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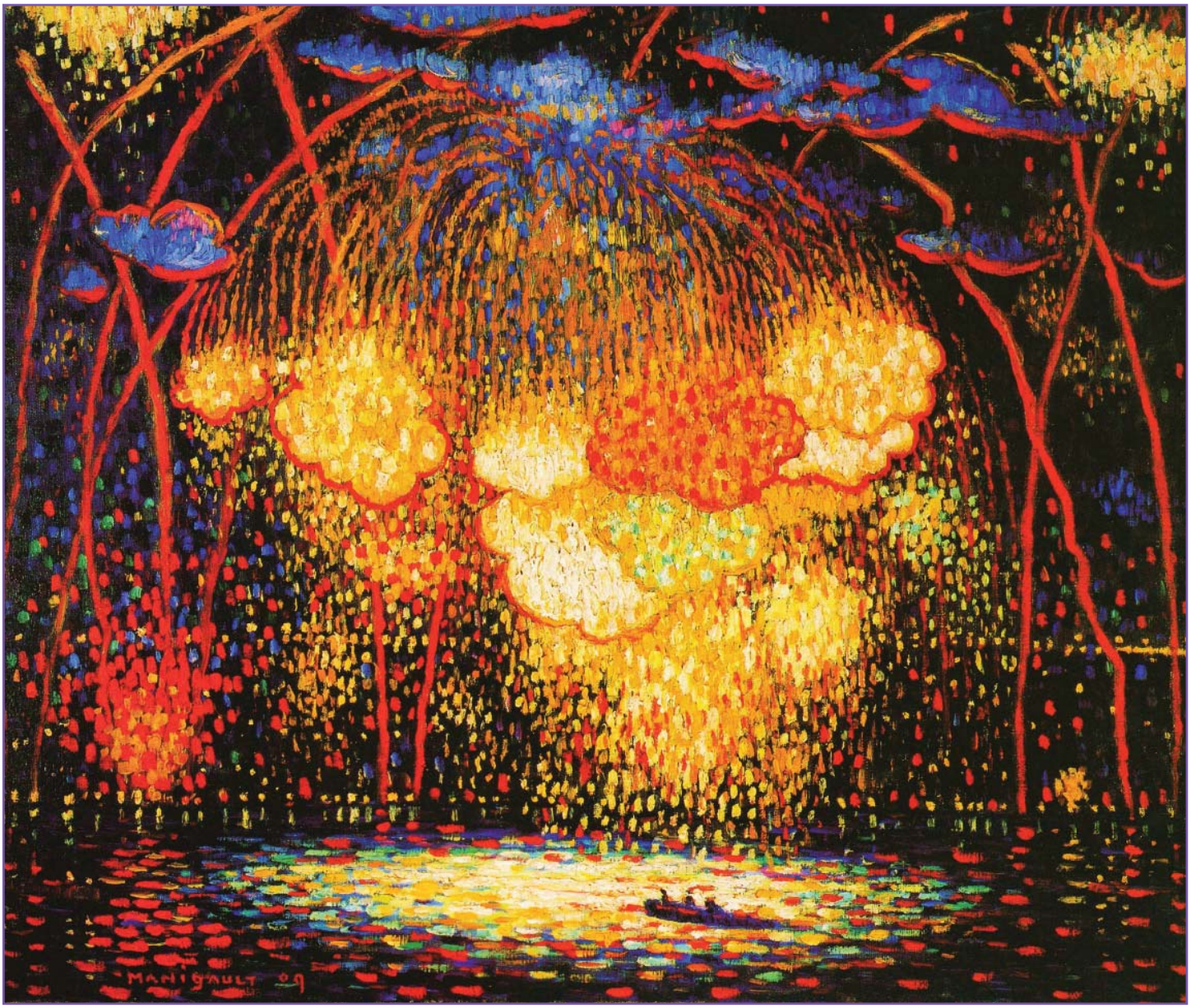
Health Law Journal

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



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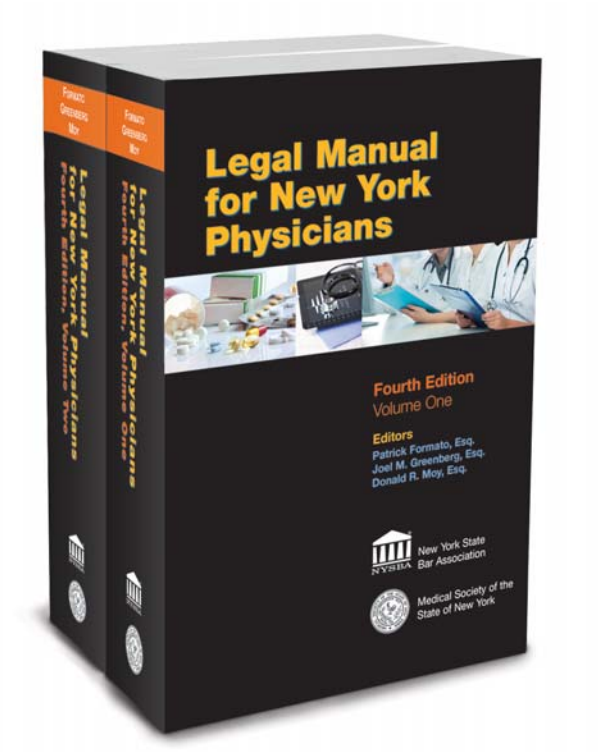

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HEALTH LAW JOURNAL

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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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***The Rocket* by Edward Middleton Manigault,1909**

Message from the Section Chairs

On June 1, Margie Davino's term as Section Chair ended, and Ken Larywon's term as Section Chair commenced.

We are proud to say that the Health Law Section has been growing and busy. We encourage all members of the Section to join a committee and get involved. We have some committee changes to allow persons with interests in these areas to get to know each other and become aware and involved with topics affecting their clients. The first is the re-constitution of the Long-Term Care Committee, which will be chaired by Jane Bello Burke at Hodgson Russ. The Long-Term Care Committee will focus on legal issues relating to skilled nursing, assisted living, home care and other providers of long-term care. It will provide a forum to discuss laws, regulations, and policies and developments relating to the operation and oversight of long-term care providers; offer members opportunities to comment on proposed statutory and regulatory developments relating to long-term care; undertake initiatives to educate members, other attorneys and the public on legal issues relating to long-term care; and provide opportunities for member networking.

Secondly, the Mental Hygiene and Developmental Disabilities Committee is splitting into two committees: the Mental Health Law and Substance Abuse Committee will be chaired by Carolyn Wolf from Abrams Fenstermann, and the Developmental Disabilities Committee will be chaired by Hermes Fernandez, from Bond Schoeneck and King. This split recognizes the sometimes different focuses of mental health law and development disabilities law, although several members are serving on both committees.

If you are interested in any of the above committees (or any of our committees), please contact the above chairs, or sign up through the bar.

We also have a number of CLEs being planned, under the guidance of Bob Borsody, Chair of the CLE Committee. These include:

- Senior Housing program, by the Section's CLE Committee in NYC—September 25 in NYC.
- Half-day program by the E-Health and Information Systems Committee—to be held in October in NYC.
- Health Law Section Fall Meeting—to be held October 30 in Albany.
- Aid in Dying program, proposed by the Committee on Ethics in the Provision of Health Care (date to be determined).
- Medical Marijuana in New York State—(date to be determined).
- Special Education and the Law: NYSBA CLE Department, co-sponsored by the Health Law Section—date to be determined in the fall.

Please get involved with the Section, and we look forward to seeing you at one of the committee meetings and/or above meetings!

Margaret J. Davino
Outgoing Chair

Kenneth R. Larywon
Incoming Chair

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In the New York State Courts

By Leonard M. Rosenberg

Second Circuit Holds Constitutional New York's Vaccination Requirement and Exclusion of Non-Vaccinated Children from Public School During Outbreak of Vaccine-Preventable Disease

Phillips v. City of New York, 775 F.3d 538 (2d Cir. 2015). Appellants, parents of minor unvaccinated children, appealed from the U.S. District Court for the Eastern District of New York's dismissal of their constitutional challenge to New York State's requirement that all children be vaccinated to attend public school. Appellants claimed that the vaccination requirement violated: (i) substantive due process; (ii) the Free Exercise Clause of the First Amendment; (iii) the Equal Protection Clause of the Fourteenth Amendment; and (iv) the Ninth Amendment. Appellants also alleged violations of state and municipal law. Under the same legal theories, Appellants also challenged as unconstitutional a New York State regulation (10 N.Y.C.R.R. § 661.10) that allows school officials to temporarily exclude from attendance those students who are exempt from the vaccination requirement (for religious or medical reasons) during an outbreak of vaccine-preventable disease.

Pursuant to the New York Public Health Law § 2164(7)(a), "[n]o principal, teacher, owner or person in charge of a school shall permit any child to be admitted to such school, or to attend such school, in excess of fourteen days" without a certificate of immunization. The statute has two exceptions: (i) where a licensed physician has certified that an immunization may be detrimental to the child's health; and (ii) where the child's parent, parents or guardian "hold genuine and sincere religious beliefs which are contrary" to the vaccination requirement.

Appellants Phillips and Mendoza-Vaca successfully obtained religious exemptions for their children

based upon their Catholic beliefs. However, they brought suit when the children were excluded from school, pursuant to 10 N.Y.C.R.R. § 661.10, after a classmate was diagnosed with chicken pox. Phillips and Mendoza-Vaca's complaint was consolidated with that of Appellant Dina Check, who sought a preliminary injunction to compel the Department of Education to allow her daughter to attend school unvaccinated. The preliminary injunction application was addressed by a Magistrate Judge who recommended that the request be denied, finding that Check's testimony showed that her views on vaccination were primarily health-related rather than based on genuine and sincere religious belief. In particular, Check testified that she did not know of any tenets of Catholicism that prohibited vaccinations and, instead, focused her testimony on her daughter's previous adverse reactions to inoculations. The Eastern District adopted the Magistrate's Report and Recommendation and denied injunctive relief.

The Eastern District granted Defendants' motions to dismiss or for summary judgment as to the consolidated cases. Affirming the District Court's decision, the Court of Appeals addressed substantive due process, the free exercise of religion, equal protection, and the Ninth Amendment. The Court held that the vaccination statute and regulation allowing children's exclusion from school were constitutionally permissible exercises of the State's police power and did not infringe upon the Free Exercise Clause. As to substantive due process, the Court cited the standard articulated by the Supreme Court in 1905 in *Jacobson v. Commonwealth of Massachusetts*, holding that it is within the police power of a state to mandate vaccination. Regarding the argument that vaccines do more harm than good, the Court held that any such determination is a question for the legislature rather than for individual objectors.

Turning to the Free Exercise Clause, the Court cited persuasive dictum from *Prince v. Massachusetts* and other Supreme Court cases, holding that the right to freely practice one's religion does not include the freedom to expose the community or a child to communicable disease, ill health, or death. Significantly, the Court also noted that NYPHL § 2164(7)(a) affords greater protection than the U.S. Constitution requires by allowing an exemption for parents with genuine and sincere religious beliefs. The Court reasoned that because the State could constitutionally bar Phillips and Mendoza-Vaca's unvaccinated children from public school entirely, a limited exclusion of such children during the outbreak of vaccine-preventable illness was "clearly constitutional."

Addressing the Equal Protection Clause, the Court held that there was no discrimination against Catholics, as both Phillips and Mendoza-Vaca are Catholic and received religious exemptions for their children. Because Appellants failed to challenge the District Court's finding that Check's approach to vaccinations was not based on genuine religious beliefs, the Court rejected the argument that Check was treated differently from her similarly situated co-Appellants. The Court further noted that Appellants alleged nothing to suggest that Phillips and Mendoza-Vaca shared similar religious beliefs to Check's.

Finally, the Court held that the Ninth Amendment was unavailable, as it is not an independent source of individual rights and Appellants failed to "plausibly…allege a violation of any other constitutional right."

Federal Law Preempts Personal Injury Claims Based on Child's Reaction to Vaccination

Stenberg v. Kalansky, 122 A.D.3d 611, 996 N.Y.S.2d 306 (2d Dep't 2014). Infant plaintiff and her mother (together, Appellants) appealed from the grant of Respondents' CPLR § 3211(a) motions to dismiss the complaint alleging medical and nursing malpractice and lack of informed consent. Respondents were West Sayville Children's Medical Services, P.C. and three individual parties.

Appellants alleged that the infant plaintiff sustained personal injuries following Respondents' administration of certain vaccines. Specifically, Appellants claimed that the injuries stemmed from the infant plaintiff's loss of consciousness and fall in which she struck her chin after receiving the vaccinations.

The Appellate Division affirmed the Supreme Court's dismissal of the claims as preempted by Federal law, under the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. §§ 300aa-1-300aa-34).

