

If you cap that pain and suffering, unfortunately the cap becomes both a ceiling and a floor. Everybody will assume that their pain and suffering is worth $250,000 and that will become a floor. And that's the downside of it.

But the upside of it is if you limited the pain and suffering to $250,000, then you have essentially—you've made all the damages in the case discernible, predictable, and made that case highly settleable.

And that's what happens in California. These cases move much more quickly, they move much faster, they save some money on pain and suffering, depending upon what the case is, as they lose some money when it becomes a floor as opposed to a ceiling. But the reality is that the cases of liability can move much faster because there's nothing left for a jury to make a determination on.

If it is a case where there's significant damage, you're going to pay the $250,000, and you don't have to go through to a jury to make an award. And plaintiff's counsel is comfortable with the predictability of the future economic losses and the capped capacity of the $250,000.

So I think it's been proven empirically to reduce rates, it's been proven empirically to move cases faster. Of course, it has a downside. It has a downside in that you're putting limitations on recovery.

We have put limitations on tort recovery for years. In Workers' Compensation we've put limitations on recovery. You know, there comes a time when society has to say enough is enough and we're going to put limitations on recoveries.

Because when you look at an injured patient and you say how much is enough, right now we're relying on juries and subsequently Appellate Divisions to control that, which has been ever-increasing for the last 30 years at astronomical proportions. As I told you earlier, it wasn't that long ago, four or five years ago, six, where a neurologically impaired sustained verdict for an infant would be $4 million or $5 million. Now it's $8 million or $9 million, and higher than that.

So I think caps on pain and suffering have a synergistic effect on moving a case faster, making it predictable, getting it settled. It does have a limitation because it does preclude a higher damage award in certain circumstances. But I think it's something that needs to be discussed.

BIENSTOCK: Is it partly because there's no objective measure to pain and suffering that you're able to set a cap on it or that you'd need a cap on it? Because unlike a lost arm, there's just no way to really measure the value of pain and suffering.

AMSLER: The difficulty with it is it's extremely amorphous and it's in the eye of the beholder.

And so much of it depends upon the plaintiff and how they can express that to a jury. I mean many plaintiff's attorneys have told me that their plaintiff is very stoic even though they have pain and suffering, but they can't express that to a jury, so therefore the award is diminished.

On the other hand, you see plaintiffs who are not as stoic and can express it to the jury very well, and their awards are much higher. Whereas, internally, those people may be suffering the same amount of pain and suffering.

So the eye of the beholder here is the jury. It's how they behold the pain and suffering and what their life experiences have meant to that. So by putting an objective standard or at least an objective limitation on it, you've eliminated that aspect.

CLARK: The trouble is that an objective limitation is not really objective. What it's doing is arbitrarily saying that everybody in the world has a maximum of $250,000 in pain and suffering. And over and over again I see cases where somebody is disastrously injured.

I represented a woman who's now a physician who has to—every night she has to take out a prosthesis in her mouth that covers half her upper jaw. When she eats, food comes out of her nose because she doesn't have the upper jaw.

She has no financial losses; she's probably making a million dollars a year. But to compensate her for the pain and suffering that she has every day of her life, every hour of every day of her life, $250,000 is an insult. And to give her the same thing that you would give to somebody who has an elbow that doesn't work as well as a newborn's is unfair.

You're discriminating against the people who are really injured for the sake of some financial consideration of some corporation that insures the doctors.

WALTMAN: Whenever we have these conversations, there are always the examples that make you uncomfortable. And I respect that. There is of course always the very responsible plaintiff's attorney who only brings meritorious cases or the case that seems to make the case for why there should not be a cap on pain and suffering.

But we must go back to the fact that we need to undertake a balancing of competing priorities in discussions about health care costs. Therefore, if you able, through a cap on pain and suffering for example, reduce 24 to 25 percent of the costs of medical malpractice coverage and there is a commitment to put those savings back into better quality care or broader health care coverage, I think it merits a very serious conversation.

Unfortunately, what typically happens, depending on the mix of party affiliations and livelihoods, is that the conversation just stops. Ed commented that there are 30 states with caps, and then you have all of these other states where you cannot even have a conversation about them.

In the end, I think we should be focusing on the broader considerations of the costs of the current medical malpractice system and better ways to apply those monies toward reducing adverse outcomes.

VII. Disclosure of Physician Conflicts of Interest

CLARK: And this is my final point. I think that there would be an interim solution that would not be all-curative, but if doctors were required, as they are required to give informed consent to their patient, if one of the items that they had to tell the patient about is that "this facility that I'm sending you to, this ambulatory surgical care, happens to be owned by my wife," it would discourage the doctor from having his own facility, and it would also discourage him in sending every procedure to his wife's facility.

So I think if there were required disclosure of conflicts of interest, it would cost nobody anything to do it. All it would take is the doctor would say, "It happens that I own 1/100th of this facility, and I'm telling you about it, you can make your choice whether to go there or not or stick with me as a physician," and have the patient sign off on it. And then maybe allow that to be a subject of cross-examination if malpractice subsequently occurs and the allegation is the doctor did an unnecessary procedure that injured the patient.

I think the disclosure of conflicts of interest will result in a lot fewer procedures that are unnecessary. And I think it's paradoxical that if the doctors are not compensated, they will probably work less and practice better medicine.

I also thought that early settlement is a way to contain medical expenses. In the beginning of my career, I worked for a law firm that defended cases for two different insurance companies. One of them would seek out the plaintiffs at the earliest stages, as soon as they knew what the case was about, and settle the case. The other insurance company would take everything to verdict. And the first insurance company, to my observation, was paying about 50 percent of what the other one was, because they got rid of the cases in a hurry.

And I think it's incumbent upon—and I think it's happening that we are starting to settle cases more early with the mediation process—that when the insurance company and the physicians realize that they've got a case of liability, mediation is initiated. And we all know that we want to settle the case, the plaintiff wants to settle the case, and cases are disposed of and medical costs are reduced.

BIENSTOCK: My sense is there's a consensus that if we can move the settlement process more quickly, both plaintiffs and defendants would benefit. That there are—I

wouldn't want to call it wasted costs in the system, because I don't want to criticize anyone, but there are costs that we could save in the system by moving up, you know, the settlements. And there are various proposals that have been built around that.

And, you know, neither side is eager to give anything, so it's hard to come up with a solution that doesn't disadvantage one side or the other. But I think everyone's agreed on let's settle these things earlier rather than later; it saves money. And I think that's a very valuable contribution.

AMSLER: I don't disagree with that at all.

WALTMAN: Many of the hospitals with which I work subscribe to that approach and have undertaken a number of initiatives to encourage early resolutions, including, as indicated, training people to provide full disclosures, meaningful apologies, and early offers of compensation. It's of course the right thing to do and it also has a favorable cost impact for the provider and the system. Many are also doing a more aggressive job of managing and moving claims more quickly.

I refer back to some of the tools that can facilitate the decision-making or resolution process, such as expert depositions. While I don't want to begin that conversation again, hospitals will say they sometimes need more information to make decisions regarding settlement offers. But they all are trying to identify ways to manage claims better, ensure fair payments, and reduce their costs.

AMSLER: One of the struggles you have is the—I guess the category is "I'm sorry" legislation. Most states that have "I'm sorry" legislation have immunity attached to it. So it lets the provider—the hospital, the nurse, the physician, whomever—come in and express remorse, apology, sympathy, empathy, *et cetera*, and be immune from that coming out at the time of trial.

If you do it without that, there's going to be a natural reluctance on the part of a potential defendant to have these discussions.

And I agree that early settlement is certainly indicated. One of the problems you have is just a basic—with HIPAA, with all the problems you have getting records, you have some basic hurdles to overcome: multiple codefendants, getting all the records, getting analysis, getting experts. These things take some time. And in fairness to both parties, they do take time.

The plaintiff has some time, assuming the statute of limitations isn't at issue, they have some time to do their investigation. The defendants and the insurance carrier both sit down when the first notice, the summons, is served, and then you've got to start your process of evaluating it. It's a difficult process of evaluating, to get all the records, etc.

But once you do that, I agree with Bruce when he says that mediation is effective. When we have experienced plaintiff's counsel and we have control of the defense and it's a case that we want to settle and we can sit down with an experienced mediator, we have had great results getting cases settled. Because it loses the posture of very high demands, very low offers. We get into a room with experienced plaintiff's counsel, where they understand the value, we understand the value of the case, and these cases get moved.

And we've done that without any legislation, without any regulation. We've done that on our own by cooperation among plaintiff's counsel, by some very effective mediators, and cooperation from insurers.

VIII. Concluding Remarks

WALTMAN: Marty, as you know from the State's Medical Malpractice Task Force meetings, I always started and I guess ended with the statement that the most important thing we can do as providers is to provide safe care and reduce adverse outcomes. I don't want to lose track of the responsibility that we, as providers, have. We are working hard to do that and are very cognizant of the areas on which we need to concentrate.

At the same time, our current system for resolving disputes is unreasonably costly, and the nation is looking very hard at how to reduce the cost of health care.

Therefore, we need to do what we can to try to improve the dispute resolution process and to reduce the costs of the system. That means that everyone needs to step back from the predictable political positions that we take. In the end, the health care system and our patients should be the focus, and we need to be open to changing the rules and the system for the benefit of all of us.

AMSLER: I just wanted to say, from my perspective, we're dealing with the physician / patient relationship. And that's a one-on-one relationship that society has always recognized.

And the whole issue of malpractice and professional liability is an issue which has come between those two people, the physician and the patient, and it's got an ever-increasing presence in that relationship—everything from money, to reimbursement, to discussion, to discourse between the two of them, to the treatment that's rendered. And we've got to do our best to minimize that, to minimize its presence in that relationship, the inherent

sense of fault, the inherent sense of somebody doing something to someone as we exist in this increasing litigious climate.

And anything that we can do, whether it's mediation, whether it's mandatory arbitration, whether it's "I'm sorry" and immunity, things that will bring the physician / patient back to a relationship of trust and confidence—as opposed to one in an adversarial position which is driven not only financially but by impediments to that relationship—I think it will serve the bar well, and I think it will serve the physicians and the patients well.

CLARK: I agree with Susan and Ed that our primary concern should be the welfare of the patients and to encourage the best medical practice that is possible.

Malpractice is a very small element of the cost of medical care, maybe 1 percent overall. One of the problems is that when doctors have the profit motive, that comes between them and the patient more than anything else. And in jurisdictions where they do not have malpractice anymore, the profit motive is causing the doctors to do procedures that are unnecessary, to practice what has been called defensive medicine and blamed on us as attorneys, but we're finding that defensive medicine turns out to be profitable medicine.

And ultimately, hopefully, the whole medical system is going to be revamped where doctors do not have a financial incentive to treat the patient but only to do the right thing and that the facilities will be made available for them to do the right thing. I think one of the biggest things is for doctors to not be private practitioners but to be members of corporations, where they're getting paid by capitation rather than by what they do, paid per patient that they treat, encouraged to treat the patient at the earliest level, to do preventive medicine, prevent the cancers while they're still coming out of the smokestack, to diagnose early before the costs of medical care escalate and when the things can be treated most effectively, as opposed to at the end when the patient is riddled with cancer and they get a quarter of a million dollars' worth of radiation that probably isn't going to do them any good.

So what we've got to do is structure medical practice so that the patient's interests are paramount and that there are not influences such as the doctor's profitability that enter into it.

BIENSTOCK: I thought one interesting facet that kept reappearing was the difference between looking at this from an individual perspective—doctor, patient, treatment, duty, breach, damages—and looking at this from a social perspective: what are our hospitals about, who's bearing the ultimate costs of this, is there a more efficient way of bearing these costs.

And those are, I think, conflicting ways of looking at this that get you to very different results. And I'm not sure that that's something that's easily resolved.

If you're a patient who's been victimized, you want a certain type of result to come out, you want to be paid for your damages. And you're entitled to be, from that perspective.

From a social perspective, it really doesn't make that much sense that two neurologically impaired infants—one who might have suffered from some element of malpractice, and one who didn't—will be treated very differently through our compensation system.

So two different ways of looking at it produce two very different results, and I'm not sure they can be resolved. But I think we did a lot to flesh out those issues and some of the others.

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A Conversation About Fraud and Abuse

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June 3, 2009

KORNREICH: This is the New York State Bar Association Health Law Section discussion which we intend to include in the New York State Bar Association *Health Law Journal*.

I understand everybody works for the Government and you don't represent the Government and you're not authorized to speak on behalf of the Government—.

SHEEHAN: I am.

KORNREICH: Oh, you are?

KORNREICH: Most importantly, I think the purpose is to have a free discussion and people should not be concerned because, as I promise you, nothing—and on the record, as saying that—nothing will be published if people don't want it published, so we should relax in that regard. There's a further opportunity for review.

Okay. Rebecca, why don't you start, at least just explaining who you are, etc.

MARTIN: Sure. I'm Rebecca Martin. I'm the Health Care Fraud Coordinator in the United States Attorney's Office of the Southern District of New York.

CENAWOOD: Sean Cenawood. I'm the ACE Coordinator, Affirmative Civil Enforcement Coordinator, for the United States Attorney's Office, Southern District of New York, and prior to that I held Becky's position as Health Care Fraud Coordinator.

SHEEHAN: Jim Sheehan. I'm the Medicaid Inspector General for the State of New York.

THOMAS: I'm Mark Thomas with the Wilson Elser law firm in Albany.

SMITH: I'm Marcia Smith and I'm a partner at Iseman, Cunningham, Riester & Hyde, which has offices in Albany and Poughkeepsie. I'm also an officer of the Health Law Section, and former Chair of the Fraud and Abuse Committee of the Health Law Section.

KORNREICH: I'm Ed Kornreich, Chair of the Health Law Section of the New York State Bar Association, incoming Chair. I think my term begins July 1. Heidi Wendel will join us.

We sent around a list of possible questions. They're really intended as a starting point for discussion. OMIG is gracious enough to give us a work plan which is very, very helpful and, of course, the OIG on the Federal side has a work plan. You don't get that, obviously, from the Department of Justice or any of the United States Attorneys' Offices of which I'm aware, and for obvious reasons.

But if you could, Sean or Rebecca, what are your enforcement priorities at this time? Do you have enforcement priorities given the bulk of False Claims Act cases, you know, that are overwhelming you, I suspect, but just curious.

CENAWOOD: Well, unlike OMIG or HHS-OIG, we don't really set out an agenda in terms of setting enforcement priorities. It's more along the lines of what

the investigative agencies bring to us, but in terms of the cases we have and in terms of deciding which cases we wish to pursue, probably the number one priority that we're always looking at is the quality of care. So if there's potential for patient harm or some adverse impact upon the quality of care, those cases obviously rise to the very top of the list of our priorities and those are the ones that we would devote the most resources to.

THOMAS: Excuse me, do you find the quality-of-care cases tend to be brought as false claim *qui tams*? Is there any pattern there?

CENAWOOD: I don't know if there's a pattern there, but we certainly have False Claims Act *qui tam* cases that come in that implicate quality of care and those are the cases that we immediately devote resources to and because they're *qui tam* cases sometimes we look into it and it turns out that the claims are unfounded or perhaps not what is alleged after we've done some looking at it, and so that case might not stay at the top of the priority list. But if in fact we find that there are serious issues about quality of care, then that case is going to get resources and a lot of priority.

KORNREICH: And have you had a number of those quality cases so far because I'm not just—I'm not familiar with—I mean I'd like Rebecca—.

CENAWOOD: I'd like Becky to respond to that, but during my time as Health Care Fraud Coordinator they were not frequent, but when they do come in they're the sort of case that gets your attention because people's health is at issue.

MARTIN: Yes. Without going into specific cases, there are certain types of cases, for instance, pharmaceutical cases, that definitely hold the possibility for quality-of-care issues or patient harm just speaking very generally; there might also be a case where there's a criminal component. There might be a clinic out there that is doing, you know, it's not even a borderline, it's really a criminal enterprise, administering various therapies to people and that should not be happening. In that kind of case, a joint criminal/civil effort will go on there and those cases are obviously of real concern in terms of patient harm.

Sometimes also in addition to patient harm there'll be issues where the conduct is so egregious that even if someone's health is not immediately at stake, but the conduct itself is so fraudulent, such as billed services that are simply not being rendered at all, and those are the things that rise to the top of our pile.

CENAWOOD: And it doesn't happen often but in terms of enforcement priorities, there are occasions when we'll get nationwide initiatives out of DOJ in D.C. that we're directed to follow up. Generally, that's not how our office pursues cases.

KORNREICH: For the record, Heidi Wendel has joined us.

WENDEL: Hi.

KORNREICH: What is your title? I know you run the MFCU. Are you the director?

WENDEL: Well, my title is Special Deputy Attorney General and Director of the Medicaid Fraud Control Unit. So it's like twofold.

KORNREICH: We were just discussing enforcement priorities, and you mentioned, Sean, an issue I'm going to come back to, which is DOJ's involvement. We don't necessarily understand that process. When DOJ's involved on a national issue, what is their role vis-à-vis the local office?

CENAWOOD: Generally speaking, when DOJ has one of these initiatives, they provide us with information, often through data mining and then we're tasked with investigating it as we would any other case that comes in. Since these are priorities that are set at a national level, the cases have somewhat greater oversight from DOJ in D.C. because they're doing this nationwide and they're trying to establish a certain uniformity across the nation.

KORNREICH: And if a provider presents a case, who makes the ultimate decision as to whether to settle, whether the investigation should continue, whether the case should settle, and if so, you know, what would be a reasonable settlement? Who makes that judgment?

CENAWOOD: It depends on the type of case. The sort of cases you're talking about where there's a nationwide initiative, the ultimate authority would likely be DOJ in D.C., but that would be informed by whatever recommendation our Office is making.

With respect to other cases, it depends. Some cases are delegated to our Office and we've got the final say; other cases are monitored and DOJ has the ultimate say. But the cases are always a collaborative effort. We keep DOJ in the loop and, generally speaking, we're usually in agreement on the proper course of action to take, so it's rare that we're at loggerheads.

KORNREICH: Thanks. So we were just talking about enforcement priorities and curious as to MFCU's priorities.

WENDEL: Well, we've talked about this before a little bit. Our chief enforcement priority is always quality of care. And, as you know, a good half of our jurisdiction is patient abuse and neglect and that's always our top

priority and we get calls pretty much—a couple calls a week at least of, you know, situations that you'd characterize as an emergency in some board-and-care facility in the state and we immediately go and investigate it and a significant percentage of those lead either to a longer investigation or a case, a prosecution that we bring, and a lot of those cases go to trial.

And as you—I don't know how closely you follow our trials, but it can—it's an uphill battle downstate with these patient abuse cases, so a lot of our resources are spent taking patient abuse cases and neglect cases to trial. We are subject to a lot of push-back from the courts and juries on prosecuting especially lower-level people in the health care system, which to us is as important as going after high-level people because we want these people to be excluded from health care.

You know, it's not that we're trying to persecute poorly paid workers by any stretch, but we feel that they ought to be excluded and they're dangerous to elderly and vulnerable people, so that's—that's half of our resources easily.

And then our next enforcement priority would be industry-wide fraud problems like, in our view, the problem in home health and that usually comes about when an industry is well, for starters, large. That—I mean I would put certain types of hospital cases that we've done in the same category, although more recently they haven't been as big a priority, but I mean we want to pursue cases that will bring more money back to taxpayers, frauds that will bring more money back to taxpayers and frauds where we think it's very important that the provider be excluded and those are our priorities within the fraud area and so we try to make—we try not to just focus on single entities but put more of our resources in industry-wide types of problems.

SHEEHAN: How many cases do you have, roughly?

THOMAS: Have they been piling in and piling in?

WENDEL: Oh, yeah. Well, but we had a lot of cases even before the False Claims Act because through NAMFCU we're involved in pretty much—through our national organization we're involved in pretty much any global False Claims Act case. And what's happened what the False Claims Act I think did for us is bring in more local cases, so we've had—we've had a couple dozen cases that are just New York oriented.

SMITH: I was going to ask Heidi about the issue of trying to get what you perceive to be bad actors out of the health care system; it seems to me, filing a criminal action is like throwing a nuclear bomb. Is there another remedy, another way to achieve your goal, such as taking away their license? Licensing is the only thing I can think of off the top of my head where you could accomplish that goal but not have to bring a full criminal case against these individuals. I don't have any of these cases. I'm speaking from a policy standpoint.

WENDEL: Well, of course, I mean I—we are not actually the entity that excludes anybody from Medicaid. That's Jim's office's jurisdiction and so when I say that we—our priority is going after people that ought to be removed from the system that could be civil or criminal, that doesn't mean that we necessarily take something criminally but we want to pursue the worst actors. It's really—that's really just another way of saying we want to pursue the worst actors. Then we hand over the case to the Office of the Medicaid Inspector General and they do whatever's appropriate, which often is exclusion.

If someone has done something, you know, that's really bad for health care, they usually get excluded. It's just—but that's not our decision. Were you saying that in certain situations a criminal action might be too harsh a sanction and we should proceed civilly, or are you talking about some kind of administrative mechanism?

SMITH: Yes, administrative.

WENDEL: If we get a case that we think should be pursued administratively, we hand it back to the Office of the Medicaid Inspector General. That's pursuant to our MOU with them. There's a procedure for that. We meet with them once a month. We'll go through things. If it doesn't seem to be a case that's appropriate for us, we hand it back to them. If we do an investigation and it appears that it should be treated administratively, and that happens sometimes, during our monthly meeting we'll address that with Mike Little or I'll pick up the phone and call Jim. Whatever other mechanisms are in place are followed and we give the case back. It happens—it happens not infrequently, actually.

KORNREICH: I know your office and Jim's office have been recruiting heavily. Did you get additional staff when the False Claims Act was adopted?

WENDEL: Yes. Yes, we did. Well, Andrew Cuomo has made a big emphasis on increasing the civil staff, in particular, so that they could handle False Claims Act cases. Obviously a small percentage of False Claims Act cases go criminally, but we already had people who specialized in that through the Special Projects Unit but, yes, we added a lot of civil staff.

Unfortunately recently, as you're probably aware, we have not been doing a lot of hiring. I mean with the State budget crisis—.

KORNREICH: No, I was not aware.

WENDEL: I don't know if Jim's office is still hiring but, you know, pretty much the State budget problems have—.

KORNREICH: Will you be negatively impacted by the inability to hire the staff that you believe you need?

WENDEL: You know, we just have to be more efficient. There are—I can't think of a single case that has gone unstaffed because we're not able to hire. Luckily Medicaid Fraud is such a great place to work. We don't lose many people. I mean I don't know if you noticed that you see the same auditors year after year. We were just—we're just about to lose the first auditor, I think; maybe it's the second auditor we've lost since I got to the Bureau, in two years.

I mean it's amazing. Most of our audit and investigative staff make a career out of the Bureau and—which is why I think we have the best auditing staff anyplace in the country probably.

KORNREICH: So the OMIG's efforts at poaching staff have been a massive failure.

SHEEHAN: I think it's because they have more money.

THOMAS: Oh, they have more money.

SHEEHAN: And they don't have Civil Service restrictions like we do. And you don't have a union either, right? Do you have unions in the Attorney General's Office?

WENDEL: I don't know about the Attorney General's Office, but our bureau, no.

SHEEHAN: No. Okay.

WENDEL: I think they're all—.

KORNREICH: You have all those things?

SHEEHAN: There are benefits, each of those things, but they do make the flexibility to hire and promote more difficult than I suspect that Heidi has.

WENDEL: He's been recruiting actively to try to poach our staff but not successfully.

KORNREICH: I'm sorry to keep you federal guys out of this, but there's one more question which is the famed "F-SHRP Targets" and these $600 million, I think it is, in 2012 or something like that?

SHEEHAN: 646, but—.

KORNREICH: 646? I can't count that high. So do you think those numbers are attainable?

SHEEHAN: Let's go back a couple of steps on the F-SHRP situation because last year the goal was 212 and, of course, the numbers that count, it's identified recoveries by both—by all the agencies who were involved in the recovery effort and that includes Heidi's office. It includes the Office of the Medicaid Inspector General. It includes some other agencies from time to time who do the recoveries. Last year the total for New York State for all those agencies was over $550 million.

Now the reality, I think, is that there's a lot of—in 2005 there was remarkably little effort in New York State on Medicaid recovery according to the *New York Times* and according to the CMS oversight group that looked at it. And so a lot of the work that we're doing now is going back to '03, '04, '05, '06 and making recoveries from the conduct that occurred in those years.

Our goal at OMIG is to reach a stage where our audits produce zero results because people are doing the right thing, right? That's unlike the Litigation Office. If in fact we find out they're doing the right thing that's a good result and what we suspect is by 2012, not just because of the enforcement and recovery efforts but also because of the implementation of the mandatory compliance programs, the whistle-blower provisions and mandated disclosure of overpayments that you're gonna see the industry as a whole is a lot more compliant than it was when our efforts started in 2007.

So will we make that 646 goal in 2012? I think it's going to be very difficult and it'll be very difficult for good reasons; that is, there's much more compliance in place than there was.

When you ask what are we gonna do about that, I don't know the answer to that question. I think we can demonstrate that our error rate is way down and that the reason we're not collecting money is because fraud has been reduced. That's a compelling argument and it's an argument we'll have to make.

THOMAS: Does the 550 include—we've had a recent report that said you [to Ms. Wendel] brought in something like 220, I believe?

WENDEL: Well, in 2008, 263.

THOMAS: Okay. Does the 550 include that?

SHEEHAN: The 550 includes the AG's recoveries.

MARTIN: How much of the 260 and the 550 are civil and how much criminal—how much is criminal restitution?

SHEEHAN: I'd say most of it's administrative and so—by far the largest chunk is administrative.

SMITH: Does New York get credit for having recovered more than the target so that we can count the total amount or is it year by year?

SHEEHAN: Every year is a new year so if you—whatever you did last year, thank you very much. Did you meet your goals this year? That's the question.

THOMAS: Does the whole 550 count towards the F-SHRP tally?

SHEEHAN: Yes. It's F-SHRP qualified. In our numbers we try to identify the FSHRP—the recoveries that are F-SHRP-able.

SHEEHAN: And there are other things we do. We do cost-of-witness activities, so we prevent money from going out on the front end and we're also working on identifying sentinel events, sentinel effects where you pick a certain category and see if you can reduce claims and improve the quality of the claims that come in and see how that works, but those—the sentinel effects and the avoidances are not calculated for purposes of FSHRP. We have a separate thing for that.

THOMAS: Under the FSHRP criteria, are all recoveries considered fraud?

SHEEHAN: No, it has to be—it has to fit under the category of fraud and abuse, all right? And an improper payment is considered for these purposes. They were not submitted in accordance with the rules and we do an audit and we find out that the claim should not have been submitted or they're not entitled to payment and yet they submitted the claim and they got the payment. That counts for purposes of FSHRP.

THOMAS: Okay. So it's really not an intent-based—.

SHEEHAN: It's not a moral judgment. It's a, you know, should this have been paid and under what circumstances?

KORNREICH: Which brings us to the issue of the FSHRP targets, of course, in providers' minds raise the fear that the agencies will be too aggressive and in a desperate effort to get that money will make cases that shouldn't be brought. How do you protect against that kind of excess zeal?

WENDEL: I mean it actually would not affect the Attorney General's Office at all. I can represent that Jim has never called me and said, "Get more money. How much money are you getting? Why can't you get more?"

I mean it's not our burden, it would be totally inappropriate, I think, for it to be the prosecutor's office's burden to bring in money and it isn't our burden and we never think about it. It's not our problem. It's OMIG's problem. We report the money over and that's all we do.

Of course we want to make sure our recoveries are as high as possible. You know, for taxpayers that's very important and that's an important part of what we do, but that's not a guide. It's—except to the extent that I was discussing before, that we think in civil cases our resources are best spent pulling in, going after larger frauds, because they obviously affect the system a lot more, they affect taxpayers more, they presumably affect more people or are at least a larger fraud.

Except for that aspect of it, we don't—it's not like we feel under this enormous pressure to meet the FSHRP goals. It's not something that we have to contend with at all.

KORNREICH: Jim, do you have—.

SHEEHAN: Okay. Let's walk through a couple of the issues that your question raises. I interviewed for this job and was offered it and then I got this package that says "FSHRP." "Oh, by the way, you gotta pull in X, one-point-something billion dollars over the next four years." I said: "Okay. What did we do last year? $137 million. Okay. What's the best the State has ever done?" I think it may have been 300 or 350. So it was a tall order.

But I don't think you can run the office saying we're gonna maximize the revenue. And you can't do it because you can't have State employees who believe that's the goal. You can't have providers—if providers think your only goal is to take money out of them, then you're not gonna get the compliance and the—the compliance with the audit process and the compliance instructions that you would need otherwise.

You've gotta have legitimacy in order to make it work and what we've done is to identify those kind of legitimacy issues so that we are transparent in the areas we go after, so that's why we have a 70-page audit plan that says here's what we're gonna look for. If you're a compliance officer you can sit down, read the work plan, and have a very good idea of what things you need to address up front.

We are distributing audit protocols for specific industries, so we started with the pharmacy and home health and we're gonna move on to other things. Our goal is to make sure when our auditors come out you have a pretty good idea what they're looking for and you have a pretty good idea how to make it right, and so that piece I think is important to retain your legitimacy in terms of process and it's important to communicate on a regular basis with the providers what we're doing, why we're doing it, how we calculate it, how the process works, sort of soup to nuts.

The second part of the issue with respect to FSHRP is I came in and I would have done this anyway, but I said up front: "Okay, let's look at where audits are. Where are we doing audits and investigations?" And they were very heavily weighted toward what I'll call the traditional law enforcement type reviews, so it was the little guys: The pharmacies, the ambulettes, the transportation players, the dentists. Which, you know, make headlines in the *New York Times* but they are a relatively small portion of the total Medicaid budget.

I said: Okay. Tell us what we're doin' on managed care, hospitals, home health and on personal care, because these are the—these plus nursing homes are the big hit areas, the big dollar areas, in the Medicaid program, and I got answers that amazed me. What have we done on personal care because the program's been up and running for five years? Nothing. Why aren't we doing anything in personal care? It's billions of dollars. Well, we were told we should stay away from it. It's a jobs program for New York City. All right.

We said—I said what about hospitals? Well, we haven't done hospitals. Well, how come? Well, they're—the percentage of hospital patients, Medicaid hospital patients, is relatively low compared to nursing homes. I said, yes, but at the end of the day it's still $7 billion and if we're not looking at it, we have a problem.

Managed care. We weren't—we were doing relatively little in managed care so we're ramping up efforts there, but I think whether or not there was an FSHRP goal, you gotta focus your resources on the areas that have the significant spending.

THOMAS: Could I ask a question? Maybe this goes back really to your first question, Ed.

How much attention are you (Mr. Cenawood and Ms. Martin) devoting these days to Medicaid issues and maybe a secondary question is how do you work with your colleagues in the State on Medicaid issues? Or are there really so many Medicare cases you just don't have the resources?

Ever since the Deficit Reduction Act of '05, you know, if you read the words it sounds like the entire apparatus of the Federal Government is devoted now to Medicaid issues—.

SHEEHAN: You've been reading my speeches.

CENAWOOD: We definitely look at Medicaid issues and how we deal with them often is a function of how we get the case, so if we get a *qui tam* and it's been filed as a False Claims Act, and simultaneously as a New York State False Claims Act, we're obviously working jointly with someone in Heidi's office from the very beginning.

If the case comes in as an investigation from HHS-OIG, we might not be working directly with Heidi's office until later in the process. By the same token, Heidi's office is working on tons of Medicaid cases that we might not be aware of until they've gotten up to speed, but we do our best to coordinate and as much as we can we try to coordinate our resources and try not to duplicate resources because there's only so much investigative resources to go around, so if we can share the burden we try to do that.

KORNREICH: Recently a client got for the first time a subpoena from Heidi's office in the MFCU and a litigation hold letter from the Southern District, which is something we had not seen before and I think it's an example of the kind of coordination that you're talking about. Just it was unusual; I've never seen simultaneous letters, one a subpoena and one a letter, from the Federal and State governments.

CENAWOOD: I understand. Oftentimes it's a function of investigations being on slightly different tracks because we'll be looking at slightly different things. There's obviously a lot of overlap, but there's times when we're looking at something in addition and often Heidi's office has other avenues for redress that may not be available to the Federal Government that they can also look at that we wouldn't be looking at because we can't recover under those avenues. So though there's a lot of overlap, sometimes there's some divergence and sometimes the investigations aren't working lockstep. That may be what's occurring in that particular case.

WENDEL: By the way, just to address what you said, Mark, about the—all the fuss that's being made about Medicaid—the new money that's been poured into it, I think like $125 million—nothing that came to my attention. So as of yet that's not affected us in a big way.

SMITH: I had a question. I know, Jim, that you are very transparent and that's very important and appreciated, and when auditors come we certainly can't say that we didn't know what was coming and when it was coming and what the rules were. I think they are pretty fair. But my concern is that when you apply the rules you're going to come up with an unfair result, an inequitable result, where you have enormous recoveries for what are essentially minor documentary issues. There's no issue regarding quality of care, there's no question the services were provided, but yet OMIG is going to take back one million dollars worth of revenue because you didn't document a progress note every five days.

And there's no question OMIG is legally entitled to do it. It seems like very easy pickings, and that's the impression that I'm getting, is the auditors are saying: This is easy pickings. I'm going to go in. I'm going to do this audit. I'm going to take the money back and there isn't really anyone looking at: Okay. How is this impacting the community served by this provider. Is anybody doing that? I just want some assurances that someone, somewhere, is considering those issues and making an assessment as to whether a particular recovery will result in a provider going out of business and, if so, it won't affect quality of care or patient access to care.

So can you speak to that?

SHEEHAN: Well, you got two separate issues. The first issue is what is a Medicaid provider who's basically a participant in an insurance program, what do they have to do in order to get paid by the Medicaid program? And there are a series of prerequisites, and we don't make them up, right? They're set forth in the statute, the State plan, and the regulations.

And, you know, you've done health care for a long time, too, and if it's not documented it didn't happen. The Feds have done that with the PATH project and we have the same rule. And when they say, well, what about, you know, really something happened here but we just didn't write it down.

But the problem is we have to, under our guidelines, we have to audit to what the regulation says you're supposed to do. And telling us three years after the fact that we really did render a service to that person who was in the continuing day treatment program, even though there's not a single note in the file to show what it is, just is not gonna cut it.

So I think, you know, you're right. But the key is to say: Here's what the regulations require. Here's what you have to do to get paid. You didn't do it. Well, we're trying to ameliorate that by saying: Here's what you have to do. Make sure that your systems are designed so that that stuff is there and I think we're gonna see, too, with electronic records, a lot of its going to be built in in ways it's not now, so that's the first issue.

I'm not going to apologize for saying if the regulation says you've got to do it, you've got to do it.

The second piece is: Okay. Now we have a result and the result says Provider X owes a million dollars and Provider X has a net worth of $300,000 and is necessary in the community. At that point we have to sit down and say—first we go to DOH where the—if it's mental health, the Mental Health Office, and we say: Okay. What is the—what is gonna happen? What is gonna happen here if we collect the full amount of the money and in some cases—and sure it's the provider is gonna go out of business. Then we try to work out a payment plan that is appropriate.

Part of the difficulty with that is our friends at the Federal Government, once we identify recovery in an audit, we have the obligation to pay them back 50 percent within 60 days, so we're basically eating the delay in the repayments or the nonpayments 100 cents on the dollar at the State level.

But even though that's true we are very careful to have a process once the audit is issued. There are a series of steps, the provider has to provide financial information that we have a chance to look at and ask for more and say where are we in the process.

So we're trying to combine the two goals. One is program integrity on the front end by saying here's what you have to do, and the second goal is making sure the communities don't lose significant providers that are required by looking at the ability to pay and what the information is on that.

THOMAS: Could I ask a follow-up on that, Jim, because I'm sure you hear about this issue and I'm sure you have over the years, as well.

Have there been efforts in the past, either at the Federal level or currently on the State level, to look at criteria, if you will. Let's say it's the filing of a signature was required by regulation within a certain time frame and you find with a provider that it's maybe five, six percent of time, just guessing, that those signatures are late. So you conceivably might say there's a pattern there.

But regardless of that, if the signature is late it tends to appear that the investigation just ends there. You didn't comply with the regulation and so therefore everything that the payment—everything that's claimed following that late signature is considered invalid and just shouldn't be paid for.

And I guess there are two parts. Have there been efforts by recovery agencies to think about whether that, number one, is necessary. I don't know that there's a rule that says a regulatory programmatic violation equals the obligation to pay back, first of all.

But secondly, pay back—the question is how much should be paid back?

SHEEHAN: Okay. So let's walk—there's like—once again, you have four questions embedded in this. Regulation says you must have a physician order to get

a prescription filled, okay, or to get a drug dispensed, including over-the-counter.

No physician order, meaning no order from the physician, no payment, and you know, we can argue about whether these are good rules, but they make sense. I think the rules are pretty clear that that's what you have to do.

The second thing that we do in New York is we give the power of the pen to physicians and, you know, not just for things like drugs, but for physical therapy, for all kinds of follow-up care, home care and so forth.

So the theory of the statute, the plan, the regulations is that a physician is supervising and guiding all this activity. Now there are weaknesses in that analysis, but the problem is once you dispense with the physician's signature requirements providers can do pretty much whatever they want.

And one can argue that they've done that in the past anyway. The difficulty to me is I recognize that two, three and four days, most of our audits are done on a sampling basis and if we look at a sample of a hundred and there's one we can have a discussion about—or two—a discussion about whether that's appropriately representative of the universe and we do have those discussions.

When you get to 10 and 15 and 20 out of the hundred then the control that is supposed to be there by the physician's signature no longer exists and the system builds in a tension between the physician who's authorizing the services, who's putting their name down, and the provider who's gonna get paid when the services are provided.

And that tension we're conscious of. Remember, this is not a moral judgment. This is an insurance program. You want to get paid, here are the five steps you have to follow.

THOMAS: Do you think it runs the risk that if you look closely virtually every claim could be recovered?

KORNREICH: Yeah. Well, let me comment before we go deeper and deeper on that. At least part of the problem is a distinction in the regulation. I think it's 515.2 that says you must comply with the payment regulations. And Jim says as a condition of payment you must comply with all of the rules and regulations applicable to the provider.

And to Mark's point, there is not a provider out there, certainly not a large, sophisticated provider, that renders thousands of services on a given day that can in fact be in compliance 100 percent of the time with every rule and regulation.

So the question really is: What is the implied materiality? In other words, there has to be an implication that the noncompliance is material to the right to payment.

SHEEHAN: There doesn't have to be. The way the regulations are drafted, in fact, it says if it's a condition, you know, if it's required by the rules in order to get paid, it's required by the rules in order to get paid.

KORNREICH: Right. I think it says anything that's required by the rules—in order to get paid, which is worse, unfortunately.

THOMAS: And you think that means fully, all or nothing.

SHEEHAN: Generally the answer is yes, and there are specific situations in which we made exceptions, but generally the—.

KORNREICH: That's—but that's my question. For providers that's the thing that strikes them as being the most arbitrary and unfair.

SHEEHAN: But think how else do we do this, okay? Apart from the fact that CMS is looking over our shoulder every 30 seconds and saying—and the qui tam Bar and so forth and saying why did you let that happen, but the larger issue is remember the audits as they stand now are audits of documents with some questioning of the people on the scene, and if we find a false document now we have a possible criminal referral, but most of these are audited documents.

And again, you know, we can argue—there are situations, for example, in clinics, right, and the issue is in your licensing application, what did you do five years ago; but there are more concrete issues which is when you—when the patient is treated you have to have a progress note and it has to include the following elements. There are patients out there being treated and being billed for five days a week and the progress note is a Xerox.

KORNREICH: Right. Of course, those are the cases where that's material, no question about it, but what if in fact the opposite occurs. You go and you look and you see—generally see excellent care, you see an effort at compliance, and in fact substantial compliance, but in fact there is a treatment plan that was not updated, you know, done within two weeks and then updated within four weeks or whatever it might be, so you've got those kinds of issues when you do it's not as if you're looking at the place saying this is a pretty good shop. Gee, the care is first rate. Instead, it's oh, gee, look at this, they didn't do a treatment plan. That's the concern.

SHEEHAN: And I think what you'll see is that when we go in and we take the first 20 cases and we find zero

mistakes in the first 20. We have the discretion, we've exercised it frequently, to terminate that audit at that point. And what we are looking for is organizations that have significant—and we can argue about what "significant" means—significant error rates in the billing submission and they are remarkably easy to find—.

KORNREICH: What kind of ballpark? And I'm not trying to get a commitment from you. It's not—.

SHEEHAN: I know that we have guidelines in-house and I think it's a relatively small number, but it's greater than one. The problem is you're telling auditors we have a work plan and we're telling the outside world we're gonna audit the work plan. We say here we come; this is what you should expect. It doesn't seem unreasonable to say get the stuff right.

KORNREICH: No, no. I think all of us—well, I shouldn't say all of us, but it seems to me that there—the question really is what is the remedy in that context and how do you treat it in a way that makes sense?

SHEEHAN: Okay. Well, let's go back. The reality is you have a discussion and when you're doing sampling you look at the stuff that's in the sample and the lawyer's argument for the auditee is that's not representative, although it showed up, it's an aberration. That's not representative of our work; it's not representative of our outcomes. And that's a sample that you should use auditors' judgment to throw out the sample and we've heard those arguments and we've responded to them.

You know, in appropriate circumstances we've followed the recommendation.

KORNREICH: You then do another sample at that point?

SHEEHAN: Now you're allowed, as I understand the audit rules, you're allowed to say—you're allowed to say that this particular one is sufficiently an aberration that we're gonna throw that case out of the sample, just work with all we've got left.

KORNREICH: Oh, that individual case. I see.

SHEEHAN: Right.

KORNREICH: Gotta try that some time.

THOMAS: On the Federal level has there been any discussion about the kind of all-or-nothing when it comes to a recovery? I mean it sounds like while there may be some discretion it's a mighty narrow—.

SHEEHAN: But remember, before you get to the US Attorney's Office in this, remember their job and to a large degree Heidi's job, is the moral culpability issue; that is, bad people doing bad things.

WENDEL: We would never get a case that's just missing a couple signatures unless—.

MARTIN: They are all IG, you know, they stay in the IG process. You know, whether it's HHS-OIG or OMIG, we just don't get those. By the time we get the, the rates of error are high and—.

KORNREICH: Sean, then you do get them in the false claims context where—.

CENAWOOD: Well, that's—.

KORNREICH: —your argument is that it's exactly—your argument is you're certifying compliance on your cost report, certifying compliance to Medicare rules and regulations and you violated—you didn't do the—.

CENAWOOD: I think the argument that the provider would make would be they may be false, but there wasn't a knowing violation and that would be their defense and we would have a discussion about—I mean if the error rate is particularly high, then you're—at the very least you're reckless or there's a deliberate ignorance of what's going on, so those are the sorts of discussions you have when the error rate reaches a certain level. But if we're talking about sort of a *de minimis* level, we've got a couple of things wrong here or there, folks can come in and make that argument that even if it was technically false it certainly wasn't knowing, you can't make out a False Claims Act claim against us—.

KORNREICH: Right, but I think you get—the point being if you have a large enough violation, the question is knowledge. In what way didn't I comply with rules and regulations? You don't know that you're out of compliance and I think what I'm hearing, Sean, is if there's a big enough record, if the evidence shows that in 75 percent of your psych bills you didn't do a treatment plan in two weeks, then the argument would be you knew or should have known when you said you comply that you don't.

The issue which is what happens if you actually know that you're in violation of some obscure New York City regulation that you've been meaning to get at but you haven't done your local Law 10 work in a timely manner so now you know there's a violation.

I'm just throwing this out as an absurd hypothetical, but where the law takes us is if you know that you haven't complied with Local Law 10 work and you sign that Medicare certification, you essentially can be excluded from the program, sent to jail and be subject to all sorts of very, very substantial financial liability.

So it's just the way it is, I mean it sort of—and all of this comes back to the same point which is what's so

frustrating for providers—for counsel to providers, is this idea that there's no materiality on regulatory compliance for purposes of reimbursement denials or even false claim liability.

SHEEHAN: I bet when you draft the first draft you want to leave that out.

KORNREICH: If it's immaterial, it's immaterial. Nobody's going to care.

That's the struggle. Rebecca, you were going to say—.

MARTIN: There's been two types of materiality, I think, that are sort of winding their way through your example. I mean there's materiality in terms of how big is the error rate and is it something that someone should have been on notice of essentially. You can't put your head in the sand, essentially.

I think that's one kind of materiality you're talking about, and for at least—.

KORNREICH: That's the kind that I believe is actually in the False Claims Act context.

MARTIN: That's what I'm referring to as the scienter. And then there's another materiality which I think you're referring to: If I am technically out of compliance with an obscure New York City ordinance, does that somehow affect my Medicare cost report when I'm certifying that I'm in compliance and I think that's a different kind of materiality, the kind that goes to whether it would have an effect on whether you're going to be paid by the agency, and those are two very different kinds of things.

And I'm not really answering your question but I just want to clarify some of the issues that are, I think, getting a little mixed here.

KORNREICH: Right.

WENDEL: That's kind of an issue, that second point.

KORNREICH: Yeah, right. It's a condition of payment, condition of participation or a condition of payment, which is actually what Jim was pointing to earlier, and I think that's the problem, is in an implied certification context. To get very specific about it, I think it's clear that you get into the condition of participation versus the condition of payment issue. In an express certification context you're expressly certifying and the payment is based on that certification, I don't know that there is much debate if you know it's wrong. The scienter comes in when you don't know that you're in violation and then the materiality of the violation goes to whether you should have known.

But when you do know, I'm not sure that technically there is an out for an express certification case, not an implied certification case where you have the condition of payment versus the condition of participation.

WENDEL: But have there—do you have a case in mind where anybody's—.

KORNREICH: No.

WENDEL: —been prosecuted for something like that? Or even covered as an overpayment?

KORNREICH: Well, I think that for providers—no, I have no case where—involving local or some similarly obscure provision.

WENDEL: Yes.

KORNREICH: No. The question for providers is, you know, they will argue that most of the—many of the regulatory violations at issue are not material and what I'm struggling for is a sense, some help in understanding where that line gets drawn and, you're right, I have not seen any ridiculous cases from anyone in this room, so I would say that at the outset, nothing like that.

But the providers' perspective, the definition of "ridiculous," you know, is so different.

And they would love to have the same rules apply as would apply to an insurance payer as to when the failure to meet rules and standards resulted in denial of the claim, because it doesn't routinely result in the denial of a claim.

SHEEHAN: In Managed Care they said even when they submit valid claims with all the bells and whistles they still aren't getting paid on a regular basis.

KORNREICH: Right. That's a whole different issue we can take up when we get to—.

KORNREICH: Anyway, it sounds like—I think what I'm hearing is you don't bring frivolous cases. You know it when you see it. There is no—but there is no formal or informal materiality standard.

MARTIN: Well, the False Claims Act has been amended and it does—it talks about materiality. I haven't really parsed through it but—.

The amended FCA provides for a natural tendency test—whether it [a false statement] would have a natural tendency to affect payments or the decision—I don't know exactly how it's phrased—but the new amendment may answer your question directly.

SHEEHAN: Can I come back to your issue because I think one of the issues that sort of amazes me in New

York is how few prosecutions have been for kickbacks. I mean especially seeing how many that I sense are out there in the world. It's remarkable how few kickback cases have been brought and if you look at the case law in other jurisdictions in the last year, there's a case from Cincinnati about the cardiac station, access to cardiac stations being a kickback and what's gonna drive the train on that is not the people around this table saying: Gosh, let's go out and look at assignment of cardiac stations.

What's gonna drive that is whistleblowers coming in and saying: Here's what the statute says. Here's what the certification is. They certify compliance with all Medicare and Medicaid laws, rules, regulations and ideas, and the next step is the kickback, is a piece, some documents, okay, off to the races.

And one of the things about the False Claims Act that's significant and even apart from what the Government does, the private party still has the right to proceed with the case and so the prosecutor is in a difficult position. You're not gonna move to dismiss the case for the most part. Are you gonna stay in the case and try to see what—control what happens? Are you gonna say, no, you know, this rule doesn't apply?

So if I were sitting on the defense side, the kickback area is to me a very significant one for lawyers advising their clients about what that certification means and the courts, the Cincinnati court, held that it's material. That representation about kickbacks is material to payments.

WENDEL: We brought a large kickback case here in New York in the last year against a bunch of hospitals—involving the detox—with the Eastern District actually.

THOMAS: Oh, the Eastern District. I would just like for a moment to acknowledge that Marcia threw us a real benign question that stimulated conversation for like 20 minutes, so if you have any more, don't be bashful, please.

SMITH: The one question that I had, and it was on the compliance with the regulations, I haven't done the research that Ed and Mark have done on the Medicaid side but I had a Medicare matter years ago, and my recollection is that Medicare applies a substantial compliance standard, so how did New York get to the point where you have to do everything all the time? Why not a substantial compliance standard? How did we get here?

SHEEHAN: Where was I—where did the substantial compliance standard come from? That's not a—that's not a rule that I'm familiar with in the—.

SMITH: On the Medicare side?

SHEEHAN: False Claims are on Medicaid, yeah.

SMITH: But it's—it comes about through the Joint Commission certifying compliance and it's many years since I did the research but the Joint Commission does the accreditation survey to determine whether or not a provider is in substantial compliance with Medicare conditions of participation, so it's a very similar situation.

SHEEHAN: (Continuing)—the State defers to that—.

But the question is: So if your committee didn't meet for one month, your patient safety committee or your credentialing committee didn't meet for one month and Joint Commission doesn't flag that, you're right. I think your deemed status counts as opposed to whether you created false documents to convince them it was that way.

But I—that's the conditions of participation versus conditions of payments discussion that comes up in these cases all the time.

KORNREICH: Yeah. The problem is, though, Marcia, it wasn't all that many years ago. The certification is new. I don't know whether you remember—Jim, you remember, you must remember when—.

SHEEHAN: I think it was '99 or '98.

KORNREICH: Maybe it was. I was going to say five years. It's amazing how quickly—but it's not that old and the certification had the effect in that case to lead the Court to say—to sort of read conditions of participation into conditions of payment through the certification, which is what's so troubling again to providers.

Can I speak to one other question, which is a tremendous concern to providers, too, which is the Statute of Limitations issues, the reach-back. It is still routine to have False Claims Act cases and investigations relate back to the mid-nineties, even today.

And at what point is there an end, and it's an issue because there are so many different mechanisms to rehash things that one would have thought had passed.

SHEEHAN: New amendments that were made effective on May 22nd, don't they allow the reach-back from—and for us. I thought once the case is filed—.

SHEEHAN: (Continuing)—the statute from the time it is under seal which was in dispute.

CENAWOOD: In the 2nd Circuit it was under *Cosens*.

SHEEHAN: So that's been—in fact, your problem is worse now than it was before May 21st.

KORNREICH: Well, there is all this idea about retaining overpayments.

SHEEHAN: Oh, yes. Yes.

CENAWOOD: That is one of the significant amendments that went through and it's the—it's just the notion, I guess, of what they call the reverse false claims, and you're right that there is—the language does denote an expansion and currently under the amended version you can be on the hook for knowingly concealing or knowingly improperly avoiding or decreasing an obligation to pay the Government, and obligation now is defined to include retention of an overpayment.

So, yes, that could be a very broad expansion and, whether or not the Government takes the most aggressive view of that, chances are there is relator's counsel out there that will—.

KORNREICH: —and there are a lot of issues that come up about that—I come to you now and tell you that something took place 40 years ago, the first days of Medicare and, what you did is outrageous and now, you know, you got this information and you don't do anything with it. Are you liable and does it in fact open up unlimited retrospective liability? I don't believe it could. I don't think it would be consti…. I'm not sure it would be constitutional. It might, it might not, I don't know but I'm just—.

CENAWOOD: I actually don't think so. I mean the standard statute of limitations that was always out there applies, and at least before *Cosens* we always thought that we had the benefit of relating back to the *qui tam* complaints, so you got the usual six-year statute of limitations and I guess timing does become important in terms of this retention of overpayment because what's knowing and improperly retaining an overpayment?

If you retain an overpayment for a couple of weeks and you discover the mistake and you immediately alert the agency, that's probably not an improper retention of it, but if it's ongoing and recurs and a long time passes, then maybe you are potentially on the hook for retaining overpayments, but it has a potential for being a significant expansion of the False Claims Act.

WENDEL: But I think the way it would come up, which I don't think anyone could argue is unjust, would be in the context of when you're looking at a hospital cost report and they're carrying forward from year to year, say, a sum of money that is asterisked as "owed to the State" or "owed back to Medicare" and nobody's caught it, but it's clear on the cost report.

You must have seen cost reports like this. It's actually annotated this money is owed back to the State, but it's never paid back and nobody ever claims it from the State or the Feds and so it's—and it's carried forward from year to year. You'd have to agree that would be—I'd think that would be the kind of situation where maybe this new provision would be invoked and the Government would say:

Look, there's an admission in your cost report you owe money back and it's a siz . . . it's a big chunk of change and it should have been paid back. Your auditors looked at this year after year and, you know, just because no one ever pursued you for the money, you basically never took it out of the—put it in assets, took it out of liabilities. You just carried it forward year after year.

You've seen—I'm sure have seen that a number of times. I certainly have. It's very offensive as a taxpayer to look at that and know that that institution well knew that money was owed back. It says—in there and the statutes run on it.

KORNREICH: Well, in fairness, Heidi, in most of those cases it's also well-known to the agencies, to the regulatory agencies. The only—you'd know—they know about it.

WENDEL: Not on an ICR. Who would have looked at it? Maybe Empire or if there—where there's a fiscal intermediary, in the case of the Medicare cost report, but in the Medicaid cost report no one is—no one necessarily would ever have looked at it. I—believe me, I've seen it happen—.

I wouldn't say lots, but there—I've seen a number of glaring instances of these marks on the ICRs that say "we owe this money back to the State" and it never gets paid back. It just gets carried over in liabilities year after year.

KORNREICH: That's a little bit unusual from what I've seen, but I know there are situations where the State is knowledgeable about an issue and doesn't pursue it and whether it's prosecutorial discretion, an agency determination in managing—.

KORNREICH:—particular reimbursement systems to structure it in certain ways. Those things do happen—.

KORNREICH: If you're doing that and you have to pay it back, no one can complain and nobody would complain in that context. The issue is whether it's a false claim and they would have to pay double or triple damages, you know, as a result of it where it's been fully, openly disclosed.

SHEEHAN: Let's go over—I'm sorry. Go ahead.

KORNREICH: No, go ahead.

SHEEHAN: There's a second set of issues, though, in addition to the False Claim question which has the scienter piece again, and New York State starting on

July 1st, every health care provider who gets more than a half million dollars from the State is going to be required to have an effective compliance program with eight elements. And one of those elements is when you identify an overpayment, you pay it back to the State, so that option which may have existed in the past to carry forward year after year, if you know it's the State's money you have an obligation to pay it back.

THOMAS: Can I ask—this brings up a more general issue that I think has come up both on the Federal level, I know on the State level with your office (to Mr. Sheehan), and I believe with your office as well (to Ms. Wendel), and that is with respect to providers' experiences with other agencies of government, and in some cases it's the behavior or the lack of behavior or the practices, whatever you want to call it, of local governments; we have all the counties and city HRA kind of administering things on their own, as well as other statewide agencies that either provide advice or approve of things or direct that things happen and they are not in compliance with the regulations. But the regulated party then is put in an odd position of essentially either being beholden to a local government or following something that a State agency has directed and yet, at least in some instances, now seems is held liable. It doesn't seem to be that the investigations are looking at the other agencies, the local governments, but it's "you got paid and this wasn't right." End of story. And that is, I know, a frustrating issue for providers and I'd just like to hear: What should providers do or what do you think about the topic, what should providers do—?

SHEEHAN: Let me try to take a shot at this because we see this on a regular basis and people keep pulling out letters from former Counsel of Department of Health which no one has seen before.

THOMAS: We all saw it.

SHEEHAN: I know you all saw it, waiting for us to show up at the door. Anyway, again it's the system is a system of statute plan, regulation, guidance, and one of the issues for our purpose is, what is the nature of—there's obviously a—under administrative procedure rules, where it is a definitive expression by the agency which has the authority to interpret the statute and in which it's expert, we are, I think, obligated to give a large amount of deference to that interpretation as something that's ambiguous, all right? So if it could be interpreted either way and the agency with responsibility for it said this is how we interpret it, for the most part that's the end of the story. But there are two other situations that we've seen in New York on a frequent basis. The one is: Don't ask us for a definitive statement on this because you may not like what you get, all right? That's the discussion between the oversight agency and the agencies out there doing—the private clients out there doing what they do, and that, to me, is an at-risk—.

THOMAS: I don't quite understand what you're saying.

SHEEHAN: Okay. Somebody calls up and says what is the—we want to look at—we interpret the regulation this way.

Can you give us an opinion that says that's okay?

SHEEHAN: And the agency says we're not gonna express that opinion because if we did express an opinion you won't like what you hear.

THOMAS: Okay.

SHEEHAN: Okay. The second one is, you know, and I give probably 60 presentations a year and at the end of each presentation there are 10 people who have questions they come up with and say—and I try to be careful but you're, you know, you don't always know all the context and certainly I'm more cynical than many people in State agencies, so they get asked the question in the abstract and then it sort of (inaudible) press it's circulated and interpreted from hand to hand to hand so by the time it gets to agency number six it means something very different from the informal conversation. So what I think providers should do is if there's an interpretation that's important to their program, they ought to confirm it in writing to the agency they got it from—and—because we will circle back when we do our audits and say: Okay. What guidance has the agency issued and show it to us and, for example, in the case you and I both know we did that—.

SHEEHAN: —and it had not been disclosed internally.

THOMAS: And that's very reasonable and I think that's a compliance—.

A message for us to take to our clients and which shouldn't be a new message but is one worth emphasizing.

I guess the question is, looking back, and it isn't often and it isn't necessarily an interpretation. It's simply a practice or—.

KORNREICH: That's what I was getting to. In many instances regulatory agencies over a long period of time develop relationships with—.

SHEEHAN: We call it capture.

SHEEHAN: The scholars in this area call it that and especially in the State where you have people who are, you know, who are two years away from retirement and

regulating communities, that the amount of transition from State agencies to the regulated entities is substantial.

KORNREICH: You mean the flow of personnel?

SHEEHAN: Yeah.

KORNREICH: Yes, I think that's honestly, I think that's—.

SHEEHAN: It's not just New York, it's Pennsylvania—.

KORNREICH: There is an element of capture which I accept, which—but you look at it negatively, it's not necessarily negative in the sense—let me look at hospitals and the Department of Health, all right?

They have to manage a system that is broken and we can get into how it got broken or why it's broken, but there's no question it's a broken system. You have, you know, the New York State hospitals don't have any money. They are broke. There's just—and I shouldn't just say all of them. You know, a third of them are doing okay, a third are marginal and a third are desperate and, therefore, the Department is trying to manage that system.

And the concern that we get into is whether in the course of that management there are practices reached or priorities established or understandings that may or may not be formalized in an official memo or in a letter but which really are critical to the day-to-day operation of the provider and I think the biggest problem we have in those instances where there is either—there is agency guidance. It's not formal but it's longstanding and accepted and widespread.

SHEEHAN: And I guess, Ed, obviously these are really—they're detailed determinations in every case. My concern is, you know, obviously there are guidances which are public and—.

CENAWOOD: I apologize. I have to take off, but I'll leave you in the hands of Becky, who's way smarter than I am. Thanks a lot.

SHEEHAN: The difficulty that I have is with the informal guidance that was never written down. Several. One is the Medicaid program which is a grant program with conditions, but the second part of this is: One of the things which we try to do in the program is we try to treat all people the same, similarly situated people equally, and to do that, at least it seems to me, you need things in writing. You can't say my lobbyist spoke to somebody in private health six months ago and she said it was okay and Albany is full of people whose job it is to have those conversations.

KORNREICH: Right. We're not talking on that level.

SHEEHAN: No, but except the gradations are not that great. There's a whole body of people whose job it is to say, please give a special favor to my hospital or my category of hospitals and, please, we'll have the conversation and then we'll go on and do what we want to do, and that's one of the reasons there's an Inspector General is because those informal alliances and agreements create significant weaknesses in the program.

THOMAS: I'll bring up an example that I don't think touches home to any of us but it's something that was brought to my attention about four years ago by a hospital. Apparently some agency, some agency of government—I don't even recall which level—said to the hospital, you're not reporting to the National Practitioner Data Bank.

And they said, yes, we are; and, no, you're not; yes, we are. And the counsel for the hospital called me and said, I'm reading these regulations and these regulations say we're supposed to report this to the State Health Department and that's what the regulation says.

THOMAS: I said, yeah, but it doesn't work that way anymore. You report directly to the data bank. He said, well, where is it written down?

SHEEHAN: Isn't there a federal statute to that effect?

THOMAS: No, sir, there is a guidebook that was issued and widespread education, et cetera, et cetera, et cetera, and that's the way everybody does it, and he said, so, are we in compliance or are we out of compliance? Of course, that's what you get with an in-house lawyer, you know? I said I don't know what to tell you.

KORNREICH: Ask Jim.

THOMAS: You know, I actually contacted the person in the regulatory agency and I said am I—I'm missing something here and I got an answer back basically saying, well, the regulations say what they say but this is what we do and it's in this guidebook. Everybody follows it.

MARTIN: Now that's not a case that we would take.

SMITH: Can we talk about the standard for when you know you have an overpayment? I think that would be helpful, especially under the new Federal False Claim Act changes because—for example, our—my approach has always been that you know you have an overpayment only when you don't have a good-faith basis or a good argument that you were entitled to keep the money and that may not fly with anybody around the table, the regulators, like Heidi, your example of the cost report, I've had that. I've given advice on that and it's never—I've never seen it blatantly with my clients that they knew. It's that they weren't sure and they're

waiting for somebody to tell them. So I think it is going to become important to have some kind of standard about when you know that the money should come back. There are certainly regulations and guidance and there's interpretations and you know OMIG would say the money has to come back if they audited, but that doesn't necessarily mean they're right. There're other arguments to be made. Do you have to do whatever OMIG has said or MFCU or whatever?

SHEEHAN: I will tell you when I see on a balance sheet due to third parties, what I think is that means due to Medicaid because we're the ultimate last third party.

And I'd be very careful as an attorney advising clients that have a good-faith legal argument because that client is gonna turn around and say, well, yeah, there's a hundred million dollars on our balance sheet, but she told us that it was okay if there was a good- faith legal argument to do it. My concern for a lawyer in that circumstance is you don't know all the details of what the client knows about how they got the payment. You know, we see these where you look in the records of the provider and they got two checks and they know they got two checks. Now they don't tell you they got two checks on the same day for the same service and they don't tell you that they zero-balanced the first payer and the claim of the second. I mean that's something as an attorney I'll be extremely cautious about advising clients that it's okay if they have a good-faith argument without a fair amount of investigations in the background. Now it seems to me that the default rule should be if you have other people's money and a reasonable interpretation that you either ought to do an investigation to find out if you do or pay the money back.

WENDEL: Or at least alert the government—.

SMITH: Yeah.

WENDEL: —that you're retaining this money and it needs to be discussed, whether or not it's owed back. You're holding it as a liability. Maybe you've been holding it as a liability for three years. Maybe your accountant—what I was describing is an instance where your accountant on their work papers has a little asterisk saying, "We owe the money, this money is owed back, but you're continuing to retain it." That type of situation, I mean, just bring it forward to the State.

THOMAS: I wonder if the safer practice now is for a provider in all honesty to contact your office [to Mr. Sheehan], your office [to Ms. Wendel], or the OIG because we find that we handle—as Ed said, we have found countless times where the provider has notified the State, the money hasn't been paid back because the State can't figure out a mechanism—.

WENDEL: You know, Mark—but then the benefit of the doubt always goes to the provider. I—in fact, we have a case right now where we had a provider ask us whether or not something, whether they'd been overpaid for something, because they had just been alerted to a certain interpretation of the regulations—and we've spent nearly a year discussing this with the provider, with DOH, and trying to hash it out and I think ultimately with this provider we—we're going—we probably will reach a position that the regulation is sufficiently ambiguous in terms of its interpretation and this is something that we have—we've spent weeks discussing with DOH. We don't take it lightly. Believe me, if there's an ambiguity either in how something's been enforced or how it's been interpreted or either of those areas that would create any kind of unfairness in terms of taking money back, and it would never be addressed as anything but an overpayment, of course. It would never be considered obviously fraud in that context. But the benefit of the doubt goes to the provider under those circumstances, at least on our side, and I—I mean—.

SHEEHAN: When they've come forward.

WENDEL: Yes, exactly. When they've come forward. This provider came forward and said: Look, we may be retaining money that isn't owed to us because we didn't realize that this regulation was interpreted in such-and-such manner. We just learned it—and we might be holding a couple million dollars that belong to the State and at the end of the day they're probably going to get to retain the money.

KORNREICH: You seem more willing to give deference in this context than when the provider comes to you, well, not to you. Comes to DOH and says I'm not telling you about an overpayment on that reg but I want you to tell me in advance. I'm going to do X; is it okay?

KORNREICH: And the State gets back and says X is—DOH when I say the State—DOH gets back and says X is okay. You know, we're okay with that, and then they go ahead and do X and that raises the issue you spoke about earlier about—in your questioning, about whether that's appropriate.

SHEEHAN: Okay. So let's walk—because they're two different situations. Let me tell you my institutional interest first. We wanna make sure the providers have effective compliance programs. One of the elements of an effective compliance program is that you come forward with overpayments and report them, but I also know that the person in a large organization that advocates giving money back to the Government is in a difficult position.

KORNREICH: Less so today than ten years ago.

SHEEHAN: Yeah, but it's still—.

KORNREICH: Yeah.

SHEEHAN: —pay money to the Government not a popular position, whether it's outside counsel or inside counsel or the compliance officer.

So I want to give those people the benefit of the doubt and the support that they're gonna get, that they're gonna get more than a fair shake with the disclosure that they make, and that's why we wanna make sure that we have it all—we have it right. But the second piece, and I've been in litigation regulation for a long time. I'll tell you a story. We were doing a laboratory case back in the '90s and the issue was: Could you unbundle certain kinds of lab charges and so right—defense counsel, here's what they did. It was a national case, so they figured out the worst Medicare carriers and the dumbest people in those carriers and they sent out three associates to make phone calls, all right, and said is it okay to do this.

And it's a Friday afternoon, like at 4:30. And they had to read a script and they said is this okay to do. Two of the three said yes.

All right? There is a certain find-the-dumbest-program opportunity out there and it's not just find the dumbest, but it's also how the question is phrased and anticipation. They—we need to look at the facts and find out what's going on.

THOMAS: Yes, and I think that the two sides of this discussion is—from the provider side is that there appears that Government decisions, and I don't—in many times it's not a decision about a policy. It's simply a practice. There doesn't seem to be much accountability demanded of the Government when those things, from your perspective, turn out to be ill-advised and are then the basis of—we had an example, and this is not a specific case because it's not going to happen, of a situation of a new payment system for I'll just say out-patient care. And the computer system—.

WENDEL: I think I know who it is.

THOMAS: Well, the computer system—.

THOMAS: No, this is a real case.

WENDEL: I'm only kidding you, Mark.

THOMAS: I think we've headed it off. It had to do with people getting treatments on different days.

And the system for paying that apparently only could function if the claim were submitted saying all these things were provided on the originating date.

SHEEHAN: Right.

THOMAS: And I was told that, you know, that was checked and that was just fine. I said, no, it's not just fine because that's a False Claim if I ever saw one. Now that was something that was driven by the regulatory agency and the provider community thought it was okay.

SHEEHAN: But here's what we would expect in that situation.

THOMAS: Yeah.

SHEEHAN: You're being told to put it on the same day when in fact they're different days?

THOMAS: Yeah.

SHEEHAN: That's advice that should be documented—.

THOMAS: Yeah.

SHEEHAN: —and relayed back to the agency that gave it because—.

THOMAS: It's in their training materials.

SHEEHAN: I know the issue we're talking about here but in that—there if you come back with a letter that says I sent this letter back to the State agency and here's what the advice I was given and I confirmed it, that's a situation where I agree with you. We shouldn't take the money back.

THOMAS: Okay.

MARTIN: And we think—.

THOMAS: And once again, the lesson for us is to advise our clients when you're given advice that seems a little cockeyed—.

SHEEHAN: Confirm it in writing.

THOMAS: Confirm it in writing.

MARTIN: Or even if it doesn't seem cockeyed, I mean, but that is the kind of defense that we've—you know, that we've had brought back to us and it's, you know, we look at it. We take it seriously. We kick the tires. I mean it's a very real issue.

THOMAS: And I think for us we see how many countless times where the clients have said but I talked to so-and-so.

WENDEL: But, you know, also I think you were also making a broader point in a way—that the Government is allowed to make mistakes and you guys aren't.

THOMAS: That's good.

WENDEL: But that's really sort of—we actually are very sensitive to that. In situations like where if we have brought a case against a provider, for example, and this often happens in the case of hospitals who have disallowance actions going with the State and some of their money is being held, and I know that the State doesn't generally pay interest. If it loses on a disallowance case and pays the money over to the hospital there's no interest paid. When we have situations like that where a hospital's involved in a situation like that or any provider, we won't charge interest because we won't charge interest on the debt owed to the State on the ground that, well, they didn't get interest back on the money they had that was being held by the State, it turns out improperly, or however you want to characterize that situation where the provider actually wins the action. I mean we try to take into account the whole context of the provider and do actual justice and not skewer the provider at every opportunity.

THOMAS: Yeah.

WENDEL: You know, both in the ability to pay context, but then also just in that small—perhaps smaller little corner of the world where we have some control over what interest rate is charged and, you know, I think you'd be in agreement with this, Jim, right? Where there's, say, even a larger sum of money is being—has been held within the exact same time period from a provider, it wouldn't really be fair for the State then to charge interest to the provider on money that we—that the State had withheld out. So I mean in those small ways we can at least be sensitive to what's—what would be—what's fair to the provider vis-à-vis the Government or State.

THOMAS: Yeah, yeah.

WENDEL: You know?

KORNREICH: Marcia, do you have a comment? You were struggling before to get a comment in.

SMITH: Thank you. I wanted to follow up on this disclosure of overpayments. What if you're dealing with a case that hasn't made it to your balance sheet, which is probably a little easier to see? If it's made it to your balance sheet you probably don't have a good faith basis, but we do audits all the time. What if you aren't sure what you did was in compliance or not? Are you saying that the only way that we can advise our clients that they can be sure that they're not submitting false claims is to go to a government agency and get their blessing that what they have done is okay? Is that the only way to do it? I mean it seems pretty—.

SHEEHAN: Let's go back a step. I think that there's—that this is an order-of-magnitude issue here. So you've got $20 million on your balance sheet and it says "owed to third parties." That's one situation. If you've got two claims and they haven't shown up anywhere yet except you got the checks, that's in there, so it's the hundred bucks, for a different picture. And I don't think anybody in this room is gonna be focused on the hundred dollars.

KORNREICH: No. I think the issue Marcia is getting at is the recklessness standard as applied to overpayments because it's the same standard. It's a knowledge standard which is defined to include recklessness so at what—and it's the same—.

SMITH: I'm asked all the time to advise whether a particular practice is in compliance and, if so, whether that's an overpayment, and if so—if it's an overpayment, do you have to return that to the Government. And, again, the approach we have taken is if you have a good-faith basis—if you have an argument that you met the requirements, then you are entitled to keep the money. That is the approach that we have used and maybe that's wrong but—or maybe you guys don't agree with that.

WENDEL: That's pretty risky. I think that's a pretty risky approach, personally.

SMITH: What approach should we take? What is the alternative to that? I heard go to the Government. That seems a little burdensome. What else—what other strategies are there?

SHEEHAN: Well, here's your option and I see these—what used to be called $30,000 Washington law firm letters which are probably now $100,000 law firm letters—that say, assuming the moon is made of green cheese and assuming that everyone is left-handed in America, then this is okay. So here are the facts you presented me, clients—.

SHEEHAN: It seems to me as an attorney you need to be very, very careful in those circumstances because in my experience in looking at cases, the information that comes to the attorney is much more limited than what is written in the work papers and what is written in the footnotes to the financial statements and what is discussed in the billing office about what we're gonna do here.

WENDEL: I have never seen an advice of counsel defense hold up actually in my entire career ever. There's always a problem with the assumptions, always. They're never—they never describe the actual facts, ever.

SHEEHAN: If the lawyers do their job and say here are the facts that we assumed in the case.

MARTIN: Then the lawyers are protected, not the client.

WENDEL: The client is never—it never ends up being able to rely on the defense. It falls apart.

MARTIN: They have to find the money to pay for it too.

SHEEHAN: That's right.

WENDEL: But can anybody think of a case where in the health care role the advice of counsel—.

SHEEHAN: Once you get to the point of trial you're right. I think—occasionally it is effective in negotiations at an early stage where—.

KORNREICH: But let's come back to—.

I think we're being, particularly the Government speakers, I think are being a bit glib on this point because it's actually—and I'm getting back to Marcia's point. It's—I don't think you—and maybe you are aware and maybe you're not—of just how complicated the reimbursement rules are, and in many cases you just can't—you know, you go to three different government agencies here and most of us are not in the habit when a client comes to you and says here's this issue. It's, you know—here's the issue but did we do it right? Did we do it wrong? And you look at it and you say, you know, it—and usually there's—frankly there's two ways of looking at it. You say, okay, prophylactically on a going-forward basis what should we do; historically what should we do—and it's difficult to quantify because we all agree if you're 99 percent certain, the fact that there's a 1 percent level of questioning doesn't mean you go to the Government. If, on the other hand, you think it's more likely than not that it's a problem and you don't go to the Government, I think it's gonna be hard to say: Gee, we were—we didn't have knowledge because you knew it was more likely than not and you didn't confirm. Now you get a different situation where, you know, it's up in the air, there are reasonable arguments on both sides, what do you do?

SHEEHAN: One of the things you can do in New York, there is an advisory opinion process that's contained in the Medicaid Inspector General Act. It goes to the Department of Health but it's part of the statute.

So you have the option and it's not just a kick-back opinion. It's also payment opinions. I've had—I've not seen any requests—.

WENDEL: I've never seen one of those.

THOMAS: It's been set up in DOH to do it but, yes, in fact, we've talked—.

KORNREICH: I tell clients that you have to understand the end at the beginning and if you're going to undertake an audit of past practices you are—you have to exp . . . you have to know that—.

SHEEHAN: What you'll do.

KORNREICH: And you have to basically—you have to know that if you find bad things you're going to disclose it.

SHEEHAN: Yeah.

KORNREICH: Because if you don't do that, you're making things much, much worse so, you know—but the question is when have you found bad things and if there is doubt. And I know it's easy to say go to the Government, they're your friends, and with present company excluded (laughter) there is a certain hesitancy as you'll—that's the tension that's inherent, and—I don't know what that line is except it's judgment—.

SHEEHAN: It can't be good faith, good-faith argument for keeping the money.

KORNREICH: No. No, it has to be a belief that it is—certainly a belief that it is more likely than not that this is a—. And your point is just because you have a reasonable argument or colorable argument, which is actually a bad argument—.

MARTIN: Yes.

KORNREICH: Yes, so that's a bad use of the word, but you have some argument you can make but it's a make-weight. Clearly that's a disclosure situation.

WENDEL: Well, but—and I think if your accountants have advised you that you should carry something over as a liability—.

KORNREICH: Oh, of course.

WENDEL: —year after year, you pretty much can know that your argument is not so hot and it might be best if, to cover yourself, you went to the State. If it's over a material amount, if it's, you know, whatever the materiality standard is, at least by accountant standards, and I would go much below that because that's usually not a really great test, you know, but if it's a significant chunk of change that you're holding and you're maintaining it as a liability year after year, you know, based—and the accountant has made that determination, whoever's auditing your financial statement—.

WENDEL: —has determined that, even if that person isn't also auditing your cost report and, you know, then you ought to go, if it's a significant amount of money, and ask the State what you should do.

KORNREICH: Absolutely.

WENDEL: Why not?

In deference to them, and then I don't know what—how you would advise a client in terms of what to do with the money in the meantime, but I mean I would—if I was—I think I would probably feel like if you've alerted the State and it's being discussed, that then you could—then you're not at least during that time period in trouble for it, unless you really know that it's due back.

KORNREICH: Right.

WENDEL: For sure, and you're just papering over that.

KORNREICH: But if the State—not that I know of any context in which this has occurred, but if the State were to tell you—you went to the State and the State said we know there's that issue statewide. We're not looking at it.

SHEEHAN: Who is the State for that purpose?

KORNREICH: High-level people at DOH.

SHEEHAN: You better write it down because that conversation—if you have doubts about that, that conversation is going to be very material somewhere down the road.

KORNREICH: Yeah. That is absolutely right.

MARTIN: It's possible that if you ask people in DOH about the conversation that happened seven years ago, they're gonna remember it differently than the way you remember it.

KORNREICH: That's right. I think we're about out of time. We've gone over and I do very much appreciate this. I think it's exactly—certainly what I expected, wanted, hoped for, so I appreciate it. Marcia, you have the disadvantage of not being able to interrupt, the fact that we—with the time delay. Did you have something else that you wanted to raise?

SMITH: Thank you. It was very interesting.

KORNREICH: Thanks to everyone. I really appreciate your time.

MARTIN: It was really interesting.

THOMAS: It was.

WENDEL: We should do this more often.

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A Conversation About Health Care Reform

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July 23, 2009

LYTLE: Our discussion today focuses on the impact of federal health reform on New York State. And I thought I'd start with an historical note: Today is July 23rd, 2009. When this is ultimately published, events will likely have overtaken us. Congress is still debating health reform, still hoping to make some progress before the August recess, although we seem to see increasing doubts about that. And the State is wondering what exactly it will have to do once health reform does actually get enacted sometime this year. As it happens the President had a nationally broadcast press conference last night focused primarily on health reform efforts.

So in fairness to the panelists there will be a lot that takes place between now and the point that anyone reads this transcript. But if you had to bet right now, and let me start with you Assemblyman Gottfried, do you think Congress will enact, and the President will sign, health reform in 2009?

GOTTFRIED: And you're asking me first because I know the least about it out of everyone at the table. If I were betting, I would bet that Congress will pass something that they and the President will call health reform. Whether it is something that I think is worth writing home about or qualifies as health reform I'm less prepared to bet. I have, I guess, an unfortunately low level of expectations as to what will come out of Washington.

LYTLE: David Rich, you were in Washington yesterday, so you're the expert at the table who knows exactly where the pulse of Washington is on this.

GOTTFRIED: That's right.

RICH: I would still bet that they will pass something this year and the President will sign it. Although it's much more iffy than it was a few weeks ago. And I think I agree with the chairman that they'll call it health reform, it may not be what any of us would have thought health reform should look like. Actually I'm sure it's not what some of us would think health reform should look like. But I think because of the fact that the President has signaled a lot of flexibility on a variety of things, which gives the left heartburn certainly.

But I think because he has, unlike '93 and '94, where I think the president drew some very clear lines in the sand. It's less clear to me where those lines are this time around. And so I think there are some compromises that could be had that could get them over the finish line.

But it's going to be tough. And some of the same concerns that were around in '93 and '94 about how to pay for it are what seem to be holding everything up at this point in time and keeping them from going ahead. So I would still bet yes, but I'll look at this tape again in three months.

(Laughter)

LYTLE: Do you want to go next Elisabeth Benjamin?

BENJAMIN: Okay. I don't know if there'll be health reform or not. But I think the President's right that we have to do health reform. It's unaffordable for most people to get health care, given the way premiums have been going up. For example, just in New York State, premiums have gone up ninety—seven percent since 2000, while median wages have gone up around eleven percent during that period of time. A Harvard study came out a couple of weeks ago saying roughly two-thirds of all bankruptcies are related to medical issues.

It's just untenable to go on this trajectory for the people, much less the system. And are powerful economic and system arguments about why we have to do health reform as well. So I don't know if it will happen, but I think it has to happen, and I think President Obama was right in saying that last night.

LYTLE: Melinda Dutton, you can be the pessimist.