Barring a Physician from Owning or Administering a Medical Facility Due to Conviction for Conspiracy to Commit Bribery While Employed as Hospital CEO Is a Penalty Authorized by the Public Health Law

Aguino v. Shah, 4 N.Y.S.3d 563 (3d Dep't 2015). Petitioner Roberto Aquino, a licensed physician, owned and was the Chief Executive Officer of Parkway Hospital, which the Berger Commission had recommended for closure. Petitioner pled guilty to one felony count of conspiracy to commit bribery, based on payments he made to a state senator for efforts to influence the state to keep the hospital open. As a result of the felony conviction, the State Board for Professional Medical Conduct charged petitioner with professional misconduct pursuant to Education Law § 6530(9)(a).

A hearing committee sustained the charge and imposed a penalty that included a one-year stayed suspension of petitioner's medical license, and permanently prohibited him from owning or administering a group medical practice or a medical facility licensed under Article 28 of the Public Health Law ("PHL"); however, petitioner is permitted to operate a solo office practice. The penalty was sustained by the Administrative Review Board, and petitioner commenced an Article 78 proceeding to challenge the penalty as unauthorized by statute.

The Court held that although a penalty that clearly is not authorized by statute is subject to amendment, in this case the restrictions on petitioner's license fall "within a reasonable interpretation of the penalty authorized by Public Health Law § 230-a(3)." [PHL§230-a(3) permits "limitation of the license to a specified area or type of practice."] The Court noted that the penalty was tailored to permit petitioner to continue providing medical care to patients while avoiding the type of administrative duties that led to his conviction.

Postdoctoral Research Fellow Exposed to Virus Is Limited to Workers' Compensation Benefits, as University Exercised Control Over the Terms and Conditions of Researcher's Employment

Schwenger v. NYU School of Medicine, 126 A.D.3d 1056 (3d Dep't 2015). Plaintiff, a postdoctoral fellow conducting research funded by a federal grant, appealed the Workers' Compensation Board's (the "Board") determination that an employer-employee relationship existed between the fellow and the Defendant medical school. Affirming the Board's decision, the Appellate Division, Third Department, held that substantial evidence supported the finding that an employer-employee relationship existed.

After obtaining his doctorate degree in 1998, Plaintiff, a research scientist, began laboratory research at the Defendant medical school. Plaintiff's salary was funded by a federal grant, administered through the National Institutes of Health ("NIH"). During his postdoctoral research program Plaintiff was allegedly exposed to the herpes virus, and thereafter brought suit against the Defendant in Supreme Court. The Defendant moved for summary judgment, arguing that Plaintiff was an employee of the medical school at the time of the exposure and thus his exclusive remedy was workers' compensation benefits. The Supreme Court found that the existence of an employer-employee relationship was a question of fact for the Board to resolve, stayed the proceedings, and remanded the parties to the Board for a ruling on this issue. Ultimately, the Board determined that Plaintiff was an employee of the Defendant medical school. Plaintiff appealed the decision.

The Appellate Division, Third Department, affirmed the Board's determination. Plaintiff argued that federal law preempted the Board's jurisdiction over the fellow and substantial evidence did not exist to support the Board's finding that an employer-employee relationship existed between him and the Defendant medical school. The Appellate Division was not persuaded by Plaintiff's arguments. The Court did not find any explicit or implicit indication in any federal statute or regulation that preempted New York workers' compensation laws. The Court opined that, absent any clear evidence, Congress did not intend to preempt state law in areas where states have traditionally exercised their police powers, such as workers' compensation laws. However, Plaintiff argued that preemption can be found in a program announcement circulated by the NIH. He cited to a program announcement which stated that individuals "supported under the [grant program] are not considered to be in an employee-employer relationship with NIH or the awardee institution," and that institution could not apply grant funds to workers' compensation expenses. The Court held that the program announcement did not justify the preemption of state workers' compensation laws, as the announcement was

made in the context of explaining the tax liability of individuals receiving grant funds, and it expressly stated that the taxability of stipends does not alter the relationship between those individuals and institutions.

With respect to Plaintiff's claim regarding the existence of an employer-employee relationship, the Appellate Division noted that to determine whether an employer-employee relationship exists, it must consider the following factors: "method of payment, right to discharge, furnishing of equipment and relative nature of the work." Here, the Court considered the following facts in making its determination: (1) Plaintiff was supervised by a professor employed by the Defendant; (2) Plaintiff used equipment provided by the Defendant; (3) the Defendant was listed as the payor on Plaintiff's paycheck; (4) the Defendant provided Plaintiff with vacation, sick leave and health insurance; and (5) the professor set Plaintiff's work schedule, exercised broad control over his research, and had authority to discipline or fire him.

Contrary to Plaintiff's assertion that he was not an employee because his salary and benefits were funded by federal grant money, the Appellate Division held that the foregoing constituted substantial evidence to uphold the Board's determination. Furthermore, the Court opined that that source of the monies used to pay Plaintiff was not determinative of whether an employer-employee relationship existed.

Physician Did Not Suffer Damages from Law Firm's Joint Representation of Her, Another Physician and the Hospital That Employed Them; Legal Malpractice Claim Dismissed

Kaufman v. Medical Liability Mutual Insurance Company, 121 A.D.3d 1459 (3d Dep't 2014). Plaintiff appealed from the dismissal of her legal malpractice claim against a law firm that defended her in a medical malpractice action. Affirming the dismissal, the Appellate Division held that the law firm's joint representation of Plaintiff and her co-defendants, another obstetrician and the hospital that employed them, did not constitute legal malpractice given that Plaintiff did not have to pay any part of the judgment, which was covered by insurance, and was not entitled to recover non-pecuniary damages for alleged reputational injuries resulting from media coverage of the verdict.

Plaintiff, along with another obstetrician, Dr. Nguyen, and their employer, Nathan Littauer Hospital and Nursing Home, were sued for medical malpractice by a former patient after the patient developed a serious infection shortly after giving birth at the hospital. Plaintiff, Dr. Nguyen, and the hospital were all insured by defendant Medical Liability Mutual Insurance Company ("MLMIC"), who assigned the defense of the case to the defendant law firm Carter, Conboy. A jury found in favor of the patient, apportioning liability between Plaintiff (35%) and Dr. Nguyen (65%) and awarding damages in an amount that was reduced to $3.2 million. Plaintiff thereafter commenced this action against MLMIC, alleging deceptive business practices and breach of contract, and against the law firm, asserting that the law firm's joint representation of all defendants in the medical malpractice action and use of a "united front" defense resulted in a conflict of interest to the detriment of Plaintiff and constituted legal malpractice.

In an earlier decision, the court dismissed Plaintiff's claims against MLMIC (92 A.D.3d 1057, 938 N.Y.S.2d 367). On this appeal, the Court held that Plaintiff failed to submit sufficient proof to raise a triable issue of fact that her attorney was negligent, that but for such negligence she would have prevailed, and that she sustained actual and ascertainable damages. The Court held that because (i) Plaintiff did not have to pay any portion of the judgment, which was covered entirely by the insurer and the hospital; (ii) Plaintiff is barred from recovering her alleged reputational damages, which are not recoverable in a legal malpractice action; and (iii) Plaintiff continued to work at the hospital after the verdict was issued and was offered a new contract on the same terms as the other physicians despite the verdict, Plaintiff failed to establish that she suffered actual and ascertainable damages. Accordingly, the Court held that the trial court properly dismissed the legal malpractice claim and affirmed the decision of the trial court.

Plaintiffs Lack Standing to Sue for Alleged Overcharges for Copies of Medical Records Pursuant to Public Health Law § 18 Absent Direct Payment or Obligation to Reimburse Attorney

Spiro v. Healthport Techs., LLC, 2014 WL 4277608 (S.D.N.Y. Aug. 29, 2014). Plaintiffs are individuals and putative representatives of a class of personal injury plaintiffs who, in connection with their underlying lawsuits, sought medical records from Defendants pursuant to N.Y. Public Health Law § 18. Defendants Montefiore Medical Center, Mount Sinai Hospital, and Beth Israel Medical Center are hospitals that outsourced their copying and furnishing of medical records to Defendant Healthport Technologies, LLC ("Healthport"). Plaintiffs were all represented by the same counsel, Simonson Hess Liebowitz & Goodman, P.C. ("Simonson"), in their underlying personal injury lawsuits. For each Plaintiff, Simonson requested medical records and was issued a bill from Healthport for 75 cents per page for copying expenses. Simonson paid each bill directly, and after each case settled, Plaintiffs reimbursed Simonson for disbursements, including the cost of obtaining medical records from Defendants.

On March 12, 2014, Plaintiffs brought this action in Supreme Court, New York County, alleging that Defendants charged them fees for the medical records in excess of those permitted by law. Defendants removed the case to the Southern District of New York under the Class Action Fairness Act and moved to dismiss. In response, Plaintiff filed an

amended complaint, which sought damages for violation of N.Y. Public Health Law § 18 and N.Y. General Business Law § 349, restitution for unjust enrichment, and injunctive relief. Defendants then filed a renewed motion to dismiss, claiming that Plaintiffs lacked standing to assert their claims, that the complaint failed to state a cause of action, and that certain claims were time-barred.

The court first addressed the issue of standing. Defendants argued that only Simonson was entitled to challenge the alleged overcharges because Simonson, rather than Plaintiffs, requested the medical records, received bills from Healthport, and rendered payment. Plaintiffs countered that they suffered an injury-in-fact when, after settling their lawsuits, they reimbursed Simonson for the cost of medical records. Therefore, they asserted, they had standing to assert their claims.

Because the amended complaint did not state that Plaintiffs were obligated to reimburse Simonson for the fees paid to Healthport, the court held that Plaintiffs lacked standing to seek damages or restitution. The court stated that absent such obligation, Plaintiffs' payment to Simonson for the cost of medical records would merely be a volitional act. This would not be "fairly traceable" to Defendants' purportedly wrongful conduct, but to their decision to reimburse Simonson's expenses. The court recognized, however, that Plaintiffs could revive their claims by pleading that the reimbursement was mandatory, provided that it was reflected in Simonson's engagement letters. The court also dismissed Plaintiffs' claim for injunctive relief, holding that they did not adequately establish that Defendants would likely cause them further injury by overcharging them for medical records.

Anticipating that Plaintiffs might amend their complaint to establish standing for their damage and restitution claims, the court then turned to Defendants' motion to dismiss for failure to state a cause of action. Defendants contended that they could not be subject to liability for violation of N.Y. Public Health Law § 18 because they did not charge more than the maximum "reasonable charge" of 75 cents per page. However, the court held that this was a misreading of the statute, which states that health care providers may impose a charge for the copying of medical records not to exceed the costs that they actually incurred in making such copies, and in no event to exceed 75 cents per page. The court asserted that the statute does not give health care providers the authority to profit by providing medical records, and does not establish 75 cents per page as a per se reasonable cost of copying.

The court also rejected Defendants' argument that it is immune from civil liability under N.Y. Public Health Law § 18(12), which states that no health care provider shall be subject to civil claims "arising solely from granting or providing access to any patient information in accordance with this section." The court stated that Defendants' interpretation of this provision would read the cost limitation out of the statute entirely. Further, upon reviewing the legislative history, the court determined that the New York Legislature intended this provision to be applied narrowly to protect health care providers for their release of patient information in good faith.

The court then turned to Plaintiffs' cause of action for violation of N.Y. General Business Law ("GBL") § 349(a). Plaintiffs alleged that Defendants engaged in a deceptive act or practice by charging 75 cents per page for the copying of medical records while failing to disclose to consumers (1) that they are not allowed to charge an amount greater than their actual costs and (2) that their actual costs were less than 75 cents per page. The court noted that parties are not obligated to disclose all relevant information under the statute, but that they are obligated to disclose relevant and material information that only they possesses. Because only Defendants had knowledge of the alleged discrepancy between the charges that they imposed and their actual costs of copying medical records, the court found that a reasonable consumer would be led to believe that the actual costs were in fact 75 cents per page. Accordingly, the court held that Plaintiffs had stated a cause of action for violation of GBL § 349(a). Further, because of Defendants' alleged failure to disclose that their costs were less than 75 cents per page, the court rejected Defendants' argument that Plaintiffs voluntarily paid for the medical records as billed.

As for Plaintiffs' unjust enrichment claim, the court held that Plaintiffs had stated a claim against Healthport, but not against the other Defendants. The court noted that Plaintiffs alleged only that Healthport received payments in excess of its expenses, not that any of the three hospitals benefited from the alleged overcharging.

Finally, the court addressed Defendants' motion to dismiss Plaintiffs' claims as barred by the statute of limitations. The court first noted that Plaintiffs' claims were all governed by a three-year statute of limitations. The court then determined that both of Plaintiff' 'statutory claims accrued when all of the elements were satisfied – namely, when Defendants received and accepted payment from Simonson in excess of their costs. The court also stated that Plaintiffs' unjust enrichment claim accrued upon Defendants' acceptance of payment, as such was the alleged wrongful act giving rise to a duty of restitution. Applying these determinations to the facts at bar, the court held that the claims of all but one of the Plaintiffs were time-barred. The court rejected Plaintiffs' argument that the claims accrued when they reimbursed Simonson for the charges paid to Healthport, asserting that such a holding would impermissibly give plaintiffs the power to toll the statute of limitations simply by having a third party pay the costs up front and then delaying reimbursement.

Hospital's Directive Barring Physician from Its Premises Sufficiently Diminished Physician's Clinical Privileges so as to Require the Physician to File an Administrative Complaint Prior to Filing Suit

Raggi v. Wyckoff Heights Med. Ctr., 123 A.D.3d 1044, 1045, 999 N.Y.S.2d 174 (2d Dep't 2014). Petitioner Robert Raggi, M.D. ("Dr. Raggi"), and Robert Raggi, M.D., P.C., the professional corporation through which Dr. Raggi provided medical care (collectively "Petitioners"), brought an Article 78 proceeding against Wyckoff Heights Medical Center (the "Hospital") seeking reinstatement of Dr. Raggi's clinical privileges, and to recover damages for breach of contract and in *quantum meruit* after the hospital placed him on a mandatory, involuntary 90-day leave of absence, prevented him from entering the Hospital, and subsequently terminated his employment.

Affirming the decision of the Supreme Court, Kings County, dismissing Petitioners' Article 78 proceeding seeking reinstatement, the Appellate Division, Second Department, held that Petitioners were required to file an administrative complaint with the New York State Public Health and Health Planning Council ("PHHPC") and exhaust their administrative remedies before seeking redress from the courts.

On appeal, the Second Department rejected Petitioners' contention that PHHPC review was unnecessary because Dr. Raggi's clinical privileges were not technically "terminated" when he was prevented from exercising his privileges as a result of being barred from accessing the Hospital's premises. The Court reasoned that the Petitioners were required to file an administrative complaint with the PHHPC because the Hospital's directive, which did not technically terminate his privileges, "diminish[ed]" Dr. Raggi's clinical privileges within the meaning of New York Public Health Law § 2801-b(1), which requires an administrative appeal as a prerequisite to bringing a complaint to the courts.

Plaintiff Stated Federal Civil Rights Claims Against Private Physicians for Actions Arising from Involuntary Hospitalization

Bryant v. Steele, No. 13-CV-5234 ADS GRB, 2015 WL 1345376 (E.D.N.Y. Mar. 21, 2015). Having allegedly received anonymous and threatening phone calls, Plaintiff sought police assistance, and a month later, made complaints about the lack of progress into the investigation. Perceiving his behavior as manifestations of mental illness, the police contacted a social worker to assess the need for an emergency mental health evaluation. When the social worker and two police officers met with Plaintiff at his home, Plaintiff mentioned hunting rifles in his home. Thereafter, the social worker reported to the Directors of Community Services that Plaintiff suffered from a mental illness, for which immediate care and treatment in a hospital was appropriate.

Plaintiff was involuntarily transported to Stony Brook University Medical Center ("Stony Brook") under New York Mental Hygiene Law § 9.45 and involuntarily hospitalized and transferred to defendant Brunswick Hospital Center, Inc. ("Brunswick") under New York Mental Hygiene Law § 9.37. At Stony Brook, a psychiatrist, Dr. Garro, examined Plaintiff, allegedly for three minutes, and applied to involuntary hospitalize Plaintiff. Stony Brook then transferred Plaintiff to a private hospital, Brunswick, where he was admitted by a psychiatrist, defendant Dr. Ihenacho, and evaluated by a non-psychiatric physician. Defendant Dr. Khan certified the need for involuntary care. Plaintiff maintained that he never suffered from a mental illness necessitating involuntary hospitalization, and he was not properly evaluated by a psychiatrist.

Plaintiff brought claims of medical malpractice and violation of his civil rights under 42 U.S.C. § 1983 against Brunswick, Dr. Ihenacho, Dr. Khan, and Dr. Garro. Drs. Ihenacho and Kahn moved under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) to dismiss the federal claims against them for lack of subject matter jurisdiction and/or failure to state a claim upon which relief can be granted.

The Court began its inquiry with the standard for a 42 U.S.C. § 1983 claim, wherein a plaintiff must allege that the defendants violated his or her federal rights while acting under color of state law. The Court stated that private entities can commit acts under color of state law if their conduct is fairly attributable to the state. This occurs when the private conduct is compelled by the state, the private conduct has a sufficiently close nexus to the state, or the private conduct has traditionally been the exclusive prerogative of the state.

Drs. Ihenacho and Kahn argued that forcible hospitalization by private health care providers cannot be attributed to the state. The Court found that Plaintiff properly stated a claim. Initially, the Court noted various cases involving involuntary hospitalization, such as *Doe v. Rosenberg*, which held that the hospital and physician conduct could not be attributed to the state. It also examined the terms of New York Mental Hygiene law § 9.37, which suggested the absence of state action due to its use of permissive language.

However, the Court then evaluated *Tewksbury v. Dowling*, wherein a private physician involuntarily hospitalized a patient under New York Mental Hygiene Law § 9.37 based on an examination performed by a state actor, a physician at a separate hospital. It found these facts were similar to those in Plaintiff's complaint because Plaintiff alleged Drs. Ihenacho and Kahn relied upon the assessment of a state actor, Dr. Garro, in deciding to involuntarily hospitalize him. Their alleged reliance on the recommendation of a state actor constituted sufficient state action because, under New York Mental Hygiene Law

§ 9.37, defendants could not involuntarily admit Plaintiff without the state actor's recommendation. Accordingly, the Court found a sufficiently close nexus existed between defendants and a state actor, and Plaintiff adequately pleaded his federal claims against Drs. Ihenacho and Kahn.

Administrative Delay in Deciding a Medicaid Rate Appeal Is Not a Sufficient Ground to Avoid Requirement of Exhaustion of Administrative Remedies Prior to Seeking Judicial Relief

Schenectady Nursing & Rehab. Ctr., LLC v. Shah, 124 A.D.3d 1023, 2 N.Y.S.3d 249 (3d Dep't 2015). Petitioner-Appellant, a residential health care facility, commenced a CPLR Article 78 proceeding to annul what it claimed to be an erroneous rate calculation, and asked the court to direct the Department of Health ("DOH") to recalculate its Medicaid reimbursement rates. Before filing the Article 78 proceeding, Petitioner filed an administrative appeal of Respondent's determination. That administrative process, however, had not concluded at the time the Article 78 Petition was commenced. As a result, the Albany County Supreme Court granted Respondent's pre-answer motion to dismiss the petition based on, among other things, Petitioner's failure to exhaust its administrative remedies. Petitioner then appealed, and the Appellate Division affirmed.

The Court noted that an administrative agency's determination must be challenged through every available administrative remedy before it can be challenged in court, except for two narrow exceptions. First, where an administrative challenge would be futile; second, where the petitioner can demonstrate irreparable harm. Here, Petitioner argued that the administrative appeal would be futile because of the voluminous backlog of appeals pending before the DOH, and also due to a statutorily imposed payment moratorium. Pursuant to Public Health Law § 2808(17)(b), the moratorium imposes an $80 million limit per fiscal year on gross Medicaid reimbursements. In administering the moratorium, DOH has the discretion to prioritize appeals based upon its consideration of which facilities are facing "significant financial hardship" and other factors deemed appropriate. Additionally, Petitioner argued that it will suffer irreparable harm because its rates will remain incorrectly calculated until the end of the moratorium in 2015.

The Court rejected Petitioner's futility and irreparable harm arguments. First, it held that it would not entertain a claim of futility based on delay because "adjudicatory delay by an agency does not authorize a court to intervene in an administrative proceeding before a final determination absent extraordinary circumstances." The Court also held that the backlog of appeals and imposition of a moratorium did not constitute an "*extraordinary* circumstance." To the contrary, Petitioner was merely subject to the same process and delay as other nursing homes seeking to appeal their reimbursement rates. Second, the Court rejected Petitioner's claim of irreparable harm because it did not seek an expedited review of its administrative appeal based on alleged financial distress, and also because such assertion was conclusory.

Second Circuit Rules That New York's Wage Parity Law Is Constitutional and Not Preempted by the NLRA or ERISA

Concerned Home Care Providers, Inc. v. Cuomo, 2015 WL 1381380 (2d Cir. Mar. 27, 2015). Plaintiffs, a trade association of home care agencies and five licensed home care service agencies, brought suit against the Commissioner of the State Department of Health, seeking to invalidate and permanently enjoin enforcement of the New York Wage Parity Law (the "WPL"). The WPL sets the minimum amount of total compensation that employers must pay home care aides in order to receive Medicaid reimbursements for care provided in New York City and surrounding counties. The WPL was created to address the inconsistency in wages among home care workers and, in turn, improve the recruitment and retention of high-quality home care aides. The United State District Court for the Northern District of New York granted the Commissioner's motion to dismiss in part and denied the motion in part.

Plaintiffs argued that the WPL interferes with the labor-management bargaining process, makes an "impermissible reference to" an ERISA plan, violated their fundamental right to political representation, and thus is preempted by the NLRA and ERISA, and violates their Fourteenth Amendment and Due Process rights. The District Court dismissed all but one of Plaintiffs' claims.

Subdivision Four of the WPL (New York Public Health Law § 3614-c(4)), provides that

> [a]ny portion of the minimum rate of home care aide total compensation attributable to health benefit costs or payments in lieu of health benefits, and paid time off,…shall be superseded by the terms of any employer bona fide collective bargaining agreement in effect as of January 1, 2011, or a successor to such agreement, which provides for home care aides' health benefits through payments to jointly administered labor-management funds.

The District Court held that subdivision 4 of the WPL ran afoul of ERISA's express preemption provision as it singled out only one type of ERISA plan for unique treatment. The subdivision excused grandfathered collective bargaining agreements that included Taft-Hartley plans from complying with certain provisions of the law, which is expressly prohibited by ERISA. Given the express severability clause in the WPL, the District Court eliminated the subdivision rather than invalidating the entire law. Plaintiffs appealed.

The Court of Appeals affirmed the District Court's finding that the WPL was not preempted by the NLRA. The Court noted that the NLRA does not have an express preemption provision but applied one form of implied preemption known as *Machinists* preemption, which forbids states and localities from intruding upon the labor-management bargaining process. This preemption applies only to the process for determining terms and conditions of employment; it does not extend to the particular substantive terms of the bargain that is struck. As such, the Court noted that states possess broad authority under their police powers to regulate the employment relationship and the substantive labor standards, to set a baseline for employment negotiations. Accordingly, the Court held that the WPL was a valid exercise of the State's authority to create such a standard. Furthermore, the Second Circuit opined that despite the WPL's effects on the package of benefits over which employers and employees can negotiate, it "does not limit the rights of self-organization or collective bargaining protected by the NLRA." The Court remarked that both union and non-union employees were not treated differently under the WPL as they are free to bargain about how to allocate total compensation between wages and other benefits. The Court also held that *Machinists* preemption does not eliminate the State's authority to create minimum labor standards for particular geographic regions or areas of the labor market.

With respect to Plaintiffs' claim that the WPL is preempted by ERISA, the Court affirmed that only Subdivision Four of the statute violated the provisions of ERISA. Plaintiffs argued that all of the provisions of the WPL make an "impermissible reference to" an ERISA plan, as the law sets the minimum rate of compensation based on the "prevailing rate of total compensation," which is the rate from the largest collective bargaining agreement covering home care aides in New York City. Because the referenced collective bargaining agreement establishes and governs several ERISA plans, Plaintiffs argued that this is an "impermissible" reference. The Court found that any connection between the WPL and ERISA to be tenuous at best, and thus would not constitute a "reference" that warrants preemption. The Court held that in order to trigger ERISA preemption, a statute must not merely mention or allude to an ERISA plan, but must also have some relationship to ERISA plans or affect ERISA plans in some manner.

Finally, Plaintiffs' argued that the WPL is unconstitutional as it violates their Fourteenth Amendment and Due Process rights. They alleged that by relying on a rate set by a legislative body outside the affected counties, the WPL infringes upon the fundamental right to representation in the legislative process and thus warrants strict judicial scrutiny. The Court held that social and economic legislation, such as the WPL, does not employ "suspect classifications" or impinge on fundamental rights. Accordingly, the Court noted that the WPL must be upheld against an equal protection attack when the legislative means are rationally related to a legitimate governmental purpose. Here, the Court found that setting the minimum rate of home care aide total compensation was rationally related to the New York Legislature's goal of providing high quality home care services.