DUTTON: Well, I actually agree that something's going to happen. Something has to happen. While there are serious

issues that are being debated, I don't think that there's a serious question that something needs to happen; that voters want something to happen.

I think the real question is whether we'll get distracted from that mandate. The longer it drags on the more likely it is that we will get distracted. So, I hope something will happen, I think something will happen. And my guess is that it'll be something that doesn't make anyone happy in the short term, and that this will continue to be something that gets debated and lobbied for a long time to come.

LYTLE: I assume all of us, in various roles, paid some attention to the last time that health reform was at the centerpiece of the agenda. How would you compare this reform debate to the efforts in the early days of the Clinton administration?

GOTTFRIED: Certainly the White House is doing it differently, starting with the fact that they did not convene a small army of a task force to draft a plan.

LYTLE: In a secure location.

BENJAMIN: Dick Cheney's still there.

(Laughter)

GOTTFRIED: And to draft an enormously complex plan. And instead they invited the Congress to either do it or work with them to do it, or to take their work product and call it their own. I'm not quite sure who did all the drafting.

I guess we'll see whether that route produces a better outcome. I think there has been a longer and perhaps deeper public discussion of the importance of health care reform than there had been in '93, '94 when the issue was a front burner political issue, but was still relatively new. Obviously the issue went back long before that, starting perhaps with Al Smith's state universal health coverage bill in 1915.

LYTLE: Which your bill is modeled on?

(Laughter)

GOTTFRIED: No, although I guess I'd have to say, that, while I have held Al Smith's bill in my hand, I've never actually read it carefully enough for me to have modeled something on it or not.

LYTLE: David, you were in Washington the last time around. What is the difference from your perspective?

RICH: I think both what Elisabeth and what the chairman said is very true. People are much farther along in thinking about health care reform and in feeling that it has to happen. And I think in '93, while people may have said we need health care reform, I think other than consumer groups I'm not sure business was quite there yet. Certainly a lot of the industry stakeholders were not.

Whereas this time around the industry stakeholders came into this debate saying they're for health care reform. Now, of course, their definition of what health care reform is and what it should include varies from industry group to industry group. But the fact that they all came to the table early and said we want to be part of this as opposed to sitting back and then pouncing and trying to defeat it, I think is a big change.

And I also think as the chairman said, the President's approach is a different one. You know how the pendulum swings to the opposite direction because you think you're going to not make the mistakes of the past. I think in some ways they've swung too far in the other direction and said, "We're just going let Congress do their thing."

And we saw some of the results of that the last few weeks when the House came out with their bill. I think if the White House had been a little bit more involved perhaps they could have avoided some of the problems that we've seen arise with the current version, at least from a political standpoint.

We actually like the bill that came out, but there are many in the House, House Democrats, who don't. And so there's some criticism of the White House almost taking too much of a hands-off position so far. I think that will probably change now though. I think they realize they have to get a handle on it. But that is certainly one of the differences, too.

So I think the public's clamoring for reform, the fact that business, employers are clamoring for reform in a way that I don't think they were in '93. And that the stakeholders are all, so far, still at the table, although they may disagree on some of the points that may be around the edges as you had said, is a big difference between now and back then.

LYTLE: Do you have a sense, Melinda, in terms of how the debates shifted?

DUTTON: I actually completely agree. I think that there's more of a mandate now than there was then. And we're more mature in our thinking about the options and there's been more experimentation at the state level. But the most important thing is the mandate. And not just among folks who don't have insurance or are going bankrupt because they don't have insurance.

I think the provider groups recognize that the health system as it is right now isn't sustainable. And everyone

knows that there will be some sort of dire consequences coming down the line because it's not sustainable. That's why folks are coming to the table and saying, well let's try to figure out how that change is going to happen. Last time it was just no change, let's just undermine and beat back and try to maintain the status quo. There are very few stakeholders who are happy with the status quo right now.

LYTLE: It seemed like a defensible position in 1992, 1993, just leave things as they are, don't mess with a reasonably good system. It's hard to imagine someone articulating that now.

BENJAMIN: And the Republicans have taken an interesting approach. They aren't saying don't do anything. They're saying, "Oh we should take time to think about this." Their whole strategic positioning sounds so reasonable, by saying we should take more time. Because they know time is on their side to do nothing. And to achieve nothing and have this be Obama's "Waterloo." So I think that is a clever strategic move on their part. And they sound eminently reasonable, this is an important thing, it's a big part of the economy, why should we rush it? I'm concerned about this posturing that's occurring right now against health reform. Because ultimately, time is not on health reform's side.

LYTLE: How would you characterize the views of the groups that have been out there looking for some sort of universal health care program?

BENJAMIN: Well, we never use the word universal.

(Laughter)

BENJAMIN: We say affordable quality health care for all. Actually, the advocacy community is not a monolith—there a number of groups working for health reform. For example, there is the single payer movement. Folks that support a single payer system are rightfully upset that this approach was taken off the table at the very beginning of the process. I think that was strategic error, actually, even for the Democrats because I think if you had had a proper airing of single payer we may not end up with single payer, but I think we would have ended up with a bill that certainly does a better job for New York, that would do more in terms of building out Medicaid and promoting the interests of safety net providers and other providers and I think that was the strategic error.

As a result, the single payer folks are organizing, they're marching, they're interrupting Congressional hearings, deflecting valuable pro-health reform energy to the question of why a single payer option was not at the political table.

The second group is a group called HCAN, it's the big national group representing consumers, organized labor, the other constituencies. And they are really pushing the public option, because they see that as a good and viable way to beat back the insurance industry, which they feel has not been serving consumers as faithfully as it might.

And then there are the AARPs, the Families USAs, and other organized advocacy groups that are being even a little more cautious. More iffy on the public option, focusing on affordability and quality and trying to bring together strange bedfellow coalitions and trying to herd all the cats so that all the folks that have real fiscal skin in the game don't extract the pound of flesh, if you will, out of the consumers. That's a quick spectrum of the advocacy world and where they're at.

LYTLE: You mentioned the risks to New York by this whole enterprise. And Dick Gottfried, you expressed concern recently, with another state legislator, over any preemptive language in the federal bill that might override state laws. What's at stake in this regard, what do we stand to lose from health care reform as a state?

GOTTFRIED: Well, New York and several other states, we're not the only one, have for many years been way out in front of anything Washington has accomplished. Whether it's on insurance, consumer and market reforms, some of the consumer protections they're talking about in Washington now we enacted in 1992, and so everybody's forgotten about them.

The federal Child Health Insurance plan was invented in the late '80s, early '90s by Minnesota. We plagiarized it from them. At least I always confessed that, that we stole it from them. And a couple of other states built on it and Congress, a few years later, adopted it as a model. Expansions of prenatal care; we in New York enacted Family Health Plus as a Medicaid expansion; Child Health Plus expansions. All these things have begun at the state level, sometimes with back-up from Washington, sometimes not.

My big fear is that when the dealing is all done, the last thing that the insurance industry and several other interest groups will say to their friends in Washington is, "Okay, fine, we agree to A, B, and C, but we don't want to now have to go back to our states and pay D, E, F and G. So pre-empt the states from doing anything." And Congress does that a lot. I would imagine in New York local governments accuse us of doing it at the state level to them. But I think there is an enormous danger that insurance reforms, public health coverage expansions, all sorts of things that we would be doing in New York, after Washington does whatever they do, will be closed off to us.

There may also be mandates in the federal legislation that will be a problem to some states, maybe less of a problem to New York. For example, in many states, expanding Medicaid eligibility levels is viewed by many governors as some horrible threat to be imposed from Washington. Happily, we in New York tend to regard those expansions as being a welcome opportunity to bring more federal money into New York to help us pay for health care.

So I think there is certainly upside potential for New York. There could be expansions in federal permitted eligibility levels for Medicaid and Medicaid expansions like Family Health Plus and Child Health Plus. But I am most afraid that at the end of the day they will preempt a lot of what New York has either done or will do in the future.

LYTLE: What do you see as the risks?

BENJAMIN: We have basically a three-prong strategy. The first issue we are concerned with is affordability. The Senate Finance Committee is proposing to terminate subsidies at 300 percent of the federal poverty level. If that went through, a family at 300 percent of poverty would be spending forty-four percent of their income on health insurance. And under the individual mandate, a family would be required to do so. Our job is to remind elected officials that if you're requiring families to purchase coverage by either fining, taxing them or throwing them in jail, to spend forty-four percent of their family income on health insurance, you're going to be out of office.

(Laughter)

BENJAMIN: That is just not workable. We really spend a lot of time talking about affordability. Either they've got to regionally adjust it, or somehow take into account the fact that New York is a high-cost state and that insurance and health care costs more here than elsewhere in the country, for lots of reasons.

The second thing we really talk about is to "do no harm." New York is a pure community-rating state. Insurance companies are not allowed to discriminate based on gender, as they do in other States, or on age, as is being proposed in the federal statute. They are suggesting that older people should spend either two or five times more than younger people. Right now, we don't allow that in New York, and we don't allow insurance companies to discriminate based on disability status either. And so we're very concerned that our community-rating law will be gutted, certainly on the age side.

LYTLE: What do you say to people who'd say if we got rid of community rating in New York—providing, just for the sake of argument, some formal subsidies for those people who would be terribly disadvantaged by that—the rates, and the premium rates for the healthy young folks, one component of the 2.5 million New Yorkers without coverage, would go down and it might make coverage more affordable?

BENJAMIN: What we say is, before passing laws that would gut community rating, why don't we do smart things as have been proposed, such as merging the direct pay market, which people claim is in a death spiral, with the small-group market. That will raise small-group market rates maybe by one percent, but it will bring down the premiums in the individual direct-pay market by a lot, as much as thirty-eight percent. So I think that there are lots of things to try before that. And I would encourage that step in New York, and that's in fact one of our top priorities for next year, assuming there's nothing else that we can push.

(Laughter)

BENJAMIN: We will be working on that.

LYTLE: That's assuming that Congress doesn't preempt New York from undertaking those steps.

BENJAMIN: And then the other thing that New York does that's sort of remarkable and is completely off the table in Washington is covering immigrants. We provide access to public coverage for every immigrant that's in the process of getting regularized and already has their green card. In CHIPRA, the reauthorization of the state's Children's Health Insurance Program, the feds actually corrected something bad which happened during the overzealous welfare reform effort. Welfare reform required people who have green cards to wait five years before the State's public insurance programs could draw down federal funds to pay for the federal share for covering those folks. We're urging the correction that happened in CHIPRA happen again in health reform. That would result in significant savings for New York. And if nothing else can happen, at least provide more funding to those seeking out institutions that really are serving the uninsured.

LYTLE: And so this approach to immigrants is for legal immigrants, not for people who are undocumented?

BENJAMIN: Well, everybody tells us that undocumented folks must be completely off the table, and that if you even start the immigration conversation, all of health reform will go down in flames. And that's what all the pollsters tell us and I don't even think it's being considered. To be honest, we obviously think it should be, and we certainly think states should have the option to do it, and maybe we could get that in. But I think that's the

most we could get in, and so that's why we urge seeking this funding.

LYTLE: Melinda, you spent a lot of your career dealing with Medicaid issues: what are the risks and opportunities presented by the federal debate from the standpoint of the state's Medicaid program?

DUTTON: Medicaid has really been a footnote in the health reform discussion at best. And Medicaid in New York is an enormous driver in our health care system, about thirty percent of our health care economy in New York, covering four million people, half of the births in New York City are paid for by Medicaid. Medicaid is an engine in New York. It's an engine in the health care system nationally, but in New York far more so than any other state, and the fact that it's really been an afterthought in the health reform discussion I think is cause for concern in New York. As Assemblyman Gottfried said, we have used Medicaid as a vehicle to expand health insurance coverage to lots of populations that other states have not.

But we've also utilized Medicaid to finance health care services in areas that, if we were not able to access this federal funding, New York would be left holding the bag. So New York has been successful and aggressive about utilizing Medicaid funds to finance a variety of safety-net needs that relate to our health care needs, such as through DSH payments and through our health care system overall. The federal reform proposals that have addressed Medicaid have been fairly modest by New York standards. I think one of the things we're going to want to keep an eye on is if we're talking about lifting the floor of Medicaid coverage a bit, is New York going to be rewarded for the fact that we're ahead of the curve or are we going to be punished? Are only states who have been less generous in their Medicaid benefits going to be rewarded?

In New York, we through Family Health Plus provide coverage up to a hundred percent of poverty. In the House bill, New York appears to be able to access a hundred percent federal reimbursement like those other states would for those populations.

LYTLE: For the increase in eligibility?

DUTTON: For the increase. That is wonderful but I think that is going to need to be protected. I would imagine that that would be vulnerable as we move forward. New York's embarked on a pretty ambitious Medicaid reform agenda over the last couple of years. People may have conflicting ideas on the details of the agenda. But I don't think there's a question that overall we've been very aggressive about treating Medicaid as a health insurance program and using Medicaid as a vehicle for improving access and quality. At the federal level, that has never been Medicaid's role.

GOTTFRIED: You know part of the problem with Medicaid in the federal debate, and it would be a problem if we were doing it in New York, is that for so many people Medicaid is, for different reasons, a dirty word. Many people think it's a dirty word because they think "it's a terrible program and you wouldn't want to make me and my family live like a poor person and get our health care through Medicaid. It's kind of like saying for the rest of your life you're going to eat the school lunch program as your diet.

And yet on the flip side many people who on the one hand regard Medicaid as a terrible program and don't make me go anywhere near it, simultaneously believe it is an excessively generous and gold plated program that we give to poor people. And they think, "Isn't it an outrage that we give such a wonderful program to the poor people, but don't make me live on it." And so, when it came time to do child health insurance, nobody said let's make Medicaid available to moderate income children. They said, well let's call it SCHIP. All of the states, I think, that have done Medicaid expansions use a different word. In New York we call it Family Health Plus. In other states it's BadgerCare and whatever.

LYTLE: Or HuskyCare.

GOTTFRIED: HuskyCare, right. God forbid you should call it Medicaid. Because then people won't want to enroll, politicians who advocated for it will get yelled at by their constituents for being in favor of Medicaid. And yet you know it is, at least in many states, a very successful public health plan.

And it provides in many states better coverage than what you can buy and does it at a lower cost. And would actually be a sensible model to build a public plan on. It's already there; you don't have to go out to the store and buy it. You don't have to invent it. But it has been—I mean what they are calling a "public option" in Washington is embarrassing and I think doomed to fail.

LYTLE: Well it's ironic: it's as if we never we had a public health insurance program before. The notion of a public plan sounds wildly bizarre and left wing and—.

GOTTFRIED: Next thing you know they're going to want the government to deliver mail.

BENJAMIN: Good public options exist for children, for example, the SCHIP programs, like New York's Child Health Plus program. The House bill actually proposes to phase that out—which is kind of amazing and has a lot of

children's advocates up in arms. There was debate when SCHIP was passed: why do we need SCHIP, we have Medicaid, shouldn't we just be building on Medicaid? Wherever you came out on that discussion, we're way down the line now, it exists. And it's quite robust and it's very popular. And so the idea that you get to keep your current coverage was part of the promise here, except if you're a child on SCHIP.

LYTLE: Is that just sort of for neatness? They say if you're going to expand Medicaid what's the point of having this sort of tag-along program?

BENJAMIN: No, it goes beyond that.

RICH: I think they say, well if everyone under a certain income level can be eligible to purchase through the exchange and get the subsidies, whether you're an adult or a child, why have something separate? But also why muck up something that works?

BENJAMIN: Right.

RICH: And also who knows what the transition would be like? Transitions are not always smooth, as you know.

LYTLE: Medicare part D went so well.

RICH: Yeah.

BENJAMIN: Well, I'm glad you brought up that transition point. I think that's one of the biggest concerns for consumer groups: what if we get federal health reform and then we're going to have this nightmare, like what happened with Part D, when Medicare's phone systems crashed. People couldn't get help, and they didn't understand what happened. So just imagine in this sort of situation in a post- reform world in which people will be required to buy health insurance suddenly. They don't know which plan to pick, they don't know how to pick it, they don't know how much they're supposed to pay, they don't know where to go: it is going to be a nightmare.

In Massachusetts, another consumer advocacy group had been fielding a thousand calls a month; suddenly after their health reform was passed, they were fielding four thousand calls a month. And so at CSS and at a bunch of other places, like California, Massachusetts, where there are these consumer assistance programs, we're really hoping that someone will wake up and realize that the exchange is just going to be another government bureaucracy and you're going to have to actually have some hand- holding and provide help in local community groups, in senior centers. Locations which can enable people to navigate this whole post reform world. Especially if the State is disenrolling a bunch of people off of a working program.

LYTLE: I want to turn to the exchange and sort of the implementation questions in a moment. But before I do that, David, from the provider's point of view, from the current health care system's point of view, looking at the proposals in Washington, it seems at least half of it is talking about cuts in current support for health care facilities. The other half is focusing on coverage expansions, but even the President's rhetoric has been evenly balanced on reducing the cost of health care. What do you see as the consequences for the existing health care system?

RICH: Well, I think a lot of the concerns we have on behalf of New York dovetail with the concerns that have been mentioned already, which include the affordability concerns. I think that the four hundred percent in the House bill is already being talked about going down to three hundred. And also how generous will the Medicaid expansions actually be when we see the Senate Finance Committee bill? It might not go as far as the House bill goes.

The issue of the covering the undocumented, even as an option, I don't think will happen. And so the issue of how much benefit to New York, and how much of a dent in the number of uninsured there really will be, is one that is a real concern.

And I think from the standpoint of our members of Congress, particularly from the suburbs, where they have wealthier constituents who feel like they're obviously going to have to pay some of the new taxes, and they feel like they already pay taxes to Albany so that we have a good Medicaid program in New York. Just to have to pay taxes so that Alabama suddenly expands the Medicaid program that is as egregiously inadequate right now and covers people at forty percent of the poverty line. That is not something they're relishing voting on.

So I think there's some concern there. Part of why we have that concern too is that, as Melinda mentioned before, DSH is an issue. "Disproportionate share hospital" payments, both on the Medicare and the Medicaid sides, are viewed as somewhat of a piggybank to pay for health care reform, which is understandable, given that some of that is supposed to be for uncompensated care. The question is how much of a dent in uncompensated care will there be? The Health and Hospitals Corporation at our meeting in Washington yesterday said that they estimate that between sixty-five and seventy percent of the uninsured that they treat every year, which is over four hundred thousand people, are undocumented. They can't know for sure because all of the difficulty you have knowing who's documented and who's not, but they feel that it's a very large percentage. And those will all

continue to be uninsured. And some of the safety net voluntary institutions would say the same, particularly in Queens and other parts of the city, where there's a large immigrant population.

So how much they cut those subsidies back is a concern. They have talked about targeting them more in the future to make sure that they go more to safety net institutions, which makes a lot of sense, and could help alleviate some of our concerns. But I think that is one of the major concerns that the provider community in New York has on the disproportionate share side.

The other concern that we have, which is a debate that is sort of raging within the hospital community, is this whole issue of geographic variation in Medicare spending and is it justified. And do you use the Dartmouth Atlas studies, which some of you are probably familiar with, which don't at all adjust for cost of living, similar to the federal poverty line, which isn't adjusted at all for cost of living. Dartmouth doesn't do that. And so they compare spending—Medicare spending for beneficiaries across the country—without adjusting for that, without adjusting for socioeconomic status, without adjusting for anything that others have said you should adjust for.

So there's this whole huge fight going in now, which has bled into what the Blue Dog Democrats are saying they want. They want redistribution of funding around the country and so that is a very big concern, as well as the new idea to allow an independent commission to set Medicare policy with very little input from the Congress. They talk about it as a "Med BRAC," sort of a Medicare base-closing commission where—.

LYTLE: Medpac on steroids.

RICH: Medpac on steroids, where they come up with Medicare payment policy and a whole package of reforms that then Congress could really just have a yay or nay vote on. And if they're smart the panel will include good and bad in there and people won't want to vote down something that has some of the good, and so we'll get the bad along with it. It would be sort of like me deciding, Dick, that it's fine to just abdicate your power as chairman of the health committee and your say over Medicaid reimbursement policy. That's actually what they're doing.

LYTLE: There are times when the Department of Health takes that position.

RICH: That's true. They would like that, I am sure. But it feels like there should be some sort of combination, where Congress still has a strong role.

GOTTFRIED: Of course, in the Medicare context, at least at the moment, that idea is perceived as being a way to cut Medicare reimbursement rates. In New York if that were the law, or if it were proposed, the executive branch would probably oppose it because it would be seen as a way of raising Medicaid rates.

RICH: So those are some of the things that are causing concern. The community knows it's going to have reductions at the very least, reductions in the rate of growth. And we all signed off on that, we said do it.

The question will be over time, though, how much deeper will they go, and the fact that the House bill is already found to not be budget neutral gives everybody a lot of heartburn.

BENJAMIN: I just wanted to say something about this whole budget-neutral thing. I mean this is something my husband says to me every single night. He's like, "I don't get it. One trillion dollars, aren't we spending three trillion dollars a year in war spending? I don't get it. One trillion over ten years to provide health care for fifty million?" And he goes, "Why are people saying that?" And I said I'm sure they polled his arguments, and sadly they go nowhere.

LYTLE: The "T" does scare people. It scares—and particularly in the context of the economy in the tank. Now that—and with all the other spending that, you know, that has appropriately been scary.

BENJAMIN: But then he gets going on the bank bailout.

GOTTFRIED: Yes, well, this is America.

(Laughter)

LYTLE: So here's the question. Health reform has now passed. It's a matter of law, things in place. I mean we don't obviously know all the ingredients as we sit here today. Let's assume these insurance exchanges, among other things, are in place. What's the state supposed to do? It's not even clear who's supposed to set these up, as I understand it. Does this require, do you think, some state legislation? How busy will you and your colleagues be, Dick? I guess it depends on whether your pre-emption goes through.

GOTTFRIED: Yes. Well, I guess it's anybody's guess as to what extent things will be set up by the federal government and to what extent states will be called upon to do things. Medicare was set up as a nationwide program; Medicaid, on the other hand, was set up to be implemented state by state. So I don't know that I'm in a position to predict that.

We'll find out. And as some people have been observing, I and many other people will probably find out half of what's in this legislation a month or two after the President signs it. Starting with: how many people know that the House bill would phase out Child Health Plus?

There will certainly be, to put it euphemistically, a lot left to be done after this legislation passes. To me the big question will be: will the states be allowed to do those undone things? If we are, I'm reasonably optimistic that at least in New York we will be prepared to do what we can to build beyond what Congress does.

And I say that just based on experience of the last twenty years or so where New York has done a whole lot of things to fill in the huge gaps the national policy has left us. And I think when people's hopes or expectations have been built up by all of this national discussion and then they realize what's left to be done, I think it will come back to the states and maybe get echoed back to Washington that there's a lot more to do.

BENJAMIN: There's just going to be such an enormous implementation challenge with this.

I mean I can't even get my head around it. I think about how long it took us to implement automatic eligibility in newborns on Medicaid. Or you know, little tiny things in the system that took us years to make—.

RICH: Newborns who you know nine months ahead of time are on the way.

DUTTON: Right.

GOTTFRIED: Right, right.

BENJAMIN: Surprise, surprise.

RICH: You had a lot of time to do the paperwork.

GOTTFRIED: A built-in transition period.

DUTTON: You know the logistics of this, on the eligibility side, are going to be enormous. This isn't Medicare, it's more like Medicaid. Because it is means tested, your ability to get the amount of your subsidy is dependent upon your personal income and circumstances. We've been moving towards a more simplified system for eligibility on Medicaid for fifteen years, at least that's how long I have been a part of that march, some of you've probably been involved with it longer. I think we all believe it's possible to have a user-friendly enrollment system, but we also know that it's not easy.

And now we're going to take this to a national scale. I can't imagine that this can be done without really significant involvement from state government and from local players. I don't see how we could possibly do this without having some real investment in local infrastructure around these issues.

BENJAMIN: And two of the bills actually contemplate that a little bit. In the House they've set up a sort of federal ombudsprogram watchdog. And then in the exchange they clearly and explicitly say that there'll have to be some contracting to get people, you know, with some kind of local entity. It's not the language that we would like, we believe there should be contracting with local groups to help get people in.

And I think the Senate HELP language—from the Health Education and Labor Committee—is pretty good. We don't know what Senate finance will do, but they've got to think about this just a little more than they have. We worry that the great minds on the subcommittees aren't really putting their attention to this. And so we think it'll require the great minds of people like Dick Gottfried to do it in New York and hopefully there're folks in other states doing the same. But it's going to be a nightmare. And that's not even going into the quality side, right? There's all this electronic health information stuff, and personal health records. And people are going to need help kind of accessing all of that, and they're going to be doing this huge investment. I know that's one of the things Melinda was going to talk about, but you've got to have a way to make this stuff meaningful for consumers or the voting population's going to just go crazy. Because it's just a lot of money being thrown around without any sort of tangible making things better for patients.

LYTLE: Has the Greater New York Hospital Association begun to examine what the implementation of this is going to look like or made recommendations about that?

RICH: Not yet, no. But I do, as we mentioned before, I really do worry about transitions. You know, someone at one point had asked us to look at the Wyden Health Reform bill, which was going to completely take everything out of employer-sponsored health insurance and make everybody just be responsible themselves. Senator Schumer and others were saying, "Well you know a lot of bipartisan members are on that bill, tell us what you think?" How in the world, what would that transition be like? Now luckily they're not talking about doing that, but I could imagine everybody being uninsured for a period of time.

BENJAMIN: On the Wyden bill I had a chance to ask Senator Wyden: "Hey, I'm from Oregon, let me ask you a question" because I grew up in Oregon. New York State, your tax credit or your bundle of money you're going to let people use is only fifteen thousand dollars. But the premiums in New York are twenty-two thousand

for a family; who's going to make up the gap?" And he says, "You clearly don't understand the bill." And I'm thinking, "No I think I clearly do."

(Laughter)

BENJAMIN: I should hope that Chuck Schumer would not really seriously consider it because all of us in New York will be in deep trouble, we will not be able to buy health insurance.

LYTLE: Are we contemplating that local social services step up and play the role in the exchange or are we talking about some other new not-for-profit entity gets created and, is it regional, or is it statewide?

RICH: The bills seem to say statewide, but there can be more than one, so I guess the state could decide, under some federal parameters, that I would assume HHS would come up with, to have more than one. So they sort of are punting on that, it seems to me.

DUTTON: There's some language about Medicaid agencies being able to apply to play that role.

GOTTFRIED: Well, it'll be interesting to see the debate when people in Washington talk about how, in order to apply for this subsidy, you have to go to the welfare office. Also known as the Department of Social Services.

And the whole notion that every year middle-class people, for the first time in their lives, are going to have to go to some government agency and pass a means test. Except maybe if applying for financial aid for their kid to go to college, most middle-class Americans think of a means test as something that only "those people on the other side of town" have to do.

DUTTON: And they can't even stand the DMV.

BENJAMIN: Wait till they get to the welfare office.

RICH: And that will be where it's done.

GOTTFRIED: And then you've got to do this every year. And you've got to show up somewhere with your paystubs and your birth certificate and all the kind of stuff that poor people have had to live with, except now we're going to be telling middle-class folks you're going to take off the day from work to go down to the welfare office to prove that you shouldn't have to pay the full cost of the health insurance that you've been mandated to purchase now that you can't afford even with the meager subsidy. That's going to be fun.

DUTTON: Actually, we won't do that to middle-income folks. The reason that we've gotten away with doing it the way do for so long is because it is low-income folks. Middle-income folks won't stand for that. And we won't implement programs that are like that.

BENJAMIN: But they did it in Massachusetts and the connector does not do that.

DUTTON: Right. And I think that what we're going to see. We know we have a huge problem in New York with people who are already eligible for low-cost or no-cost coverage, just not being signed up. There've been a million reports on this topic. And we know at least part of the reason is because we still haven't made that system user-friendly enough. We've, inch by inch, made it a little bit better each year, but we still aren't all the way there. We're going to have to figure this out because we can't treat people that way. The program is going to depend on figuring out more streamlined ways to do it. Do we just use tax returns? Do we allow people to attest and do sampling instead of asking every single individual to produce papers? I think the involvement of middle-class people in these systems will open up new doors to simplify and streamline and make this a more user-friendly system.

And I think one of the nice side benefits of that, particularly in New York where we have so many folks who are eligible for Medicaid already and not enrolled, is that I think those programs will be more successful and those populations will have more access, too.

LYTLE: We've talked a bit about what makes New York different. It's not always a compelling argument that New Yorkers have to be dealt with on our own terms, that New York brings special things to the table that have to be viewed that all other states have to kind of roll over and support.

But, notwithstanding whatever the politics is of a diminishing population in New York State, and what political power we still have, there are some unique characteristics that make New York a harder fit into health reform. Is it worth just kind of trying to list all the things that make health reform a little different in New York? You mentioned some of them obviously. Immigrants, what are some of the other things? Oh, you mentioned costs.

BENJAMIN: Affordability.

RICH: I think cost and affordability. And also the sheer fact that we have, as Dick said before, expanded our Medicaid program to the point that we have.

I mean when you look at what other states' Medicaid programs look like, I don't know how anyone's eligible to tell you the truth. So that's an issue. And when they talk about expanding and providing one hundred percent

federal reimbursement for the expansion, that's another thing where New York sticks out. They say, "Well, you're already there, why do we need to suddenly give you a hundred percent federal financing when we've only given you fifty percent in the past to do the same thing?" So those issues certainly come up.

The fact that our delivery system is similar to some other big cities in the country—we're certainly not alone in this, but we do have a lot of academic centers. The fact that we do have a big public hospital system makes us a bit different than elsewhere. So that's one of the issues that comes up and that's where some of the delivery system reform issues come into play.

LYTLE: And just yesterday, I think, Governor Paterson outlined a number of concerns that he has about how this health reform might play out. And he noted some of the New York characteristics that I thought were interesting. Speaking of academic medicine, he very much defended the importance of graduate medical education support for hospitals. Did you see any irony in that?

GOTTFRIED: For those who were not following New York state's annual Medicaid budget debates as closely as we all do, gubernatorial support for graduate medical education funding has, I guess since the late '80s, been a matter of annual controversy.

RICH: When we're in Washington we're all New Yorkers—.

LYTLE: There's very little that's been discussed in this whole context about the long-term care and chronically ill population: a population that has enormous costs attached to it, but an area where New York has taken special steps. What's the sense on what all this means for the long term care system in general?

RICH: There's not been much. There was a major proposal in the Senate HELP bill called the CLASS Act, which is designed to try and provide more coverage for long-term care services, and then people within the long-term care community have really liked that proposal a lot. It wasn't in the House bill, although Congressman Pallone has a large amendment that would also include trying to add that to the bill. But I think the long-term care community right now is concerned that basically they're a piggybank. Because there are Medicare reimbursement cuts for skilled nursing facilities as well as for home health. When they've talked about home health, in particular, it's talked about as part of the solution on some of the delivery system reforms, on cutting down on readmissions to the hospital, for instance. Trying to make sure there're better linkages and there's more home health available as they're leaving the hospital setting.

You know one of the concerns that has been raised about readmissions for the Medicare population to the hospital within thirty days of discharge, is that it was found that a very large percentage of those who were readmitted had not even seen a doctor or any health care professional in the thirty days after they left the hospital.

So certainly people look at a segment of long-term care as part of the solution to some of these quality issues. But I don't think very much is being done. And one of the other things that had been in the house discussion draft, that fell out completely, was an effort to try and find better ways of managing the care of dual eligibles—the dual Medicaid and Medicare eligible population, which is extremely important because their care is so unmanaged now. And, just from a cost standpoint, they drive a lot of the Medicaid costs because Medicare and Medicaid have such different rules, there's often very little incentive for the state to better manage that population's cost because a lot of the benefits accrue to the Medicare program. For instance, if you were to cut down on readmissions to the hospital it's the Medicare program that would save money as opposed to the Medicaid program. We've all been talking about the dual eligibles for years and yet now it's not in the House bill at all, and so I think that is frustrating to the long-term care community. If thought of at all, they're somewhat of an afterthought, or they're basically looking at cuts.

LYTLE: You mentioned the discussions about quality and reducing hospital readmissions, primarily as a cost saver, but also from a quality point of view. And a lot of what the President's rhetoric has been is very much about making this a better performing health care system with better results, better quality. What are the quality measures that might have some real potential for us?

RICH: There are some on the delivery system reform side that I think have some potential—when they're talking about medical homes, for instance. I think they, perhaps, over-think them a little bit and make them more complicated than they need to be. But the idea of really changing reimbursement policies so that you are able to look at the whole person with a multi-disciplinary approach that is not "siloed": you pay the hospital, you pay the doctor, you pay the nursing home, you pay the home health provider, and all the other providers in between separately.

But trying to bring them all together through a primary care physician. They've also talked about bundling Medicare payments so that you could have the hospital get this bundle for thirty days of care, and then rather than having what you have now, where the hospital gets

a DRG regardless of how long the person stays but the doctor gets paid more, the more he or she does those incentives are completely not aligned. And then neither actor, hospital or doctor, has that much of an incentive to figure out what happens after the person leaves. We need to try and figure out ways of bringing all that together.

Now those are very complicated concepts and require new infrastructure, new systems. So while Senate Finance at one point said let's just have the Secretary do some of these things nationwide, you know, three years from now, they're sort of talking, I think rightly so, about piloting those things a lit bit more.

So I think coordinated care in a good way, unlike managed care in the past, I think is really important. And I think that those concepts are there. I think the only thing I agree with Peter Orszag on right now is that the bills probably are not thoughtful enough, and are not daring enough and bold enough in terms of taking us forward for delivery system reforms that can drive quality. So there's a lot of "gotcha" stuff that just saves money without really improving quality.

LYTLE: Right. It could end undoubtedly more fraud prosecutions.

RICH: Yes, you've got even more auditing than we already have.

LYTLE: Melinda, health information technology is a big piece, not only of the health reform debate and discussion, but even before that in the stimulus package. From what we've seen thus far, what's your sense of how the federal government's going about trying to introduce that element into the quality discussion?

DUTTON: Well, we are pretty early on in the discussion on Health IT. New York in this area's also ahead of the curve. We've been putting real money into Health IT through HEAL for a number of years here. Most states have not; in fact, I think we're unique in the amount of investment we've put into Health IT.

It's really too early to know exactly what the impact of it's going to be. Though I do think that we've reached a point where it's completely accepted that a lot of the quality initiatives that we're talking about, such as medical homes, are not possible without interoperable EHR in the doctor's offices and the ability to exchange information across siloed proprietary institutions. But everybody knows it's going to take money to get to the point where the health care system is fully wired—where we have EHRs in every doctor's office, and each of them are connected to hospitals and other providers.

I think the question now is so what's the most efficient way to get that done. We saw with the stimulus package the federal government putting some serious dollars into Medicaid and Medicare to help hospitals and doctor's offices purchase and operate EHRs, and conditioning those payments on compliance with federal standards. The EHRs need to be used for meaningful use, which includes health information exchange. But the feds are still defining what those standards are and it's a complicated process.

It's a good investment. I think it's just going to take us a long time to figure out how to do it right and to implement it fully so we can take full advantage of it.

LYTLE: Okay, the medical home concept is something that the states also debated and discussed. How do you see that actually being implemented in New York?

GOTTFRIED: Well, I guess an interesting, a difficult question would be whether the federal legislation does enough and influences enough payers to have any leverage promoting the growth of medical homes or integrated delivery systems or what have you. And the more the system remains something run through fifteen hundred different health insurance companies, where the public sector doesn't get to tell them what to do, the less ability anybody has to try to promote better outcomes or smarter organization of health services.

The President—today or yesterday was off visiting the Cleveland Clinic and talking about the Mayo Clinic and the Seattle Plan, etcetera. All of which, from everything I've ever heard, are terrific ideas. I keep wondering what is it that we're supposed to be doing to help make them sprout around the country?

BENJAMIN: Just one last thing on quality. I think there's a real opportunity that may get missed here to do something about health disparities and promoting health equity. And I think, you know, there's some real sort of fundamental obstacles, which is we don't have a nationally agreed upon way to collect race data. We have some, but we don't really know how to disaggregate race data in a meaningful way and reaggregate it and we don't have any sort of meaningful conversation, I think except in New York where I think we've started to talk about that, about how to use, you know, health reimbursement to promote health equity. And I do feel like this is perhaps going to not make it through the health reform conversation. But I do hope that it does come up in the post-reform conversation because the level of health disparities is unconscionable that we tolerate in America. And we've got to do something about it. It's unacceptable.

RICH: And even beyond that, we need for a lot of the quality and management of care initiatives unique patient identifiers, which is something that people still don't like to talk about. But if you're going to have IT work, if you're really going to follow people in a medical home, an accountable care organization, any of the different things that they're talking about, you need to be following people and helping them to comply with their regimens. Helping them to do all of that. You also need to be able to transfer information to make sure that when someone shows up in an emergency room they've never been in before, that they can quickly get the records from the emergency room they usually visit or the physician's office or the hospital where they've been and what we haven't quite figured out yet is the balance of privacy concern and making sure that that happens from a quality standpoint. I don't think we're even going to scratch the surface on that in this debate because—.

BENJAMIN: And there's so many prickly questions.

RICH: Yeah, and they're good questions. And they shouldn't be dismissed, and yet on the other hand, done in certain ways they can create barriers to what we're all trying to do.

LYTLE: You know if one steps back from this conversation, there are a host of issues like that one, complicated privacy issues and access to information issues.

Complicated questions about how you implement a lot of these ideas, even the ones that you all think may make some sense, including the exchanges, including medical homes, dealing with some of the quality issues, post-discharge from hospitals.

Which would lead even someone who didn't say this for political reasons, to say well maybe we're going a little too fast here. Maybe we need to take a few baby steps, do some more piloting, do some more model programs, check some of this stuff out. Take a couple of states and see if we can make this work before we do it nationally. I mean from a pure public policy perspective, putting the politics aside for a moment, that sort of makes sense to me.

But I think the dilemma is there's a view that if we don't just shove this down the throat of the American public and Congress as quickly as possible it's never going to get done and then we can fix it in the end. Would you agree that, in the best of all worlds, a number of these proposals might warrant a kind of a test phase for a little while to see how it all works before we announce to the American public that we have a new health care system for you?

RICH: I would hope on the coverage side we would not do that. I think when it comes to brand new delivery system reforms and changes, yes I think we really do need to pilot things that have really only been on paper in the past. But when it comes to the coverage we've all raised a lot of issues about implementation, but they are talking about not really starting until 2013. So, of course, that is probably a lot closer than it sounds.

(Laughter)

RICH: It may seem really far away but it'll come really fast, but at least I think that should be time to have those debates. So hopefully we wouldn't have to wait on that.

The problem is that this is really being viewed, and I think rightly so as, as much a cost discussion for everybody as it is a coverage and insurance discussion for the forty-seven million, well, thirty-five million when you subtract the undocumenteds, I guess. And so that's the part that I think causes a lot of concern and angst. How do you really affect the cost side for, you know, the eighty- five percent of people who have insurance. And that's in some ways the harder part. And so some of the cost containment maybe should be piloted more. Although that's also how you pay for the bills.

GOTTFRIED: Now I was just going to say part of the problem is that phasing in some of this is difficult to do because costs savings are, at least in Washington terms, necessary to have built in before you're going to do coverage expansions. And so a lot of things would be hard to separate out. Also I don't think delaying doing things is going to make implementation any easier. It just makes it more likely that nothing ever happens.

BENJAMIN: And also just on the coverage side, we can't wait. Twenty-five percent of New Yorkers are doing without prescriptions, and that's insured and uninsured. Twenty-two percent are putting off getting medically necessary care because of lack of insurance or lack of money because of the cost sharing that is embedded in our current insurance structure. So we can't wait on the coverage side.

And I feel like this whole ten-year bending the cost curve has to be budget neutral, when we don't have any budget neutrality. I mean in a way my husband's right, we don't have budget neutrality in military spending, maybe it's not so realistic to have budget neutrality in its health care spending, but you know that's obviously the right thing to try to achieve.

And yeah, we can revisit that ten year window in five years. But we've got to start getting people in and when we get people in I think it'll be clear how we can bend that so-called cost curve.