Plaintiffs also argued that the WPL violated the Due Process Clause of the Fourteenth Amendment as it delegated authority to a private entity, namely the SEIU 1199, as it was the current largest collective bargaining agreement, which set the prevailing rate of total compensation. The Court noted that governmental action may be challenged as a violation of due process only when it may be shown that it deprives a litigant of a property or a liberty interest. Plaintiffs claimed a property right in the future revenues generated by their businesses. The Court held that because the WPL applies only to the payment of state Medicaid funds, and there is no property interest in or contract right to reimbursement at any specific rate, or for continued participation in the Medicaid program, Plaintiffs failed to adequately plead a violation of their due process rights. Moreover, the Court noted that the WPL did not delegate decision making authority to the SEIU 1199, as the statute pegs the prevailing rate of compensation to that in existence as of January 1, 2011. Because the union has no authority to alter the agreement, and any future negotiations would have no bearing on the prevailing rate of compensation, the Court held that even if Plaintiffs had a property interest in future Medicaid reimbursements, their due process challenge would fail.

Physician's Factual Findings Are Necessary for Court to Evaluate Denial of Physician's Application to Become Workers' Compensation Health Care Provider

Matter of Cohen v. New York State Workers' Compensation Bd., 122 A.D.3d 1222, 997 N.Y.S.2d 822 (3d Dep't 2014). Appellant, a licensed doctor of osteopathy, appealed the dismissal of his Article 78 proceeding to review Respondent's denial of his request to become an authorized workers' compensation health care provider.

Pursuant to Workers' Compensation Law § 13-b, a physician must obtain Respondent's approval before treating patients who receive workers' compensation benefits. Based upon the existence of a non-disciplinary order of conditions imposed on Appellant's license by the Office of Professional Medical Conduct, Respondent rejected Appellant's application without further explanation. Agreeing with Appellant that the rejection was improper because it was based solely upon the existence of the order of conditions, the Court annulled the denial and remitted the matter for reconsideration.

The Court noted that the purpose of § 13-b is "to insure the quality of the medical care and treatment ren-

dered to injured claimants by limiting payment to lawfully qualified persons.…" The Court then noted that the non-disciplinary order "did not constitute an admission to or finding of misconduct"; was no longer in effect; and did not include any factual findings as to Petitioner's capabilities as a physician. The Court emphasized that its review of Respondent's discretionary determination was limited to ascertaining whether such determination was (i) arbitrary and capricious or (ii) an abuse of discretion. Because this standard required the court to decide whether the administrative determination was "justified" or "without foundation in fact," the Court held that it was unable to "conduct a meaningful review" of the determination based solely on Respondent's mere reference to the order of conditions, or the content of the order of conditions.

Compiled by Leonard Rosenberg, Esq. Mr. Rosenberg is a shareholder in the firm of Garfunkel Wild, 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

Health Policy Legislation in the 2015-16 State Budget: What Didn't Get Done

It is accepted wisdom in Albany that if you want to get the Legislature to enact legislation quickly, you should try to get it inserted in the Governor's proposed Executive Budget. While so-called Article VII legislation (named for the provisions of the State Constitution that govern the budget-making process) is supposed to be included in the budget only to the extent the legislation is deemed "necessary to provide moneys and revenues sufficient to meet" the proposed expenditures in the State Budget (State Constitution, Art. VII, §2), governors have, for many years, used the budget-making process to obtain approvals of policy proposals that may have only the vaguest connections to fiscal imperatives. The combination of the April 1 deadline for budget adoption and the extraordinary budgetary powers of the Governor (see *Pataki v. New York State Assembly et al.* and *Silver v. Pataki*, 4 N.Y.3d 75 (2004)) were thought to guarantee enactment of budget legislation in short order, even when the legislation had only a tangential relationship to the proposed spending plan.

That conventional wisdom may have to be reconsidered.

In the 2015-16 State Budget, Governor Cuomo advanced a substantial package of health-related legislation, addressing a host of policy objectives (each with fairly minimal budgetary implications). Many of these proposals were rejected by the Legislature—some for the second and third time.

While this column might more typically (and usefully) review what actually *did* get enacted in the State Budget, I thought it might be interesting to focus on a number of the policy proposals that *did not* ultimately make their way into the legislation

enacted this year at the April 1 budget deadline. As noted below, many of these proposals are the subject of ongoing consideration by the Legislature and may ultimately be enacted, either in a similar or revised form, either during this legislative session or a subsequent one.

Private Equity Ownership of Hospitals: For several years, the Administration has sought to enact a proposal that would, on a limited basis, alter New York's long-standing prohibition on corporate ownership of hospitals. And, for several years, the Legislature has refused to enact it.

This year's proposal would have established a pilot program to "assist in restructuring healthcare delivery systems" that would allow for the establishment of up to five business corporations to operate hospitals. The stock of the hospitals would not be publicly traded. The business corporation would affiliate with at least one academic medical institution that is approved by the Commissioner of Health, and the entity would be eligible to participate in Dormitory Authority, the Local Development Corporation, or other Empire State Development Corporation debt financing. The business corporations would be relieved of various requirements that would otherwise apply to them under the Public Health Law, relating to stockholders, disposition of voting rights, and other provisions, although the Public Health and Health Planning Council (PHHPC) would be authorized to impose requirements relating to the disclosure of shareholders.

The corporations would only operate the specifically named hospital, as well as any affiliated home care agencies or hospices. The corporation's board would have to consider a range of factors as it exercised its fiduciary obligations, including the impact of its actions on the corporation itself, its shareholders, employees, the interests of patients of the hospital, the community and societal considerations, local and global environmental issues, and the short- and long-term interests of the corporation. To overcome prior year's objections, the 2015 proposal would have required assurances that the investors would remain for at least three years, would mandate disclosure of any opportunity for the not-for-profit hospital to buy out the investors, and would require the establishment of a local advisory board to make recommendations regarding issues such as the mission statement, approving the chief executive officer, and approving policies related to charity care.

Notwithstanding these "sweeteners," the proposal was not adopted.

Certificate of Need Reform: Perhaps more surprisingly, relatively modest reforms of the State's Certificate of Need (CON) process were also rejected by the Legislature. The proposal would have streamlined the CON program by:

- Eliminating the necessity of establishing "public need" when general hospitals or diagnostic and treatment centers propose to construct primary care facilities;
- Expressly authorizing PHHPC to approve primary care diagnostic and treatment centers without regard to their public need or financial feasibility;
- Reducing the "look back" period for review of the character and competence of proposed sponsors or directors of health care entities from ten to seven years; and

- Standardizing the review of transfers of less than 10% of the voting rights or ownership in Article 28 facilities.

For at least the last two years, this or a similar proposal failed to secure passage.

Retail Clinic Legislation: Another proposal would have authorized DOH to license and regulate the growing number of diagnostic and treatment centers that operate in retail establishments, which are variously known as "limited services clinics," "retail clinics" or "minute clinics." The proposal was premised on the risk that there may be confusion among consumers as to what services are offered, as well as concerns over continuity of care. The legislation would have established operating standards, oversight mechanisms, and licensing requirements—and this year's proposal further required the clinics to meet accreditation requirements, employ a medical director, establish regular operating hours and accept walk-ins, as well as mandated that patients may not be required to buy supplies or fill prescriptions at the retail establishment.

Urgent Care Centers: Likewise, a separate budget proposal would have provided for the regulatory oversight of urgent care centers and require that all entities that hold themselves out as urgent care facilities are either Article 28 certified entities or fully accredited health care providers. Each clinic would also need to meet a minimum scope of practice limited to treatment for acute episodic illness and minor trauma. This year's version clarified accreditation requirements and would have authorized PHHPC to determine the minimum services that an urgent care center must provide.

Each of these proposals were included in one of the two houses' one house budget proposals—but, in the end, the Senate rejected the urgent care proposal and the Assembly rejected retail clinic legislation. Nothing passed.

Value-Based Payments: The movement toward value-based payments in the health care system seems inexorable. The State's Delivery System Reform Incentive Program (DSRIP) requires 90% of Medicaid payments be value-based in five years and Medicare and private payors are heading in the same direction. The budget proposed authorized value-based purchasing through a series of provisions that allowed managed care organizations to enter into value-based payments with providers, that authorized DOH to enter into value-based payments with performing provider systems (PPS) that are participating in DSRIP, and that authorized DOH to "utilize methodologies of reimbursement that are value based."

While the Legislature rejected all of the value-based payment provisions that had been advanced in the budget, the Legislature's actions may not necessarily reflect hostility to the concept, but instead may have been motivated by the view that the legislation was not necessary, since managed care organizations and the DOH already had the authority to incorporate value-based methodologies into their payment policies. Legislators also expressed the view that the ultimate shape of state policy on the subject may require some further debate and discussion. Shortly after the budget was enacted, Senate Health Committee Chair Kemp Hannon hosted a roundtable discussion of key stakeholders to discuss the movement toward value-based payments, reflecting the continued interest of the Legislature in the topic.

Repeal of the Physician Profile Program: The Executive Budget proposed to repeal section 2995-a of the Public Health Law to relieve DOH of the obligation to collect and to post individual physician profiles for dissemination to the public—and to eliminate the obligation of New York's physicians to supply the necessary information. The Physician Profile program requires DOH to assemble a substantial amount of information relating to physicians in New York State, including criminal convictions, professional medical conduct findings and license limitations, loss of hospital privileges, medical malpractice judgments or settlements, and a host of other background information.

Although DOH contended that the information is otherwise available through other public sources, citing WebMD, the Legislature from the outset appeared very much committed to the continuation of the profile program, which it argued uniquely made this information accessible in one place and did so in a more definitive or "official" manner. Although the proposed discontinuation of the physician profiling initiative would have saved $1.2 million a year, the Legislature declined to repeal the program.

Collaborative Drug Therapy Management: Four years ago, a demonstration project was enacted that permitted pharmacists in teaching hospitals to engage in the management of drug therapy—including adjusting and altering the drug therapies for patients in these settings—in accordance with protocols with participating physicians. A May 2014 report by the State Board of Pharmacy declared the demonstration project a success, noting that pharmacist interventions avoided adverse drug reactions, reduced re-hospitalization rates, reduced cost and increased patient satisfaction. Last year, the program's "sunset" (or expiration date) was extended through September, 2015 and the Governor's 2015-16 budget proposed to extend the demonstration for another three years.

The Senate and Assembly rejected the Governor's proposal—but not because they opposed the program. Both houses have bills introduced that would extend the program permanently and would extend it to a host of additional settings, including all Article 28 facilities (including nursing homes) and to community

practices. Debate on those proposals is ongoing.

Advanced Home Health Aides*:* A proposal to create a broader scope of practice for home health aides was also rejected by the Legislature—although substantial progress was made on the issue that may bode well for consideration during the balance of the legislative session. Under the proposal, Advanced Home Health Aides (AHHAs) would undergo advanced training and certification, be supervised by a registered nurse and practice under the limitations of a plan of care developed by an authorized practitioner, which may involve a greater medication role. The precise scope of practice would be developed by the Commissioners of Health and Education in consultation with stakeholders. A broad coalition of health care entities and associations have coalesced around the bill, which could not only facilitate the provision of certain medication regimens to home health patients, but would provide an important career ladder for home health aides. Debate on the proposal is continuing.

Jim Lytle is a partner in the Albany office of Manatt, Phelps & Phillips, LLP.

In the New York State Agencies

By Francis J. Serbaroli

Disclosure of Quality and Surveillance-Related Information

Notice of Adoption. The Department of Health added section 400.25 to Title 10 NYCRR to disclose identified nursing quality indicator information upon request to any member of the public. Filing date: December 22, 2014. Effective date: January 7, 2015. *See* N.Y. Register January 7, 2015.

Rate Rationalization—Intermediate Care Facilities for Persons with Developmental Disabilities

Notice of Emergency Adoption. The Department of Health amended Subpart 86-11 of Title 10 NYCRR to amend the new rate methodology effective November 1, 2014. Filing date: December 30, 2014. Effective date: December 30, 2014. *See* N.Y. Register January 14, 2015.

Rate Rationalization for Community Residences/Individualized Residential Alternatives Habilitation and Day Habilitation

Notice of Emergency Adoption. The Department of Health amended Subpart 86-10 of Title 10 NYCRR to amend the new rate methodology effective November 1, 2014. Filing date: December 30, 2014. Effective date: December 30, 2014. *See* N.Y. Register January 14, 2015.

Vital Access Program and Providers

Notice of Adoption. The Office of Mental Health added Part 530 to Title 14 NYCRR to establish a process by which providers may be designated as Vital Access Providers to receive supplemental funding. Filing date: January 9, 2015. Effective date: January 28, 2015. *See* N.Y. Register January 28, 2015.

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

Notice of Adoption. The Office of Mental Health amended Part 578 of Title 14 NYCRR to eliminate the trend factor effective July 1, 2014 through June 30, 2015. Filing date: January 13, 2015. Effective date: January 28, 2015. *See* N.Y. Register January 28, 2015.

Amendments to Rate Setting Methodology: Rates for Residential Habilitation Delivered in IRAs and CRs and for Day Habilitation

Notice of Adoption. The Office for People With Developmental Disabilities amended Subpart 641-1 of Title 14 NYCRR to amend the new rate setting methodology that was effective in July 2014. Filing date: January 13, 2015. Effective date: January 28, 2015. *See* N.Y. Register January 28, 2015.

Amendments to Rate Setting for Non-State Providers: Intermediate Care Facilities for Persons with Developmental Disabilities

Notice of Adoption. The Office for People With Developmental Disabilities amended Subpart 641-2 of Title 14 NYCRR to amend the new rate setting methodology that was effective July 2014. Filing date: January 13, 2015. Effective date: January 28, 2015. *See* N.Y. Register January 28, 2015.

Telepsychiatry Services in OMH-Licensed Clinics

Notice of Adoption. The Office of Mental Health added section 599.17 to Title 14 NYCRR to establish basic standards and parameters to approve telepsychiatry in OMH-licensed clinic programs choosing to offer service. Filing date: January 27, 2015. Effective date: February 11, 2015. *See* N.Y. Register February 11, 2015.

Supplementary Reports of Certain Congenital Anomalies for Epidemiological Surveillance; Filing

Notice of Proposed Rulemaking. The Department of Health proposed amending sections 22.3 and 22.9 of Title 10 NYCRR to increase the maximum age of reporting certain birth defects to the Congenital Malformations Registry. *See* N.Y. Register February 25, 2015.

Immediate Needs for Personal Care Services

Notice of Revised Rulemaking. The Department of Health amended sections 360-3.7 and 505.14 of Title 18 NYCRR to provide for meeting the immediate needs of Medicaid applicants and recipients for personal care services. *See* N.Y. Register February 25, 2015.

Physician Assistants and Specialist Assistants

Notice of Adoption. The Department of Health amended Part 94 of Title 10 NYCRR to allow LPAs to prescribe controlled substances (including Schedule II) to patients under the care of the supervising physician. Filing date: February 24, 2015. Effective date: March 11, 2015. *See* N.Y. Register March 11, 2015.

Transgender Related Care and Services

Notice of Adoption. The Department of Health amended section 505.2(l) of Title 18 NYCRR to authorize Medicaid coverage for transgender-related care and services. Filing date: February 24, 2015. Effective date: March 11, 2015. *See* N.Y. Register March 11, 2015.

Patients Committed to the Custody of the Commissioner Pursuant to CPL Article 730

Notice of Proposed Rulemaking. The Office of Mental of Health proposed amending Part 540 of Title 14

NYCRR to conform regulatory provisions to statute with respect to the performance of competency reports. *See* N.Y. Register March 11, 2015.

Consolidated Fiscal Report Penalty Amendments

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amending section 635-4.4 of Title 14 NYCRR to change requirements for imposing a penalty on providers that fail to meet filing deadlines for cost reports. *See* N.Y. Register March 11, 2015.

Standards for Individual Onsite Water Supply and Individual Onsite Wastewater Treatment Systems

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 75 of Title 10 NYCRR to establish minimum water quality standards for individual onsite water supply systems. *See* N.Y. Register March 18, 2015.

School Immunization Requirements

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 66-1 of Title 10 NYCRR to update regulations to ensure children entering grades kindergarten through 12 receive adequate number of required immunizations. *See* N.Y. Register March 18, 2015.

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

Notice of Proposed Rulemaking. The Office of Mental Health proposed amending Part 578 of Title 14 NYCRR to amend the date of trend factor elimination to December 31, 2014 instead of June 30, 2015. *See* N.Y. Register March 18, 2015.

Personal Care Services Program (PCSP) and Consumer-Directed Personal Assistance Program (CDPAP)

Notice of Emergency Rulemaking. The Department of Health amended sections 505.14 and 505.28 of Title 18 NYCRR to establish definitions, criteria and requirements associated with the provision of continuous PC and continuous CDPA services. Filing date: March 6, 2015. Effective date: March 6, 2015. *See* N.Y. Register March 25, 2015.

Amendment of Certificate of Need (CON) Applications

Notice of Adoption. The Department of Health amended sections 600.3 and 710.5 of Title 10 NYCRR to eliminate requirement for Public Health and Health Planning Council review of certain types of amendments to CON applications. Filing date: March 10, 2015. Effective date: March 25, 2015. *See* N.Y. Register March 25, 2015.

Direct Care and Clinical Compensation Payments

Notice of Adoption. The Office for People With Developmental Disabilities amended Part 641 of Title 14 NYCRR to amend rate-setting for eligible services in order to implement increases in direct care and clinical compensation. Filing date: March 10, 2015. Effective date: March 25, 2015. *See* N.Y. Register March 25, 2015.

Updates to SSI Offset and SNAP Benefit Offset

Notice of Adoption. The Office for People With Developmental Disabilities amended sections 671.7, 686.17 and Subpart 641-1 of Title 14 NYCRR to adjust reimbursement to affected providers for rent and food costs. Filing date: March 10, 2015. Effective date: March 25, 2015. *See* N.Y. Register March 25, 2015.

Credentialing of Addictions Professionals

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 853 and added new Part 853 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: March 16, 2015. Effective date: March 16, 2015. *See* N.Y. Register April 1, 2015.

Criminal History Information Reviews

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services added Part 805 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: March 16, 2015. Effective date: March 16, 2015. *See* N.Y. Register April 1, 2015.

Incident Reporting in OASAS Certified, Licensed, Funded or Operated Programs

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 836 and added new Part 836 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: March 16, 2015. Effective date: March 16, 2015. *See* N.Y. Register April 1, 2015.

Patient Rights

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 815 and added new Part 815 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: March 16, 2015. Effective date: March 16, 2015. *See* N.Y. Register April 1, 2015.

Establishment, Incorporation and Certification of Providers of Substance Use Disorder Services

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 810 and added new Part 810 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: March 16, 2015. Effective date: March 16, 2015. *See* N.Y. Register April 1, 2015.

Children's Camps

Notice of Emergency Rulemaking. The Department of Health amended Subpart 7-2 of Title 10 NYCRR to include camps for children with developmental disabilities as a type of facility within the oversight of the Justice Center. Filing date: March 13, 2015. Effective date: March 13, 2015. *See* N.Y. Register April 1, 2015.

Standards for Adult Homes and Adult Care Facilities Standards for Enriched Housing

Notice of Emergency Rulemaking. The Department of Health amended Parts 487 and 488 of Title 18 NYCRR to revise Parts 487 and 488 in regards to the establishment of the Justice Center for Protection of People with Special Needs. Filing date: March 17, 2015. Effective date: March 17, 2015. *See* N.Y. Register April 1, 2015.

Implementation of the Protection of People With Special Needs Act and Reforms to Incident Management

Notice of Emergency Rulemaking. The Office of Mental Health amended Parts 501 and 550, repealed Part 524 and added new Part 524 to Title 14 NYCRR to enhance protections for people with mental illness served in the OMH system. Filing date: March 11, 2015. Effective date: March 11, 2015. *See* N.Y. Register April 1, 2015.

Clinic Treatment Programs

Notice of Adoption. The Office of Mental Health amended Part 599 of Title 14 NYCRR to amend reimbursement structure for delivery of psychotherapy services and eliminate utilization threshold for court-mandated services. Filing date: March 11, 2015. Effective date: April 1, 2015. *See* N.Y. Register April 1, 2015.

Implementation of the Protection of People with Special Needs Act and Reforms to Incident Management

Notice of Emergency Rulemaking. The Office for People With Developmental Disabilities amended Parts 624, 633, 687 and added Part 625 to Title 14 NYCRR to enhance protections for people with developmental disabilities served in the OPWDD system. Filing date: March 13, 2015. Effective date: March 15, 2015. *See* N.Y. Register April 1, 2015.

Medical Use of Marijuana

Notice of Adoption. The Department of Health added Part 1004 and amended Subpart 55-2 of Title 10 NYCRR to comprehensively regulate the manufacture, sale and use of medical marijuana. Filing date: March 31, 2015. Effective date: April 15, 2015. *See* N.Y. Register April 15, 2015.

Rate Rationalization—Intermediate Care Facilities for Persons with Developmental Disabilities

Notice of Adoption. The Department of Health amended Subpart 86-11 of Title 10 NYCRR to amend the new rate methodology effective July 1, 2014. Filing date: April 7, 2015. Effective date: April 22, 2015. *See* N.Y. Register April 22, 2015.

Rate Rationalization for Community Residences/Individualized Residential Alternatives Habilitation and Day Habilitation

Notice of Adoption. The Department of Health amended Subpart 86-10 of Title 10 NYCRR to amend the new rate methodology effective July 1, 2014. Filing date: April 7, 2015. Effective date: April 22, 2015. *See* N.Y. Register April 22, 2015.

Rate Rationalization—Prevocational Services, Respite, Supported Employment and Residential Habilitation

Notice of Proposed Rulemaking. The Department of Health proposed adding Subpart 86-13 to Title 10 NYCRR to establish new rate methodology effective July 1, 2015. *See* N.Y. Register April 22, 2015.

Prevention of Influenza Transmission

Notice of Adoption. The Office of Mental Health amended Part 509 of Title 14 NYCRR to provide clarification and flexible system for documentation. Filing date: April 2, 2015. Effective date: April 22, 2015. *See* N.Y. Register April 22, 2015.

Site Based and Community Prevocational Services

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amending Subparts 635-10 and 635-99 of Title 14 NYCRR to distinguish requirements for site-based prevocational services and community prevocational services. *See* N.Y. Register April 22, 2015.

Supported Employment Services (SEMP) Redesign

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amending Subparts 635-10, 635-12 and 635-99 of Title 14 NYCRR to redesign SEMP by establishing requirements for the provision and funding of Intensive and Extended SEMP. *See* N.Y. Register April 22, 2015.

Emergency Medical Services

Notice of Adoption. The Department of Health amended Part 800 of Title 10 NYCRR to clarify terminology, eliminate vagueness, address legal statutes/crimes and incorporate modern professional, ethical and moral standards. Filing date: April 21, 2015. Effective date: May 6, 2015. *See* N.Y. Register May 6, 2015.

Opioid Overdose Programs

Notice of Adoption. The Department of Health amended section 80.138 of Title 10 NYCRR to modify the rule consistent with new statutory language and with the emergency nature of opioid overdose response. Filing date: April 21, 2015. Effective date: May 6, 2015. *See* N.Y. Register May 6, 2015.

Computed Tomography (CT) Quality Assurance

Notice of Proposed Rulemaking. The Department of Health proposed amending section 16.25 and adding section 16.59 to Title 10 NYCRR to protect the public from the adverse effects of ionizing radiation. *See* N.Y. Register May 6, 2015.

Compiled by Francis J. Serbaroli, who is a shareholder in the Health & FDA Business Group of Greenberg Traurig's New York office. He is the former Vice Chairman of the New York State Public Health Council, writes the "Health Law" column for the *New York Law Journal*, and is the former Chair of the Health Law Section. **The assistance of Caroline B. Brancatella, Associate, of Greenberg Traurig's Health and FDA Business Group, in compiling this summary is gratefully acknowledged.**

New York State Fraud, Abuse and Compliance Developments

Edited by Melissa M. Zambri

New York State Department of Health OMIG Audit Decisions

Compiled by Margaret Surowka Rossi

Island Wide Ambulette Service (DOH administrative hearing decision dated February 15, 2015, William J. Lynch, Administrative Law Judge). This was an audit of transportation services for the period July 1, 2003 through December 31, 2008 with alleged overpayments of $1,708,489. The provider who made a timely request for a hearing failed to appear. The provider notified OMIG that it had recorded the date of the hearing incorrectly and asked that the failure to appear be excused. The provider did not make an application to vacate the default. As such, the ALJ determined that the request for a hearing to challenge the recovery had been abandoned.

M.J. Trans. Corp. (DOH administrative hearing decision dated January 27, 2015, James F. Horan, Administrative Law Judge). This was an audit of transportation services for the period from January 1, 2008 until December 31, 2011. At issue were payments for services where the required driver's license number file contained a number with all zeros. This error was made during data entry. OMIG disallowed all such claims. The provider did adjust certain of the claims and those adjustments were allowed. OMIG indicated that adjustment of claims, though usually allowed within two years from claim submission, is not supposed to occur during an audit. In this case, however, OMIG decided not to seek the repayment for those claims that were adjusted. Thus, that issue was not before the ALJ. As to those claims that were not adjusted and for which OMIG did seek repayment, the ALJ upheld the overpayments despite the provider's argument that the error was a billing or computer "glitch." The ALJ also rejected the provider's argument that the overpayments of $26,862.59 would result in a "death penalty" to the provider.