DUTTON: But the only way we're really going to start bending the curve is by having more organized national approach to the coverage issue. And you know that you can't finish without referring to the ubiquitous *New Yorker* article on McAllen, Texas, right?

We don't have a system right now that is cohesive or coherent enough to bend the curve. This provides a vehicle for us to start addressing those more systemic issues and it's going to take longer than the budget office would like it to, than all of us would like it to. But if we put off the coverage issue we'll never get to the cost issue.

LYTLE: So the question is how do they actually sell this? If in fact it's going to cover not forty-seven million uninsured Americans, but maybe twenty-five of them, or whatever. I don't know how much of the 2.5 million New Yorkers who ultimately—who currently don't have insurance—will get coverage. So you're basically going to the American public and saying we're making a whole bunch of changes, you may have to show up at a DMV office to get your health insurance but you'll feel good about this because, well, maybe half of the people who don't have coverage now will have it. The quid pro quo, at least, stated in those terms, doesn't sound like overwhelmingly a good bargain.

BENJAMIN: Yeah, well I want to jump in. I mean the one thing that is going to happen if you have a mandate and, you know, get rid of the preexisting conditions bar and do at least some control on the rating and insurance stuff, we are going to have insurance premiums go down. I mean there is going to be some cost savings—maybe not a trillion, but you know, I just, something's going to happen if you have that mandate. There is going to be some decrease in premiums. So I just feel like we shouldn't say, oh, there's going to be no cost savings.

RICH: But will the decrease be for—it'll be for those who struggle so much now in the individual market and the small-group market, but do you think it'll impact premiums for others as well?

GOTTFRIED: And will it be a decrease in premiums for a bare-bones product? Is that how the process—.

BENJAMIN: I think no one knows, but I think that's going to make a difference both in the group market and in the small-group market too.

GOTTFRIED: Part of the way I look at this is as you all know, I advocate a program in which the state offers publicly sponsored coverage to everyone and that the premium be paid by the state through progressively graduated taxes.

And as I say to a lot of audiences, a governor is going to look at this and say, "You know, Dick, we've got two-and-a-half million uninsured in New York. Half of them are already eligible for our publicly sponsored coverage, we could get them all into it. So maybe we're talking about a million people who need to be covered. Why, in heaven's name, would I even look at your proposal to more than double the state's tax revenue, to take care of a problem for a million people?" And my answer to that is: Ninety-six percent of the people who vote are people who have health coverage.

And yet this is a raging front-burner issue. Why? Because this isn't about the uninsured. This is about the problems all of us have with the health coverage system. And when you come down with a Massachusetts kind of approach, which is sort of what they're talking about in Washington, an awful lot of people are going to look at that and say: "It doesn't seem to be doing anything for me, except I read in the papers it's going to bring socialized medicine and ruin everything and raise my taxes. And you're doing this all for those people on the other side of town who don't have health coverage." To me that doesn't sound like a winning political recipe.

So ultimately, when Congress comes down to confront this, I don't know how members of Congress are going to look at it and say, "Gee, you know, this is going to be popular with my constituents."

Now whether that induces them to make the plan better or let it die, I don't know. Now, of course, the political analysis that I've just recited to you makes enormous sense to me. It has apparently not impressed a whole lot of other people who make a living out of getting elected to office. I don't know.

LYTLE: Let me ask another narrow question. You always talk about medical liability reform at one point. It's something that the—the health industry is obviously very interested in. Particularly in New York the idea that there might be significant change in the way medical malpractice is determined is will be a heavy lift.

RICH: We've actually put forward some ideas because, you know, the President has said a number of times that he does think that something should be done. And he had a proposal as a Senator which was known as the "I'm sorry stuff" which I think actually sort of diminishes the concept, but it's early offers of compensation and disclosure and apology and we think that's very worthy and that that should be part of the solution. We put forward the idea of having the institute of medicine, along with HHS, come up with clinical practice guidelines so that if people really are using them, that they can use that as a defense in court. There may be

something about helping with the costs of OB and the cost of neurologically impaired newborn care over time, because those costs are so high. And because society has, I think, an obligation to take care a lot of children for whom there's no negligence, but they have very high needs for their entire lives and so—and often they're not taken care of the way they need to be, which is why they often end up in the court system.

LYTLE: Well my theory is that the way to make certain that a lot of those cases go away is that you have a real universal health care system that assures the parents of whatever medical interventions are going to be necessary for the rest of their child's life will be there and that they're not going to be bankrupted figuring out how to pay—.

RICH: True, although the medical interventions are often so expensive that no normal health insurance plan, let alone maybe some that we'd be talking about that you could get through health reform, would cover it for them.

GOTTFRIED: You know a lot of it is what we would characterize as long-term care, health care reform is not going to do it.

RICH: Exactly. I mean Child Health Plus, for instance, doesn't really deal with a lot of these children's needs.

LYTLE: Do you think medical liability ought to be a part of the conversation?

GOTTFRIED: I think not for a couple of reasons. I see it as being a series of land mines that almost no matter what you try to do has a high potential for blowing things up and taking people who would otherwise would have voted for a bill and making it impossible for them to vote for it.

And even if you were putting in a series of pieces that might to almost everyone seem reasonable, from the plaintiff advocacy side of the issue, would be seen as inviting the federal government into legislating in this area, where I think so far there has been next to none.

And I think an awful lot of people with a high level of interest in this topic, shall we say, would regard that as a very dangerous and threatening eventuality. And so I think that just heightens or magnifies the dangers to any legislation passing.

LYTLE: What do you hope will now be the case in the United States once health reform is in place and the beginning of this implementation is taking place? What is it conceivably that we have to look forward to?

DUTTON: I think a year from now it's going to feel remarkably soon. We hopefully will have come to a meeting of the minds about a basic infrastructure, about what's affordable, about what our goals are related to quality, related to Health IT adoption, related to how we're going to pay for all of this. But this is a long road. As the President said last night, we're making a choice whether we do nothing or we do something. And the choice to do nothing is untenable. People who are thoughtful and participate in the health care dialogue believe that we need to do something different than what we're doing right now.

So I think a year from now it'll be very early in the process but hopefully we'll be over the political hump of having a bill passed. And once we have gotten over that political hump I think people can really roll up their sleeves and we can get to work with—not throwing bombs at an existing system, or looking at what little piece we can pick off of it, but really building something that's better.

RICH: Hopefully a year from now we'll still be celebrating the passage of a bill that we all think moves the ball forward, if not as far as we would have wanted it to go.

What I hope from the hospital perspective is that we could have a number of hospitals in New York State involved in demonstrations on medical homes, accountable care organizations, bundling of payments, to really be able to move forward and get at unnecessary utilization where it exists, really looking at the whole patient in a way that managed care was supposed to do and never really did. And certainly we don't have that on the fee-for-service side at all, which is where most people get their care.

So I think there's some really exciting opportunities for changing the delivery system. If we change some of the incentives and get rid of the silos. And I'm hoping that a bill really will enable that. And so that we can combine some of what people in Albany are talking about they'd like to do whether it's the medical home or some of the other reforms that they're talking about up there, combine that with the federal piece so that we really can have multiple payers moving in the same direction. Providing the same types of incentives for really caring for people in better quality ways going forward and in more coordinated ways.

GOTTFRIED: You know, I think the health care system in this country needs dramatically more things done than seem to be on the table in Washington. On the other hand I've always believed that it's important to know what you consider a whole loaf, to fight for what you consider a whole loaf. But never turn down an opportunity to get one or two or three more slices. Let alone half of loaf.

As long as you're moving step by step in the right direction. And I think most of what is on the table in Washington is steps in the right direction. So I'm very hopeful that we will do that. And not to sound like a broken record, I think all of those steps in the right direction will to me be almost totally undone if at the end of the bill it says states can't do any better. This has got to be a floor and not a ceiling.

BENJAMIN: I think federal reform will be a floor and not a ceiling. I hope a year from now we will be sitting here and really thinking about how to build up from whatever the federal floor is. This means we will need to determine how to keep our pure community rating system and pass on this two-to-five age rating that the federal reform is trying to cram down upon New York. We will really need to think about whether there are additional ways to fund the subsidies for people in the moderate-incomes, you know what would be considered moderate-income everywhere I guess, but really people in New York are going to need more help and how to sort of make it geographically viable in New York to work in this newly reformed system. So I'm excited, because I think it will be a lot more work and I'll be able to live another day to fight another battle.

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A Conversation About End-of-Life Decisionmaking

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OUELLETTE: Welcome, I'm happy to see everyone here. Thank you all for joining us. I'm looking forward to talking with you over the next hour-and-a-half or so about end-of-life issues in New York. Before we begin I'd like to just do some quick introductions. If we can each give a little bit of background about ourselves, that would be great. I'll start with myself, I'm Alicia Ouellette. I'm on the faculty at Albany Law School and in the Union Graduate College / Mount Sinai School of Medicine Program in Bioethics. At the law school I teach New York Practice and Bioethics. I spend most of my research time thinking about end-of-life issues, reproductive ethics, and disability rights. Robert?

SWIDLER: I'm Robert Swidler. I'm General Counsel to Northeast Health. We operate hospitals, nursing homes, home care agencies and other providers in the Capital District. In the past I was Counsel to the New York State Task Force on Life and the Law, an Assistant Counsel to Governor Cuomo for healthcare issues, and Counsel to the NYS Office of Mental Health. I'm Editor of the NYS *Health Law Journal*, and I'm also on the faculty of the Alden March Bioethics Center at Albany Med and the Union / Mount Sinai Bioethics Center at Union College.

OUELLETTE: Nancy?

DUBLER: I'm Nancy Neveloff Dubler. I am an attorney, presently Senior Associate at the Montefiore-Einstein Center for Bioethics, Ethics Consultant to the New York City Health and Hospitals Corporation and Professor Emerita at the Albert Einstein College of Medicine. I've written about end-of-life care, research ethics, bioethics consultation, and—especially—in the area of mediation in bioethics. I see many bioethical dilemmas as conflicts that need to be managed or resolved. I am a member of the New York State Task Force on Life and the Law and the New York State Stem Cell Ethics Research Board.

OUELLETTE: Thad?

POPE: I'm Thaddeus Pope. I'm a law professor at Widener University in Wilmington, Delaware, which is not in New York State. I teach Bioethics, Health Law: Quality & Liability, and Health Law: Finance & Regulation. I serve on a large hospital ethics committee in Delaware and on a regional long-term care facility committee in New Jersey. I've written quite a bit, recently, about medical futility disputes, about the health care ethics committee as a dispute resolution mechanism, and about advance directives. I am now on a task force to introduce MOLST (Medical Orders for Life-Sustaining Treatment) in the state of Delaware.

OUELLETTE: Great. And Dr. Quill?

DR. QUILL: Tim Quill. I'm a professor of medicine, psychiatry and medical humanities at the University of Rochester Medical Center and I direct its Center for Ethics, Humanities and Palliative Care. I'm a general internist with a long-standing interest in hospice and palliative medicine, and I now run a pretty large and growing palliative care program at the University of Rochester. I'm on the board of the American Academy of Hospice and Palliative Medicine. I've been the chairperson of their ethics committee for a year-and-a-half, and been involved in researching areas of doctor patient communication, doctor patient relationship, patient empowerment and thinking about areas of choice for patients who are struggling at the end of life.

OUELLETTE: All right. Thank you. We are going to talk about end-of-life decisionmaking. I do want to get to the

Family Health Care Decisions Act, which is, of course, a hot topic in New York law, but I wanted to start with a general question to put the discussion about end-of-life decisionmaking in context. My question is this: one of the things that I hear at academic conferences quite often is that it's harder to die in New York State than it is anywhere else in the United States. Why do you think people say that? Do you think that it's a fair statement?

DUBLER: They say it because it's true.

OUELLETTE: How so?

DUBLER: Because medicine in New York has been constrained by and deformed by the law of the state. Case law, dating from the 1980s, which has never been overruled by the legislature, which places the burden on the patient to create the terms and conditions for death rather than permitting the patient's family and physician to respond to the situation of, and the needs of the patient, as the patient nears death.

QUILL: As a clinician, I will say a positive with regard to end-of-life care in New York is a very strong penetration of palliative care in academic medical centers. There are many well-trained clinicians available to care for patients at the end of life. Probably more so than any other state in the country. On the other hand, if you have an ethically complex end-of-life decision in New York (or probably elsewhere), one of the operating principles is you almost never formally ask for a legal opinion or go to court. Because, in New York, you're going to get answers that you don't want to hear. In fact, the advice that I've been given is the courts don't want us there. But if you get into court or ask a lawyer, you're going to get information from case law and other sources that may not helpful to you. This creates a very restrictive environment because there is a lot of fear of the law in New York State which means that end-of-life care is extremely uneven. If you are lucky enough to be taken care of by someone with sophistication and experience, you're probably going to be fine. And if you have somebody who's fearful of the law, who goes to the law first, you could be in real trouble.

SWIDLER: I agree with the statements by both Nancy Dubler and Dr. Quill. I think one of the reasons that I've been a longtime supporter of the Family Health Care Decisions Act[1] is that under the current state of the law providers have to choose between providing care that is medically and ethically appropriate on one hand, and care that is legally safe on the other hand, and they're not the same thing. So we should be changing our legal requirements, not our ethical and medical standards. So, I agree with that.

But returning to the original question, "Is it harder to die in New York than anywhere else?" I would start by noting, without trying to be flippant, that I'm sure it's hard to die anywhere. Even in Washington or Oregon, states which allow physician-assisted suicide, I'm sure patients often go through enormous pain and suffering before they get to that point where they get palliative care, withdrawal of life-sustaining treatment, or assistance in dying.

But on the issue of respecting decisions towards the end of life and fulfilling the kind of end-of-life course that a patient would want, I think New York is very strong on respecting the wishes of patients who either make their wishes known or appoint a health care agent or plan in advance. I know there are problems everywhere with overly aggressive treatments that are provided in defiance of patient wishes. I don't think that's different in New York than elsewhere. But I think that in New York providers are very respectful, and the law is very respectful, of patients who plan in advance or make their wishes known.

But the place where our law is really deficient and exceptionally harsh is in the rules governing patients who didn't make their wishes known and didn't plan in advance. That's where I think we're more harsh in end-of-life care than other states. So that's what we need to correct.

DUBLER: The problems with that analysis, Robert, seems to me to be as follows: One, we know that most people don't think in advance about what they want. Two, advance directives are very unevenly executed by patients. Three, there seems to be a correlation between socioeconomic status and executed advance directives. If you have a lawyer who does your will and arranges your estate, that lawyer will also suggest an advance directive. So that people who have property often have advance directives. I worked for 36 years in the Bronx. Most patients in the Bronx don't have advance directives. Many have been without medical care in their lives; they don't want to limit care at the end of life, which is usually the goal of an advance directive even if the concept is value-neutral; they want access to care. I always like to comment when talking about ethical issues, that access to care, fairness in health care and universal coverage by medicine complicate every problem including end-of-life care.

POPE: I was just going to say the problem results from a combination of not just the absence of the Health Care Decisions Act but also from the presumption in favor of treating. It's the combination of the two that means, unless you have an advance directive, which 80% of the people don't, or unless you have clear,

convincing evidence of what the patient wanted, then the presumption is to continue treating. Now, I think Dr. Quill implied, or suggested, that some people are less risk-averse and are willing to "polish" the family's recollections of the patient's preferences, so the current standard can be satisfied. Even today, where there is consensus and agreement, things work at some manageable level. So, I guess what I'm trying to do is "target down" exactly why it is so hard to have a "good death" in New York. In short, there is giant gap, a chasm between the law and what people think proper medical practice is. I am not suggesting this as a realistic option. But I do want to note that the gap might be narrowed or closed without legislative action, if providers were less risk-averse and more willing to fudge or polish evidence of patient preferences.

OUELLETTE: What do you mean by fudge and polish?

SWIDLER: I do a lot of fudging and polishing so I can answer that. It describes when hospitals, and hospital counsel like me, struggle to find a way to square the circle, to reconcile compassionate care with the unrealistically high clear and convincing evidence standard that the law demands for limiting life-sustaining treatment.[2] So what we do, frankly, is find clear and convincing evidence in the strings and bits and pieces related to us by family members.

DUBLER: But, Robert, what you've just described is a dysfunctional system. It demonstrates precisely where the goals of medicine are deformed by the demands of the law. So everyone fudges and polishes and encourages family members to provide information that will permit compassionate and appropriate end-of-life care. Consider the case of a Yugoslavian immigrant family. A beloved 98-year-old matriarch of the family had experienced an overwhelming stroke. She had no possibility of recovery to a state where she could ever recognize or respond to loved ones. She was intubated, stitched together with wires and tubes. She had led a good life and was at the end of that life. The family was desperate to let her die. They stated, "How could she have told us that she didn't want a ventilator? She never knew a machine like this existed." What a terrible thing to do to families at the end of life. We basically encourage them to create a fiction to fall within the law. And what a terrible thing to do to physicians; we force them to think about these inappropriate legal stipulations when their goal should be compassion and care.

DR. QUILL: There's no question that there is a large gap between what clinicians, patients and families are facing and what the law says to do in New York, making the system at times very dysfunctional. Some of the end-of-life legal standards in New York are completely unreachable clinically. For example, the "clear and convincing standard" for allowing for someone without capacity to forgo a ventilator or a feeding tube is in most cases impossible to attain. You will find huge variation in how much leeway families are given to refuse such treatments for their loved ones who may never have considered these options in the past. So, in that sense, the current system is completely dysfunctional and arbitrary in terms of how much discretion families are given to make these important decisions. The Family Health Care Decisions Act, if passed, will empower caring families and clinicians to make the best decisions they can under all that clinical uncertainty. In that sense, it is hugely important. In fact, it's more important than advance directives because the data say that the way we imagine our future as healthy people is not necessarily the way we are going to want medical decisions to be made when we're sick. So advance directives, even if completed, don't rigidly solve these issues either. It's still going to be this complex group of people sitting down and doing the best they can. And the Family Health Care Decisions Act, as I understand it, really is going to allow that to happen. So it's going to close a lot of gaps where we are currently pretending to have more clear information than we really have. The application of standards of evidence is very arbitrary and inconsistent. Depending on the clinician's personal values and fear about the law, you are going to see tremendous variation in how the "clear and convincing" standard is applied. And nobody wants us to get into court on these cases, as being a test case is potentially frightening to all involved.

OUELLETTE: Speaking of dysfunction, let's turn to the New York Legislature. When we first planned the panel, Robert had assured me that this was the year that the Family Health Care Decisions Act would pass through the Senate. Our thought was that the panel would educate the Bar about the new law, but two days before we thought there would be a vote to pass the bill, there was instead a legislative coup. Things fell apart and business stopped, or had stopped until sometime around 10 o'clock or 11 o'clock last night, when business in the Legislature picked up again. So I'm going to ask Robert to fill us in about where we are with Family Health Care Decisions Act.

SWIDLER: Sure. The Family Health Care Decisions Act (FHCDA) is based on a proposal by the New York State Task Force on Life and the Law, and was set forth in a booklet in 1992, 17 years ago, called *When Others Must Choose*.[3] The Task Force noted the same problem then that we're noting now: that it's unrealistic to expect clear and convincing evidence that a patient would want to forgo a particular treatment under a particular circumstance. And that as a result we're putting physicians and families in an intolerable situation where they either have to get treatment that is unduly burdensome toward the end of

life, or they have to go outside the scope of what the law permits to allow compassionate care.

The Task Force also recognized that that the problem of surrogate decisionmaking is the bigger part of the problem that will not be solved by advance directives, just as both Nancy and Dr. Quill recognize that this is bigger part of the problem. So they proposed a surrogate decisionmaking law that says, "In the event that patient loses capacity and the patient didn't appoint a health care agent and didn't leave clear and convincing evidencing or make the decision themselves, then you go to specified family members for the decision, or if there's no family member, then to a close friend, and the family member can make health care decisions for the patient based on the patient's wishes if reasonably known, or else the patient's best interests, and if it's an end-of-life decision and the patient meets certain strict clinical criteria, then the family member can make the decision to withdraw or withholding of life-sustaining treatment, without clear and convincing evidence, but based on the patient's wishes, if reasonably known, or it they're not reasonably known, based on the surrogate's assessment of the patient's best interest."

What's interesting is that bill has been around now 16 or 17 years and I think for the past six, seven maybe even longer years, there has been broad consensus on the need for the bill and the basic principles of the bill. But it was hung up on two ridiculous side issues, in fact on two ridiculous *words*. One was the word "fetus." For years, the Senate wouldn't consider the bill unless there was some recognition in it that if an incapable patient is pregnant, the surrogate should consider the impact of the decision on the fetus. The Assembly would not agree to that. The other word was "domestic partner." Okay, that's a phrase, not a word. Anyway the Assembly said when choosing the surrogate, a top category should be the "spouse or domestic partner." The Senate wouldn't address the bill with that phrase in there.

Well, the State Senate became Democratic in 2009, and the new Health Committee Chair, Tom Duane, went over and took the Assembly position on both those issues and put in a "same-as" bill identical to the 2008 Assembly bill. That resolved those two longstanding issues and really created the ground to get the bill passed this year.

As a result of that, there was a lot of activity in the Spring 2009 with people now taking the FHCDA very seriously, and working on some of the technical questions with the expectation that it might really finally become the law

So recently there have been new issues that have become the focus of discussion. But these are more the type of issues that arise when policymakers agree on the key substantive matters but are trying to anticipate and address the implications of a complex bill. One of the issues is how should the bill apply to persons with mental retardation or persons in mental health facilities because both of those populations already have surrogate decisionmaking laws,[4] and those laws differ a little bit from the terms of the Family Health Care Decisions Act. And the resolution ultimately, and it may just be an interim resolution, was that the FHCDA should provide that , if you're mentally retarded and a decision can be made for you under what's called the Health Care Decisions Act for Mentally Retarded Persons,[5] then that law applies, not the FHCDA.

And if you are mentally ill and you are hospitalized and OMH regs provided for surrogate decisionmaking for you, then those regs apply, not the FHCDA. But that approach was regarded simply as a placeholder until there is further study about bringing those populations within the scope of the FHCDA.

The only other issue that was the subject of a lot of discussion was the question of where this law should apply. Prior drafts had not been very clear about all the different settings in which the FHCDA would apply. It clearly applied in hospitals and nursing homes, and the bill designed many safeguards with those settings in mind, like the expectation that hospitals and nursing homes would convene ethics committees and have the ability to secure concurring opinions of incapacity from professionals with specific qualifications.

But it became much more complicated to think how would this apply to a surrogate decision for an incapable patient in a doctor's office, or in home care, or in an ambulatory surgery center, or a physical therapist's office. So the bill was amended in 2009 to specify that at least initially it applies only in hospitals and nursing homes. Then there was a lot of discussion about the extending the bill to at least cover hospice patients in whatever setting they are in. But for the moment it just applies to patients in hospitals and nursing homes.

So in May and June, I was invited to some of the legislative meetings on the bill as a technical resource. And on June 6, I was packing my briefcase to go to a meeting of Senate, Assembly, and Governor's Office staff to walk through the bill one last time, to make sure that there were no final technical issues, and to reflect some of the comments that had come in the previous week. I was already thinking about the post-enactment party that we would have to celebrate it being passed. That was the day that there was a coup in the Senate, and then the Legislature became deadlocked and nonfunctional for a very long period. A situation that was just remarkable and unprecedented. Those of us who have been in Albany for a long time have never seen anything as chaotic as

this. And it just brought a halt to all legislation, including the FHCDA. This event was just about the only scenario that could derail the FHCDA at that point, and indeed, it derailed it.

But there are still hopeful signs. In particular, the Senate recently updated its bill to reflect the Assembly's 2009 bill, and is advancing it in the Senate. So I am still hopeful something will happen this session.[6] Over the past three months what I've seen with this bill is, "It's dead! No it's alive! No wait, it's dead! No it's alive," and this is another reiteration of that. It's exciting, and I think the prospects have been resurrected for the moment and I'm hopeful that it will pass. And if it does pass, it will significantly alleviate the problem that we have, where good care is not lawful care. That's simply not tolerable.

OUELLETTE: Okay, so how important is it that FHCDA pass?

DR. QUILL: The only thing I would say is that this would reconcile New York State and the vast majority of other states, and put common sense back into the process. It would allow us to do what families want us to do, which is if a person is incapacitated, sit down with the family and try to achieve a consensus about how to make the best possible decisions we can under these very hard clinical circumstances that is respectful of the patient's values and clinical situation. It is going to be a huge step forward in reconciling what we actually should do with good care and what the law said we should do. So there will still be a significant number of challenging cases where the law and good clinical care will still be somewhat at odds. People who never had capacity will still be a challenge legally and clinically, for example, but those numbers are very small and maybe those should be resolved in a more complex way. But I think that passage of the Family Health Care Decisions Act would be a huge step forward if it can finally be passed.

SWIDLER: Dr. Quill, can I ask you a question about this? One thing I often hear, particularly from doctors, "Well, it ain't broke, so don't fix it. I'm finding ways even within the constraints of the law to provide good care, I just don't pay that much attention to the limits you're talking about and I don't want things to get more bureaucratic with some law that tells me I need to determine incapacity this way, then I need document that certain clinical criteria have been met, and so on." I know there's going to grousing and resistance about that. Is it worth it?

DR. QUILL: From my point of view, it is well worth it. When clinicians are not following standards—when we say we are going to ignore the standards and do the best we can on a case-by-case basis we know that the way decisions are made tends to be pretty uneven and unpredictable. And there are some agreed-upon, practical ethical standards to guide these decisions, so if you have good policy and good law, we ought to be able to document and carry out good clinical care. Under the Family Health Care Decisions Act, if you document good clinical care, you will meet the legal criteria, and I think reinforcing that is a good thing. There may well be some grousing about new bureaucratic requirements, but having your fear of the law guiding what you're going to do clinically is just not tolerable.

DUBLER: I would add, I agree entirely. And I would add a number of other points to what Dr. Quill has said. One. Self-conscious care in making decisions at the end of life is a good thing. These are not decisions that should be made casually. The law has been most effective, when it raised consciousness regarding the gravity of the situations that are faced. Two. The burdens appear to be reasonable in this law. There are, however, always unanticipated negative consequences of any legislation. In this instance, I am concerned about home care and the hospice setting. Although I think the hospice setting is sufficiently self-conscious to not be disturbed by the law.

What this new legislation will do, hopefully, is remove the law from the clinical setting. What the present legal structure has done is make it comfortable for lawyers to say we have a role in clinical-care decisions. And what I hope this bill will do is to return these decisions to the bedside where loved ones and physicians can jointly fashion a care plan that is appropriate and kind for this patient.

DR. QUILL: The home care gap is a huge issue in the sense that at the end of life generally you want to keep people out of the acute hospital, and many people would much prefer to die at home and not in a nursing home. Whatever the standards are for the hospital and the nursing home, they should be followed in the home care setting, even if that's not what the letter of the law says. So this could be an area where there's a small gap. But I don't see having to admit somebody to the hospital to make a decision that could have been made at home. That would be ridiculous. But I do think if you had a standard in the nursing home and the hospital that people will generally follow that same standard at home, even if that's not within the letter of the law.

DUBLER: The decisionmaking that goes on in the hospital as part of the discharge planning process will need to assume the burden of this decision. It will take some creativity to make it happen, but I, like you, Dr. Quill, think that it's probably possible to set up some guidelines and standards that will extend the reach of legislative intention into the home.

SWIDLER: Nancy, I agree with you. That was the exact point, you made the same point I was going to make,

and better than I would have made it. But for your information, I had this question from the state hospice association: If, after the FHCDA is passed, the patient is in the hospital or nursing home, more likely hospital, and is discharged to home, with surrogate consent to a care plan that provides for palliative care and comfort care only, can the hospice program then honor that in the home? And I think the answer, clearly, is yes.

DUBLER: Yes.

SWIDLER: The decision was made lawfully per the FHCDA in the hospital setting by a surrogate. There's nothing in the FHCDA that tells you that same decision should be disregarded when the person has stepped outside the hospital. But what we still need to do, though, is find appropriate ways with appropriate safeguards to extend the law to decisions that are initially made in the home and in the doctor's office and in the ambulatory surgery center.

DUBLER: Yes.

SWIDLER: But I think there may be a need to think more about what those safeguards are. Because the safeguards in the hospital, for instance, the ethics committee, are not going to extrapolate well or easily to a decision made at home. So, we need to think about that.

DUBLER: I would suggest, however, that the "best is the enemy of the good." At this point, 18 years into the process, I'm willing to take the good and proceed from there.

SWIDLER: Here, here. One other point Dr. Quill made is that there are still going to be a lot of problems this doesn't solve. One of the biggest problems it won't solve, and I think this is a source of misunderstanding, is the Terri Schiavo–type problem. The family dispute. People have come to me and said, "Oh, is this law designed to solve the Terri Schiavo type problem?" And it clearly is not. What this law does is enable a decision to be made where there *isn't* a dispute, which I think is the main problem in New York. Right now we can't even make end of life decisions when everybody is in agreement on it. But when there is very sharp disagreement and somebody wants to go to court, well, yes then there's going to be a court proceeding. And the issue will be whether what reflects the patient's wishes, if known, or the patient's best interest if not known. And that could get litigated and that could get appealed and that could become politicized. So the FHCDA is not an inoculation against a Schiavo problem. It just makes good medical practice lawful.

DUBLER: Many disputes at the end-of-life can be mediated. By empowering the parties, hearing their voices, enlarging options and devoting focus and time to the project, many disputes can be resolved. However, some disputes cannot be either managed or resolved. Disputes that are animated by hatred, mistrust, and ideological chasms must be referred to courts for resolution. That is the usual and comfortable role for judges to play.

POPE: I certainly support the Family Health Care Decisions Act, like everybody else. But in a sense it not only fails to solve *Schiavo*-type problems, it also actually seems to create such problems. By demanding advance directives and clear and convincing evidence, the current law sets an unrealistically demanding standard. Still, it is a nice ideal, because it maximizes, we think, the idea that we're best protecting the patient's authenticity and the patient's autonomy. We want—under current New York law—solid, very, very good evidence that what we're doing is what the patient would have wanted. Absent that, we're going to presume that life (in any almost any state of sentience or suffering) should be prolonged and that life-sustaining treatment should not be withheld or withdrawn. Now, under the proposed Health Care Decisions Act, merely by status, without any evidence, merely by status, the surrogate is empowered to make medical decisions on behalf of the patient. That should cause us a little pause because we know that the uniformly consistent evidence is that surrogate decisions diverge from patient instructions, preferences, and best interests. Surrogates often do not really know what the patient would have wanted. And even if they do know, they often choose treatment different than what the patient would have wanted. This is why I am suggesting the FHCDA may create more *Schiavo*-type conflicts. Under the FHCDA, you are going to have surrogates who are going to get challenged by both other family members and by providers. And even if they are not formally challenged, even if it never goes to litigation, we know, statistically, that there are going to be many surrogates, who are legally authorized decision-makers, who are probably not making the decision that the patient would have wanted. The overall good achieved by the FHCDA surely outweighs any problems that it creates. As Nancy suggested, this may be one of those things that while, not perfect, creates overall good on balance.

DUBLER: Thad, I think you've raised a number of very interesting problems. One is, the New York State case law that put us in the bind that we now find ourselves begins in 1981. In 1981 it was important to emphasize the autonomy of the patient. In the dynamic of the history of the doctor-patient relationship, it was important to say, at that time, autonomy rules. I'm one of the people who now think that autonomy as the single organizing principle of medicine has diminished power and force. Individual wishes are important. Individual rights are important. However, there are other equally valid issues in end-of-

life care. Like what the patient can foresee, what suffering the patient is undergoing, and what people of good will and skill can bring to a discussion of the patient's best interest.

The default notion that death is to be avoided at all costs is, I think, morally deficient as a way of responding to the human condition. So I am comfortable in saying ethically, that autonomy, in and of itself, is the only factor that ever matters, which is basically what New York State case law states, is rigid, overly simplistic and deficient in nuance, compassion and a broadly humanitarian view of the human condition.

From my perspective as a communitarian, from someone who thinks that the greatest ethical problem in American medicine is the lack of access to care, for those people who are uninsured, the notion that individual rights should always trump is one that I find increasingly obnoxious. As we move into discussions of extending care and health care coverage, autonomy as the single defensible principle for distributing care must be re-examined.

I realize that one should never talk about rationing. But one has to talk about the fair disbursements of the goods of medicine. So from the perspective as a citizen in this nation and from one who looks at the struggles of physicians and families at the end of life, I'm not distressed by the notion that autonomy is not the only or even the single most important issue to be grappled with.

QUILL: I agree with you in general terms. In practical terms, working with a family to try to protect and represent the patient's autonomy is still a very fundamental issue….

DUBLER: Absolutely.

QUILL: …and as you're trying to figure out what a person would have wanted when they cannot speak for themselves, getting a family together to imagine what the patient would say under this very special and particular circumstance is the fundamental challenge. If and when the Family Health Care Decisions Act is passed, the job clinically and ethically will be reconciled with the job legally. This will be a huge step forward for the state.

DUBLER: I agree entirely. Which is why when I sit down with a family, and I always sit down, the first question I ask is, "Tell me about momma." Because the physicians are experts on medicine, but the family is the expert on momma. And they are experts not only because of what she said and made explicit in discussions, but because of who she was and what she presented to her family in the web of relationships that she established. So we agree entirely.

OUELLETTE: To follow up on this sort of scenario that we're talking about, how would the Family Health Care Decisions Act help when there is a conflict in a *Schiavo*-type scenario, between what the appointed surrogate wants and what another family member wants? What's the mechanism for challenging that decision? Does it involve ethics committees or going to court, as Nancy suggested?

POPE: Well, it could involve both. Initially, the FHCDA provides for an ethics committee to act in dispute mediation or make an effort at dispute mediation. I must also point out that nature has a way of solving an awful lot of these disputes. Many times, the patient dies during the course of the dispute, no matter what efforts are made. But under the mechanism of the Family Health Care Decisions Act, there is dispute mediation. If that doesn't resolve the issue, the surrogate's decision can be honored. But either party can go to court and try to get a different decision.

QUILL: Practically, there is a sequence that usually occurs. In these tougher cases, if you have palliative care consultation available, they get involved and try to mediate the dispute and achieve a consensus. If they can't resolve the issue, then it's the ethics committee that gets involved next. They try to reconcile the parties, and if that can't happen, then it goes to court. So there are mechanisms for dispute mediation that don't involve the courts that are actually quite sophisticated at most major medical centers. So in the cases that actually get to court, there's already really been a lot of effort to find common ground and to invent solutions.

DUBLER: I just want to drop a footnote to Dr. Quill's statement since I've written widely about bioethics mediation. I tremble, gently, to say that mediation requires skills. There is formal training in mediation and dispute resolution and a body of materials to be mastered; the reason I was drawn to mediation is because it contains a litany of skills that I can teach. And therefore I think it will be extremely important if this law passes to be certain that we really provide professionals with the skills to do the tasks that we ask them to do.

POPE: I have a comment and then a question. Mediation takes care of most end-of-life disputes—mediation in one form or another.[7] But when these sorts of disputes do reach the courts, judges seem increasingly willing to replace errant surrogates. For example, surrogates who are asking for treatment that's contrary to the explicit instructions in the patient's advance directive are replaced with another substitute decision-maker. One example is the Dorothy Livadas case decided by a Monroe County court just last year.[8]

In Ontario, they have a whole special mechanism just to do this: the Consent and Capacity Board. If an Ontario healthcare provider thinks that what the surrogate is asking for is contrary to the patient's known preferences or (if we don't know what those are) the patient's best interests, then the provider can go to the CCB and have somebody else appointed as decision-maker for the patient.[9]

In New York, Massachusetts, and other states, this surrogate replacement is happening more and more. That case law is starting to cast a shadow on what happens in the informal, intramural resolution process.[10]

That is my comment; here is my question. I was wondering if and when the Family Health Care Decisions Act gets enacted, whether the sort of conferences that Nancy was talking about would change. In the FHCDA world, it seems there might be less incentive to try as hard. In today's world, you don't have anybody who's legally authorized to make the decision. So you must get everybody together and get them talking. Now, under FHCDA, if the legally authorized decision-maker is daughter number two, it seems that you do not really need to talk to all these other people. You do not need to go through such an elaborate process. I am not suggesting that Nancy would do this. But some might slack off because there would be less incentive to be thorough.

DUBLER: I don't think so, because as clinicians know, disagreements within the families are very disruptive to the process of providing care. And so it's not the letter of the law that governs, but rather it is the comfort of the clinical setting. If there is real discord among the surrogates, that must be resolved for care to go forward even if one of the family is the legally appointed decider. Some scholars have argued that surrogates decide as much on the basis of what they think their siblings and family will bear as what they think the patient wanted. That may be one of the reasons you see the data on the discrepancy in surrogate decisionmaking. Whatever the reason, discord within the family disrupts the provision of care. Therefore, you really have to intervene as aggressively as possible to try to resolve disagreements.

Even if there is a health care proxy that the patient has named, you are still, at a practical level, sitting down with that proxy and the rest of the family and imagining what the patient would want, even though the named person's opinion of what the patient wants is given more weight perhaps than the others. If there is genuine disagreement and fulminating conflict, you're then into trying to engage in dispute resolution and mediation: diffuse the anger, create a level of trust, maximize the options for agreement and construction a consensus. And so I don't see this need changing at all with this law. I think even with a named proxy, it's a tremendous task to make an end-of-life decision and it's sufficiently weighty so that you really do need a consensus. And when there is not a consensus that characterized a difficult process, that will likely require more sophisticated second opinions and expanded ethics opinions, before making a decision. When there's really a dispute in this process, I don't see that the need for dispute resolution and mediation will diminish to any degree.

SWIDLER: I tend to agree with that. In America now, families typically are dispersed, and their level of contact with patients varies. And what I see is that there often are one or two close, involved family members, and then there are other family members who are not that close or involved. And in the absence of any clear law, when an end-of-life decision arises, providers have a self-protective inclination to go track down everybody and make sure that everybody's on board with it. But if you have a law like the FHCDA, it makes it clear that any person who is in this priority class can provide a lawful decision. So if the priority class is adult children, then the provider can rely upon a decision from the closest-involved adult child, that would be the appropriate way to do it. And then you have a lawful decision from that person. There is no requirement to track down everybody, to take a vote or anything of that nature. Where several family members are closely involved, it would be only natural for the provider to discuss the matter with them together, but that would be a practice tip, not a legal requirement. So I think what the FHCDA does, ideally, is to make lawful the good practices that are currently going on.

In fact, the proposal I sometimes hear that providers should have to notify every family member of an end-of-life decision reminds me to place on the record the standard rant I have about against the "due processization" of health care decisions. [laughter]

I often talk to lawyers that conceptualize end-of-life decisions by family members as the deprivation of a right on the part of the patient. They say, "Well the most important right that a person has is the right to live, and you're depriving them of that. So, at the very least, you should first provide procedural due process—such as, notice to a broad range of interested persons, legal representation for the incapable patient, an opportunity to be heard, an impartial decision-maker, a written decision, and an opportunity to appeal that. After all, we're talking about life and death here." And that argument, well it makes me just want to, you know, shake the person, and say, "You know, this is not a capital punishment case, this is a medical treatment decision!" No one is trying to "deprive" the patient; it's not an adversarial proceeding. Rather, health care professionals and family members

are struggling to figure out the right thing to do for the patient. Those kinds of due process procedures, in my view, will harm the patients and the system through delays, expenses and burdens, will generate disputes where they did not exist before, and will likely to lead to a worse result than a better one, from both a patient's rights and medical ethics perspective. So I think the due processization of health care is the road to damnation. Nancy, I suspect you're a kindred spirit in that rant.

DUBLER: Well, I couldn't agree more. Involving clinicians is the key to getting guidelines that work. Death is often not the enemy. We don't want to recreate old paternalistic, non-transparent structures in which "pneumonia was the old man's friend" but patients die, and in this process of dying the task of medicine is to help them remain comfortable and to help their families grieve.

SWIDLER: And yes, there will be cases where family members disagree. And if the dispute is sharp enough, and can't be resolved by mediation, well that's when more formal procedures are needed.

DUBLER: These situations will demand robust interventions in mediating disputes performed by professionals who are experienced and skillful in dispute resolution. I offer one example.

I had a very interesting consultation once during which 17 family members were gathered together in a far-too-small room. One, who was the legal health care proxy, was demanding that mamma get the most aggressive care. Mamma was moribund, obtunded, and ventilator dependent following a massive stroke related to many co-morbid conditions. The proxy did not accept that mamma was dying. Many of the others could see that this powerful woman, who had been the center of the extended family both in this country and in another, was no longer there. They grieved. The proxy railed and raged. Finally, some many hours after our discussion began, he lessened in his rage at life and death and the hospital. There had been some vitamins that mamma had always taken at home, that he wanted to bring them in for her now. So I cut a deal with the pharmacy. I said "Would you analyze these vitamins and if there's nothing wrong with them, can we give them to mamma?"

This family was in chaos. This mediation, over many sessions, with different family members over many days required someone dedicated to resolving the family dynamic of conflict. Resolving conflicts in the context of a dying patient is labor intensive. It required multiple conversations to reach agreement that mamma was dying and that her son, who was the most distressed, needed support. In the process the mediator did a lot of "stroking" [supportive admiration for their love and concern], maximizing of options for the care of mamma, small group conversations or caucuses and much listening. Was it worth the time and effort? Well, the process itself removed much of the strain from the ICU staff, lowered the tension among staff and family and ultimately permitted a family to come together and grieve together. I would argue that it was helpful.

OUELLETTE: One of the points that you raised earlier, Nancy, was about rationing care, and you made a critique of autonomy as being the driving force that keeps us as a country from talking about rationing. One of the places that rationing comes up is when a family wants everything done even when the health care team says enough, we've done what is appropriate. As I read the Family Health Care Decisions Act, that Act really doesn't address that type of situation of demanded care or what some people talk about as the futility problem. Is that an area of concern for New York? Do we need some kind of futility law?

DUBLER: Oh no.

SWIDLER: The FHCDA says that a surrogate can't demand any care that the patient could not have demanded. So the surrogate's rights are confined by the scope of what the patient's rights would be and patients can't demand futile care. But do we need a law in New York like Texas has, a law that would define this more clearly? I'd like to hear more about the Texas law first but it is an area of a lot of tension in New York.

DUBLER: I take a particular stance on issues of futility. Most of the time the use of the term "futility" demonstrates that the conversation between the family and the physicians has broken down. Futility is the trump that's brought out to say, "We won't do this." I would argue that the "futility" issue should be solved in the way other disputes are solved—by mediating.

When families say "do everything," they often don't realize what that means. They often don't accept the fact that the patient is dying. They often haven't resolved conflicts between and among themselves. So futility is not the end of a discussion for me, it's the beginning of a discussion. And my sense of the Texas law is that it's been a dismal failure.

DR. QUILL: I actually agree with that completely. Truly futile care, care that has no value and will not work, does not need to be offered or even discussed. You don't need a law for that. Surgeons don't do surgery when the patient's going to die on the table. They say, "I can't do it because it would hurt the patient." We don't do truly futile care. What the futility controversy is about is treatments of very marginal utility. So a patient might live an extra few days or an extra week with a very expensive,

invasive treatment like being intubated and put on a ventilator. It seems like there will be a lot of suffering and expensive resource utilization with minimal gain to warrant putting the patient through such a treatment. Yet in the current medical environment, such treatments are within a patient's rights to receive if they have even a tiny amount of utility and the patient or family wants it and is willing to put up with the consequences. Now, if we want think about fairness or justice and say as a society we are not going to offer certain kinds of treatment because they're so minimally effective, they have such little utility that they make no sense from a cost effectiveness point of view, then that's a whole other discussion. I believe that as a society we should have this discussion, but so far our culture in New York and elsewhere in the United States is no where near that. So, I think it's a waste of our time to have that discussion right now with regard to individual cases since there is no consensus about setting limits on treatments of marginal utility, and there is no broader national discussion about limit setting of any kind. I doubt we will get near that discussion in the current debate about universal access because it is too easy to marginalize and polarize as we look for areas of consensus, but eventually we will need to have this discussion if health care expenses are going to be kept within any reasonable boundaries.

POPE: I want to espouse and elaborate on that last point. If you can barely pass the Family Health Care Decisions Act, then you surely are never going to have the New York Legislature enact a unilateral refusal statute. I also agree that may not be a big loss because you probably do not really need a unilateral refusal statute. The overwhelming number of futility disputes are resolved informally through better communication and mediation. On the other hand, not every facility has a Nancy Dubler to do that, so the success rate is going to vary. So let's say there is a residual number of what you might say are "intractable disputes." Here, providers, chaplains, social workers, and clinical ethicists all have conferences with the surrogate. But the surrogate remains adamant and retractable. At that point, the providers might try replacing the surrogate as they did in the *Livadas* case. Only if not even that works, would one need to resort to a unilateral refusal law. In short, there are going to be very few disputes for which a unilateral refusal law would be necessary. Bob Truog, at Boston Children's Hospital, would say that current New York law can handle most of the intractable disputes.[11]

Today, if a surrogate is asking you to do something that you think is (i) really, really bad, (ii) really causing the patient suffering, or (iii) really not what the patient would have wanted, then you could use the laws that authorize surrogate replacement and guardian appointment. In the end, there is basically one type of case where you really can't do that, where you have an intractable dispute and cannot even use the current available legal mechanisms: the religiously motivated case. The surrogate is saying, "The reason I want you to continue aggressively treating this patient is because this patient's religion demands it." You cannot replace that surrogate because the surrogate is acting as the patient's good and faithful agent. The surrogate is a faithful fiduciary, doing what the patient would have wanted.[12]

There are many filters along the way, and very few cases will evade all available mechanisms. You can pass a law to handle those truly intractable disputes or, as Truog suggests, just suck it up, treat that patient, and live with it.

QUILL: The legal mechanism is in place to protect patients under some of these circumstances, but it takes a huge amount of time and energy to carry it out. Let's say you have clear evidence that a patient wouldn't want certain kinds of things, and you have a surrogate who his demanding those things. Your moral and legal obligation is to carry out the patient's wishes, so if mediation fails you are going to have to try to replace that surrogate. It takes a long time and a lot of legal resources to replace such a surrogate, and significant harm can happen to the patient during that period. So that is a real problem and the amount of moral distress that occurs around those cases in hospitals is tremendous because you feel like you're doing things that are absolutely wrong, and your hands are tied not to do them until you get legal authorization to replace the surrogate.

SWIDLER: If I can get in on this one. I think the place that the rubber meets the road on the futility issue is in DNR decisions. And that's the one area where I would advocate consideration for some narrow futility exception. We have an unfortunate AG opinion in New York[13] that says that even when the doctor concludes that resuscitation would be futile, if the surrogate does not consent to the DNR order, then the DNR order can't be written. So when there is no DNR order, if this patient's heart stops, a physician responding to the code could perhaps make an on-the-scene clinical decision that this isn't going to work, or it's not working, so I don't have to keep up the pretense. But I think it should be lawful to write a DNR order on a narrow ground of physiological futility irrespective of the patient's or surrogate's wishes, because people don't have a right to demand a treatment that is not going to work.

DUBLER: But Robert, I have two responses to that. Number one, you know best that the Bar Association, the Medical Association and the Task Force on Life in the Law, in the early '90s crafted a document which created that futility exception since the law had not. This

futility exception was the narrow physiologic definition of futility: (1) It will not work—like using an antibiotic for a virus, or (2) the patient will code repeatedly in a short period of time. That consensus stood as an informal guideline until the AG's office decided to intervene. But please don't solve a flawed law with another possibly flawed law. The reason we are confronted with this problem is that the law codifies thinking at a moment of time. It seemed to make sense in a moment of time to have a DNR law. I would argue to you that, in general, it's a bad idea to have laws that address specific issues in medicine. The law should address general setting of standards. Let medicine evolve publicly through discussions in scholarly journals, through developing and analyzing empirical evidence. Don't ossify a moment in the evolution of medicine by enshrining it in law. Let medical discussion create the climate to support emerging guidelines. Let us not throw another law at it.

DR. QUILL: Futility around DNR is a big problem. The patients and families who want "everything," and we repeatedly (and generally futilely) try to convince them to make the patient DNR because we feel it is very unlikely to help the patient and very invasive. We've just written a paper on this subject basically trying to reconcile the possibility of doing a very short code under these circumstances, and if nothing reverses within one cycle you stop. So again, because the repeated discussions about DNR with patients and families who want "everything" are so counterproductive, they're so undermining of any kind of trust, that it's just not worth it—it's much more painful than one cycle of CPR and much more disruptive. So anyway, that's our recommendation around this issue. It's a very tough issue.

DUBLER: And that makes perfect sense to me. And if it comes out in the literature, let's hope it is widely accepted; that would be, I think, a reasonable way to go. Much more reasonable than attempting to fix a bad law by what might be another bad law.

SWIDLER: That sounds reasonable to me but it illustrates what the question is, namely: What is the province of the doctor and what is the province of the patient? You're saying how long to do the code is the province of the doctor, not the patient. But I'm thinking, by that same rationale, why can't a patient say, "I want to be resuscitated and don't let me catch you doing one of those short codes on me, I want the full nine yards."

DUBLER: But, Robert, it's never the patient. It's never the patient. It is almost always the family. If the patient were to say that to you, Dr. Quill, if the patient were to say. "I want a full code, no matter that I'm dying," what would you do?

DR. QUILL: Well again, what we said in this paper, and this is actually what we would do, we would do a full code. One cycle of CPR. If after one cycle there is no response and a person who had a one-in-a-thousand chance of having any response from the beginning, and there is now one-in-a-million chance that they're going to respond for a few hours, and that meets my criteria for absolutely futility. So again, that's a medical decision. You stop a code when it's not going to work any more.

DUBLER: Exactly.

DR. QUILL: So there are things you might find in a code at the beginning that might allow the patient to live longer; let's say they have a mucous plug that you might suck out and they might live another week. And so you can't use absolute futility to not do it in the first place. You could say, "It doesn't make sense to me," or that "I don't want to do it" or it is "a bad use of resources," but you can't use absolute futility as a way to avoid trying CPR under these circumstances, at least according to my way of thinking about futility.

DUBLER: You might call that, I don't know what you called it in your paper, but you might call that "demonstrated futility."

DR. QUILL: Maybe.

OUELLETTE: The Texas futility law goes far beyond CPR, right? It applies to situations where there is ongoing treatment. There've been a couple of cases that have generated a great deal of public attention in which the law was invoked by hospitals to terminate ongoing treatment over the objection of the families. There seems to be consensus in the group here that it's not a good law. Thaddeus Pope is an expert in medical futility. Could you just tell us a little about the Texas law so the people who read this transcript understand what that law does.

POPE: Sure. The Texas Advance Directives Act, of which the unilateral refusal provisions are just one small part, was originally drafted in 1997, but was vetoed by Governor Bush. Between 1997 and 1999, the law was redrafted through a true consensus process. Every single relevant stakeholder in Texas participated: the Catholic Bishops, right-to-life groups, disability groups, hospital associations, physician associations. The resulting product had unanimous support, and was thereby effectively "gift wrapped" when it was sent to the legislature. It was passed and Governor Bush signed it in 1999. So, this year marks the tenth anniversary of the Texas Advance Directives Act. Alicia is correct. TADA permits the unilateral refusal of not only CPR but also any other life-sustaining treatment. So if a surrogate—and it's almost always a surrogate, since the patients we're talking about don't have capacity—is asking for treatment

that the physicians think is not medically indicated, not medically appropriate, then the physician usually will try to mediate and have consultations, though that is not required by the statute. If that doesn't work, then the provider may initiate the formal process of the statute, which is spelled out in Texas Health Safety Code 166.046. The first step requires the physician to give the family, the surrogate, at least 48-hours notice of an ethics committee meeting. Next, the ethics committee will meet and discuss the case. Almost always, the ethics committee agrees with the physician that the requested treatment is medically inappropriate. The ethics committee must memorialize its decision in writing. Unfortunately, the quality of the decision process and the written decision varies tremendously because the statute is silent on key issues such as the composition and functioning of the ethics committee. Next, after the surrogate has been served with the ethics committee's written decision, the surrogate has 10 days to transfer the patient to another facility that is willing to provide the treatment that they're asking for. Of course, the surrogate (and the provider) may have already been trying to do this. Almost always, the surrogate is unable to find a transfer because, for the same reasons that the current physicians at this institution don't want to provide the requested treatment, nobody else does either. Plus, this is a case that is now patently prone to liability, conflict, and trouble. On the 11th day, if the patient is still in the provider's facility, then the provider may stop life-sustaining medical treatment over and against the wishes of the surrogate, or the patient's advance directive. So long as this process is followed, the Texas Advance Directives Act clothes the provider with civil, criminal, and disciplinary immunity. The statutory unilateral refusal process has been utilized many times across the state.[14]

Often, as Dr. Quill mentioned earlier, given the timing of things, you actually don't need to override the surrogate, you don't have to withdraw over objections. The patients who we're talking about are so frail that they may not actually last the full 10 days. But sometimes if they do last, then there is unilateral withdrawal. Physicians are comfortable doing that because there's no legal risk. That's basically in a nutshell how it works. But it is hardly without controversy.

During the first eight years of the statute's operation, right-to-life and disability groups found that transfers are very hard to make. I think that they initially thought that the ten-day transfer period was going to be a much more meaningful safety valve than it actually has proved to be. So, they tried to kill the statute in 2007. That failed, and then they tried again in 2009. That too failed, just a few weeks ago. The statute has also been attacked in the courts on constitutional grounds. This is an area where the due processization of the law might be appropriate because more than one-third of Texas hospitals are state hospitals, so we have the state withdrawing life-sustaining medical treatment. It is a deprivation of life and liberty. So, you want to have due process. Given obvious problems with notice and neutrality, among other things, section 166.046 has been repeatedly attacked as violating procedural due process. Still, no judgments have been issued because the patient invariably dies during the litigation. The family then loses interest in the case and voluntarily dismisses. Notwithstanding its due process defects, many people perceive TADA as a success because it's an effective vehicle that permits physicians both to practice what they think is good medicine and to avoid being forced to practice bad medicine by the fear of liability brought to bear by surrogates. A lot of great data has been published by Bob Fine at Baylor. Other states have explored copying Texas' unilateral refusal provisions: Wisconsin, North Carolina. The Idaho Senate passed a bill earlier this year.

OUELLETTE: So the upside of a TADA-type of law would be that it allows physicians to avoid practicing defensive medicine at the demand of surrogates. What's the downside to it? Nancy, you said it is a bad law—why would it be a bad law?

DUBLER: The major downside, in my judgment, is that physicians will have far less incentive to really talk with patients and families. And again, it will be largely families. And I think, from experience, that that incentive will increase commensurately as the socioeconomic status of the patient and family declines. I am always concerned about the fact that American medicine is largely peopled by professionals who are white, and that people who happen to be of color or of a lower socioeconomic class, who don't have the same language, the same intellectual fighting words, the same connections, or the same culture of discourse as we do, will be disregarded. I don't know what the data shows on the sorts of families who've been trumped by futility discussions, but it makes me uncomfortable that this is a trump card that will not require physicians and the institution to engage in mediation and dispute resolution. It does not require the institution to be certain that families understand. I think it interferes with the good, although labor-intensive practice, of medicine at the end of life, which Dr. Quill so eloquently exemplifies.

POPE: I think you're right. As you know, the people who are most adamant, most demanding of aggressive end-of-life care happen to be from a lower socioeconomic class, black, and Hispanic. So, those populations are most often the subjects of the implementation of the Texas Advance Directives Act. Now, there is zero evidence that the unilateral refusal provisions were used against a patient

specifically because of their wealth or race. Correlation is not causation. Still, you're absolutely right that they are overwhelmingly the population.

DUBLER: But that should give us huge pause. When the AIDS epidemic first came to the Bronx and there was a huge push in the white/gay community for advance directives, we had patients of color who weren't concerned about limiting care at the end of life, they were concerned about "access" to care. And I come back to access to care. If you have a law that's disproportionately used against people of color, that's a bad law. And therefore, the fact that it would be considered by other legislatures in other states is, as far as I'm concerned, an outrage. I apologize for the outburst but I have some passion on this subject.

DR. QUILL: You simply can't define futility in a way that makes sense clinically. You can say it did not work in the last 100 cases or the last 1,000 cases, but you can't consistently define futility in a way that is clear enough to trump a family's wishes. You do find tremendously variability about people's threshold for what is considered futile care. And again, those thresholds may vary about whether you're like me or different from me, white or black, rich or poor. So for me such definitions of futility are not helpful. Now if we're talking about lack of utility and introducing issues of societal good and justice, that's a whole other discussion, but we are not having that discussion as a culture right now in this country.

DUBLER: If we want to talk about futility in the terms that were framed by Atul Gawande, in the *New Yorker* piece of about a month ago, about the misuse of resources in Texas, or if you want to talk about David Leonhardt's piece yesterday in the *New York Times* about how to deal with prostate cancer, if we want to talk about futility in terms of national policy that will affect all people equally, then I'm with Dr. Quill. Let's have that discussion. But if you want to talk about trumping grieving families who have insufficient support at the end of life, I think that is moral outrage.

SWIDLER: I make a distinction here. I don't think there's any escaping the futility issue. Clearly if you're looking at a PVS patient, that to me is a value judgment, not a futility issue. If a family believes that that existence has quality of life or the patient would want to be maintained as long as possible, that is a judgment call that belongs to the patient. On the other hand, when you get to the issue of whether somebody ought to have a heart transplant, there's a big difference between a 60-year-old with heart trouble and a very frail end-stage Alzheimer's patient with heart trouble. And the answer to that ….

DUBLER: But that's not futility.

SWIDLER: Let me just finish. Of course, we wouldn't offer this to the end-stage 95-year-old because it would be futile because they're not clinically appropriate for it. All you've done is really say, "Here's an example of pure futility so nobody would do this." But there will be close cases concerning whether somebody is a candidate, where the doctors are saying they're not and the family is saying they are.

DUBLER: But that's a really good example of where the futility discussion is not relevant. There you have a clear algorithm for the allocation of scarce resources. And for this allocation of scarce resources, we have actually engaged in a national discussion which is reflected in the rules and the procedures of United Network for Organ Sharing. And therefore, futility simply doesn't enter the discussion. You have guidelines and rules for who is appropriate for a heart transplant that does not involve futility but looks at the appropriate use of a scarce resource.

SWIDLER: And if I change the example to open heart surgery, would your analysis change?

DUBLER: It depends on whether open heart surgery is a scarce resource. And whether the surgeon thinks that he or she may benefit the patient. You may have an elderly patient who is otherwise healthy, who would be an appropriate candidate for open heart surgery. Now, if …

SWIDLER: I don't want age to be a qualifier.

DUBLER: Okay.

DR. QUILL: This is a discussion about marginal utility. It's about cost-benefit analysis. It is not about futility. I just consulted on a 95-year-old man, huge decubitus ulcers in the intensive care unit, on a ventilator from which he is not going to get off alive. Is a ventilator futile for him and should we stop? The consensus was that he would prefer to be on the ventilator and alive than off the ventilator and dead. He eventually regained capacity, and confirmed we were following his preferences. Now was it futile to put him on the ventilator? His quality of life was not something that I would found acceptable, but it was okay with him. It was probably not a good use of resources for us as a society, but for him as an individual it was clearly what he wanted under the circumstance. So we are not having any systematic societal discussion about limiting the resources being allocated to any individual patient. You can't trump his request based on futility, and it can't currently be overridden because it is not a good use of society's resources. It's a case of marginal utility. It's a cost-benefit analysis that as a society we are not yet mature enough to have.

SWIDLER: I'm not sure I see the difference. You're saying that a doctor cannot decline to provide requested care

based on futility, but can decline to provide requested care based on a cost benefit analysis. That seems to me to be the more problematic basis.

DR. QUILL: No. I'm saying you can't deprive somebody of care in this society based on a cost-benefit analysis or marginal utility. That is a subject that has to be negotiated with the patient, or usually family, in these circumstances. And using futility to unilaterally avoid that discussion (which is a hard discussion) would be very tempting because it doesn't make sense to me, and doesn't seem like a good use of resources. But we don't have a consensus as a society about these matters, and therefore I think we shouldn't be using futility to override patient and family decisions because it's going to be done very arbitrarily, and you get into everybody's biases confounding the picture.

SWIDLER: Thank you. I have to say, it's not like I have a strong view on this issue that I'm promoting. I'm struggling with the issue myself. And this is helpful. So thank you.

DUBLER: At this point I would like to contradict something that I stated earlier on. This is a circumstance in which autonomy does trump. It's very difficult to say to a patient who is capable of making health care decisions and aware of his or her surroundings, "I will not keep you on this ventilator." And I think in this instance that the patient's wishes become the absolutely dominant factor in decisionmaking. But I want to emphasize what Dr. Quill said, which is, these legislative approaches to futility provide a club that permits physicians to beat back uncomfortable wishes of patients and families without engaging in the very difficult and time-consuming discussions that are required.

Furthermore, even this small vignette might change in the event of a swine flu epidemic. In the event of an epidemic it might be necessary to allocate ventilators and to remove some patients from ventilators even if the family objects. It will be even more difficult if the objecting agent is the alert and aware patient herself.

POPE: I would like to play the other side a little bit more. Your point assumes that surrogates don't already have a club. I actually am very critical of the Texas mechanism as currently implemented, not in concept. But a strong argument in defense of a Texas-type mechanism flashed into my mind when Dr. Quill mentioned the code, although he may have been talking about something different than this. I remember the Queens Hospital grand jury indictment back in the early 80s. They were doing the purple dots and things like that; they were making unilateral futility judgments. "CPR is not appropriate for these patients." They never got consent; never discussed it with the family. And I think that the current evidence suggests that, nationwide, there is significant "underground" unilateral refusal of life sustaining medical treatment. Providers often are not open about it. If you don't think you're going to get consent, or if you've already tried to get consent and failed, then you have to be secretive about it because it's not really allowed. And so the argument in defense of a Texas-type mechanism is similar to one employed in defense of physician-assisted suicide. It is already being done, but covertly where it is far more subject to abuse. So, why not create a mechanism, so at least it can be done transparently, openly, and regulated by a fair process?

DUBLER: I think the reason for not so doing is that the creation of legislation reflects the values of stakeholders that may not necessarily reflect the values of medicine. We are now engaged in a much more transparent practice of medicine than we had in the 1980s. When I began working in a hospital we had boards with little dots on them indicating resuscitation status, and shift wars where a patient would be DNR from 8:00 in the morning to 4:00. It was ridiculous. But I think there is a generally accepted openness about ethically fraught issues in medicine today. Scholarship regarding the ethical guidelines for patient / family / physician decisionmaking is published in major medical journals. Discussions are held in public, in the media, in the press about these decisions. The danger of legislation is that you codify thinking at a moment in time which may not reflect later thinking.

DR. QUILL: There are some real challenges and subtext issues here because you want doctors to exercise clinical judgment, and there are things that don't get offered because they are truly futile or because they don't make sense. But when there are treatments of substance that are not going to be offered or that you are recommending against, you really do want that to be the subject of a discussion. CPR is a paradigmatic case. It is both a real issue and it's a metaphor for talking about how sick and near death a patient may be. The patient is dying, but that does not give a clinician the right to unilaterally withhold potentially effective treatments even if effectiveness is marginal. If you're not going to use antibiotics to treat pneumonia because the patient is dying and you don't think it makes sense, that's going to have to be discussed. If you're going to stop checking bloodwork four times a day and instead you are going to do it once a day because it makes more sense in that circumstance, that seems to me a clinical judgment because otherwise you're just burdening people with every conceivable possibility in making them make a decision. On the other hand, if you were to stop checking any bloodwork at all, that would be a substantial change that would need to be cleared with the patient or surrogate.

DUBLER: And also, it is mean. It's mean to treat the family at the end of life as if they were some sort of junior consultant. They are not. They are grieving family. The skill and real honor of medicine is in the ability to make difficult decisions. What burden do I as a physician bear and where do I need to involve the family? And intruding into this delicate emotional and professional fabric with legislation does not generally help matters.

POPE: I think it's worth mentioning that while we can use Texas as a convenient target, Texas merely codified the AMA policy on this. And the AMA is hardly the only national professional medical association to endorse a process where the last step in the process entails unilateral refusal.

DUBLER: I think they were wrong.

POPE: Okay. Right. I just wanted to flag that this isn't just about Texas. There's a much broader support for the concept of having a mechanism like Texas than it might appear, since only one state has a law like this.

OUELLETTE: And there are at least some cases that have come out of Texas that have wound up in the courts where there's been young children or babies and the doctors really felt that the children were being harmed by the care that the mother was seeking. For example, there was the Baby Sun Hudson case,[15] and the Emilio Gonzales case.[16] I don't think that the physicians in those cases were trying to do harm in the family in any way; they were trying to do what they thought was right for the patients. So it may be that legislation isn't the right tool to address the problem, but there may be cases where providing the care that is requested that would prolong a life that is painful to someone who can't speak for him or herself. That is really not something that should happen. So that there's a huge difference, I think, between the case that Dr. Quill described where someone could speak for himself and say this is what I want and a case where there may be a child or someone who is being actually harmed by being kept alive.

SWIDLER: Well, Alicia reminds me that in New York we have had a couple of cases of babies or small children who had been declared brain dead where the hospital wanted to discontinue ventilation from the brain dead patient, but the parents objected to it.[17] And in at least one of those cases the hospital was authorized to discontinue.[18] It's analogous to the futility case, but it is placing the hospital against the patient or against the family in that the hospital's advocating the discontinuance of treatment.

DR. QUILL: In that circumstance, you have a societal consensus that if you can be declared brain dead, you are dead. There is a legal, ethical and medical consensus on that point. In other cases, whether it's with children or with the elderly, clinicians are going to have to partner with families in deciding which treatments can be stopped. Physicians are not going to be able to unilaterally stop treatments that have an even minor utility, even if suffering is high and it seems harsh to continue with treatment, without an in-depth conversation with families. But if there is a family consensus that treatment is not serving the patient's interests and therefore "futile" using a common sense definition and the doctor's agrees, then you can stop. So I think there is some ability to stop treatment in New York, but you have a consensus-based definition that it's futile or it doesn't make sense because suffering is too high and the prognosis is too poor.

DUBLER: There is an ethical formula often used in cases with children that does not require legislation; if physicians determine that what the families are demanding would cause harm, pain and suffering to the child without compensating benefit then it is appropriate to say to parents, after a deep and engaging discussion, "We will not perform that intervention. You are welcome to take the child to another institution." If parents refuse care that is clearly in the best interest of the child, is uncontroversial, and would relieve suffering, then it is appropriate to inform parents that the intervention will proceed. And, in the great, gray middle where uncertainty looms large, the parents must choose. However, implementation of this, and other such ethical / medical algorithms, does not require new legislation. These discussions evolve as our database increases and sophistication about decisionmaking is honed more finely. I would argue to you, Dr. Quill, that if the family for the 102-year-old patient wanted an intervention that you thought would cause great pain and suffering to the patient without compensating benefit, my guess is you would say no. But very few interventions fall in that narrow bright and brittle category.

DR. QUILL: And there are processes for working on those issues. I would say "no" and if the family really disagreed, then we would probably sit down together and see if we could find a common ground. If we could not achieve agreement about what we will do and what we won't, and the differences were substantive, then we go to ethics consultation. Only if that failed, and we were really at an impasse again, would we go to the courts. *Livadas* would be a good example of that. In this case, there were clear clinical criteria for stopping treatment, and family would not consent to stopping. We went through this sequence. Now this process for Livadas took six months before we actually stopped treatment based on brain death criteria. So it took this long even in a clear-cut case. Now one could argue that the patient probably was not harmed because she was so brain injured in the

first place that she was not aware enough to experience suffering, but I don't find much solace in that argument, and she clearly was harmed in significant ways. It's a very long process to go through all these steps, and there is significant suffering all around in this process. And the staff providing care that was extremely invasive, seemed to be inducing suffering and didn't make any sense to them for six months. They felt like we were working against this patient's expressed wishes, and she was suffering significantly in a way that could only end in her death. So again, there are many layers of harm that can happen in these cases.

POPE: I think this is actually right in the Family Health Care Decisions Act, the bill. Say that you are a physician and the authorized decisionmaker asks you to do something that you think is medically inappropriate. You cannot convince them otherwise. In that case, transfer is a specifically mentioned vehicle. Transfer is always built in as this way to solve treatment disputes. So the real type of futility dispute for which a new special legal mechanism would be useful is the dispute in which you can't transfer the patient. Here, I think it's worth mentioning that there is a case right next door to New York, in New Jersey, the *Betancourt v. Trinitas Hospital* case. Basically, the patient is actively dying, has all sorts of multi-organ failure and all sorts of problems. The providers thought it was inappropriate and cruel to continue to treat the patient. But the trial court ordered them to continue to treat. "Notwithstanding what you think is medically inappropriate, you must treat." That ruling worries health care providers in New Jersey, because they were unable to use their medical judgment. Hopefully, there will be guidance from the Appellate Court in New Jersey. This may actually be one of the first U.S. appellate opinions that actually gives some much needed guidance as to the rights of the providers and surrogates in these sorts of situations.

OUELLETTE: We could talk about these topics for a long time, but at this point, we are out of time. We need to conclude what I think has been a really interesting conversation. I had hoped we would have time to discuss New York's new Medical Orders for Life Sustaining Treatment (MOLST) law,[19] which created a process for creating a single document that functions as a medical order covering a patient's wishes for CPR and other life-sustaining treatment. The MOLST is effective and transportable in all health care settings. Unfortunately we don't have time to discuss the impact of the MOLST or its importance in health care planning. Nonetheless, I hope our readers will educate themselves about the MOLST, which can be a very effective tool for end-of-life planning. I thank you all for participating today.

Endnotes

1. S.3164-A (2009)(S. Duane et al.)(passed by the Senate July 16, 2009); A.7729-C (2009)(A. Gottfried et al.) (in Codes).
2. See *In re Westchester County Medical Center* (O'Connor), 72 N.Y.2d 517 (1988).
3. New York State Task Force on Life and the Law, *When Others Must Choose: Deciding for Patients Without Capacity* (1992).
4. See NY Surrogate's Court Procedure Act § 1750-b (Health Care Decisions Act for Mentally Retarded Persons); 14 NYCRRR § 633.11 (medical treatment for residents of OMRDD facilities; 14 N.Y.C.R.R. §§ 27.9, 527.8 (medical treatment decisions for residents of OMH facilities).
5. Surrogate Court Procedure Act § 1750-b.
6. As of the publication date, the FHCDA had been passed by the State Senate, but was still in the Codes Committee in the State Assembly.
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17. *Alvarado v. New York City Health & Hosps. Corp.*, 145 Misc.2d 687 (Sup. Ct., N.Y. Co. 1989); *Long Island Jewish Med. Ctr. (Doe)*, 168 Misc.2d 576, 641 N.Y.S.2d 989 (S. Ct., Queens Co. 1996).
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19. N.Y. Public Health Law § 29 77 (13) (McKinney's 2009).

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A Conversation About Difficult Inpatient Discharge Decisions

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Introduction

SWIDLER: Welcome everybody and thanks for coming. This conversation is going to be about the very difficult problems that can arise in discharging patients from hospital inpatient care to home or to a post-acute facility.

I read an Op-Ed piece last year that urged hospitals to study practices at companies like Toyota, and to strive to be more efficient and standardized. To run things more like a production line. And it occurred to me that the Toyota analogy would be a lot closer to what we face in hospitals if every now and then a chassis got up in the middle of production and walked out, or if the finished car refused to exit at the end of the production line, or if there was no place to send the car at the end of the production line. And in general, the analogy would be closer if cars on the production line had emotions, and individualized, often idiosyncratic, wishes and interests. Because those are the problems that we're dealing with, and they're not problems that Toyota is dealing with.

Key Laws and Regulations

SWIDLER: A good place to start is to note the relevant law in New York. The principal sources relating to hospital discharges in New York are the Medicare conditions of participation on discharges which are at 42 C.F.R. § 482.43, and the New York State regulations governing hospital discharges at 10 N.Y.C.R.R. § 405.9. In general, the obligations of hospitals relating to discharges are to provide discharge planning, to address the likelihood that a patient is going to need post-hospital services, to involve the patient and family in discharge planning, to respect the patient and family preferences when they're expressed, and to arrange and implement the discharge plan. Also, hospitals must give patients upon admission notice of their right to contest being discharged too early, and give that notice again when they are going to be discharged.

And, of course, one of the hospital's overriding obligations is to ensure that the patient has a discharge plan that meets his or her post-hospital needs,[1] and then is safely discharged in accordance with that plan. But as we will discuss at length, at times that obligation runs counter to other regulatory requirements, including obligations to respect the patient's autonomy rights, and the obligation not to allow a patient to stay after being discharged.[2]

So those are a hospital's general legal obligations relating to discharging patients. Pamela, do you have anything to add with respect to a hospital's mental health unit?

TINDALL-O'BRIEN: Obviously, we have additional statutes and regulations. We have Mental Hygiene Law § 29.15 and 14 N.Y.C.R.R. Parts 580 and 582, which have to do with discharge practices both at OMH-certified hospitals and Article 28 psychiatric units. The only thing I would like to remind us as we do go through this exercise, which I think is a terrific idea, is that as much as we can I'd like to think about children's issues as we're doing the adult issues. I know it wasn't something that you necessarily focused on, but, for example, when I was reading through the questions, one of the things that came up in my mind was the difficulties that we have with discharging children from hospitals. So if we

could keep that in mind a little bit, I would think that that would be also useful for this exercise.

SWIDLER: Thanks. I think that's a good point and it certainly comes up a lot.

Case 1—The Patient Who Won't Leave

One case I suspect we all encounter is the patient who won't leave when they're discharge-ready. This is one of the most difficult discharge problems to solve, and maybe I should have eased into our discussion with a simpler case. But let's try.

What we see again and again are cases like this: an elderly but decisionally-capable patient is admitted and treated for some condition like diabetes. The patient is stabilized and later is ready for discharge, but won't leave. The patient just says, "I don't feel ready to go home."

I'm interested to know, first, do all of you encounter this kind of problem, or am I just the lucky one that seems to run into this again and again? Or do we provide such good care at the hospitals where I work that people like staying there indefinitely?

FOUASSIER: We all encounter this for a variety of reasons we'll get into during the course of the conversation. Sometimes it's because the patient doesn't feel he or she will get proper treatment at home or there are other social issues. Sometimes there's a disagreement among the medical staff as to whether a patient's ready to go. Often we find that some members of our staff will advocate for patients beyond what I personally feel is necessary because, at the end of the day, we're care givers. We're interested primarily, if not exclusively, in making the patient feel better. That's a physical as well as an emotional state of mind. So because we're hospitals, it's something we run into all the time.

SWIDLER: In some ways it's an easier case if there's a dispute about whether the patient is discharge-ready. But just to sharpen the issue, let's say the patient is unequivocally discharge-ready. Let me ask it this way: What's the harm in letting the discharge-ready patient just stay in the hospital indefinitely, or at least an extra few days or weeks? After all we all pride ourselves on respecting patient autonomy.

FOUASSIER: Leaving aside the regulatory problem with letting a patient who's no longer acutely ill remain in an acute care hospital? There are a variety of problems. The patient continues to occupy an acute care bed which then can't be occupied by a patient who's stacked up in the emergency department. The patient could fall out of bed. The patient could develop decubiti. We run into these problems, all kinds of hospital-acquired infections and conditions as the patient stays. We have reimbursement issues and we try not to focus on those because we're routinely criticized for only being concerned about the money. But understand, we can't run our hospital on love and kisses. At the end of the day the financial consequences are also important. Who pays? We can't bill an insurance company for stays that are not medically necessary. That's fraud, and we would not want to do that anyway. The patient? If the patient has resources that's a possibility. But many of these patients do not. So the hospital ends up eating the cost of maintaining that patient, even a patient who's not acutely ill, is still going to require daily maintenance, a regimen of medication, feeding, physical or occupational therapy to keep the patient from getting sick.

HORWITZ: We all have problems with the patient who becomes very comfortable when they're in a hospital, whether it's the enjoyment of three squares a day or the attention from caring staff. Although the difficult discharge issues for years have been part and parcel of the discharge planning challenge, I am unaware of any regulatory statement of deficiency being issued for a violation of the regulations that indicate that inpatient hospitalization is limited to those requiring acute care—not long-term care and not custodial care. In some situations, and I'm certain Robert will get into this later, guardians have been appointed as a tactic to remove patients who otherwise refuse to leave. The basis of such a proceeding is that the patient has a "failure to understand" limitation reflected in a failure to understand that only acute care can be provided in the hospital setting.

In 1996, for example, this hospital successfully petitioned for the appointment of a guardian when a seemingly otherwise capable patient refused to leave. This case was upheld on appeal to the Third Department.[3] Clearly not all refusals to leave will satisfy the elements required for guardianship. If guardianship elements cannot be established, steps such as turning off the television and telephone service can be considered.

Other steps that can be considered include an eviction or a trespass action against the patient. In general, there are a number of considerations that must be balanced when determining whether to undertake such steps, particularly eviction or trespass. Eviction or trespass should be actions of last resort. One should be mindful of the public relations nightmare that could result, internally or externally, from such an action. It would not be unusual for the local newspaper to find a trespass or eviction action against a patient to be a matter of public interest; it also is not uncommon that a patient will either be related to or a friend of a hospital employee. I think it important that prior to the institution of an eviction

or trespass action, that counsel has the support of both senior administration and even the Board.

SWIDLER: Let me ask about that. Why would you bring an eviction action if you not only are permitted to discharge a patient who is discharge-ready, you are required to discharge the patient who is discharge-ready? Why can't you simply go over to the patient, once their procedural rights have all been fulfilled, and say, "You're discharged. You are not longer a patient. You're no different now from somebody who has wandered in off the street and is sitting on one of our beds."?

FOUASSIER: Assuming the patient can simply be escorted to the door and shown out, then clearly that's a remedy, but I think I share Jim's concern that often the political consequences of this type of activity have to be taken into consideration. Occasionally, a hospital is going to make a decision which might be against its financial best interests simply because it doesn't want to incur the heat. The guardianship is fine if you can make the argument that the patient is not only functionally limited but, like Jim said, is also incapable of understanding and appreciating the consequences of his own functional limitations. In a case where that clearly is not so, that's going to be a losing proposition and you're going to have to do something else. And that something else may very well be literally ejecting the patient from the premises if the patient is otherwise medically appropriate for that type of summary treatment. I for one would not recommend that my hospital engage in that even if the patient is completely hale and healthy. It's just too difficult to reconcile it in a public relations context. You know you're going to get hammered on it.

SWIDLER: What other avenues do hospitals take when faced with the patient who won't leave?

GOLDBERG: In our urban hospital setting, we have developed an informal core group who respond when a patient won't leave. It is not an uncommon occurrence, unfortunately. The group consists of me as the risk manager, the social worker and her supervisor and our public safety officers—usually at least two of them, depending on the situation. We also always include the head nurse, and sometimes the consulting psychiatrist, if one has been involved in the care. Practically speaking, patients who refuse to be discharged are generally not easygoing, compliant patients. They're often management problems, they can be loud and disruptive, and they can be physically intimidating or violent. It's important to involve the people who have the right skills and/or the best relationship with the patient to address the situation. We have never physically removed a patient. Sometimes the mere presence of a pair of serious and well-trained uniformed officers can be very effective. I think it's also worth observing that a patient who is medically ready for discharge but who will not leave the hospital—in addition to the problems that we've already mentioned—presents a morale problem for the health care team, the social workers and the case managers. It is distressing to the staff, and if the situation is not managed properly, it can create an atmosphere of disorder and a feeling of powerlessness—that a patient who is not sick can simply refuse to leave. Sometimes, the fact of a team working together can combat the feelings of powerlessness and lack of order—even if we are not always as expeditious as we'd like to be in these very difficult situations.