Coalo Ambulette Service, Inc. and Azaire Paul (AKA Paul Azaire) (DOH administrative hearing decision dated November 10, 2014, James F. Horan, Administrative Law Judge). This was a review of an OMIG determination to exclude the transportation provider and owner and to recover for overpayments for services from January 1, 2008 to January 23, 2011. Provider's TLC license had expired in 2007 and provider failed to maintain workers' compensation and disability insurance. Provider conceded that certain services billed and purportedly referred by one physician were in fact never provided. The ALJ found that the OMIG proved that provider engaged in unacceptable practices. The provider tried to argue that the failure to renew its TLC license was not Medicaid fraud, but the ALJ noted that fraud was not alleged or necessary for there to be a finding of unlawfully furnished services. The ALJ found that and the absence of the TLC license, compensation and disability insurance were unacceptable practices. As such, the ALJ found that the OMIG was entitled to overpayments. Moreover, the false billings alone, and here where coupled with unacceptable practices, warranted the three-year exclusion of both the owner and the provider.

Lifeline Infusion Services, Inc. (DOH administrative hearing decision dated October 28, 2014, Denise Lepicier, Administrative Law Judge). This was an audit of infusion pharmacy for all 235 paid

Medicaid claims during the period January 2007 through December 2009. The infusion pharmacy is not patronized by the public, but rather only serves between four and seven patients at any particular time. At issue were refills of prescriptions which admittedly did not have refills noted on the prescription but were required companion prescriptions to those that did have refills noted. The prescription course was routine and had been dispensed previously on other occasions for this patient and the pharmacy admittedly missed that no refills were authorized by the prescriber. The pharmacy admitted that no call was made to the prescriber and there was nothing noted on the prescription to indicate that an oral authorization for the refill had been obtained pursuant to Education Law § 6801(4)(a). The ALJ sustained the audit findings noting, "[i]t is a significant error for a pharmacist/pharmacy to refill a prescription when no refills have been ordered." The ALJ noted that OMIG had not alleged that these were anything more than errors, but the ALJ noted that they were "errors for which the Pharmacy should not have been paid."

Devendra Kumar Shrivastava, M.D. (DOH administrative hearing decision dated October 28, 2014, Denise Lepicier, Administrative Law Judge). This was an audit of physician claims for services provided to patients who were eligible for both Medicare and Medicaid. The OMIG reviewed 467 claims that it alleged had inaccurate information about the existence of or extent of Medicare coverage. The ALJ noted

that a provider must bill Medicare or other insurance first for covered services prior to submitting a claim to Medicaid and is responsible for maintaining the Medicare Explanation of Benefits. Since the appellant offered no evidence to dispute OMIG's calculations, the ALJ upheld its overpayment findings in the amount of $63,716.

Ambulette P.R.N., Inc. (DOH administrative hearing decision dated May 1, 2014, Denise Lepicier, Administrative Law Judge). This was an audit of transportation services. The Final Audit Report was issued November 8, 2013 and received at the provider's mailing address on November 12, 2013. Over 60 days elapsed and on January 21, 2014, OMIG received a letter, postmarked January 18, 2014 requesting a hearing. At issue was the timeliness of the request. The provider argued that it did not receive the Final Audit Report and that OMIG gave it additional time to request the hearing. OMIG had the signed return receipt of the mailing to the address of the provider and the United States Postal Service online tracking. The Final Audit Report was never returned to OMIG. In light of this, the provider cannot overcome the presumption of delivery. As to additional time to request the hearing, although OMIG acknowledged that the provider called after the time to request a hearing, the provider was advised to contact the legal department. Without proof that OMIG granted an extension, the time to request the hearing would not be extended. The ALJ therefore denied the provider's request for a hearing.

Lake Grove, Durham and Maple Valley Schools (DOH administrative hearing decision dated April 30, 2014, David Lenihan, Administrative Law Judge). This was an audit of a school seeking restitution of over $1.1 million. The Final Audit Report had sought over $1.4 Million but after the request for a hearing, OMIG removed several findings. The School failed to reschedule the hearing and failed to appear. The ALJ deemed that the School had abandoned the request for a hearing and upheld the lower overpayment recovery with interest.

New York State Attorney General Press Releases

Compiled by Aubrey Roman, Colm Ryan and Karen S. Southwick

$1.025 Million Settlement with Trustees of Nonprofit—April 29, 2015—The trustees and former trustees of a fund benefiting underprivileged children reached a settlement with the Attorney General's office to return $1.025 million. The Fund's leader depleted the nonprofit's entire investment portfolio and shifted the nonprofit's focus to fund his, and a fellow trustee's, personal interests resulting in the Fund's purchase of a million-dollar Southampton home. Prior to the leader taking office, the Fund's focus was making grants to settlement houses and other institutions serving children in New York City, providing approximately $250,000.00 per year in grants. The Attorney General's office will turn over the settlement payments, less costs, to the Fund whose entire board will be replaced by new trustees, acceptable to the Attorney General's Charities Bureau. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-1025-million-settlement-trustees-nonprofit-squandered-assets.

Charges Against Herkimer County Certified Nurse's Aide Accused of Striking a Nursing Home Resident—April 28, 2015—A Certified Nurse Aide was arrested and arranged on charges of Endangering the Welfare of an Incompetent or Physically Disabled Person in the First Degree and at least one other charge after she allegedly struck a resident. A second defendant in the action was charged with making a false statement to protect the Nurse and for failing to promptly report the incident. The maximum penalty for the endangerment charge is three years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-charges-against-herkimer-county-certified-nurse%E2%80%99s-aide.

Bronx Home Health Care Agency Owners and Consultant Who Failed to Pay Workers Pled Guilty—April 23, 2015—Owners of a home health care agency and a consultant for the agency pled guilty to charges for failing to pay 63 home health aides employed by the company. The plea requires the owners to pay more than $80,000.00 in restitution to their former employees. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-pleas-bronx-home-health-care-agency-owners-and.

Lawsuit Against Board of Directors Alleging Mismanagement of Two Brooklyn-Based Nonprofits Serving Vulnerable Families—April 9, 2015—A lawsuit has been commenced against the board of directors of two not-for-profits for alleged mismanagement of certain properties and gross negligence. These organizations were created to provide housing and support services for pregnant women, young mothers and their children. An investigation by the Attorney General's office revealed that board members listed certain townhouses jointly operated by the nonprofits for sale without necessary approval from the Charities Bureau or a state court after being "[l]ured by a lucrative real-estate market in Brooklyn" for personal gain. The lawsuit has been filed in Brooklyn County Supreme Court. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-lawsuit-against-board-directors-alleging-mismanagement-two.

EMT Who Stole from Queens Volunteer Ambulance Corps Sentenced to Jail—April 3, 2015—A volunteer emergency medical technician who was convicted of stealing more than $300,000.00 from a volunteer ambulance service was sentenced to serve four months in jail and five years probation, in addition to paying full restitution.

The individual pled guilty to Grand Larceny in January 2015. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-jail-sentence-emt-who-stole-queens-volunteer-ambulance-corps.

Arrest of Aide Accused of Assaulting Queens Nursing Home Resident—April 2, 2015—A certified nurse aide was arrested on felony charges in Queens County, accused of assaulting an 80-year-old resident. It is alleged that in August of 2014, the nurse pushed and hit the resident multiple times, and caused her face to hit the bed rail. Ultimately the resident required treatment at a local hospital to treat her resulting injuries. The nurse no longer works at the facility. If convicted of the top count, the nurse will face up to seven years in state prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-aide-accused-assaulting-queens-nursing-home-resident.

Fishkill Nonprofit Serving New Yorkers with Disabilities to Repay Medicaid $363,000 for Using Unqualified Staff—April 1, 2015—A Fishkill-based nonprofit providing services to disabled New York residents and their families used unqualified individuals to provide services to Medicaid recipients who participated in the Home and Community Based Services Program offered by the New York State Office of Persons with Developmental Disabilities ("OPWDD"). As a result of utilizing an underqualified staff to provide services to Medicaid recipients, the agency agreed to reimburse Medicaid $363,643.00. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-agreement-fishkill-nonprofit-serving-new-yorkers.

New York Attorney General Announced Agreement to Implement Landmark Reforms for Herbal Supplements—March 30, 2015—A landmark agreement was announced between New York and the Pennsylvania-based retailer GNC. The agreement will outline and implement new standards in authenticating herbal supplements, ensure the purity of herbal supplements, and increase consumer education about herbal supplements' chemical content. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-agreement-gnc-implement-landmark-reforms-herbal-supplements.

Arrest of Nurse for Stealing Narcotics from Nursing Home—March 26, 2015—A former employee of a nursing home was arrested for allegedly stealing several pills containing oxycodone from the nursing facility's emergency pain medication supply between January 23, 2013 and February 2, 2013. It is alleged that the theft was concealed when the accused falsified records and forged the signatures of medication nurses, indicating that the medications were administered to residents at the facility. The nurse faces up to four years in prison for the Class E felony of falsifying business records in the first degree and up to one year in jail for several other Class A misdemeanor charges. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-nurse-stealing-narcotics-nursing-home.

Arrest of Former Not-for-Profit Director for Defrauding Medicaid and Stealing from a Developmentally Disabled Individual—March 19, 2015—A former executive director of a not-for-profit serving developmentally disabled individuals defrauded Medicaid for services rendered to the not-for-profit's consumers and stole funds of a developmentally disabled person. The executive director provided group services to the same consumers of two entities on overlapping dates and times resulting in Medicaid paying the not-for-profit $2,207.79 for services that should not have been paid. She also used over $1,000 from the bank account of a developmentally disabled consumer to pay for personal expenses including her school taxes and pet and farm supplies. She faces 1 1/3 to 4 years in prison if convicted. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-former-not-profit-director-defrauding-medicaid-and.

Settlement with Health Plan to End Wrongful Denial of Mental Health and Addiction Services—March 18, 2015—A Health Plan agreed to cover residential treatment for behavioral health conditions and reform its procedures for evaluating behavioral health treatment claims. In addition, the settlement agreement requires the Health Plan to provide notice of a new appeal right to 3,300 members whose requests for inpatient substance abuse rehabilitation and eating disorder residential treatment were previously denied. The estimated value of the denial of these requests is up to $9 million. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-excellus-health-plan-end-wrongful-denial-mental.

Indictment of Nonprofit and Its Top Executives for Participating in an Organized Crime Ring—March 18, 2015—The chief executive officer, former chief executive officer and controller of a nonprofit substance abuse treatment provider were arrested and indicted in a superseding indictment that expanded on an earlier indictment from October 2014. The Attorney General alleges that the provider stole $27 million from the Medicaid program by providing excessive services, operating an unregulated residential treatment program and violating patient rights. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-indictment-nonprofit-narco-freedom-and-its-top-executives.

Kickback Settlement with Pharma Manufacturer—March 16, 2015—A global pharmaceutical company agreed to a settlement with

all fifty states to resolve allegations it violated the False Claims Act by using lavish meals and speaker programs to induce physicians to prescribe its drugs. The company agreed to pay the United States and state Medicaid programs $39 million. The New York State Medicaid program will receive $2,339,671. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-kickback-settlement-pharma-manufacturer-daiichi-sankyo.

Agreement with Pharmacy Ensuring Accessibility for Deaf and Hard-of-Hearing Customers—March 12, 2015—A Pharmacy agreed to install an assistive listening system and implement new policies concerning communication with customers who are deaf or hard of hearing to improve access to services and ensure effective communication with pharmacists. http://www.ag.ny.gov/press-release/ag-schneiderman-secures-agreement-kinney-drugs-ensuring-accessibility-deaf-and-hard.

Agreement with Health Plan to Boost Coverage for Preventative Services—March 11, 2015—A Health Plan agreed to send nearly $400,000 to its members for anesthesiology services provided in connection with an in-network preventative colonoscopy. The Plan should not have required its members to make a copayment, coinsurance or deductible for these services because the Affordable Care Act requires health plans to cover recommended preventative services without member cost-sharing. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-agreement-emblemhealth-boost-coverage-preventive-services.

Individual Enters Guilty Plea for Engaging in Scheme to Defraud for Hospital Visits—March 10, 2015—An individual who made frequent hospital visits received $201,335 from his insurance company over approximately five years, but failed to utilize these funds to pay bills relating to his hospital treatment. The individual pled guilty to one count of Scheme to Defraud in the First Degree and agreed to six months of incarceration and five years of probation. http://www.ag.ny.gov/press-release/ag-schneiderman-and-ig-scott-announce-guilty-plea-oneida-county-individual-who-engaged.

Settlement with Rockland County Mental Health Facility That Altered Records Prior to a Medicaid Audit—March 9, 2015—A mental health facility agreed to pay $304,000 to resolve claims that its managers altered records in advance of a Medicaid audit. The facility admitted that over forty handwritten changes were made to records prior to the audit so that they would appear to support claims that the facility submitted for reimbursement. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-rockland-county-mental-health-facility-altered.