BARREIRO: I was just going to comment with respect to the guardianship alternative that Mental Hygiene Law § 81.16(b) gives us a dispositional alternative to the appointment of a guardian, of course, which is a protective order. There's some commentary to suggest that the court need not find incapacity to the extent that it would be required for appointment of a guardian in order to provide relief under that section, and so sometimes I think it can be politically possibly more palatable to obtain relief under Article 81, essentially a discharge order, as opposed to going to a proceeding for eviction. That's just something to keep in mind.[4]

MASSETT: Thank you. I just wanted to add on this scenario, but actually it comes into play in all of them when you're looking at not only the legal advice but the practical advice that hospitals need to take into consideration in crafting a response to a patient who won't leave is looking, one of the questions asked in the preparatory materials was, does the reason matter in some of them, and I think that if you look at the reason underlying, let's take the scenario we're dealing with right now, decisionally capable patient who is otherwise ready to go. The question being, well, why won't they go? In cases where it's just: I really like it here. The food is good and I live alone at home and I like your nursing staff. I want to hang out versus I do have some—notwithstanding my doctors all saying I'm ready to go home and that the home care people are going to take care of me—I have some fear and trepidation about whether I am really physically ready to go or not. I know we said that the appeals process would have all gone through but depending on what the underlying reason of the patient is, might determine which legal and operational approach you take. I think that there is, both from a public relations standpoint and if you choose to seek some type of judicial intervention, be it an 81 or be it an eviction or a trespass proceeding, if you've just got somebody hanging out in a bed because they like it here better, for all of those reasons taking that type of a judicial intercession is probably a lot more palatable. If the patient, notwithstanding of the appeals procedures,

still has concerns for their own personal health and safety, then you might forgo jumping into that judicial intervention process to try to figure out how to bring them some peace of mind around those issues and figure out if there are ways of addressing that so that they will consent to it. I think that in each of the cases, this one and the others, those things come into play.

SWIDLER: Marguerite, how would you weigh this scenario on your scale: The patient needs nursing home care. The nursing home that's willing to take the patient is not that attractive a place. Also the patient is not paying for care currently because they're on a DRG, but the patient would start paying immediately or at least soon if they're in the nursing home. So predictably patient is not in any particular rush to get transferred there. Where does that fall on your scale?

MASSETT: I would put that, all else being equal, meaning it's a nursing home, just not one of the more attractive ones on the, well, that's the place that's ready for you. This isn't a hotel where you can stay until your choice hotel becomes available. On that end, versus, I mean I suppose there are other issues of if it's a nursing home but instead of being 10 miles away from my family, it's 50 miles away from my family. Again, that's not so much just I want to be comfortable, that's there are some other social concerns.

FOUASSIER: These are things we do now. We wouldn't really be having this dialogue if we were able to convince these difficult patients to see the error in their ways. We really try hard to make these people understand that although it may not be a perfect solution, it's medically appropriate to go to, for example, a skilled nursing facility. It's when it crosses the line into an unreasonable resistance on the part of the patient. Sometimes you get different levels of sensibility amongst your own staff because the family doesn't want the patient to go because it's too far away. Somebody's mother heard from a friend that it was dirty or the food wasn't any good, and the hospital has to decide at what point in time the patient's concerns can no longer dictate the hospital's discharge policy. So we always try to make the difficult patient understand that while some of the concerns may have merit, at the end of the day he or she is better situated in a long-term care facility more appropriate for his or her needs. Where we run into problems is when we're unsuccessful in trying to convince the patient and have no other remedy but to compel the patient one way or another.

MASSETT: I indeed agree that there is that line that you have to find and say notwithstanding that we have not been able to cajole you into this situation, we are going to start taking the necessary legal and operational steps we need to make you go. I guess what I was suggesting is that sometimes, sometimes, not always, it's not just a matter of making the patient understand what you're saying. Sometimes they do understand what you're saying, but don't agree with you. Then you need to find out the underlying reason that they don't want to go.

I can give you an example. A case where a nursing home was ready to accept the patient, but the patient didn't want to go. The patient was an elderly woman who had always lived alone, and didn't have family. When someone who wasn't involved in her clinical care sat and talked with her for a few minutes, it was found out that she was actually just kind of scared of the unknown. She had gotten used to the nurses and she didn't know what the other place was going to look like. I know this sounds simple, and this is not the case in all those situations, but having her day nurse go with her when she checked into the nursing home made all the difference in the world.

All I'm suggesting, and I know not all situations are that simply answered, but really, hospitals shouldn't simply try to get the patient to understand that he or she has to go, listening to information from the other direction is also important. You might then realize that you're not with someone who's just trying to manipulate the system to stay in.

SWIDLER: Well it's interesting. My perception is that better listening, along with good social work and good clinical care, can reduce the frequency of this problem, but ultimately they can only reduce it. There still will be cases where the clinical team ends up phoning the hospital lawyer in exasperation. But I agree with you, the focus ought to be on reducing it first.

HORWITZ: Marguerite is right on the mark that the assessment must be on a case-by-case basis and that resort to legal intervention should be the last stop. The social workers, the case managers, the nurses, family, whomever, really should exhaust all other options to determine what issue the patient is facing.

The recent article published by Robert and others is quite interesting;[5] it delineates the ethical, medical and legal concerns. This concept of "justice" as we enter a new era of health care and health care reform is becoming more paramount than it was ten years ago. We have scarce resources, we've debedded a number of hospitals. A daily patient census can vary greatly, in a community hospital perhaps from 170 to 300 patients. There can be bed vacancies one day and the next patients stacked in the corridors. Difficult discharge patients during high volume times represent not only a waste of resources but the possibility that care and treatment for others will be delayed. The stakes are higher now; scare resource and de facto rationing compels us to find these answers

and perhaps take a harder line to discharge the difficult patient in a more timely fashion. Timely discharges are not only for the benefit of others but also for the benefit of the patient. And after all, hospitals are dangerous places for a host of reasons.

SWIDLER: It strikes me that mental health units have a higher percentage of these cases than other units, and it's a difficult population for a number of reasons. So let's consider the same scenario in the mental health unit: we now have a patient who has decisional capacity, maybe a voluntary patient. We identified a safe discharge for the patient, perhaps to a community residence, but the patient just doesn't particularly want to go to that community residence. "I've been there before, that place stinks." A suppose there isn't any other place that's ready to take them at the time. So, how much trouble are we in if we use self-help methods or just tell the patient, "You're out of here at 2 o'clock today"?

TINDALL-O'BRIEN: I think you'd probably have problems with the Office of Mental Health when it came time to look at your license! But there are several scenarios. One of the problems for persons with mental illness is that Article 81 doesn't work very well for most people who have mental illness if they don't have family members willing to act as guardian. If you don't have family members who are willing to act as the Article 81 guardian, then, in fact, it makes Article 81 difficult to pursue, unless the local Department of Social Services Adult Protective Services Unit is willing to act as the guardian.

The problem that we frequently have when we go for guardianships is there just isn't anyone who wants to act as the guardian. So, the guardianship has not worked well for us.

I would have to agree with Marguerite who said work with the social work staff, work with the physician; sometimes we've asked the hospital to take the person actually to the community residence to look at it, to talk to some people there, to be creative and to get consultations also. The OMH hospitals, the psychiatric centers can, in some instances, if there is a child with a multiple disability or some unusual circumstances, we've even obtained some sort of a clinical consultation as to how to best handle the patient. You know, our staff has been available for that on occasion.

We tend to see this much more, not in the adult side, but much more in the children's side where you have children in a psychiatric unit and the parents have had the respite of having the child in the unit, the child is difficult to handle at home and they just are exhausted from caring for the child and really don't want to take them back home, and yet the child doesn't need a community residence, doesn't need to be in intermediate care. So then the question is how do you get the family to agree to take the child home? Usually the only way that can be done is by building clinical supports around the family.

FOUASSIER: I know this sounds harsher than I intend, but why should the parents have that option? If it's a question of their incapacity to handle the child's needs, that's one thing. I can understand that. I realize it's difficult, but I'm weighing things here. I'm weighing strain on our health care system of decisions being made by parents that because it is difficult they'd rather not take their child back. If they decide that they just don't want to do it anymore, they can't do it anymore, they don't want to devote the emotional resources to it, should a hospital, for example, contact CPS? Is that a form of neglect? Is it abandonment? What do we do? Because we have an affirmative obligation to discharge this patient.

TINDALL-O'BRIEN: First of all we try to accommodate the parents, deal with them, set up the clinical supports necessary for them to take the child home under appropriate circumstances. But we have, on occasion, informed parents that if, in fact, they won't take the child home we will have to "hotline" them with the Department of Social Services Child Abuse hotline as guilty of medical neglect. So that has happened on occasion. It's not something that we like to do, it's not very helpful to the therapeutic relationship that the hospital has with the parents, but if necessary we have done it.

SWIDLER: I've seen this case a few times and when I've seen it, it's not the patient's first hospitalization and discharge, it's about the ninth or tenth or twelfth. So the family evidently is unable, or no longer able, to offer a safe discharge. So in some of these cases going home is not a safe discharge, and then we've got to find something else.

TINDALL O'BRIEN: And luckily, in New York State, we have a Home and Community-based waiver for children who are under the age of 18. So we do have the ability to build those supports around the parents, but not all children who are going to be released from an in-patient setting are necessarily eligible for that waiver, so it depends on their level of disability. But you know, we have on occasion found that if we talk to the parents or guardians about the fact that we might have to hotline them, that makes the problem go away. We have very seldom had to actually hotline them, but we have, on occasion, done that.

Case 2—The Family That Objects to the Proposed Discharge

SWIDLER: Well this is actually a good segue to the next case because we're now starting to talk about family decisionmaking for patients who lack capacity. So let me simply tweak our first example: An elderly patient in the general medical unit, but this time the patient is decisionally incapable, say with dementia. And say the patient was hospitalized for diabetes again. Now the patient is ready for discharge to a nursing home and the discharge planners have identified a nursing home that's ready to take the patient. But the family and adult children don't like that nursing home. Or they just aren't ready to have their mom discharged to it. Maybe their concern is that there is a limited Medicare benefit and after that the nursing home is going to start being a cost on them. For whatever reason it is, the family doesn't want the patient to go to the available nursing home. Are there any additional issues that are raised with the family decisionmaking that we haven't already encountered in connection with the capable patient case?

HORWITZ: I spoke with our Director of Case Management to get a sense of how often family difficulties impede our discharge. We have roughly about 15 patients a month where difficult discharges are caused by difficult family situations. Families will not cooperate for a variety of reasons. They may just not like the nursing home. Also, we're in a rural area and so our nursing homes can be anywhere within a 50 mile radius, which can be burdensome to families, particularly with transportation problems. So there may be disagreement with discharge plans. Perhaps the family is not providing the hospital or the Department of Social Services with the information necessary to file for Medicaid. Perhaps it is simply a dysfunctional family. We deal with these situations, and again legal tools are the last resort. But we've had some success by simply discussing with the family the fact that resort to guardianship may be required if we are unable to discharge the patient. We've successfully resorted to court proceedings in situations where a family member, even a health care agent or guardian, is not acting in the interest of the patient but primarily in their own interest or that of the family.

In our geographic area we have been fortunate that it ordinarily doesn't take months to obtain a court appointment of an Article 81 guardian. We can generally do it within a month. Now that is a month where the patient's not going anywhere, but generally those patients aren't going anywhere anyway. We also find that the nursing homes are very reticent to accept patients when the family does not want them there. So the appointment of a guardian may be the response to the family reluctant to endorse placement of the patient in a certain nursing home.

FOUASSIER: I wholeheartedly endorse that. We have become much more enthusiastic about pursuing guardianship when we feel that we've made good-faith efforts to convince the family members who are preventing the discharge, but they either cannot or will not see it our way. We institute the proceedings. Then we deal with the fact that guardians are becoming scarcer and scarcer (because fewer and fewer people want to serve) by framing our pleadings in a way that asks for very limited relief. We ask that the guardian be given only the powers necessary to facilitate the discharge. We find that where we need to seek a third-party guardian, usually an attorney, that the attorney is less reluctant to take it on even if there's very little chance of compensation, where the duties are limited. He or she will facilitate the discharge and the admission into the alternate level facility and then he or she can petition to be relieved, and it's done. Rather than a guardian who's on the hook for the long haul. In too many cases when we wait and wait and explore all kinds of other alternatives, three months down the road we find ourselves in the same situation and we end up falling back on the guardianship proceeding anyway.

SWIDLER: Is the guardianship proceeding a good process for the resolution of this kind of case, or is it just the best process now available? Is there a policy response to this that we should be considering?

FOUASSIER: Well, to the extent we soon may have the family surrogate decisionmaking act, it might help, but you may get the same resistance from a family member acting as a surrogate as you would from a family member not acting as a surrogate. The problem is not so much the decision to discharge, but the arrangements for subsequent admission somewhere else. Without someone legally authorized to admit the patient, you're not going to get an acceptance by the step-down facility. That's where we run into a problem. So, to the extent there is no person legally authorized to sign admission papers at, for example, the skilled nursing facility, then without the guardian we would not be able to facilitate the discharge. And, depending on the circumstances, a surrogate or guardian may not solve the problem.

Also, the problem may be financial. Simply having a guardian appointed doesn't mean there's suddenly a source of funding where there may not have been one yesterday. I suppose we'll get into that in a little while.

SWIDLER: Right, we will. But you raised the implications of the proposed Family Health Care Decisions Act.[6] And today is kind of a historic day because at 4:30 a.m. this morning the State Senate passed

the Family Health Care Decisions Act for the first time. There is a very good chance the Assembly will pass it before the year is out and that it will become law next June. That law would give family members clear legal authority to make decisions for incapable patients who didn't make the decisions previously themselves and who didn't appoint a health care agent.

Now, I've been an advocate for this law…forever. Since I was young. And I think it's an important law that we need, and it will be a great advance. On the other hand, when I think about discharge problems like the case we're discussing, you have to wonder: will the FHCDA make discharge disputes even more difficult for hospitals, by empowering family members more explicitly?

But then, to answer my own question, I would point out that the family member's legal obligation under the FHCDA will be to make the decision the patient would have wanted, if known, or else the decision that is in the patient's best interest. And, of course, the surrogate can only make a decision that the patient himself or herself could have made. So in our hypothetical case, applying that standard would lead you to the question of whether the patient himself or herself would have been able to oppose a discharge indefinitely. So at the end of the day I'm not sure that the act would really impact this kind of dispute one way or another. At least that's as far as I've been able to think it through.

BARREIRO: I was going to make a similar comment. In fact, we have a fact pattern coming up that is similar. Even having a health care proxy doesn't necessarily solve these problems. When that agent says, "Mom said, never send me to a nursing home," and there's no safe discharge plan other than a skilled nursing facility, you still have the problem. So guardianship is always going to need to be there to fill in the blanks. The FHCDA may, in fact, make it more difficult for some of these cases.

SWIDLER: Well, I think the issue comes down the limits of autonomy, whether exercised directly by the patient or by a surrogate on behalf of the patient. In these cases, the decision-maker may be stepping beyond what can be done in the name of autonomy.

TINDALL-O'BRIEN: One of the things that we have found in trying to discharge to skilled nursing facilities is that many facilities want not only someone to consent for the resident to enter the nursing facility, they want someone who is willing to make decisions once the person is in the nursing facility. And if you don't have involved family and friends, and you don't have a guardian, that can be a very difficult situation.

HORWITZ: That's a great point.

SWIDLER: That's an excellent point.

TINDALL-O'BRIEN: There's been some talk about having the surrogate decisionmaking committees[7] expanded to have some ability to be involved in nursing home cases, but that has not happened to date. But that's a very difficult situation in that it's not even getting the consent to enter the nursing home, it's who's going to make the decisions, the medical decisions, once the person is in the nursing home if they lack capacity. The nursing homes are not willing to take on that concern and that potential legal burden.

SWIDLER: Well, the FHCDA will help with that by clarifying who has authority among family members, and a process other than guardianship for getting treatment consent for residents without family. But frankly, even without the FHCDA, nursing homes are identifying from among family members a designated representative who can exercise at least some rights of the incapable resident.[8]

BARREIRO: Many contracts use the term "responsible party" as opposed to designated representative, although that term is also used. And that is the key problem, because as we all know the nursing homes, once they have these patients, cannot discharge for non-payment for all intents and purposes. It's very rare. So what the nursing home is concerned about is having a patient in a bed with no source of payment. Therefore, they're increasingly looking for someone to sign not just for the resident but as a responsible party or as a financial agent. Particularly under the new Medicaid rules, nursing homes need people who actually have access to the patient's financial information in order to make Medicaid applications, and that is where you get the problem. It's also a problem on the hospital discharge side, because the nursing homes, even those with available beds, are increasingly reluctant to take patients into them when they fear there is no source of payment. And there can be a long period of disqualification under the new rules.

MASSETT: Marguerite's exactly correct, there are times when the discharge problem is not just a dispute about a health care decision, or about where is a good place for me to go live, it is a problem about the underlying financial issues for the institution. If we're talking about an institutional discharge into a nursing home, a key question is how are payments going to be made? And it's not just a matter of the nursing home saying, look we want a responsible party to sign and be financially responsible for this particular patient. Even if you can find someone, they might not have the legal authority to marshal all of the information necessary to determine if there's Medicaid eligibility. Or even if they have the authority, they might be hiding some of those assets because, you know, they are trying to maintain it for the family.

So you have to worry not just about the door out of the hospital, but also the door into the nursing home. You have to deal with both of those issues or you're not going to be able to discharge a patient. So, the underlying business issues, or frankly the underlying financial issues, are going to be critical. I think this is why we have seen almost a three-fold increase in the number of Article 81's that we've been asked to do by hospitals. They are not just for health care decisionmaking, but also to give someone, as Alyssa said, the authority to collect the financial information. And to make the Medicaid application, if that's appropriate. Or to identify resources that are available to help pay the bills.

SWIDLER: Why a three-fold increase? Is that just the economy or is there something else going on in society that's driving that?

MASSETT: You know, we tried to find this out when we suddenly realized there was this huge increase. And this is probably over the last five to seven years. Certainly part of it is financial. As Jim said, and he's just right, we've shifted costs to hospitals by making them the only health care provider that is mandated to accept nonpaying patients, assuming they come in through the emergency department. Frankly, even when an attending physician admits a patient, you know, the hospital usually has to take them. So that has driven the need for guardianships to accomplish the later discharge.

The other thing is that prior to this time there were personal relationships developed between hospital discharge staff and various nursing homes in kind of a "we just have an understanding that you're going to take a few of these difficult situations every once in a while," and that's the way we kept it neat. Oddly enough, I think the increase in regulation in the health care industry, patient confidentiality, a lot of the fraud and abuse issue, etc. have started to kind of wear away these relationships that, previous to this time, would have permitted some of that happening. But I have to tell you, I think the biggest driver is financial.

HORWITZ: Yes. The last piece of this, we talked about getting the patient out of the hospital. Getting the patient into the nursing home. But what about coming back to the hospital? A lot of these patients, unfortunately, are going to be, I'm not going to call them frequent flyers, but they're in and out of the hospital on a number of occasions. I happen to like the Article 81 full-blown, so to speak, so I know Jim talked about a limited Article 81, at least where I live this is the only hospital, so we can fully anticipate and expect whenever one of our patients who has been discharged needs a readmission, they're going to be coming back here. So we don't want to go through these issues every time there's a discharge. I think that it's certainly not a panacea but it's been a great aid to us in terms of knowing who's going to consent, who's going to make the payments, who's going to make all kinds of arrangements with respect to the disposition of the patient when they're ready for discharge.

So I think the Article 81 has worked well, at least for us. I'm not sure that we've seen an increase, Marguerite, like you've had. We've had a fairly steady number. Actually maybe the numbers are going down a little bit. I like to think of that as a result of our case managers and social workers and practitioners perhaps getting better in terms of their discussions with patients. But it's certainly there and we certainly utilize it.

FOUASSIER: We can attribute some of our rather dramatic increases to the fact that the mindset of the hospital institutionally has changed. We simply can't afford to absorb the kinds of financial losses which we previously took for granted and we have to be more proactive in trying to cut those losses. And this, quite frankly, is one way to do it. I mean leaving aside the issue of the best interest of the patient, we simply can't afford to allow these people to stay.

Case 3—No Place to Go

SWIDLER: Let's turn to another example, the example of no place to go. I saw a good illustration of this in Jim Fouassier's article in the *Health Law Journal*.[9] He wrote about a ventilator-dependant dialysis patient who is morbidly obese, who needs nursing home care that can meet his specialized, high-cost, difficult-to-manage needs. Predictably a hospital is going to encounter great difficulty finding any facility to take the patient. But the patient doesn't need acute care any longer, and is ready for discharge. In fact, the patient is anxious to be discharged, and the hospital is anxious to discharge him. There's just no place to go.

The first question is, have you seen this before? How should facilities handle this?

BARREIRO: I'll tell you that recently we were consulted by a family member of a patient with this scenario. These are extremely difficult because of the paucity of facilities that can handle these patients. We don't have a lot of specialized facilities in Broome County, and so often we have to arrange discharges out of the area. And the patients are reluctant to go, family members are reluctant to consent to the discharge. Perhaps others are more experienced with this.

SWIDLER: Well, it's not like I expected you to have a quick, snappy answer to this. This is one of these problems that doesn't have a good solution. Except that we can all agree to beat up on Pamela and the State, and

ask them to beef up the care network that's available, and to take more difficult-to-discharge patients like this.

GOLDBERG: In New York City, we will eventually find a bed for a patient like this. It may take a long time, but it will happen. The more difficult problem—really intractable and also not uncommon—is the undocumented patient who has no insurance. This is the patient who will be with us for the duration, because there is simply no placement for a patient like this. I am sure that we've all read about the recent Florida case in which the hospital chartered a plane to send a severely brain-damaged patient to his mother in Guatemala, over the objection of the patient's legal guardian. No hospital wants to be in court or in the news under those circumstances. But when there is no Medicaid, there is no discharge planning.

There's an interesting article on the subject of medical repatriation by Joseph Wolpin in the Spring 2009 volume of the *Journal of Law and Medical Ethics* that explores the subject of medical repatriation from a legal and ethical perspective.[10]

SWIDLER: You said that a patient can end up with you "for the duration." Won't that gradually turn you into a chronic care facility, as these patients mount up?

GOLDBERG: Yes. And then it's a very hard situation for everyone, including the patients—some of whom need only relatively inexpensive, though continuing, aftercare, but who are uninsured.

In New York City the discharge of a homeless patient is another difficult situation. The NYC Department of Homeless Services has an application process that is designed to ensure that discharge from hospital to shelter is a plan of last resort. For the hospital, it is a very time-consuming bureaucratic process, taking from four to six weeks, and it only begins once the patient is medically ready or almost ready for discharge. I am not sure that it benefits anyone, including the patient. Most often, a patient will begin the process and stay in the hospital for a few weeks, awaiting shelter placement. Then the patient gets disgusted with the process and just leaves the hospital—but only after occupying a bed for several weeks that was needed for a sick patient.

TINDALL-O'BRIEN: The Office of Mental Health has the same problem in its hospitals. We have a lot of undocumented aliens. And if you can't get Medicaid and/or any kind of public assistance or SSI, it can be very difficult to move individuals out of the hospitals into an appropriate after-care placement. We have tended to take a lot of undocumented aliens into our family care program, which is almost like foster care for adults. But it is not necessarily a good fit, but it's the only fit because most of the after-care that's done in our system is done by not-for-profit providers who do not have the financial wherewithal to absorb a client who can't pay. So, it's a big problem for us too.

HORWITZ: Robert, you asked whether or not we might need any policy changes. Well, take a look at the categories of patients that nursing homes are reluctant to accept. We have nursing homes unwilling to accept patients that require high-cost medications, those that may be on IV antibiotics, those with MRSA, and of course the Medicaid-pending patient. My understanding of the Medicare/Medicaid anti-supplementation laws is that they preclude a hospital from participating in cost sharing.[11] Now I know there was a Syracuse plan, and Marguerite I'm not sure how familiar you are with that, where there was a consortium of hospitals that engaged in assisting nursing homes and supplementing their income to assist with those types of patients. But in the absence of a consortium, I don't think that a single hospital would be permitted to, for example, assist a nursing home with payment for those high-cost medications. I think that it might be worthy of some policy or legal change, legislative change or regulatory change, because frankly a hospital would be better off financially saying, "Okay, nursing home, we will assist you in the procurement of these high-cost medications, so long as you agree to take this patient." So that would be one suggestion, consideration.

SWIDLER: There you go, Marguerite: Why can't a hospital pay to *give* referrals, instead of to get them?

MASSETT: The problem is not on the hospital side. The hospital can certainly provide the support. The problem is, it's illegal for the nursing home to ask for it and accept it. The nursing home is risking regulatory retribution, depending on the payment source for that particular patient. That's where the issue is.

And Jim, I am familiar with the situation in Syracuse. We worked with the hospital executive council and the nursing home group to come up with a way for the hospitals to fund a generally available grant, not connected to any one particular patient. Nursing homes, to access some of that support and financial aid, had to agree to take certain difficult-to-place patients. And it's a nice model. I have to tell you, no nursing home has been challenged for this practice, which we think is defensible even in light of the regulatory prohibition on supplementation.

But I agree with Jim. We all understand that the evil that was meant to be prevented by that particular rule was where a nursing home would extort money from a family, particularly, saying, "I'm not going to get paid enough by Medicare or Medicaid to take care of your family member,

but if you make sure there's a little bit of extra on the side, everything's cool." We all know that's the evil that was meant to be prevented. But that's not this situation. And there should be a way from a policy perspective where you can distinguish a community cooperative standard to try to make sure that the most cost-efficient and best place for the patient is supported financially, rather than just lump it in with that other evil.

SWIDLER: I represent a health care system that has both hospitals and nursing homes, and we often have a case where a hospital in our system has a difficult-to-discharge patient, and calls me up to ask, "Can't you help us out and get one of our own nursing homes to take this patient?" And so we've discussed the idea of creating a fund within our own system, not tied to any particular patient discharge, but just tied to the overall quality and cost-effectiveness benefits of discharging expensive patients to nursing homes.

I think we can do it lawfully. But the problem that we've been encountering is the difficulty, basically, of figuring out an amount for that fund so that the hospitals don't feel they're paying too much and the nursing homes don't feel they're going to be stuck with endless costs associated with somebody who they might not otherwise have taken. But it is an area where I'm convinced there are mechanisms for hospitals to provide financial support to nursing homes in connection with transfers without violating the Medicare and Medicaid anti-supplementation rules.

MASSETT: Yes. It goes to my point, and I think Jim Fouassier made the point as well: that one can't ignore the financial cost shift and the financial issues underlying certain of these situations. And it's not just a case of noting that who can pay the most gets the best care, although there's an element of that. The core issue is the cost shift. Because that's part of what the national health care policy debate is about. There's just not enough money in the system.

BARREIRO: We see the same problem here and I think that creating a community fund is a great way to resolve it. And I think that you're right, it's not the same evil that was intended to be avoided by that broad prohibition on taking anything in consideration for the admissions.

SWIDLER: By the way, I've even heard Health Department officials speak in support of what was done in Syracuse to create that fund.

BARREIRO: I can't imagine that being challenged on policy grounds.

MASSETT: Yeah, I wouldn't think so. Although it, we'd probably all be disingenuous if we said we never heard of a hospital, one of our hospital client patients going to a nursing home with an oversized wheelchair, a special bed, or with a nurse who went down the street to help with IV antibiotics every once in a while. That happens all the time, that happens all the time. And it frankly is in the best interest of the patient often, so you've got to find a way that the law doesn't get in the way of that.

SWIDLER: Right.

BARREIRO: I agree.

SWIDLER: Also, regarding the no place-to-go issue, we often run into this in connection with mentally ill patients, mentally retarded patients and substance-abusing patients. In particular, we run into difficulty finding residential programs or even independent housing. This is a good chance to ask Pamela about what's going on in that area. I know, among other things, OMH is being sued by disability advocates groups arguing that the state has an obligation to provide a greater range of residential options, options to ease up the discharge of the patients from hospitals. What's going on with that?

TINDALL-O'BRIEN: Actually I'm involved in two cases. One has to do with patients that have been discharged, not just from the OMH hospitals, but also from Article 28 psychiatric units to nursing homes, who DAI alleges could be cared for in the community.[12]

SWIDLER: DAI? Disability Advocates Inc.?

TINDALL-O'BRIEN: Yes. The case has a lot of implications for us. At the state level, we're very concerned about it because it's holding the State of New York responsible for Article 28 discharges. Which I think is a leap that has never happened before. Just by the mere fact that we license the Article 28 hospitals, they are saying that it is a sufficient nexus to hold us responsible for the discharges that are done by the Article 28s.

SWIDLER: You know, I suspect my colleagues and I think that's a good idea.

TINDALL-O'BRIEN: I'm sure you would. We think it's a very bad idea.

SWIDLER: (Laughs).

TINDALL-O'BRIEN: So that's one of the cases. And the other one has to do with adult-home residents. And again, DAI wants the Office of Mental Health to create more housing.[13] I should note that the State of New York has more housing units per capita, by far, than any other state in the United States. We actually have about 31,000 housing slots, but the fact is that, you know, people who have mental illness, not all but many of them, have difficulty with employment and therefore are poor. They get SSI, they get SSDI, and they have a hard time, particularly in New York City, affording housing. You

know, the fact is there's not enough-low income housing in the United States. There's particularly not enough low-income housing in New York City, and most of our housing issues come up in New York City. My guess is, and I could be wrong on this, but my guess is that you don't see the issue as much up in Glens Falls as probably you do downstate, just because housing costs are so different.

And one of the things that I would like to make everybody aware of, is that there was a change in the OMH regulations regarding discharges from community residences and all of our licensed community housing to provide much more due process. And, in fact, you cannot discharge someone from a community residence if they go into an Article 28 hospital unless you follow the process and unless you meet the criteria that are set forth in that regulation.[14]

SWIDLER: I don't think I knew about that, when did that happen?

TINDALL-O'BRIEN: This is a relatively new regulatory change.

SWIDLER: Is there anything similar on the OMRDD side?

TINDALL-O'BRIEN: Nothing similar on the OMRDD side that I am aware of. It happened in January, 2007. There were changes to 14 N.Y.C.R.R. §§ 595.9 and 595.10. Basically the process that's been set up is if a community residence wants to discharge someone, first, they have to have appropriate reasons, they have to give notice, the community residence itself first has to look at the issue, then the resident can go to the local office of the Office of Mental Health for what you would call a "mediation session." If that isn't successful, then the resident can appeal to the Commissioner of Mental Health if he or she thinks that they should not be discharged from the residence. So it was an attempt by the Office Mental Health, which was sued on this issue, to make it clear that community residences are programs, that they are not housing the same way an unlicensed apartment is housing. And it was a way to try and keep those issues out of housing court, and yet provide appropriate due process to people that are in OMH-licensed housing.

SWIDLER: It's helpful to know that, because very frequently somebody's admitted to the hospital from an OMH-, OMRDD- or OASAS-licensed community residence. And later the residence won't take the patient back for whatever reason. So it is helpful to know what the process is with a discharge on that end.

TINDALL-O'BRIEN: And the important thing, also, for everybody to know, is that in every county in New York State there is something called the Single Point of Access, which is an entity run by different providers in the county. Local DSS is on it, there are a variety of people who are on it, and they are the ones that make decisions as to who should get priority access to housing. They prioritize who goes into OMH-licensed and supported housing. In New York City, however, because it's so much bigger, there is a SPOA, but the SPOA only handles what we call the difficult-to-place people, someone who could be difficult to place in regular housing. So the Single Point of Access, which in New York City is operated by a not-for-profit agency called the Center for Urban Community Services (CUCS), under contract with the State. CUCS acts as the SPOA and if a hospital is having problems placing a difficult client into OMH housing, they should be contacting CUCS and putting together a SPOA application. And that's something that all of your social work departments should know, regardless of whether you're in New York or whether or not you're in Glens Falls, that counties have set up this entity called SPOA, Single Point of Access, in order to assure that people who are most in need of housing can, in fact, access appropriate housing.

FOUASSIER: I had a question for Pam, a little bit off the beaten track about the new regulations on community residence procedures. Does the hospital have any remedy in a situation like this? Most regulations don't give the hospitals or any other providers any private right of action other than sanctions from the regulatory agency. What happens in a situation like this, where the hospital is dealing with a patient who is improperly discharged from a community residence?

TINDALL-O'BRIEN: I would suggest that the hospital's social worker call the field office, the OMH field office. We have five field offices located throughout the State of New York: Buffalo, Syracuse, the Hudson River Field office is in Poughkeepsie, the New York City office is in Manhattan, and we have one also in Long Island. I would suggest that you call the field office and talk to the housing person about the fact that you believe that this individual has been inappropriately discharged. The field office can look into it. In addition, they also act to assist in difficult-to-place discharges. If nothing else, they can hook you up with a SPOA. OMH operates 24 or 25 hospitals, so we are both a provider *and* a regulator. So we understand a lot of the issues that hospitals face, because we face them ourselves.

SWIDLER: I always say OMH has a reality check when they write regulations, because they have to follow them as well as dish them out.

Case 4—The Isolated Patient

SWIDLER: OK, now let's consider another case: the patient is ready for discharge and we've identified an appropriate discharge location, let's say a nursing home. But let's say that the patient lacks capacity and doesn't have any family or friend who is ready, willing and able to make decisions. And the nursing home won't take the patient unless there's somebody in place to either help arrange personal care or the financial matters. Do you encounter that problem? And what are some ways to address that?

BARREIRO: We've already spoken, you know, at length about the fact that increasingly hospitals are using Article 81 and certainly this fact pattern suggests relief under the statute. I thought it was probably worth mentioning that the Article 81 is applied with great variety throughout the state, and so it's very place-sensitive with respect to how the courts are going to receive your application. The hospitals have to be aware of that, particularly with respect to evidentiary issues.

For instance, if you have a patient who is not able to comment at all concerning the proceeding, it's one thing, but if you have a patient who's able to express to a court evaluator or counsel appointed for them by the court that they don't want a guardian, which is sometimes the case even with an individual described in the fact pattern, then the evidentiary rules are going to apply. And for a petitioning health care provider that can be problematic because the CPLR privileges as to doctors, nurses and social workers are applicable.[15] And there's a line of cases which suggest judges may sustain objections based on privilege if the health care provider is trying to admit testimony from a nurse or social worker.[16] And so, locally you have to know your judges and how they're likely to rule on these issues.

I think that increasingly there's going to be a move towards more uniformity in guardianship throughout the state so that even in places where judges have been more user-friendly, you're going to find the evidentiary rules may be more stringently applied. We get around it with first-hand observations from uncertified, not-licensed social workers or aides. Sometimes the lowest common denominator is the best testimony in these cases, oddly enough.

SWIDLER: Well, Alyssa, before you move on, are there any proposals to modify New York law to allow for the introduction of protected health information in connection with the guardianship proceeding? Because that just seems like basic common sense to allow that evidence in a guardianship proceeding where the issue is whether the patient has decisional capacity.

BARREIRO: Not that I am aware of. Well, the standard in guardianship is not a medical issue so much as a functional capacity issue.[17] And those are two different things. So what the court needs to hear is, you know, evidence concerning the patient's activities of daily living, their orientation, and their lack of understanding of their own limitations. So, again, it's truly lay testimony and there are plenty of cases concerning this issue. [18] So, clearly medical testimony is not required.

The problem a petitioning health care provider, whether it's a nursing home or a hospital, has is that often the only people it has to offer testimony, or the first ones it would think to call to testify, are health care professionals. So in many courts the objection, the evidentiary objection, will be sustained and you have to be prepared for that if you're in a jurisdiction or you're in a locality where your judges are going to block that testimony. I don't know if others that do these proceedings have that experience, but it's certainly the case in many courts throughout the state, and there are many decisions, one of which I can talk about actually.

It's United Health Services Hospitals.[19] The holding in that case was that the alleged incapacitated person has the right to remain silent. But that question only arose because family members who were supposed to show up to testify didn't, and the only other observations were from health care providers, including a hospital social worker and a nurse case manager who had been providing care in the community. Evidentiary objections to admission of health care provider testimony were sustained. The outcome was that no one was ready, willing or allowed to testify in the courtroom, and the case was dismissed.

HORWITZ: Just a question for Alyssa. It's interesting, we've been fortunate, we haven't had the privilege asserted, even though we've had counsel as well as court evaluators appointed. And this is over many, many years, so knock wood we've been lucky. But I'm just thinking, what would happen if we were unable to present any evidence? We'd be unable to sustain our clear and convincing evidence requirement. If the court finds that the guardian is not required, whether it's for lack of evidence or otherwise, does the legal presumption of competency attach to enable discharge of the patient who wants to leave, even though we think from an ethical perspective that there's going to be personal harm attendant to that? Is this different, from a liability perspective, from the mental health patient who is released because a hospital cannot sustain its burden of demonstrating through clear and convincing evidence the need for involuntary retention? From the hospital's perspective, on difficult discharges, I wonder if we're

dealing with different laws here, or if a finding by a court would enable us to discharge that patient?

FOUASSIER: No. No, you certainly would not want to do that. I certainly would not rely on the fact that I was not able to make out my *prima facie* case as a presumption that the patient has decisional capacity. And if I just may add here, in Suffolk County we sort of have the middle ground. The problem we see is not so much the nature of the witness as it is the nature of the evidence. We can have a social worker testify about his or her lay observations, but not about medical information.

BARREIRO: And that's an argument that I made. But in the United Health Services Hospital's case, the court rejected it. So it really is so judge-sensitive, there's such a lot of variation throughout the state. But, again, the guardianship advisory committee,[20] which I sit on, is moving towards creating more uniformity within the state. That may mean for folks who are lucky enough to be in jurisdictions like yours where the evidentiary rules aren't insisted upon, that it may be harder for you in the future.

The other thing is, just because you don't meet your evidentiary burden doesn't mean you're going to be able to discharge that patient, for all the reasons we spoke about before. No nursing home is going to take that patient if there's no one to make the Medicaid application or to make health care decisions.

SWIDLER: In the case that I'm suggesting where the patient is isolated and doesn't have family, who do you usually propose as the guardian? Is it Adult Protective Services, and are they usually cooperative in serving as guardian for these patients?

BARREIRO: This is also very sensitive to locality. So here in Broome we're very fortunate that the Commissioner of Social Services really never shies away from a case, and rarely relies upon conflict of interest as a means of avoiding service. We probably all know, Departments of Social Services are usually reluctant to take these cases because they have to assign case workers, they have to do annual reporting, they have to open up their own case reporting system. It's a drain on the county when these cases are assigned to them. So many times we find counties looking to kind of squirm out. But most times judges will appoint the commissioner of social services as the guardian of last resort. Again this is upstate counties where we don't have community guardianship programs.

I also want to remind everyone that there is a case out there, Samaritan Medical Center (*Marian E.B.*), which is a Fourth Department case.[21] It comes out of Jefferson County, which is a county which I hope is unique in the State, where the judge simply refuses to appoint the commissioner of social services over commissioner's objection, under any circumstances. The reported case concerns a woman in her 80s who had come from a trailer without running water, with cats in and out because it was open to the air. She had alienated all her family members. She was one of those really difficult patients that you don't like to have in your hospital beds for prolonged periods of time. We met our clear and convincing burden without a problem. But the judge denied the petition anyway because we had not proposed a guardian. The reason we hadn't proposed the Department of Social Services in that case is that this court in the past had simply refused to schedule hearings if we did. The case was reversed and sent back for a determination as to who should be the guardian, and unfortunately the Fourth Department reminded us that the statute allows for a creditor to serve in that capacity. The hospital was certainly a creditor in this case. I won't tell you how much it was owed, but for over a year this patient had been there with no source of payment.

In this case the patient was represented by mental hygiene legal service and that attorney advocated for the appointment of DSS, because what could be a worse guardian than the acute care hospital that would no longer have the patient in the bed?

Nonetheless that's what the judge did in this case, he appointed the hospital. The hospital reluctantly agreed to accept it and we narrowed down the orders as much as possible.

So it is possible that DSS will come in and argue it has a conflict or is otherwise unable to serve, claiming it really should not be the guardian for some reason, and then suggest to the court that the hospital be appointed. That's what this case stands for really.

TINDALL-O'BRIEN: Actually for people who have mental illness this happens all the time. Many county DSS agencies do not want to serve as guardians for persons with mental illness. If a patient has been in one of the OMH hospitals, DSS's attitude tends to be "they're yours." Even though we are a hospital like you are a hospital and therefore really don't have the ability to serve as a guardian. But that has been DSS's stance in most of the cases that I have been involved in. They don't want to act as guardian for a person who has a mental illness.

BARREIRO: Right, they feel they don't have the resources or the experience to deal with it. That's usually the excuse.

HORWITZ: Right. We deal with DSS in three counties and they are all reluctant to serve as guardians. But they will if need be. They do raise a conflict issue. I would

like to return, though, to the evidentiary question regarding the privilege precluding entry of the medical record of the alleged incapacitated person. Let's say we have a non-comatose patient who doesn't want to go to a nursing home and would be a risk for discharge to their home. This patient passes a mental evaluation assessment but is off a little bit. They have some activities of daily living issues. Is this panel of the opinion that the privilege should apply to hospitals and that as a matter of law consequently the hospital petitioner may be unable to sustain its burden of proof? In our counties we have been fortunate that the privilege issue, to my knowledge, has not been raised. I would be dismayed if the practice in other parts of the state were more uniformly applied. I can foresee where the presumption of competency coupled with application of privilege will be a significant barrier to the ability to sustain the burden, yet the liability and ethical concerns foreclose the discharge of a patient. Is the hospital stuck with that patient forever?

SWIDLER: Can I jump in to ask about one aspect of that? Doesn't the court evaluator have the ability under the statute to get access to the medical records? If so, the evaluator can use that in their presentation to the court I would assume?

BARREIRO: Let me address that. Certainly the court evaluator has the ability to get itself a court order to review medical records, and sometimes medical evidence can be admitted in that manner if there is no objection. Not all judges appoint a court evaluator. There are a number of judges that skip over the court evaluator and appoint counsel for the alleged incapacitated person, which the statute permits. And that is what happens to us here in Broome. And so in that case you must meet your evidentiary burden and you need to plan to do it without medical testimony, because that alleged incapacitated patient is represented by counsel who may well raise the evidentiary objection.

So, again, hopefully discussing it will raise awareness of the issue because I have heard of several cases that have been dismissed. Although judges often will try to get to some resolution. Their overriding concern is for the well-being and best interest of the alleged incapacitated person. I think in some cases, you may end up having to re-petition.

MASSETT: In Onondaga County, we have one judge who hears all of the 81s and who has very strict rules about not entering medical evidence into the record without over the objection of or without the consent of the patient. In those cases, however, the court may simply evaluate the patient him or herself. I mean, as you all know these hearings quite often happen right at the bedside in the hospital, and in many such cases it is plainly obvious whether you have a patient who has capacity or not. But we are precluded from providing any medical information.

But even in those cases, like the case you brought up, Jim, where the patient is oriented, but there is some decisional ability problems or judgment problems that give rise to concerns for the patient's safety if their discharge desires are followed through on, the judge, God bless him, is very good at talking these patients into consenting to the appointment of a guardian with limited powers for purposes of making discharge planning. And actually sometimes that is how you can get to that result. I am not saying that it is a solution for everyone, but if a patient can consent to the appointment of a guardian for themselves, then you don't have to deal with the evidentiary issue.

SWIDLER: I don't want this panel to end without some reference to the legislative proposal for transitional authorization panels, the "TAP" proposal that a few of us have worked on together.[22] All of us are familiar with it, but our readers are likely to be unfamiliar with it.

The TAP proposal is an approach to the problem of getting a discharge decision for the patient who lacks capacity, and is ready for discharge, but who is isolated and has nobody to make the discharge decision. Although the facility or a social services district could seek a guardianship as a way to make a discharge decision, that can be a very lengthy process, and can encounter the kind of procedural problems we are talking about. More importantly, it is not in the interest of the patient, or the facility, or the payors, or the other person who is waiting for that bed, to wade through the whole guardianship process just to get the OK to transfer a patient to an appropriate post-acute setting, when there is no dispute about the transfer. The idea is that there should be an administrative mechanism—a fair administrative mechanism—to evaluate the patient, see that he or she is actually discharge ready, and that there is an appropriate discharge option for them, that the patient lacks capacity to make this decision personally, and that there are no other appropriate surrogate-decision-makers. If so, that process could authorize the discharge and the expenditure of funds for that discharge. Then if there still is a need for the guardianship, it can take place after the discharge.

There is a legislative proposal in the Assembly, Bill No. 8647, that would create a demonstration program to test this out. And it will be interesting to see if one, if it is passed, and two, if it actually proves to be valuable.

I should add that even if the FHCDA passes, it is not going to address this problem. There will still be a need

for a device like TAP as an alternative to guardianship, and I think it is an idea worth testing. Any other views about this?

TINDALL-O'BRIEN: What I would say is that the surrogate decisionmaking committees have been very, very successful in our opinion, at getting consents for certain kinds of medical treatment without having to go the guardianship route. So if they are structured at all like the surrogate decisionmaking committees, I think that they would be very helpful.

SWIDLER: Well, the TAP proposal is similar to Article 80 in some ways. But one, it is a more streamlined process than the Article 80 panels, and two, it relates only to discharge and admission decisions, not treatment decisions. And three, the panel would have authority over the property decisions necessary to effectuate the discharge for a limited period of time until a guardianship could take place, if one is needed. So we will see how that works out. Yes, Alyssa?

BARREIRO: I will just say that I think it definitely has a role, even if the FHCDA passes. You know, we all have these cases where the family just doesn't agree and guardianship can be a cumbersome and slow process just to get someone appointed. But the transition proposal, I think, is excellent in that it is going to get the patient out of the hospital bed promptly, and you know, that is a good thing. The only limitation that I see is when you get that objecting patient. Unfortunately, a lot of times patients have just enough decisional capacity to say, "I don't want to go to the nursing home."

TINDALL-O'BRIEN: Has there ever been anyone who that said, "I want to go to the nursing home?"

SWIDLER: Well, I have to note, at Northeast Health we just built a new "Green House" model nursing home campus in Cohoes N.Y., which has separate homes with only 12 residents living in each, and a different approach to care provided in them. The model makes the prospect of entering a nursing home far more attractive. But OK, I agree, it's not like hospital patients welcome the news that they need to go to a nursing home.

Health Care Agent's Authority

BARREIRO: I have a question. What does the rest of the panel think about the authority of someone with the health care proxy to make the decision concerning whether a patient should or should not be discharged to a nursing home? I mean, when someone has a health care proxy, would you allow the agent to just sign the patient out against medical advice, for instance?

FOUASSIER: Maybe one way to ask this is: "What authority does the health care proxy actually bestow upon the agent? Is it the authority to make all medical decisions?" Because if the patient could discharge himself against medical advice, then the argument would be that the holder of the proxy, the agent, would be able to make the same decision in the place and stead of the patient.

SWIDLER: I think the agent would in theory have the authority to make a decision to discharge a patient AMA. However, they have to exercise their authority based on the patient's wishes, reasonably known, or else if they are not known, in the patient's best interest, and it is kind of hard for me to picture a scenario in which an agent can say, "I reasonably know that this incapable patient would want to have an unsafe discharge." And an unsafe discharge certainly would not be consistent with the best-interest standards. So I think there is a check and balance in the decisionmaking standard for the agent, even though the agent does have the same authority that a patient would have.

Now, I gather you also raised a technical issue of whether the agent's authority to make "a health care decision"[23] even encompasses a discharge decision. In my view, if the agent is making a hospital discharge decision that needs to be made, I'd be saying, "Absolutely yes, they can do it." Somebody has to make that decision and the agent is there, so I would reach the practical, and reasonably supportable, conclusion that the agent has this authority. But I have to admit, if the agent was about to make a terrible discharge decision, I'd be tempted to read the statutory language about their scope of authority more narrowly.

BARREIRO: I looked at it recently. The public health law, I think, gives the agent the ability to make decisions with regard to diagnosis and treatment. Do we read that broadly, or do we read that narrowly?

MASSETT: We have actually run into this question. Remember the comment that "there is the door out and the door in." Even if the hospital takes the position that the discharge plan and consenting to the discharge plan, which includes the admission to a nursing home, is a medical or a health care decision and therefore agent can do it, it's not much help unless on the nursing home side of it, the agent has the ability to provide a commitment relative to the financial admission agreement. So it's not enough for the health care agent to say, "Yeah, I agree to admit the patient." That comes with the financial obligation. True, not on the agent, but we will have to ask the agent, "Do you know where the assets are? Can you get to them? And can you make a Medicaid application?" That is where we have the problem.

GOLDBERG: I think it's illogical to say that we would allow a health care agent to withdraw or refuse care to the point of the patient's death, in the case, for example, of a terminal extubation or any other refusal of care, but then refuse the agent the right to choose what the physician has called an unsafe discharge. Of course the physician and the hospital have the obligation to protect a patient who lacks decisional capacity, so we have to look at the particular situation. But a discharge AMA might actually be consistent with the incapacitated patient's wishes. This is also a situation in which an ethics consultation can help sort out what the patient's wishes might have been or what would be in the best interests of this particular patient—given his or her own personality and values and religious or moral beliefs. A good ethics committee consultation can play an important role in a case like this.

HORWITZ: I think the question is in some respects an interesting academic question more than a practical matter. If we have a patient who does not have capacity, which of course we all know triggers a health care agent's authority, and if we are of the opinion that an unsafe discharge is being promoted by that agent, we will take steps to challenge that agent's authority, whether or not we think the statute empowers that agent or not. We do this because the agent would not be acting in the best interest of that patient. So, as a practical matter, I don't think it really makes much difference whether or not the statute authorizes that agent to effect a discharge decision, which I personally think, by the way, is a medical decision. But I think the effect would be the same.

MASSETT: Back to the situation that Jim brought up, where you have an incapacitated patient and a discharge plan, and the agent is saying, "No, I am going to sign the patient out AMA," I'm with Jim. If one of my hospital clients were to call me and say, "So, what do we do? Do we treat him just like the patient?" Because if a patient with capacity said, "Get me my pants and my shoes, I am going home," you get them their pants and their shoes and you let them go home, unless there is a capacity decision. But when it is the agent making that decision, there would be very few cases where we would recommend anything other than bringing an action to question or to have the agent's authority limited or changed.

You know, the only situation I can see not taking that step—if there is some evidence presented that the patient himself or herself said, "You know, if the decision comes down to it and I am, you know, I am terminal, I want to die in my home and that is where I want to go." If there is something in the record to show almost the clear and convincing evidence of what the patient would have wanted, which theoretically you could rely upon whether or not you had an agent, that would be the only circumstance that we would not advise the hospital, you know. If you have concerns about this agent who is wanting to discharge the patient AMA, we should seek some judicial intervention. And unfortunately, we see that situation not infrequently, and it is usually in a case where there is either some suspicion of elder abuse, or there is a suspicion that the family or the agent is really more interested in the financial assets being preserved of the patient, not in their best interest from a medical perspective.

SWIDLER: Happily, I haven't seen that very often, but I do occasionally see a case where the agent runs amok. But when an agent is about to make a dangerous, unsafe or idiosyncratic decision, I expect any of us would want to probe that agent closely to make sure that he or she is fulfilling his or her agent's duties and making the decision based on the patient's wishes and not based on his or her own idiosyncratic inclinations.

Public Policy Changes and Conclusion

HORWITZ: You had asked earlier, Robert, if there are any policy changes that we would suggest. I can't remember whose comment it was, but we talked about the obligation of the hospital from an EMTALA perspective to treat all patients that come to our door. I really think that we need a similar type of obligation and responsibility when nursing home beds are available. I think this should include a discussion to provide fiscal relief to the nursing homes.

BARREIRO: I think it is a laudable goal. There has to be coverage for that facility, because you remember that when the Medicaid regulations recently changed, they effectively talked about it in terms of being the "nursing home bankruptcy act." And that is the problem—that is why you are sensing more hesitancy on the part of the nursing homes to take these patients, because while it used to be that there may be a brief period of disqualifications for some financial improprieties by residents, now it can be a very long period of disqualifications. And that is not anything that gets discovered until after the nursing home patient is already in the bed. So it is a cost-shifting issue, and it is a big problem both for the hospital and for the nursing homes.

FOUASSIER: I for one would like to see some statement of policy actually instilling the hospital—bestowing upon the hospital more authority to make affirmative discharge decisions and implement them in the face of patient or patient/family opposition with perhaps some shield from liability in doing this. And again, I don't want to make it sound completely arbitrary and unilateral, but

where the physicians have certified that the patient is no longer acutely ill, where the insurance plans, if any, concur by refusing to pay for continued care, where there is a medically appropriate, acceptable placement that is subacute or long-term care facility, then the hospital can go ahead and effect the discharge over the opposition of the patient and the patient's family.

MASSETT: I certainly agree that we need to look at all the little idiosyncratic pieces of our current patchwork policy—the current statutes, regulations and policies we have to follow in implementing a discharge plan.

But there is part of me that also feels that, you know, is Article 81 perfect? It's not. Should you always have to seek judicial intervention? It has a lot of downsides. But first of all, I don't think that you are going to come up with a universal policy solution that solves all the issues. But also, there are times where judicial intervention is what is needed, either to protect the patient and the patient's rights, or to protect the facility. So I don't think that completely eliminating that guardianship process should be the ultimate goal. I think that we have to look at some of the aspects of the current patchwork that prevents sensible, streamlined decisions in some of the rather obvious cases from happening. But those cases in those gray areas, you know, that is what the courts are there for. That is how I feel.

SWIDLER: Anyone else. Should this be an issue on the national health care reform policy debate?

FOUASSIER: Well, I don't know whether with the full plate at the national level this is going to get on the national agenda, but it really is important because we would be hard-pressed to find a colleague in our situation who would not have had a plethora of problems similar to the ones we have discussed today. But, we are talking about Medicare going broke, health insurance premiums becoming unaffordable, hospital care becoming unaffordable. This is strictly going to devolve into a discussion of limited resources in all these varieties of contexts. And one drain on those resources is due to the ability of families and patients, for reasons that really don't have a lot to do with medical necessity, to dictate the kind of medical care that they want to receive. There isn't going to be an easy answer, but at the end of the day it is a question of the allocation of resources.

SWIDLER: Another way to view this is to note that the question here is the same question raised in almost all social policy issues, which is: "How do we get scarce resources to people that really need it, without leaking scarce resources towards people that don't really need it?" That is what we are discussing.

HORWITZ: I would actually endorse—I would endorse more discussion on the discharge planning issues. I think that this issue has been around for a long, long time. If we went on the American Health Lawyer's listserve, for example, in-house counsel, have been discussing the difficult discharge for a number of years. There really have been no good solutions. We reference the eviction, trespass and guardianship tools but these are all case-by-case and do not provide a satisfactory answer to a growing problem. I agree with Jim that the problem raises, in part, the rationing issue in part. I think the TAP concept is a great first step. Perhaps at least on a statewide basis, we can do more education and more discussion regarding this topic.

SWIDLER: You're reminding me of a story. We once asked our Ethics Committee what they thought of the idea of disconnecting the TV in the room of a patient who no longer needed inpatient care but wouldn't leave. The Ethics Committee was absolutely appalled that staff would even consider doing that, so we never did. But after the meeting someone quipped that the committee found that to be the most objectionable "plug-pulling" proposal it had ever seen!

Well, thank you all. After struggling with these issues so much in my own system, it is great to hear from colleagues who are encountering the same kind of problems, and to brainstorm with you. If nothing else, you know, this was helpful for the commiseration value.

So thank you all again very much. I thought this was a really valuable conversation as well as a really enjoyable one.

Endnotes

1. 10 N.Y.C.R.R. 405.9(f)(1).
2. *Id.*, 405.9(f)(7)(ii).
3. *In re Marguerite*, 226 A.D.2d 786 (3d Dep't 1996).
4. Another procedural approach to obtain a discharge order that may succeed in some localities is illustrated in a Kings County case decided just shortly before this panel discussion took place. *In re New York Methodist Hosp.*, 2009 NY Slip Op. 29328, 3 (Sup Ct., N.Y. Co. July 8, 2009) granted petitioner hospital's application by order to show cause, seeking judgment pursuant to Public Health Law § 2801-c requiring the respondent to discharge himself from the hospital and to accept placement in any appropriate skilled nursing facility offering admission.
5. R. Swidler, T. Seastrum and W. Shelton, *Difficult Inpatient Discharges: Ethical, Legal and Clinical Practice Issues*. 7 Am. J. Bioethics 23 (March 2008). *See also* J. Jankowski, T. Seastrum, R. Swidler and W. Shelton, *For Lack of a Better Plan: A Framework for Ethical, Legal and Clinical Challenges in Complex Inpatient Discharge Planning*, 21 Health Ethics Forum 311 (2009).
6. Assembly Bill 7729-C (2009) (Gottfried et al.); Senate Bill 3164-A (2009) (Duane et al.).
7. MHL Article 80. Surrogate Decisionmaking Committees.

8. 10 N.Y.C.R.R. § 415.2(f) (definition of "designated representative").
9. J. Fouassier, *The Perennial Problem Discharge—How It Hurts the Patient, the Provider, the Payer, and the Health Care System*, 14 NYSBA Health L. J. 38 (Winter 2009).
10. Wolpin, Joseph, "*Medical Repatriation of Alien Patients,*" 37 J. L. Med. & Ethics 152 (Spring 2009).
11. 42 U.S.C. § 1395cc(a); 42 C.F.R. § 489.20. *See generally*, OIG Supplemental Compliance Guidance for Nursing Facilities, 73 Fed. Reg. 56846 (Sept. 30, 2008).
12. *Joseph S. et al. v Hogan, et al. (BMC)(SMG),* No. 06-cv-1042.
13. *Disability Adcovates, Inc. v. David A. Paterson, Richard F. Daines, Michael F. Hogan*, 03-CV-3209 (NGG), decided September 8, 2009, 2009 U.S. Dist. LEXIS 80975.
14. 14 N.Y.C.R.R. §§ 595.9(c)(2); (f) and (g) and 595.10(a)(2)(vii).
15. CPLR 4504, CPLR 4507, 4508.
16. *E.g., In re Rosa B.* (1 A.D.3d 355, 767 N.Y.S.2d 33 (2005), *In re Lukia QQ*, 27 A.D.3d 1021 (3rd Dep't, 2006); *In re Bess Z.*, 27A.D.3d 568 (2nd Dep't 2006); *In re Marie H.*, 25 A.D.3d 704 (2d Dep't 2006); *See also In the Appointment of a Guardian for E.J.*, 13 Misc.3d 1223 (Bronx Co. 2006).
17. N.Y. Mental Hygiene Law § 81.02 (c).
18. In addition, the Court cannot require the Petition to contain medical information. N.Y. Mental Hygiene Law § 81.07(b)(3).
19. *In re A.G.* (*United Health Services Hospitals, Inc.),* 2004 NY Slip Op. 24454, 6 Misc. 3d 447. The holding has been inconsistently applied.
20. N.Y. Office of Court Administration Guardianship Advisory Committee, Hon. Thomas Aliotta, JSC, Chair.
21. *In re Marian E.B.*, 2007 NY Slip Op. 2186, 2 (N.Y. App. Div. 4th Dep't 2007).
22. Assembly Bill No. 8647-A (2009) (Canestrari).
23. N.Y. PHL § 2980.6.

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Health Law Section
Summary Report on Healthcare Costs: Legal Issues, Barriers and Solutions

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Summary Report on Healthcare Costs: Legal Issues, Barriers and Solutions

The costs of the healthcare system are an ever increasing drain on the federal budget, the economy, and on employers, particularly small employers. Total health spending in the United States is currently 16 percent of gross domestic product (GDP), up from eight percent in 1975, and without changes, is projected to reach 25 percent by 2025.[1] Medicare and Medicaid comprise more than 25 percent of the federal budget. Medicaid alone comprised approximately 22 percent of total state spending in fiscal 2007, with a projected spending growth rate of eight percent annually for the next decade, according to a report released December 5, 2007 by the National Governors Association.[2] Overall, states' single largest expenditure for fiscal 2007 was healthcare, accounting for on average nearly one-third of state spending.[3]

Healthcare costs also have social and public policy consequences. Insurance premiums increase every year, driving down the number of employers that offer health insurance to employees: 61% in 2007 versus 69% in 2000.[4] Uninsurance has costs: the uninsured delay seeking medical care and end up sicker when they do go for care; when hospitalized, the uninsured are likely to be in worse condition and die than the insured, and over half of all personal bankruptcy cases are due to medical bills.[5] Increased costs have also been found to not result in better care, in fact, areas of the country with higher costs (due in large part to higher utilization) may have worse outcomes.[6] While we recognize the enormous achievements of the United States healthcare system, for example in prolonging healthy maturity through treatments for cancer, heart, and vascular disease, cost reduction is a clear priority in the current reform environment (to provide resources to support broader coverage) and opportunities for such cost reduction certainly appear to exist.

This report explores many of the legal issues involved with healthcare costs, how various laws and regulations stand in the way of reducing costs, and how the law may need to be changed to allow reduction to healthcare costs. It will discuss the components of the healthcare costs formula (units of services used, multiplied by price per unit, plus administrative costs), and discuss legal issues involved with each, including

- how the law affects efforts to reduce unnecessary utilization of goods and services
- legal difficulties involved with end-of-life care
- lack of payer incentives to promote appropriate utilization
- legal barriers to changing a healthcare payment system that rewards utilization
- how a change in the law may be considered to allow "quality performance payment programs" whereby hospitals may make payments to physicians for improvement in measured quality or sustained levels of quality
- comparative effectiveness research and clinical practice guidelines' role in preventing overutilization,
- legal concerns of providers leading to high "list prices" charged to the uninsured, and laws that cap charges by hospitals to the indigent
- legal barriers to transparency / sharing of healthcare providers' charges for services
- the role of statewide and regional health planning
- the high level of administrative costs in the U.S., and legal issues involved with mechanisms to reduce such
- the burden placed on providers by the multiple layers of applicable regulations
- the potential legal restrictions placed on medical homes by state insurance laws, and
- reducing political influence in making healthcare costs decisions.

A. Components of Healthcare Costs, and Potential Strategies to Reduce Costs

There are three components of the healthcare costs formula: (a) how many services of each type we use (i.e., utilization of care), multiplied by (b) how much we pay per unit of service, plus (c) the administrative costs involved with the healthcare system, including payment of claims, profits, shareholder return, broker costs,[7] litigation, and other factors.

The cost of care may be directly associated with the "business" of healthcare, largely unique to the United States (and perhaps recently to China). To quote the New England Journal of Medicine February 7, 2008, "the dominance of for-profit insurance and pharmaceutical companies, a new wave of investor-owned specialty hospitals, and profit-maximizing behavior even by nonprofit players raise costs and distort resource allocation." To the extent that economic incentives are working in perverse ways,

policy, legal and legislative changes may be in order. The commercialism of healthcare is strongly related to findings of the 2007 McKinsey study ("Accounting for the Cost of Healthcare in the US") that the overriding cause of high US healthcare costs is the failure of the system to (a) provide sufficient incentives to consumers to be value conscious in their demand decisions, and (b) establish the necessary incentives or mandates to promote rational supply. Although maximization of profit may be standard practice on an institutional level, society as a whole bears the cost when applied to healthcare, because it is generally tied to higher overall costs.

Reduction in healthcare costs will only come about with a reduction in utilization, a decrease in price of services (perhaps through driving consumers to more efficient providers), and/or a reduction in administrative costs. Although opponents of reform attempt to scare the public with words such as "rationing care," the reality is that healthcare dollars are not endless and choices must be made that will direct care to the activities that are the most effective. However, this paper will not discuss issues related to the overt rationing of care by government or private payers. Those policies may lower the costs a particular payer may bear, but they do not affect the cost of the service, and an argument exists that rationing already exists, albeit based on the ability to pay.

B. Legal Issues Involved with Reducing Healthcare Costs

Consideration of restructuring the healthcare system to provide appropriate incentives and reduce costs raises a large number of legal issues. Legal issues include statutory and regulatory limitations, creating legally allowable structures that provide appropriate incentives (e.g., the inability of hospitals to pay non-employed physicians for changes in utilization), rights under existing law, contractual obligations (e.g., confidentiality clauses in provider-payer contracts and effect on transparency), antitrust issues, ERISA, insurance rating systems, ability of payers and employers to change employee/subscriber behavior under existing law, and more. Legal options to address healthcare costs may include possible state and/or federal legislation to limit some of the administrative costs (e.g., establishing a brain-damaged baby fund similar to the national vaccine pool or having a single healthcare claims adjudicator), incentivizing insurers to keep subscribers healthy and manage care (not just costs) by requiring the insurers to be to responsible for patients' care over the long run, removing regulatory impediments to alignment of incentives among providers, payers and patients, and providing immunity to providers who follow certain delineated standards. Neutralizing the incentive of each player to protect their own position through lobbying and the political system may best occur through the establishment of a politically immune "healthcare board" similar to the Federal Reserve Board or the military's base closing commission. The legal community can assist in formulating and structuring both healthcare system reform and payment reform.

Exploration of how the United States can reduce healthcare costs optimally involves trying to predict what challenges may be posed. Because affected groups will likely attempt to halt a reduction in healthcare costs that affects those groups' profit margins (or, in the case of consumers, access to care), thought should be given to what legal issues are involved in strategies seeking to reduce healthcare costs. Consideration of the legal issues as part of the structuring of cost reduction strategies can minimize later challenges, and save time and resources.

This paper will discuss only those legal issues involved with healthcare reform that are targeted at healthcare costs. There have been and will continue to be many efforts at healthcare reform whose aim is different from reduction of healthcare costs, e.g., Massachusetts' effort to reduce the number of uninsured. The goal of providing coverage to those without insurance, while admirable, is to be distinguished from cost containment. Although conceptually there is an argument that providing insurance coverage to more people may reduce costs by allowing care to be received on a preventive basis rather than later in a disease process, the net effect may be more care provided to more people, which is a laudable but costly result. If the result is improved health, there is an obvious benefit to increased insurance coverage, but a reduction in healthcare costs should not be an expected benefit. Obviously, certain advocates disagree.

This paper will also not discuss the issues surrounding health information technology. The use of information technology in the healthcare system will likely expand given the financial incentives for such in the recently enacted American Recovery and Reinvestment Act (ARRA). Although health IT has long term benefits including (i) mistake reduction and (ii) reduced payment delays and lower administrative costs, at least one study found that health IT will add to costs in the short run.[8] Even the government's generous ARRA subsidies will not fund all of the costs, and use of alternative funding services will raise multiple legal issues, including Stark, anti-kickback, and privacy/HIPAA issues beyond the scope of this paper.

Below is a discussion of each of the three components of healthcare costs (utilization, cost of goods and services, and administrative costs), various strategies that may be considered as part of any effort to reduce healthcare costs, legal challenges that may be asserted, and legal issues involved with such.

1. Use of Goods and Services, and Efforts to Reduce Unnecessary Utilization of Care

Utilization is the number of services of each type that we consume, whether hospital services, physician services, home care, drugs, imaging, etc. The significance of utilization as to costs is best illustrated by the Dartmouth-Atlas study, which explains the variation in Medicare

costs per beneficiary in different areas of the country as due to differences in utilization of services.[9] Each of the parties in the healthcare equation (patients, providers / suppliers and payers) must be incentivized to utilize the "appropriate" number of services. (Of course, part of the problem is that there is no definition of what amount of services is "appropriate utilization," as addressed below.) Following is a discussion of the involvement of incentives on each of the parties driving healthcare costs, and the legal issues involved with such.

a. Patient Incentives to Utilize the "Appropriate" Number of Services

i. Incentives to Reward Patients/Health Insurance Beneficiaries for Healthy Behavior

Given that over seventy percent (70%) of healthcare costs are spent on chronic disease, promotion of behavior that reduces the incidence of obesity or other health conditions associated with chronic disease, can conceptually reduce health care costs. Healthy behavior may be encouraged by employer "wellness" programs, in which an employer provides a benefit to employees who, e.g., stop smoking or lose weight. However, there are several federal and state laws that limit an employer's ability to put into place a wellness program. For example, the Americans with Disabilities Act (ADA), which prohibits discrimination on the basis of a disability, restricts employers from inquiring about employers' medical conditions or requiring medical exams. Under the ADA, an employer may not take action against an employee (including with regards to health insurance or other benefits) that treats a disabled employee differently than other employees. Under Equal Employment Opportunity Commission (EEOC) guidelines, wellness programs may be part of an employer's *voluntary* wellness and health screening program, but a penalty may not be imposed for not participating. Thus, an employer may offer a weight reduction program, and if an employee is not able to participate because of a disability, the employer must make a reasonable accommodation to that employee so s / he is not penalized because of the employee's inability to participate.

In addition, under the federal Health Insurance Portability and Accountability Act (HIPAA), group health plans may not base eligibility for benefits on health status, medical condition (including physical and mental illness), claims experience, receipt of health care, medical history, genetic information, evidence of insurability, or disability. A group health plan also may not require higher premiums on the basis of any "health related factor." However, discounts may be offered (or copays and deductibles adjusted) for employees who participate in a "bona fide wellness program." The requirements of a "bona fide wellness program" are set forth in regulations jointly issued by the US Department of Labor, the Internal Revenue Service and the Centers for Medicare & Medicaid Services. These regulations allow differentiation of premiums and cost-sharing for employees who succeed in "wellness" programs such as smoking cessation or weight loss programs, only if the reward or penalty for success is limited.[10]

Various state laws also protect against employment discrimination, or regulate benefit programs, and can be relevant to wellness programs. Legal analysis regarding an employer's ability to institute a wellness program may also include review of a unionized employer's collective bargaining agreement, pursuant to which an employer may be required to negotiate wellness programs with a union. This may be due to the employer's agreement in its collective bargaining agreement to negotiate any changes in benefits, or a union's position that the National Labor Relations Act's requirement that employers bargain over "wages, hours, and other terms and conditions of employment" encompasses benefits (and wellness programs).

While the importance of not discriminating against the disabled must be recognized, also important is taking action to encourage prevention of those conditions leading to disabilities (and costs), to the extent such can be prevented or their incidence reduced. Another option to promote healthy behavior that may help avoid employment discrimination or risk-gaming by insurers is to distribute payments for healthy behavior through public health or other government entities. Mexico's Oportunidades program, which Mayor Bloomberg has proposed emulating in New York City, provides a model.[11] If there is a Congressional commitment, however to give employers "sweeping new authority to reward employees for healthy behavior," as reported in the New York Times on May 9, 2009, changes to the above regulations may need to be explored.

ii. High Deductible Health Plans

Another structure that incentivizes patients to be prudent purchasers is the High Deductible Health Plan. These plans set large deductibles, and can be used along with health savings accounts, which allow individuals to set aside monies pre-tax to pay healthcare expenses within the deductible amount. All savings (the difference between the amount so funded and expenditures) accrue to the insured, who thus has an incentive to limit expenditures. Although widely available since 2004, only approximately 8% of beneficiaries throughout the U. S. were covered by this form of health insurance as of September, 2008.[12] Although there are questions as to whether high deductible plans are workable for lower income individuals, these programs do not appear to raise material legal issues.

iii. Disease Management

Like wellness programs, disease management programs are often focused on encouraging patients to do the right things for themselves (e.g., diabetics losing weight and taking medication to control blood sugar). Behavior modification incentives are often crucial to success of disease management programs, but their use

is very limited by the legal restrictions placed on such. Legal limitations exist not only with employer programs, but even more so with government sponsored wellness programs and disease management programs. Due to the near ban on financial incentives to encourage healthy behavior in Medicare and Medicaid beneficiaries, disease management providers have struggled even in attempting to encourage Medicaid patients to complete health assessments, the first step in managing chronic disease. A provider or plan may be subject to penalties for offering anything more than a nominal incentive to encourage individuals to control their disease better.

The limitations on providing incentives to Medicare and Medicaid patients are due in large part to the Civil Monetary Penalties (CMP) provisions in Section 1128A(a)(5) of the Social Security Act, which prohibits offering remuneration to a beneficiary that is likely to influence the patient to seek items or services from a particular provider, practitioner or supplier, for which payment may be made by Medicare or Medicaid. The OIG has interpreted this law as allowing only goods or services valued at less than $10 per item and $50 per patient in the aggregate on an annual basis.[13]

In addition to the CMP, a disease management program may violate the anti-kickback statute, which makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by the federal health care programs. "Remuneration" includes anything of value.

As with wellness programs, any desire to encourage disease management programs will require review and revision of the above laws, unless the disease management process is moved to the public health arena and administered separately from the health financing system.

iv. End-of-life Care and Challenges to the Concept That Healthcare Dollars Are Unending

Medicare spends 25 percent of its dollars on care of its approximately six percent of beneficiaries in the last year of life,[14] due in large part to the high utilization of high-cost services (intensive care, drugs and technology) at the end-of-life. Although health care services overall may engender an attitude of "spare no cost" by those patients and family members whose health is at stake, this attitude can be particularly pronounced with end-of-life decisions.

The legal issues involved with end-of-life care often revolve around consent, and the intensity of services a patient would want utilized to prolong their life / death. Advance directives have been promoted as a mechanism to allow patients' wishes to be expressed when the patient cannot do so personally, and may reduce costs through reducing utilization of services and technology. In the absence of a directive, family members often feel obliged (and providers can be required) to continue care despite its lack of long-term benefit, at least for some time. Only a small percentage of the US population have advance directives, and although work should occur to increase this number, efforts to reduce end-of-life costs must encompass more than promotion of advance directives. Options to reduce end-of-life costs must address legal and non-legal factors involved with utilization of end-of-life services and technology, including (i) discomfort of physicians and providers in discussing death with patients and / or family and offering the option of less aggressive end-of-life care, (ii) the absence of clear legal authority for family and friends to direct the withdrawal or withholding of life-sustaining treatment under appropriate circumstances, based on the reasonably known wishes or the best interests of a patient without capacity to consent, (iii) reluctance of providers to withhold or discontinue treatment that offers no real benefit to the dying patient, (iv) the low rate of hospice use among Americans in general, and certain minority groups in particular, (v) concern with legal liability, (vi) overuse of ICU beds, and (v) lack of standards as to treatment at the end-of-life.

Some of the options that may address the above include:

(i) promotion of clinical practice guidelines in end-of-life care, which may help to reduce long-term use of expensive modalities on patients whose benefit from such is questionable;

(ii) comparative effectiveness research to determine whether certain expensive drugs and treatments used at the end-of-life provide more benefit than less expensive alternatives;

(iii) clarifying and in some states broadening the authority of family members to authorize the withdrawal or withholding of end-of-life treatment for their loved ones;

(iv) have a federal law similar to the law in Texas, which provides a process that hospitals may take if family members refuse to allow discontinuation of care which the hospital and physicians feel is extraordinary / non-beneficial, and recognize the right of healthcare providers not to participate in non-beneficial care;[15]

(v) define treatment that provides no medical benefit other than prolonging death as "non-beneficial treatment;" avoid the terms "care" (all patients should receive care) or "futile care"; and provide immunity for ceasing non-beneficial treatment if approved by an ethics committee or other appropriate body, or if consistent with clinical practice guidelines issued by a specialty society or other nationally recognized body.

Of course, debate as to the above should also include considerations of patient autonomy, informed consent, and the value placed on the lives of the elderly and disabled.

b. Payer Incentives to Promote (Pay for) Appropriate Utilization

Under the current system, payers' incentives are to reduce their financial responsibility for services, which lack of payment often reduces utilization. Patients / insureds often change insurance plans, and a payer likely will not have responsibility for a patient over an extended period of time. Therefore, the payer has no incentive to pay for services which may prevent long-term problems, because it is more likely than not that the payer will not be responsible for the individual in the long term when that problem arises.

In other countries such as the Netherlands, insurers are required to take responsibility for patients as long as the patient wishes to remain with that insurer. The benefit to this concept is that it truly "invests" the insurer in the patient, and motivates the insurer to keep the patient healthy so as to reduce the patient's long-term costs. Although making insurers responsible for patients potentially until such time as the patient is old enough to qualify for Medicare does not entirely abrogate a payer's incentive to deny care, it removes the incentive to deny care that will improve health over a period of time that may be longer than a one year subscriber contract. This concept legally may be strongest if enacted through an amendment to ERISA, as was COBRA, so as to maximize the number of health plans to which it applies.[16]

c. Provider Incentives: Decreasing Unnecessary Utilization Through Changes in Payment Mechanisms (a/k/a "follow the money")

One of the recognized impediments to a change in utilization of resources is the present payment system and the fact that physicians and many other providers are largely paid upon volume of services provided, inducing providers to offer more testing and procedures to compensate for an overall reduction over the past years in reimbursement for cognitive services. This was well illustrated in a July 2009 New Yorker article[17] exploring how such incentives have resulted in utilization of services in McAllen, Texas that have caused McAllen to have the second highest per capita healthcare costs in the nation: $15,000 each year per Medicare enrollee. Compared to El Paso, with a similar population, McAllen has sixty percent more stress tests with echocardiography, 200 percent more nerve conduction studies to diagnose carpal tunnel syndrome, and 550 percent more urine flow studies to diagnose prostate troubles, yet McAllen's hospitals ranked worse than El Paso's on most Medicare metrics of care. Noting the financial focus of healthcare providers in McAllen, the surgeon author diagnosed "the primary cause of McAllen's extreme costs [as] very simply, the across-the-board overuse of medicine."

Not only does the current payment system reward utilization, it creates a perverse incentive whereby hospitals and physicians are financially penalized for keeping patients healthy, because healthy patients have less need for medical services. Equally disturbing, the law as is creates substantial barriers to creating structures that can focus on quality rather than volume. Although Medicare and other payers are exploring other mechanisms of payment, e.g., for episodes of care, hospitals that are not in a demonstration project face legal burdens to attempting to structure arrangements that change the incentive for physicians to order more care and perform more procedures. These hurdles are largely due to restrictions set forth in (i) the physician self-referral (Stark) law, which prohibits physicians from referring to an entity in which they have a financial interest unless an exception exists (and no exception exists for rewarding physicians who decrease utilization), (ii) the anti-kickback law, which prohibits the offering or receipt of an inducement in return for referrals of patients or business paid for by Medicare or Medicaid, and (iii) the Civil Money Penalty statute ("CMP" law) at Section 1128A(b)(1) of the Social Security Act (42 USC Section 1320a-7a(b)(1)).

The purpose of these laws is to prevent financial considerations from interfering with patient care decisionmaking, and these laws are often necessary, given the dollars in the healthcare system. However, provision needs to be made for arrangements that allow doctors and hospitals to work together within certain guidelines to encourage quality, which promotes appropriate utilization. Although hospitals have some latitude with employed physicians under the Stark and anti-kickback laws, many hospitals do not have the financial resources to add numerous physicians to their payrolls, and there will always be independent attending (non-employed) physicians whose decisions as to patient care affect not only the patient, but impact on the hospital and overall healthcare costs.

The impact on healthcare costs of the relationship between hospitals and physicians can be seen from the Dartmouth Atlas study. The version of the study released in 2008 showed the difference in the number of physician services received by patients whose care was through Mayo Clinic as compared to those patients whose care was through an academic medical center in New York City. Patients who received their end-of-life care through Mayo Clinic received during the last six months of their life, on average, 24 physician consults, whereas patients who received their end-of-life care through the New York City academic medical center received in the same time period on average 76 physician visits. The patients' outcomes or quality of care were not deemed changed by either practice.

Of the above three laws, the anti-kickback law may be the least worrisome for hospitals that wish to implement or participate in a gainsharing or quality improvement project, as this statute requires intent. However, the current exceptions under the Stark law allow hospitals extremely limited ability to formulate a structure that provides physicians with an incentive to achieve quality mea-

sures and cost efficiency. CMS proposed an exception for incentive payment and shared savings programs in the 2009 Medicare Physician Fee Schedule proposed rule,[18] but this was not finalized. In the final Medicare Physician Schedule for 2009, CMS posed fifty five (55) questions regarding shared savings programs and incentive payment plans and asked the industry for comment as to how such could be structured to allow flexibility without program abuse. One set of comments sent to CMS[19] promoted the concept of allowing "quality performance payment programs ("QPPP")," whereby hospitals may make payments to physicians for improvement in measured quality or sustained levels of quality, which measures are defined and applied through the term of the program. The comments suggested certain safeguards for a QPPP, including that it be based on a written document identifying the measures, payments, qualifications, baseline and targets; that the program be required to use measures substantially related to nationally recognized measures, that no physician be able to be paid based on volume or value of referrals, and that the hospital conduct on-going monitoring of the program. An exception under the Stark law for QPPPs could potentially assist with not only an improvement in quality, but a decrease in costs, as ineffective or wasteful services are avoided.