Sentencing of Former Office Manager for Stealing $11,828 from Residents of an Assisted Living Facility—March 5, 2015—A joint investigation between MFCU and the Newark Police Department found that the office manager of a senior living center stole $11,828 from three residents by failing to deposit money a family sent a resident, stealing a check from a resident and using forged checks to illegally obtain money. The office manager pled guilty to one count of Criminal Possession of a Forged Instrument in the Second Degree and two counts of Petit Larceny and was sentenced to "shock probation" which includes six months' incarceration, five years' probation, an order of restitution and an order of protection in favor of the victims. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-sentencing-former-office-manager-stealing-11828-residents.

Settlement to End Wrongful Denial of Mental Health and Substance Abuse Treatment Services—March 5, 2015—A managed care company that administers behavioral health benefits for about 2.7 million New Yorkers agreed to reform its claims review process and pay a $900,000 penalty. The Attorney General's Health Care Bureau found that the company issued denials twice as often for behavioral health claims as insurers did for other medical or surgical claims and four times as often for addiction recovery services. In addition to overhauling its claim review process, the company agreed to cooperate with an independent appeal process for claims that had been previously denied due to lack of medical necessity or lack of coverage for residential treatment. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-valueoptions-end-wrongful-denial-mental-health.

Sentencing of Oral Surgeon who Stole Over $14,000 from New York State—February 26, 2015—An oral surgeon who contracted with DOCCS to provide specialty dental care for inmates at correctional facilities pled guilty to billing DOCCS for surgical procedures that he did not perform by "upcoding" lower rate procedures at a higher reimbursement rate. The oral surgeon pled guilty to Offering a False Instrument for Filing in the Second Degree and was sentenced in Albany County Court to six months' incarceration and ordered to pay $14,640 in restitution. http://www.ag.ny.gov/press-release/ag-schneiderman-and-ig-scott-announce-sentencing-oral-surgeon-who-stole-over-14000-new.

$800,000 Settlement With Bronx Nonprofit That Diverted Money Intended for Services for Elderly—February 25, 2015—A downstate nonprofit has agreed to pay the Medicaid program $800,000 after allegedly spending Medicaid funds in violation of the organization's funding agreement with the NYC Human Resource Administration. The Attorney General's investigation revealed that these funds were used to make mortgage payments on the organization's headquarters. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-800000-settlement-bronx-nonprofit-diverted-money-intended.

$6 Million Settlement with Bronx For-Profit Hospice Provider Following Joint Investigation Between Attorney General and U.S. Attorney Bharara—February 18, 2015—A Bronx County hospice agency agreed to pay $1.68 million to Medicaid and $4.32 million to Medicare in response to state and federal government allegations that it submitted claims for reimbursements and received payment for hospice services not rendered or inadequately provided. As part of the settlement, the hospice provider admitted that it did not treat patients according to an individualized plan of care, did not ensure that plans of care were being followed for each patient, failed to make nursing services routinely available, failed to ensure that nursing services were provided in accordance with a plan of care, failed to maintain adequate clinical records and failed to ensure that compliance audit results reflected adherence to all applicable regulations. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-6-million-settlement-bronx-profit-hospice-provider-following.

Capital Region Nursing Home Aide Arrested for Allegedly Injuring 83-Year-Old Nursing Home Resident—February 17, 2015—A Glens Falls Certified Nurse Assistant was arrested and arraigned on charges that she endangered the welfare of a nursing home resident by failing to provide appropriate care to an 83-year-old woman, resulting in the resident fracturing her hip. The nurse is accused of failing to follow the resident's plan of care that required the assistance of two people and left the resident unattended. The nurse was arraigned on charges of Endangering the Welfare of an Incompetent or Physically Disabled Person in the Second Degree, a class A Misdemeanor, and Willful Violation of Health Laws, a Misdemeanor. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-capital-region-nursing-home-aide-over-injury-83-year.

Utica Nurse Arrested for Allegedly Failing to Provide Notification of Patient's Panic-High Potassium Level in Laboratory Results—February 17, 2015—A Utica Licensed Practical Nurse was arrested and charged with Endangering the Welfare of an Incompetent or Physically Disabled Person in the Second Degree and Willful Violation of Health Laws for allegedly failing to report panic-high potassium levels appearing in a patient's laboratory test results. Panic-high potassium levels can cause arrhythmia and cause the heart to stop. The nurse allegedly failed to follow protocol by not reporting the laboratory results to a doctor or a nursing supervisor, placing the patient's health at serious risk. The patient was given another medication to lower his potassium level. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-utica-nurse-allegedly-failing-provide-notification.

Westchester Nonprofit Executive Arrested for Alleged Involvement in Scheme Involving State Program to Assist Seniors and the Disabled—February 4, 2015—The executive director of a Yonkers-based nonprofit that specialized in securing state-funded service contracts that provided construction and moving services to the elderly and disabled when moving from nursing homes into the community was charged with falsifying bids to the Nursing Home Transition and Diversion Program ("NHTD Program"), a New York State Department of Health program. The individual allegedly falsified and submitted bids for NHTD Program projects. By falsifying the bids, the individual controlled which contractor won the bid. He then used the falsified bid to inflate the amount Medicaid paid the nonprofit as its share of the project. In addition, he allegedly demanded and received kickbacks from a NHTD Program project contractor and filed claims in the transition program for moving expenses that were never provided or significantly inflated over the costs. The individual and the nonprofit are each charged with one count of Grand Larceny in the Second Degree, a Class C felony; five counts each of Criminal Possession of a Forged Instrument in the Second Degree, a Class D felony, and Offering a False Instrument for Filing in the First Degree, a Class E felony; and ten counts of Falsifying Business Records in the First Degree, a Class E felony. The individual faces up to fifteen years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-westchester-nonprofit-executive-scheme-involving.

Erie County Nurse Aide Pleads Guilty for Taking and Exchanging Compromising Photograph of Incontinent Patient Via Snapchat—February 3, 2015—A former employee pled guilty to the charge of Willful Violation of Health Laws and was sentenced to one year conditional discharge with 100 hours of community service for taking and exchanging a compromising photograph of an elderly patient in a state of undress and sharing it via Snapchat. A manager for the aide stated the photograph was taken for no legitimate purpose and the resident lacked the mental capacity to consent to the taking of the photograph. The aide surrendered his CNA certificate. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-and-guilty-plea-erie-county-nurse-aide-taking-and.

Settlement Reached With Health Plan Over Excessive Co-Pays—January 12, 2015—An agreement was reached with a health plan requiring that its contracted health care providers issue refunds to nearly 3,000 customers in the Rochester area for charging excessive co-pays. The plan had issued incorrect Explanations of Benefits, which imposed an additional specialty co-payment for member visits to a primary care provider. Upon inquiry, the plan acknowledged the erroneous Explanations of Benefits and explained the issue stemmed from the

changing of certain tax identification numbers. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-health-insurer-over-excessive-copays-customers.

Manhattan Dentist Arrested and Charged With Filing False Claims for Dental Services—January 8, 2015—A Manhattan dentist was arrested for filing false claims and stealing $11,479 from Medicaid for providing services to patients he never met or treated only in prior years. The complaint alleges that a patient of the defendant was unaware of the dentist and never received the services for which the dentist billed Medicaid. The dentist was charged with one count of Grand Larceny in the Third Degree, a Class D Felony, and one count of Offering a False Instrument For Filing in the First Degree, a Class E Felony. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-dentist-medicaid-theft.

$300K Settlement Reached with Queens-Based Transportation Provider Resolving Allegations of Overbilling—January 5, 2015—A Queens-based transportation company will pay $300,000 to settle claims that it overbilled Medicaid for transportation services. Apple admitted that between January 1, 2004 and October 30, 2008, it frequently billed Medicaid for ambulette services even though no personal assistance was provided to Medicaid recipients, which resulted in Medicaid paying for ambulette services at rates that were higher than the applicable livery rates. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-300k-settlement-queens-based-transportation-provider.

Certified Nurse Aide Arrested and Charged with Endangering the Welfare of a Nursing Home Resident—December 15, 2014—A certified nurse aide was arrested on charges she endangered the welfare of a 92-year-old wheelchair-bound resident for allegedly illegally moving the resident from her wheelchair to her bed without the assistance of another staff person. Documents filed in the case allege that as a result of the transfer, the resident sustained a laceration to her right leg that the aide and another uncharged aide attempted to cover up by bandaging the wound and failing to report the injury. The felony complaint filed in the Suffolk County First District Court charges the aide with felony Falsifying Business Records in the First Degree, misdemeanor Endangering the Welfare of an Incompetent or Physically Disabled Person, and misdemeanor Willful Violation of Health Laws. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-aide-accused-endangering-suffolk-nursing-home.

New York State Office of the Medicaid Inspector General Update

Compiled by the Editor

Performing Provider System Lead Guidance Posted—April 6, 2015—http://www.omig.ny.gov/latest-news/847-the-new-york-state-office-of-the-medicaid-inspector-general-omig-has-posted-new-compliance-guidance.

Holding Company and Joint Venture Structures Compliance Guidance Posted—April 3, 2015—http://www.omig.ny.gov/latest-news/844-compliance-guidance-posted.

2015-2016 Budget Testimony—February 3, 2015—http://www.omig.ny.gov/latest-news/841-omig-budget-testimony.

Medicaid Providers Revalidating Enrollment: Mandatory Compliance Program Obligations and Certification Requirement Upon Revalidation—January 27, 2015—http://omig.ny.gov/images/stories/compliance_alerts/20150127_Compliance_Guidance_2015_01_final_1_27_15.pdf.

Complete List of Posted Audit Protocols—http://www.omig.ny.gov/audit/audit-protocols.

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In the Law Journals

A Compelling Interest? Using Old Conceptions Of Public Health Law To Challenge The Affordable Care Act's Contraceptive Mandate, Joshua Joel, 31 Ga. St. U.L. Rev. 613 (2015).

Are Physician-Patient Communications Protected By The First Amendment?, Martha Swartz, 2015 Cardozo L. Rev. De Novo 92 (2015).

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Enforcement Overdose: Health Care Fraud Regulation In An Era Of Overcriminalization And Overtreatment, Isaac D. Buck, 74 Md. L. Rev. 259 (2015).

Enforcing Mental Health Parity Through the Affordable Care Act's Essential Health Benefit Mandate, Kathleen G. Noonan and Stephen J. Boraske, 24 Ann. Health L. 252 (2015).

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FTC Orders In Health-Related Advertising Cases: From A New Approach To The New Normal, Eric Berman, 29 Antitrust ABA 98 (2015).

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Holding Health Insurance Marketplaces Accountable: The Unheralded Rise And Imminent Demise Of Structural Reform Litigation In Health Care, Sarah L. Grusin, 24 Ann. Health L. 337 (2015).

Implementing Health Reform In An Era of Semi-Cooperative Federalism: Lessons from the Age 26 Expansion, Sara Rosenbaum, Alexander B. Blum, Amanda Giordano, M. Jane Park and Claire D. Brindis, 10 J. Health & Biomed. L. 327 (2015).

Kickbacks and Contradictions: The Anti-Kickback Statute and Electronic Health Records, Daniel E. Rheiner 17 Vand. J. Ent. & Tech. L. 493 (2015).

Narrow Networks, the Very Sick, and the Patient Protection and Affordable Care Act: Recalling the Purpose of Health Insurance and Reform, Valarie Blake, 16 Minn. J.L. Sci. & Tech. 63 (2015).

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Protecting Our Herd: How A National Mandatory Vaccination Policy Protects Public Health By Ensuring Herd Immunity, Ellen C. Tolsma, 18 J. Gender Race & Just. 313 (2015).

Removing Access To Health Care From Employer And State Control: The ACA As Anti-Subordination Legislation, W. David Koeninger, 44 U. Balt. L. Rev. 201 (2015).

Removing The Menacing Specter Of Elder Abuse In Nursing Homes Through Video Surveillance, Katherine Anne Meier, 50 Gonz. L. Rev. 29 (2015).

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Rule Of Reason Without A Rhyme: Using "Big Data" To Better Analyze Accountable Care Organizations Under The Medicare Shared Savings Program, Shaun E. Werbelow, 90 N.Y.U.L. Rev. 361 (2015).

Separation Of Powers— New York Court Of Appeals Affirms Invalidation Of Soda Portion Cap, 128 Harv. L. Rev. 1508 (2015).

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- *Clash of the Titans: Medicaid Meets Private Health Insurance*, Sara Rosenbaum
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For Your Information

By Claudia O. Torrey

Dear Colleagues,

As I pen this message to you, it has unfortunately been one month since one of my parents suffered a stroke; at this writing, it appears that the prognosis is a "long," but hopefully productive Summer in rehab. Thus, the absence of the usual "FYI" column; the plan is to return in the next Journal issue.

I share this information with you for two reasons: (1) you are "like extended family" that I interact with and (2), because as health lawyers we know that at some point on this journey called life we will all be patients! We also know that sometimes we have to be a non-controversial patient advocate, wherein "a little bit of medical knowledge" is a good thing (smiles).

Thank you in advance for your prayers and/or positive thoughts. Best wishes for a reflective Fourth of July holiday and a good Summer!