Additionally, the CMP law has been widely interpreted to prohibit hospitals from trying to incentivize physicians to contain costs, as it subjects to civil monetary penalties and exclusion from Medicare / Medicaid a hospital that knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided to Medicare or Medicaid beneficiaries who are under the physician's direct care. The OIG has taken interpreted this law very broadly, stating in a July 1999 Special Advisory Opinion that:

> "The statutory prescription is very broad. The payment need not be tied to an actual diminution in care, so long as the hospital knows that the payment may influence the physician to reduce or limit services to his or her patients. There is no requirement that the prohibited payment be tied to a specific patient or a reduction in medical necessary care. In short, any hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly violates the statute."

According to the OIG, this law prohibits hospitals from implementing "gainsharing" arrangements, whereby the hospital shares with physicians part of the money that a hospital has been able to save due to, e.g., use by physicians of less expensive equipment or following certain guidelines.

The OIG in 2001 began issuing advisory opinions allowing specific gainsharing arrangements, and has issued 14 favorable opinions as of 2009. However, the OIG does not seem to have changed its view that the CMP law prohibits gainsharing, but instead in its advisory opinions has either found that certain elements of the proposed arrangement do not have clinical significance (and therefore do not implicate the CMP law), or do have clinical significance but do not pose a risk of abuse. A recent article in the March 6, 2009 American Health Lawyers Journal[20] makes a very plausible argument that the CMP law was intended to prohibit only payment for reduction in ***necessary*** care, and that it does not clearly prohibit paying physician to refrain from furnishing ***unnecessary*** medical care or to use one clinically equivalent medical supply or device rather than another. CMS and the OIG certainly have the ability to take a fresh approach to the CMP statute to allow alignment of hospital and physician incentives to improve care and reduce costs.

d. Compare the Effectiveness of Care and Develop Clinical Practice Guidelines Against Which Utilization of Services Can Be Measured

One reason for the large variations in utilization across the country is that there is no "standard" as to what amount of utilization is appropriate. Analysis of the "appropriateness" of treatment requires consideration of what treatments (or levels of treatment, or amounts of treatment) are most effective in achieving the goal of maximizing the patient's health.

The 2009 American Reinvestment and Recovery Act included $ 1.1 billion for comparative effectiveness research. Comparative effectiveness in and of itself is not designed to control costs, but is to compare the effectiveness of treatments, for the purpose of improving quality, reducing wasteful variation, and enhancing how taxpayer dollars are used when paying for medical care. The Congressional Budget Office, in a 2007 report, defines comparative effectiveness as "a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients."[21] This report suggested that comparative effectiveness research could reduce health spending in the long term, and the CBO in a later report stated that it could help ensure that costly services were used only when they offer a clinical benefit greater than the benefit offered by less costly services. Review of use of comparative effectiveness research by other countries shows that it is used not as a way to refuse to pay for a service or drug, but as a way to determine relative payment based upon how effective the modality is compared to others. For example, Britain has used "pay for performance" pricing whereby the government receives a rebate if a technology does not perform in accordance with manufacturers' claims, or pays an enhanced price if greater effectiveness is demonstrated. Other countries such as France have used comparative effectiveness research to produce disease and product information for professionals and patients, allowing providers information from sources other than drug companies and device / technology vendors.[22]

That certain treatments and drugs have been proven to be more effective than others does not guarantee that the more effective (or equally effective and less costly) treatments / drugs will be used by practitioners. Encouraging use of treatments or drugs whose comparative effectiveness has been shown may require a reason to use an equally effective drug or treatment. One reason may be the extent of coverage of each treatment or drug. As part of the need to look at whether this nation can continue to afford treatments whose clinical effectiveness is no greater than other, less expensive treatments, Congress may wish to consider specifically authorizing Medicare to exclude more expensive treatments or drugs from coverage when, based upon clinical effectiveness research, they are shown to be no more effective than less expensive treatments or drugs. Application on a going-forward basis could increase chances of withstanding legal challenges, so that patients are allowed to finish a course of treatment or medication that has already begun; obviously, a process that recognizes possible individual discrepancies in drug response—which may make some drugs non-comparable for a given patient, and / or an exception process for patients who have developed stable complex long standing drug regimens—would also enhance the litigation position and address some consumer advocacy concerns.

Comparative effectiveness could potentially be translated into clinical practice guidelines (CPGs). These evidence-based guidelines guide clinical decisions by providing guidelines and / or criteria for diagnosis and treatment of specific diseases and medical conditions. CPGs are intended to document the best medical and scientific evidence and standardize medical care. Use of CPGs can assist not only in payment, but can also reduce costs in other ways, including reducing utilization. For example,

(a) The Dartmouth Atlas study demonstrated how utilization of services differs in various areas of the country, illustrating how the "standard of care" can be flexible. Although flexibility can allow for patient preferences and patient response to treatment, lack of a standard of care can allow overutilization, e.g., with end-of-life care. Clinical practice guidelines for end-of-life care can help physicians discuss the use and benefit (or lack of benefit) of such in dying patients.

(b) Clinical practice guidelines can also be used to help to prevent overutilization by physicians who order tests and procedures to avoid allegations of malpractice. A November 2008 study by the Massachusetts Medical Society estimates that physicians' ordering of unnecessary tests, procedures, referrals and consultations because of their fear of being sued adds at least $1.4 billion per year to healthcare costs in Massachusetts alone. The study reported that 83 percent of physicians surveyed admitting practicing "defensive medicine," with an average of 18-28 percent of tests, procedures, referrals and consultations, and 13 percent of hospitalizations, ordered to avoid lawsuits. A physician who follows clinical practice guidelines could be allowed a rebuttable presumption in a malpractice suit that the legally expected standard of care was used in the care of that patient. Although not conclusive, because a plaintiff could rebut this presumption through use of other evidence, use of clinical practice guidelines in this fashion could reduce unnecessary utilization and potentially reduce non-meritorious lawsuits against physicians, as well as reduce unnecessary services.

Development of clinical practice guidelines may raise antitrust concerns, depending upon who sets the standards. If CPGs set a standard for a market, a decision has effectively been made for that market. The antitrust law as applied to standard setting focuses on ensuring that the standard setting organizations are not captured by one or two of the market players, and that the process by which standards are set is fair and is not slanted to favor a particular player or outcome. This was illustrated in a May 2008 settlement between the Connecticut Attorney General and the Infectious Diseases Society of American (IDSA) regarding the IDSA's alleged anticompetitive behavior in development of clinical practice guidelines for diagnosis and treatment of Lyme's disease. The IDSA guidelines concluded that there is no scientific basis for "chronic Lyme disease,"[23] that antibiotics beyond 30 days are not appropriate (despite other studies as to the effectiveness of long-term antibiotics) and that patients who fail to improve with the IDSA's protocol have no treatment options other than palliative care.

The IDSA was alleged, in combination with members of its Lyme disease guidelines panel, to have engaged in an unlawful refusal to deal in, and monopolization of, the market for Lyme disease, by abusing the guideline development process. After the AG's investigation found conflicts of interest with panel members, and refusal to appoint scientists with divergent views, the parties settled. The IDSA agreed to form a new panel to reassess the guidelines, appoint an ombudsman to ensure no conflicts of interest exist, and allow presentations by persons with different interests and views. These concerns are met in other countries by conflict of interest policies, careful composition of a panel reviewing specific effectiveness research, and engagement with stakeholders.[24]

The loudest objection to CPGs will be from technology, pharmaceutical and device providers / manufacturers / suppliers whose technology or medications are not determined to be as clinically effective as another, or not superior in effectiveness to a lesser priced item. There will likely also be objections from practitioners who deride clinical guidelines as "cook-book medicine" that remove discretion to treat patients differently. The most effective objections to practice guidelines are likely to come from

patient advocacy groups, who will resist any program that reduces patient choice of care modalities.

While Congress and state legislatures would appear to have broad authority in the area (particularly when determining payments under public programs), many states (such as New York) afford State constitutional status to healthcare, which would be implicated in an extreme case. Moreover, Federal requirements that States must meet in operating Medicaid programs may further limit policy options in the area or require amendment. Challenges to federal or state administrative action creating such a program would be expected.

e. Allow Exploration of "Medical Homes"

Medical homes are models of care based on the concept that patients with a "medical home" will receive closer coordination of care that can prevent exacerbations of illness and unnecessary care (and cost). Most issues involved with medical homes are financial (compensating physicians for their time in coordinating care) or operational, rather than legal. However, to the extent that state insurance laws may prevent medical homes, the law is restricting use of a model that may be able to improve patient care and reduce costs. For example, an operator of a medical home in Seattle that requires patients to pay low monthly fees ($39-79 depending upon age) but gives 24/7 access for all primary physician care has found that the people who are attracted to them are the high utilizers.[25] Given that seventy percent of healthcare costs are spent on chronic disease, this model could conceivably reduce medical complications and attendant costs, while expanding access. However, in March 2009, the New York State Insurance Department stopped a physician from offering patients, including the uninsured, unlimited office care for $79 per month plus a $10 co-pay, claiming that the physician's fixed-rate plan was equivalent to an insurance policy.[26]

2. Cost of Healthcare Goods and Services/ Healthcare Consumer Protection

a. Limitation on Charges for Healthcare Services for the Uninsured/Underinsured

Overall healthcare costs are largely determined by the charges per unit of healthcare services, supplies, pharmaceuticals and goods provided by tax-exempt and for-profit hospitals, long-term care providers (some of which are large national chains), physicians, large pharmaceutical companies, and suppliers of various sorts. In a capitalist society, it is problematic to dictate what parties can charge (although charge limits are imposed by the Federal Government and some States as a condition of participation in Medicare). Instead, control is exerted over what the government or private payers pay for those goods and services. (For example, the debate on pharmaceutical pricing has primarily focused on the government acting as a purchaser for government labeled programs, and not on direct pricing controls.) However, parties without a contractual arrangement with a healthcare provider or supplier (such as an uninsured patient who doesn't have the benefit of a negotiated rate with a hospital or pharmaceutical supplier) can be charged almost an unlimited amount, and certainly an amount that is a multiple of what a well-positioned buyer of services pays. This was illustrated by the rash of lawsuits against hospitals in the mid-2000s, in which patients alleged that hospitals were abusing their tax exempt status by charging uninsured patients high list prices that far exceeded what Medicare or private payers pay.[27] The courts generally dismissed these suits, acknowledging there is no legal limit on charges.[28]

Some states such as New York and Illinois have passed legislation which caps the amounts (based upon Medicare payments) that hospitals may charge the indigent, and it may be appropriate to expand such legislation to include all persons without insurance (as well as potentially the underinsured), to apply to providers other than just hospitals, and to apply such on a federal level rather than have varied state laws. Alternatively, and perhaps preferably, thought might be given to ending the practice of maintaining a consistent charge for non-contracted patients and use by providers of a high "list price" charge unless financial need is demonstrated.

b. Price Transparency

If healthcare providers and suppliers can charge what the market will bear, then changes should be made to the healthcare market to have it function like other markets. Perhaps a reduction in the cost of healthcare goods and services could be achieved by making the cost of services transparent and allowing consumers to compare prices, which will hopefully drive consumers to more efficient and less costly providers. However, one reason that a "rational" market does not seem to exist with healthcare services is because there is no ready way for healthcare consumers to compare prices and make reasoned decisions based upon the cost of the contemplated service. Medicare has made attempts to provide information to Medicare beneficiaries as to the charges by various providers for certain services, and some managed care providers have formulated databases of charges by certain providers in their network, which database is available to subscribers in that health plan. However, there is no database that a patient without insurance (or a patient with a high deductible plan) can view of all, e.g., providers in that locality who provide a certain type of service and their charges, so that a patient can compare charges in making a decision as to which services to purchase.[29]

Contracts between payers and hospitals, physicians or other providers generally contain confidentiality clauses, prohibiting the provider from disclosing the terms of the contract, including the payment terms. In addition, some payer contracts have "most favored nation" clauses, requiring the provider to give the payer the best rate that it gives to any other payer. Even without a most favored

nation clause, providers are generally concerned that a payer that is aware that a lower price was offered to another plan will use such as a reason to reduce payment to the provider. Therefore, any provider who lists its charges and who has any payer contracts would be unlikely to list less than (a) the provider's charges (which for most hospitals are unrealistic) or (b) the highest rate allowed under any of the provider's managed care contracts, to avoid any of its payers from attempting to negotiate a lower rate based on the lower "transparent rate." Congress could increase transparency by requiring that providers have available (e.g., on their websites) published prices for individual patients (i.e., those not covered by a third party payer). This would allow individuals to know and make decisions based on cost before a service is rendered.

Antitrust issues may also arise from making healthcare prices "transparent," as competitors' prices would be viewable by others, and competing providers may adjust their prices either to undercut their competitors, or to seek additional reimbursement if competitors' negotiated rates with payers are higher. Federal legislation exempting providers who post price information from antitrust liability may encourage such transparency.

c. Determine Which Goods and Services Should Not Be Compensated at Current Prices or Compensated at All

Although Medicare has done much to reduce inequality of payments among providers (e.g., tying fees for surgery at ambulatory surgery centers to those paid to hospitals), some disparities still exist. In addition, there may be some services that are no more effective than a clinically equivalent service that is less expensive. If such determination is made (through a comparative effectiveness study), consideration should be given to payment by Medicare based on the "value" of that service, i.e., its clinical effectiveness. Lastly, federal law has already determined that situations exist where payment should not be made at all (e.g., for services referred by physicians to entities in which they have an ownership interest in violation of the Stark law), and it may be appropriate to review whether other such situations also exist, e.g., radiation oncology provided by urologists who refer and treat the patient.

d. Statewide and Regional Health Planning

Many states have used (and some continue to use) public allocation processes such as certificate of need (CON) laws to limit overutilization of tests and procedures by controlling the number of facilities and providers able to provide such. Although these laws have been repealed in many states, they can indeed be effective, as illustrated by the difference between New York and New Jersey in the number of ambulatory surgery centers (ASCs) in each state (New York requires certificate of need approval for establishment of ASCs, whereas New Jersey does not).[30] Similarly, centralized planning and CON laws may also be utilized to allow certain "high need" hospitals, e.g., those serving a disproportionate share of the medically underserved, to obtain certain services that may not be approved for provision by other, wealthier providers in that region.

3. Efforts to Reduce Administrative Costs, Including Shareholder Returns, Costs of Processing and Administering Claims, Profits, Broker Costs and Malpractice Costs

There are a large number of administrative costs in the US healthcare system. Some estimates are that 31 percent of healthcare dollars are spent on administrative costs. Health administration costs total at least $294.3 billion in the United States, or $1,059 per capita, significantly more than other countries.[31] These include the cost of processing and administering claims, shareholder returns, executive compensation, profits, broker cost, and malpractice costs. Advocates of single payer systems argue that substantial savings can be achieved through eliminating multiple parties from the financing system,[32] and quote as support a recent Urban Institute report commissioned by New York State to study the costs associated with various models that may be considered to expand coverage.[33]

a. Malpractice Cost Reduction

Malpractice costs also contribute to the problem of healthcare costs, although the extent of that contribution is a matter of contention between the attorneys who bring malpractice suits and the insurance companies that pay out on these claims. Even more expensive than the costs of defending and litigating malpractice cases, and paying out jury verdicts, are the costs associated with "defensive medicine," i.e., physicians ordering tests or performing procedures whose primary purpose is their value in defending the doctor against a claim of medical negligence. A 2006 study by PriceWaterhouse Coopers attributed up to ten percent of the insurance premium dollar as due to a combination of the cost of litigation and defensive medicine.[34]

If the federal government were to pass legislation restricting malpractice suits, a legal challenge might come in the form of the appropriate balance of state-federal power. Instead (or in addition to tort reform), an option could be removal of some of the most expensive malpractice cases (i.e., cases alleging brain injury in newborns) from the tort system through establishment of a compensation fund. There is both federal and state precedent for such action. In 1988, Congress passed the National Childhood Vaccine Injury Act of 196 (Public Law 99-660), creating the National Vaccine Injury Compensation Program (VICP). The VICP was established because of numerous lawsuits alleging injuries to children from vaccines, and the difficulty in obtaining insurance by vaccine manufacturers. The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims that provides compensation to people found to be injured by certain vaccines. Individuals who believe that they have been injured by a covered vaccine can file a claim against the

US Department of Health and Human Services in the U.S. Court of Federal Claims, seeking compensation from the Vaccine Trust Fund. If found eligible, claimants can recover compensation for related medical and rehabilitative expenses, and in certain cases, may be awarded funds for pain and suffering and future lost earnings. More than 1,500 people have been paid, with awards averaging over $800,000. Although an individual who is dissatisfied with the award may reject it and file a lawsuit in state or federal court, very few lawsuits have been filed since the program began.

State precedent also exists for special compensation funds. In response to increasing costs of claims against medical providers and medical malpractice insurance in the late 1980s, Virginia and Florida both created funds to compensate families whose babies are born with neurological impairments. Brain damaged baby claims were singled out because of the large awards that can result from these claims. A family that receives compensation from these funds does so in lieu of malpractice litigation. A family may receive compensation for medical, rehabilitative and custodial care, special equipment or facilities, and related travel, except to the extent these expenses have already been paid by insurance. Lost earnings are also available, although limited in Florida. In Virginia, the Workers' Compensation Commission determines eligibility; in Florida, the State Management Department assigns an administrative law judge to resolve claims. In both states, annual assessments from physicians and hospitals capitalize the funds, both of which are currently actuarially sound.

Other malpractice reform initiatives could include increased disciplinary sanctions tied to a pattern of unexpected adverse outcomes, improved credentialing and licensing programs, and/or limiting certain forms of damages and mandating binding arbitration. A federal statute would likely be constitutional under the Commerce Clause.[35] State laws are subject to State constitutional law challenges.

b. Payer Cost Limitations as a Percentage of Premiums

Some administrative costs are inevitable, but there are a number of methods that have been tried or considered in attempts to reduce administrative costs from the healthcare system. Some states require managed care companies to spend a minimum defined percentage of their revenue on medical care/costs rather than overhead and profits, although in some states the requirements are that managed care companies must spend as little as 60% of the premium paid by policyholders on medical costs. Although disliked by the managed care companies, these have generally not been challenged. However, such minimum percentage expenditure requirements may only increase the incentive to maximize premiums, and thereby, profit.

c. A Single Claims Adjudicator/Claims efficiency

Another option to substantially reduce administrative costs of administering the healthcare claims and payment system is to change the claims administration system. In the present system, the same entities responsible for paying claims are responsible to make decisions as to whether the claims should be paid. A number of class action lawsuits have alleged that health plans delay and deny payment, through deeming claims not properly "authorized," care not "medically necessary," losing claims, and the like. A proposal from late 2007[36] suggested formation of a unified health claim clearinghouse system to separate approval and payment of claims from the ownership of premium cash pools. This proposal would create an independent and electronic healthcare clearinghouse to coordinate the approval of and payment for covered services, and avoid the conflict that payers presently have in trying to maximize profits by denying claims and delaying payment. Given that Medicare's administrative costs are roughly 5-6 percent, whereas private payers' administrative costs fall between 8.9 and 16.7 percent (which does not include provider costs, which are substantial),[37] a proposal to restructure administration of claims payment to a system similar to Medicare could allow for substantial savings (although some of Medicare's administrative costs are expensed elsewhere in the federal budget[38]). Congress could pass such legislation under the Commerce Clause or potentially its spending power,[39] which should give authority against legal challenges by health insurers related to the displacement of part of their functions to an independent entity, and removal of their control of claims (a vast pool of money).

Other action can also be taken to reduce administrative overhead that is short of a single claim adjudicator, but that provides for more efficiency than the current decentralized system whose requirements vary depending upon the particular payer. Although HIPAA's administrative simplification requirements and the Medicare National Provider Number (NPI) have helped somewhat to decrease the administrative burden on providers and patients, much more remains to be done. For example, (i) benefit packages could be standardized, so that a provider does not have to ascertain whether a patient has 20 or 24 physical therapy visits and a $10 or $20 co-pay, (ii) payers could be required to set up electronic portals allowing providers to electronically check patient eligibility and benefits on a 24 hour basis, (iii) payers could be required to provide subscribers with ID cards that can be electronically "swiped" at a providers' office with connectivity to a payer's system, (iv) payers could be required to use a standard claims forms and codes. In fact, two states (Colorado and Texas) have mandated the use of standardized health insurance identification cards.[40]

d. Use of Standard Managed Care Contract Provider/Payer Interaction Terms

One reason that Medicare's administrative costs may be lower is because it does not negotiate separate contract terms with its providers; the terms are uniformly prescribed in regulation and policy manuals. In contrast, commercial payers and providers expend enormous amounts of time and money negotiating contracts terms, such as coordination of benefit provisions, clams submission time periods and authorization requirements. Providers' need to comply with multiple inconsistent plan provisions is burdensome and costly. One way to reduce administrative costs for both plans and providers, with no effect on quality or access, may be to enlist government to promote equitable routine provisions in provider-payer contracts.

e. Regulatory Reform

Lastly, the regulatory burdens on healthcare providers increase costs for healthcare services. Hospitals and healthcare providers are among the most highly regulated of businesses in the United States. Both federal and state laws and regulations contain myriad requirements regulating every area of a hospital's practice, from how it can compensate its physicians, to the type of staff it must have, to how many hours its nurses can work. Although some degree of regulation is clearly necessary, over-regulation imposes layers of cost on an already expensive area. HIPAA, with the confusion as to whether providers are releasing too much or not enough information, is an example. News reports of families believing their loved ones have died because the hospital staff were concerned about releasing information about the patient's transfer, demonstrate the confusion and questionable benefit of portions of this law.

Although excessive regulation can be beneficial to lawyers who practice in the field (as no one else can keep track of the regulations), the bar asks Congress to be wary of passing additional legislation and regulations imposing burdens on healthcare providers, which burdens simply add to the cost of the healthcare system. Congress may consider a cost benefit analysis be mandated before each new regulation is passed, and that the cost-benefit analysis be repeated after implementation to determine if the regulation is working as desired. It is interesting that part of the extensive regulation has come about as a punitive set of mechanisms to counteract the perverse incentives in the system that reward utilization. It has been estimated that at least three percent of healthcare claims are based upon fraud.[41] Revision of payment incentives to pay for efficient and effective health improvement, rather than units of service, may be most effective in reducing "fraud" in the system.

On the other hand, although regulation of providers is myriad, regulation of other parties in the healthcare system may be appropriate for review and enhancement, including, e.g., requirements that payers implement claims efficiencies such as setting up electronic portals allowing providers to electronically check subscriber / patient eligibility and benefits twenty four hours a day, and use a standard claims form and codes.

C. Reducing Political Influence in Making Healthcare Costs Decisions

Healthcare is a segment of the economy in which multiple players attempt to profit, from pharmaceutical companies and managed care companies to medical device manufacturers and durable medical equipment manufacturers, to hospitals and physicians. Although a part of capitalism, the desire to protect profit has caused various constituencies to attempt to avoid regulation or cost containment, often though political means, resulting in decisions skewed by politics, and the use of "healthcare dollars" on lobbying activities. One of the mechanisms that has been used in other political arenas to attempt to remove decisionmaking from the political process has been appointment of a neutral commission or body to make certain decisions. Recent examples include the federal base closing commission, and the New York State Commission on Health Care Facilities in the 21st Century (the "Berger Commission") used by New York State to make recommendations on closing hospitals in New York State.[42]

A number of challenges were brought by governors and senators in states containing bases recommended for closure or realignment by BRAC. Similar challenges had been raised under the 1990 BRAC Act. In these challenges, the US Supreme Court precluded judicial review under the Administrative Procedure Act of the President's discretionary decisions to close certain military installations, noting "longstanding authority holds that such review is not available when the statute in question commits the decision to the discretion of the President."[43]

It may be most effective to follow a similar process in the healthcare field to make decisions as to, e.g., funding or reimbursement.

D. Conclusion

In summary, changing the incentives that drive up healthcare costs requires consideration of changes in the law to (among other things): (i) allow incentives to be used as a part of wellness and disease management programs, (ii) promote use of clinical guidelines, (iii) allow providers (including hospitals) to refuse to participate in (and discontinue if appropriate) non-beneficial treatment after a process including family discussion and ethics committee review, (iv) allow hospitals to act as "accountable care organizations" and reward non-employed physicians based upon achievement of defined quality measures, (v) tie hospital charges to the uninsured to Medicare rates, (vi) reduce malpractice costs, (vii) require that cost implications be considered prior to further regulation of providers, and (viii) allow exploration of medical homes without restrictions of state insurance laws. Other

actions that can be taken that may involve legal action (but not necessarily a change in the law) include setting up a healthcare claims processing clearinghouse to reduce administrative costs involved in processing healthcare claims, prescribing uniform terms in provider-payer contracts, and appointing a neutral commission or body to make certain healthcare costs decisions and reduce the political influence on cost decisionmaking. To the extent that the healthcare bar can be of service it is ready to do so. The bar calls on its members, Congress and all members of the extended healthcare community (including patients, payers, and providers/suppliers) to work together and put aside self-interest to decrease healthcare costs and strengthen our healthcare system.

Endnotes

1. Congressional Budget Office, The Long-Term Outlook for Healthcare Spending (November 2007).
2. The Fiscal Survey of States, December 2007, National Governors Association, National Association of State Budget Officers.
3. *Id.*
4. The Kaiser Family Foundation and Health Research and Educational Trust, *Employer Health Benefits, 2007 Summary of Findings* (2007).
5. David U. Himmelstein et al., *Medical Bankruptcy in the United States, 2007: Results of a National Study*, THE AMERICAN JOURNAL OF MEDICINE (2009), http://pnhp.org/new_bankruptcy_study/Bankruptcy-2009.pdf.
6. National Coalition on Health Care, *Health Care Quality, 2009* (2009).
7. As cited in the Commonwealth Fund's July 2009 Issue Brief, "How Health Care Reform Can Lower the Costs of Insurance Administration," by Collins, et al., the costs of broker commissions alone in the small-group market, where brokers play a key role in identifying pertinent insurance policies, run from 4 percent to 11 percent of premiums.
8. Richard Hillestad et al., *Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Cost*, 24(5) HEALTH AFFAIRS 1103 (2005).
9. John E. Wennberg et al., *Tracking the Care of Patients with Severe Chronic Illness*, DARTMOUTH ATLAS OF HEALTH CARE (2008).
10. *See* 71 Fed. Reg. 239 (Dec. 13, 2006); *see also* 26 C.F.R.§ 54 (for the IRS regulations); 29 C.F.R § 2590 (for the Employee Benefits Security Administration regulations); 45 C.F.R § 146 (for the CMS regulations). The reward for the wellness program, coupled with the reward for other wellness programs, may not exceed 20 percent of the cost of the employee-only coverage under the plan. A reward can be in the form of a discount or rebate of a premium or contribution, a wavier of all or part of a cost-sharing mechanism (such as deductibles, copayments or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan.
11. Mexico's Oportunidades program offers families a monthly payment, free or low-price medical services, and scholarships in exchange for their participation in health, nutrition and education programs. *See* Theresa Braine, *Reaching Mexico's Poorest*, BULLETIN OF THE WORLD HEALTH ORGANIZATION (2009).
12. Employer Health Benefits, 2007 Annual Survey, Kaiser Family Foundation, 2007-09-11.
13. *See* Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, 67 Fed. Reg. 55855 (August 30, 2002); *see also* Op. OIG No. 02-14 (2002).
14. Melinda Beeuwkes Buntin & Haiden Huskamp, *What Is Known About the Economics of End-of-Life Care for Medicare Beneficiaries?* THE GERONTOLOGIST 42:40-408 (2002), http://gerontologist.gerontologyjournals.org/cgi/content/abstract/42/suppl_3/40.
15. A recent case in NJ, *Betancourt v. Trinitas Hosp.*, Docket No. C-12-09, Superior Court of New Jersey, March 4, 2009, illustrated the need for recognition of healthcare providers' rights not to participate in non-beneficial care, which the court stated was an issue of first impression in New Jersey, did not recognize such, and appointed as decision-maker the patient's daughter, who desired continued maximal efforts in a patient for whom physicians agreed care was non-beneficial (and who had also indicated intent to bring a lawsuit against the hospital and therefore had another potential motive for delaying the patient's demise).
16. COBRA, at 29 U.S.C. § 1162 *et seq.*, was enacted in 1986 (effective 1986) as an amendment to ERISA.
17. Atul Gawande, *The Cost Conundrum: What a Texas Town Can Teach Us About Health Care*, THE NEW YORKER, July 1, 2009.
18. 73 Fed. Reg. 38502 (July 7, 2008).
19. *See* December 12, 2008 letter by Alice G. Gosfield and Associates, P.C.
20. Donald H. Romano, *A Fresh Look at the CMP Statute: It May Not Be as Proscriptive for Gainsharing Arrangements as the OIG Believes*, HEALTH LAWYERS WEEKLY (2009), http://www.arentfox.com/email/romano/Don%20Romano%20HLW_article.pdf.
21. Congressional Budget Office, *Research on the Comparative Effectiveness of Medical Treatments* (2007).
22. Kalipso Chalkidou et al., *Comparative Effectiveness Research and Evidence-Based Health Policy: Experience From Four Countries*, 87(2) THE MILBANK QUARTERLY 339 (2009).
23. Chronic Lyme disease is a situation in which patients suffer ill effects after a tick bite for months or years, and the guidelines allowing antibiotics for only 30 days are based on a conclusion that the spirochete that carries the disease does not live in the body long-term.
24. Kalipso Chalkidou et al., *Comparative Effectiveness Research and Evidence-Based Health Policy: Experience From Four Countries*, 87(2) THE MILBANK QUARTERLY 339 (2009).
25. John Commins, *Direct Medical Home Offers Healthcare Without Insurers*, HEALTHLEADERS MEDIA, July 13, 2009, http://www.healthleadersmedia.com/content/235830/topic/WS_HLM2_PHY/Direct-Medical-Home-Offers-Healthcare-Without-Insurers.html.
26. VOSIZNEIAS, STATE BUREAUCRATS FIGHT DOCTORS' $79 FLAT FEE FOR UNINSURED, (2009), http://www.vosizneias.com/28392/2009/03/04/new-york-ny-doctor-trying-to-help-uninsured-patients-with-annual-low-fee-is-being-fought-by-state-bureaucrats.
27. *See, e.g., Galvan v. Northwestern Mem'l Hosp.*, 382 Ill.App.3d 259, 888 N.E.2d 529, 321 I. Dec. 10 (2008); *Cox v. Athens Reg'l Med. Ctr.*, 279 Ga.App. 586, 631 S.E.2d 792 (2006); *Pitts v. Phoebe Putney Mem'l Hosp.*, 279 Ga.App. 637, 631 S.E.2d 830, *cert. denied* October 16, 2006; *Urquhart v. Manatee Mem'l Hosp.*, 2007 WL 781738 (M.D.Fla. (2007); *Colomar v. Mercy Hosp. & Catholic Health E.*, 461 F. Supp.2d 1265 (S.D. Fla. 2006).
28. Physicians also typically have a list of charges, which also are used as the basis for payment by patients whose insurance doesn't contract with that physician, at all or for a particular service. Physicians and other providers who participate with a third party payer (and are part of that payer's network) get paid either according to that payer's fee schedule, or a negotiated rate.
29. Complicating the lack of a database of local providers and their charges is the fact that the issue of "quality" is also important in medical care, and considered in choice of a health care provider. Consumers now have significantly more quality information than ever before with the various "Compare" databases from Medicare

(e.g., Hospital Compare and Nursing Home Compare), and services such as Health Grades.

30. New York has 0.45 ambulatory surgery centers per 100,000 people, and New Jersey has 2.31 ambulatory surgery centers per 100,000 people, according to statistics from the Ambulatory Surgery Center Association cited in "Ambulatory Surgery: National and State Environments and Key Policy Considerations," presented to the Public Health Council, New York State Department of Health, January 23, 2009.

31. Steffie Woolhandler et al., *Costs of Healthcare Administration in the United States and Canada*, 349(8) N. Engl. J. Med. 768-775 (2003).

32. The Lewin Group estimates that if a single payer system were implemented with other major features of a reform plan—such as an employer requirement to offer coverage, expanded eligibility for Medicaid, a standard benefit package, and premium subsidies, that more than $200 billion could be realized in administrative cost savings during 2010-2019. *See* Sara R. Collins et al., *How Health Care Reform Can Lower the Costs of Insurance Administration*, 57 THE COMMONWEALTH FUND pub. 12299 (2009).

33. The Urban Institute, *Achieving Quality, Affordable Health Insurance for All New Yorkers: An Analysis of Reform Options (2009)*, http://www.health.state.ny.us/health_care/reports/docs/2009-07-17_analysis_of_reform_options.pdf (prepared for the New York State Department of Health and the New York State Department of Insurance).

34. PriceWaterhouse Coopers, *The Factors Fueling Rising Healthcare Costs 2006*, Prepared for America's Health Insurance Plans (2006), http://www.ahip.org/redirect/PwCCostOfHC2006.pdf.

35. The Commerce Power of the United States Constitution, US CONST. art. 1, Section 8, cl. 3, in pertinent part, provides that Congress shall have the power "[t]o regular commerce…among the several states." The Supreme Court, *in United States v. Lopez*, 514 U.S. 549 (1995) held that this power grants Congress authority to regulate activities having a substantial impact or relation to interstate commerce. Most health insurers conduct business across state lines. However, these regulations must be specifically directed at health insurers, as a statute requiring or compelling states to regulate insurers themselves will be considered a violation of the Tenth Amendment and not upheld, as decided in *New York v. United States*, 505 U.S. 144 (1992).

36. Edward S. Kornreich et al., *The Unified Health Claims Clearinghouse: A Prescription to Simplify and Save on Health Care Services*, 14(1) NYSBA Health Law Journal 29 (2009).

37. A recent national study found that US physicians spent an average of $68,274 per physician per year interacting with health plans, for a total $31 billion annually, according to "What Does It Cost Physician Practices to Interact With Health Insurance Plans?," Casalino, Nicholson, Gans, Hammons, Morra, Karrison and Levinson, Health Affairs Web Exclusive, May 14, 2009.

38. William G. Schiffbauer, *The Level Playing Field Myth: Comparing Administrative Costs for Public, Private Health Insurance*, BNA'S MEDICARE REPORT, April 24, 2009.

39. Under Article 1, Section 8 of the U.S. Constitution, "Congress shall have the power to lay and collect taxes, duties, imposts and excises to pay the debts and provide for the common defense and general welfare of the United States. The U.S. Supreme Court in *South Dakota v. Dole*, 483 U.S. 203 (1987) validated Congressional conditioning of federal funding/spending on states' compliance with the demands of the federal government (in Dole, to change the drinking age to 21), even if Congress does not have the constitutional power to regulate it in the first place. With health care, Congress could potentially invoke the Spending Power of the Constitution to induce all states to require private health insurers, conducting business in their respective states, to participate in the unified clearinghouse. This could be accomplished through conditioning federal funding related to healthcare (conditioning of 5% of funds was upheld in Dole) upon meeting such requirement.

40. 8 TEX. INS. CODE ANN. § 1660 (2007), and 10 COLO. REV. STAT. ANN. § 16-135 (2009).

41. Anti-Fraud Resource Center, *The Problem of Health Care Fraud*, NATIONAL HEALTH CARE ANTI-FRAUD ASSOCIATION, http://www.nhcaa.org/eweb/DynamicPage.aspx?webcode=anti_fraud_resource_centr&wpscode=TheProblemOfHCFraud.

42. For example, the Base Closure and Realignment Act of 2000, 104 Stat. 1808 as amended, following Title 20 U.S.C. § 2687 (the "BRAC Act") was passed in 2000 to set forth the process by which military bases in the United States and its territories were identified for closure and realignment, to avoid objections of politicians to closure of bases in their states or legislative areas. Pursuant to the BRAC Act, a process was set up whereby the Secretary of Defense was authorized to make recommendations for the closure and realignment of military bases in the U.S. to the BRAC Commission. The Commission then forwarded this recommendation to the President of the United States, who was required to either approve or disapprove the recommendations in the report in their entirety. *See* BRAC Act 2914(e)(1). The law provided that if the President approved either the original or revised recommendations, he was required to send the approved list and a certification of approval to Congress. *Id.* at 2914(e)(3). Unless Congress enacted a resolution disapproving the approved recommendations within 45 days after receiving the President's certification of approval, the Secretary was required to carry out all of the recommendations. *Id.* at 2904(e).

43. *Dalton v. Spector*, 511 U.S. 462, 474 (1994).

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The opinions expressed in this Report are solely those of the New York State Bar Association's Health Law Section, and do not represent the position of the New York State Bar Association unless and until adopted by the New York State Bar Association Executive Committee and House of Delegates.

Note: The Health Law Section of the New York State Bar Association includes a wide range of perspectives, including advocates for physicians, other healthcare providers, hospitals, health plans, regulators and consumers. Some members believe that some important policy alternatives to control costs (e.g., a single payer plan) should be included in any analysis, and that there should also be deliberate consideration of policy arguments concerning such matters as consumer protections in discussion of some of the measures analyzed in the report. It should be noted that the report does not advocate adoption of any particular policy alternative.

Recent Events

- **Fall Meeting**. On October 23, the Section held its Fall meeting at the Sagamore Resort in Bolton Landing, NY. The program was organized by Kathleen M. Burke, Lawrence Faulkner and Tracy E. Miller. Topics included Health Care Quality: From Financial Incentives to Enforcement; Policy Initiatives on End-of-Life Decision-Making; Health Care Reform: What's Next in New York State; Federal Health Care Reform: The Implications for New York State, and a Fraud & Abuse Update.

  Among the many prominent speakers were Deborah Bachrach, Deputy Commissioner of the Office of Health Insurance Programs (OHIP) and NYS State Medicaid Director; Senator Thomas K. Duane, Chair of the NYS Senate Health Committee; James Sheehan, NYS Medical Inspector General; Daniel Sisto, President, Healthcare Association of New York State; and Heidi Wendel, Esq., Deputy Attorney General, Medicaid Fraud Control Unit, New York City.

- **Report on Health Care Costs.** In September, the Section approved and adopted an extensive report by the Public Health Committee entitled "Summary Report on Healthcare Costs: Legal Issues, Barriers and Solutions." The report, reproduced in full in this edition of the *Health Law Journal*, explores the legal issues associated with health care costs and offers numerous policy proposals. Since its adoption by the Section (which was confirmed by the NYSBA Executive Committee), the report has been broadly distributed to policymakers involved with federal health care reform efforts. Many Section members and other contributed to the report, but Margaret (Margie) Davino of Kaufman, Borgeest & Ryan, LLP (New York, NY) was the principal author.

Save these Dates

- **Annual Meeting.** The Section's Annual Meeting will be held on Wednesday, January 27 in connection with the Association's week-long Annual Meeting. This year the meeting will be held at the Hilton New York, 1335 Avenue of the Americas, NY, NY. The Annual Program will focus on Health Care Reform, with presentations by prominent and experienced national and NYS figures. Marcia Smith of Iseman, Cunningham, Riester & Hyde (Albany) is the Program Chair. Also, at 8 a.m. that morning, instead of committee meetings, the Section will offer a "Year in Review" for health lawyers.

Recent Supraspinatus Topics

- Comptroller: Nursing Agencies Siphoned Off Medicaid Monies Intended for Complex Care Nurses
- Deal for Adirondack Medical Practices
- Governor Signs Raft of Legislation Including Several Health Bills
- More Arrests in AG Fraud Investigation
- North Shore/LIJ to Offer Physicians Substantial EMR Subsidy
- Blue Cross Blue Shield Association Data Breach Compromises 850,000 Physician Files
- Counting on vaccine doses for policy and law
- NHGRI launches the next generation of its online Talking Glossary of Genetic Terms
- House Committee Passes Health Insurance Industry Antitrust Enforcement Act
- NY Caves on Healthworker Flu Vaccination Mandate
- New York Disadvantaged Under Current Health Reform Bills

Supraspinatus, the Health Law Section's blog, may be viewed at http://nysbar.com/blogs/ healthlaw. The site is supervised by Paul Gillen of Capital District Physicians Health Plan.

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

Section Committees and Chairs

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

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Representing People with Disabilities

Third Edition, 2007 Revision

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