Claudia O. Torrey, Esq. is a Charter Member of the Health Law Section.

Medical, Ethical and Legal Obligations to Honor Individual Preferences Near the End of Life

By Patricia A. Bomba and Jonathan Karmel

I. Introduction

The Patient Self-Determination Act[1] affirms an individual's right to accept or refuse treatment. This right does not end when a person is near the end of life. Specifically, an individual has the right to accept or refuse any or all life-sustaining treatment near the end of life. Decisions to forgo life-sustaining treatment may change in the final year of life as the person's health status, prognosis and personal goals for care transition from focusing on longevity, to functionality, to quality of life. A seriously ill person who might die in the next year, and has the ability to make medical decisions regarding life-sustaining treatment, should discuss goals, values and wishes with a physician, and complete the New York State Department of Health (NYSDOH) Medical Orders for Life-Sustaining Treatment (MOLST) form (DOH-5003).[2]

Based upon the individual's goals for care, the patient may choose to allow natural death and forgo an attempt at cardiopulmonary resuscitation (CPR). For example, an individual may request a Do Not Resuscitate (DNR) medical order, while still wishing to have a trial of intubation and mechanical ventilation, and hospitalization. As the health status worsens, the patient may consent to a Do Not Intubate (DNI) medical order in addition to the DNR order. When this individual's condition further deteriorates, having no further hospitalizations may be requested by the patient. At each stage, no matter the decision, this individual has a right to be treated with dignity and respect.

Health care providers will always offer comfort measures (palliative care) despite the medical orders to discontinue certain treatment contained in the MOLST. Comfort measures have the primary goal of relieving pain and other symptoms and reducing suffering. Food and fluids will be offered by mouth. Medications, repositioning, wound care, and other measures such as oxygen, suctioning and manual treatment of airway obstruction will also continue to be used to relieve pain and suffering.

There are several statutes governing the ethical framework for withholding and/or withdrawing life-sustaining treatment, if an individual loses the capacity to make these decisions. The Health Care Proxy Law empowers an adult to appoint a health care agent (HCA) to make treatment decisions based on known wishes or best interests.[3] The Family Health Care Decisions Act (FHCDA) enables a patient's family member or close friend (Public Health Law surrogate) in a hospital or nursing home setting to make health care decisions when the patient is not able to do so and there is no HCA.[4] In addition, the Surrogate's Court Procedure Act (SCPA) section 1750-b permits a SCPA Article 17-A guardian or an actively involved family member to make medical decisions for individuals with developmental disabilities (DD) who lack the ability to make these decisions.[5]

HCAs and Public Health Law (PHL) surrogates may not undo health care decisions the patient already made before losing capacity.[6] Nor can they disregard the preferences and values of the patient, including the patient's religious and moral beliefs, and substitute their own preferences or values when making new health care decisions after the patient loses capacity.[7] Health care professionals also have an ethical obligation to honor individual preferences and cannot disregard the values, preferences and prior decisions made by the patient in favor of requests for treatment made by the HCA, PHL surrogates, family or other loved ones.[8]

Both FHCDA and SCPA1750-b have explicit guidelines and special requirements for making decisions to withhold and/or withdraw life-sustaining treatment. In all cases, the statutes affirm "person-centered" care and require that treatment decisions be based upon the individual's personal values, beliefs and goals for care and not those of the decision-maker.

II. The Ethical-Legal Framework for Making Medical Decisions

A. Health Care Proxy Law

A HCA may make medical decisions on behalf of a patient (principal), after two physicians concur that the patient lacks medical decision-making capacity. A HCA is generally authorized to make decisions as if the HCA were the principal. Occasionally, the health care proxy document may limit the authority of the HCA. A HCA is required to make decisions according to the principal's wishes, including religious and moral beliefs. If these wishes are not reasonably known and cannot with reasonable diligence be ascertained, the HCA may make decisions according to the principal's best interests, except for a decision to withhold or withdraw artificial nutrition or hydration. A HCA is authorized to make a decision to withhold or withdraw artificial nutrition or hydration only if the HCA has reasonable knowledge of the principal's wishes regarding the administration of artificial nutrition and hydration.[9] "Clear and convincing evidence" of the principal's wishes is NOT needed for a HCA to make decisions about life-sustaining treatment. However,

a HCA cannot override a principal's prior instructions to health care professionals or the principal's advance directive.[10]

Before choosing a HCA, there are very important issues for the principal to consider. This person must, or at least should:[11]

- Meet legal criteria (be a competent adult, at least 18 years old);
- Be willing to speak on behalf of the principal;
- Be willing to act on the principal's wishes;
- Be able to separate the HCA's own feelings from those of the principal;
- Live near the principal or be willing to come to that geographical location if needed;
- Know the principal well;
- Understand what values, goals and morals are important to the principal;
- Be willing to discuss sensitive wishes;
- Be willing to listen to wishes expressed by the principal;
- Be willing and able to work with those providing care to the principal to carry out those wishes;
- Intend to be reasonably available in the future;
- Be able to handle potential conflicts between the family and close friends of the principal;
- Be willing and able to handle the responsibility of carrying out end-of-life wishes; and
- If chosen as an alternate, be willing and able to act if the primary HCA is unwilling or unable to act.

B. Family Health Care Decisions Act

Under FHCDA, a surrogate is selected from the surrogate list when there is no HCA to make all medical decisions in a hospital, nursing home or hospice after the attending physician and another health or social services practitioner at the facility have concurred that the patient lacks capacity. For decisions to withhold or withdraw life-sustaining treatment, there are specific clinical criteria which must be satisfied. Additionally, the facility's ethics review committee must agree with the decision in certain situations.[12]

The FHCDA surrogate is also required to make treatment decisions "in accordance with the patient's wishes, including the patient's religious and moral beliefs," or, if the patient's wishes are not reasonably known and cannot be ascertained, "in accordance with the patient's best interests."[13]

The FHCDA surrogate must be fully informed about the patient's medical condition and the risks, benefits, burdens and alternatives of possible life-sustaining treatment. The FHCDA surrogate must then consent to withholding or withdrawing life-sustaining treatment, for which medical orders are written. The surrogate's assessment must be based upon the consideration of:

- the dignity and uniqueness of every person;
- the possibility and extent of preserving the patient's life;
- the preservation, improvement or restoration of the patient's health or functioning;
- the relief of the patient's suffering; and
- any medical condition and such other concerns and values that a reasonable person in the patient's circumstances would wish to consider.

C. Surrogate's Court Procedure Act § 1750-b

SCPA1750-b allows an Article 17-A Guardian or actively involved family members to make medical decisions, including end-of-life decisions related to the withholding and/or withdrawing life-sustaining treatment for individuals with developmental disabilities (DD) who lack the ability to make these decisions. A person with DD who has capacity can make end-of-life decisions. A person with DD who has capacity to choose a HCA can complete a health care proxy and choose a HCA. If the person with DD subsequently loses capacity to make medical decisions, the HCA then can make decisions in accordance with Health Care Proxy Law. If the person with DD lacks the capacity to make decisions and does not have a HCA, the provisions of SCPA 1750-b apply. In that case, the guardian shall base all advocacy and health care decision-making solely and exclusively on the best interests of the person with DD and, when reasonably known or ascertainable with reasonable diligence, on the person's wishes, including moral and religious beliefs.[14] Clear and convincing evidence of the patient's wishes is also not needed in order for a surrogate to consent to MOLST decisions in accordance with FHCDA and SCPA 1750-b.

D. Medical Orders for Life-Sustaining Treatment

Preferences for treatment and decisions about the care of seriously ill persons near the end of life are acutely needed in an emergency. More often than not, a seriously ill individual lacks the capacity to make these decisions when chronic medical conditions acutely decompensate. MOLST orders provide health care professionals with clear direction for the life-sustaining treatment the individual wishes to receive, as well as those to be avoided, based upon *current*, not future, health status and prognosis.

MOLST is a clinical process that emphasizes the discussion of the patient's goals for care and shared medical decision-making between health care professionals and patients who are seriously ill or frail, for whom the physician would not be surprised if they might die within the next year. The completion of the MOLST form results in a standardized set of documented medical orders that reflect a patient's preferences for life-sustaining treatment. MOLST, however, is *not* an advance directive.

NYSDOH approved MOLST for use in all health care facilities throughout New York State in October 2005. A Dear Administrator Letter (DAL) was sent to hospitals, nursing homes and EMS in January 2006. Upon completion of a successful community MOLST Pilot Project in Monroe and Onondaga Counties from 2005-2008, legislation enacting MOLST was passed and then signed by Governor David Paterson. This law also changed the scope of practice for EMS responders across New York State to permit MOLST orders for DNR to be honored in nonhospital settings in addition to non-hospital DNR orders and non-hospital DNI orders only on the MOLST form.

In 2010, MOLST became a NYSDOH form. This is the ONLY form approved by NYSDOH for both DNR and DNI orders in the community. All health care professionals, including EMS, must follow the MOLST orders in all clinical settings, including the community.

On January 21, 2011, the Office for People with Developmental Disabilities (OPWDD) approved use of the DOH-5003 MOLST form for individuals in the OPWDD system in all clinical settings, including the community. However, the individual's physician must follow certain legal requirements before a MOLST can be signed for a DD person. Further, the OPWDD MOLST Legal Requirements Checklist must be attached to the MOLST form.

III. Authority to Make MOLST Decisions

When a patient has properly consented to MOLST orders via a shared, informed medical decision-making process and has made decisions regarding life-sustaining treatment, the MOLST form will document the patient's wishes, given the patient's current health status and prognosis.

A HCA CANNOT overrule the clear wishes of the principal as expressed in the MOLST, unless the agent has a good faith basis for believing that the principal's wishes have changed or do not apply to the present circumstances (e.g., the principal's condition has changed, and he or she would have made a different decision, had he or she known about the change). Similar logic is applied when a surrogate makes MOLST decisions in accordance with FHCDA and SCPA1750-b.[15]

A. An Example of What Should Happen with MOLST

A nursing home resident indicated that he wished to meet a life goal—e.g., attend a grandson's wedding. Because of that, he requested to receive full treatment, including CPR, on his MOLST. His daughter was his HCA. She was aware of his goals for care based upon his current health status. He then had a catastrophic stroke, which precluded the possibility he could attend his grandson's wedding. This major change in his health status triggered a review of his MOLST orders. Since his HCA stood in the principal's shoes, she had to establish new goals for his care and treatment based upon his prior preference that he did not wish to live hooked up to machines like his late brother. Therefore, a palliative approach was discussed with the HCA with the focus on the quality and not the longevity of his life. The HCA could then request the change in the MOLST orders in accordance with the principal's wishes based upon the change in circumstances and the determination of new goals for care.

If, however, this same resident had previously consented to DNR/DNAR/Accept Natural Death on page 1 and Limited Medical Interventions on page 2 of the MOLST, the HCA could not "undo" the DNR order, because the MOLST had provided a clear statement of the resident's wishes and represented *clear and convincing evidence*. There was in that instance no reason to believe that the resident's wishes would have changed or would not have been applicable in the event of a catastrophic stroke. The MOLST DNR order provides more than just "reasonable knowledge" of the principal's wishes; it provides clear documentation of those wishes.

B. One of the Most Frequently Asked MOLST Questions

One of the most frequently asked questions with respect to MOLST is whether a HCA or a PHL surrogate can demand life-sustaining treatment and hospitalization for a nursing home resident, when the resident loses capacity and the resident's health status worsens. If that request conflicts with the resident's prior decisions, made when the resident had capacity and the medical orders were issued by the attending physician on the MOLST, the answer is NO. Yet this situation continues to occur.

C. An Example of What Should Not Happen with MOLST

A 77-year-old female with multiple medical conditions, including agoraphobia, was admitted to a nursing facility approximately six years ago, when she was no longer able to manage her activities of daily living. Her family rarely, if ever, visited or communicated with her. Her grandson served as her HCA. At the time of her admission, she had the capacity to make medical decisions.

About four years ago, she began to refuse to leave her bed with very rare exceptions. As a result, she developed severe pressure sores due to her refusal of bathing, turning, and positioning. Serial psychiatric consultations were obtained. These confirmed that the patient still had the capacity to understand the risks and benefits associated with her refusal of care.

Approximately two-and-a-half years later, her attending physician and the psychiatrist both agreed she continued to have the capacity to make decisions regarding life-sustaining treatment. A MOLST form was completed. Her goals for care were to focus on the quality of her life. She specifically wished to avoid aggressive interventions, and wanted to die a natural death in the nursing home, being cared for by the staff who had served as her surrogate family. Her MOLST reflected DNR, DNI, no feeding tubes, no hospitalization and Comfort Measures Only. Her goals and preferences for care and treatment remained unchanged with the passage of time, when the MOLST orders were reviewed and renewed in accordance with the nursing home's policies and procedures.

The resident became acutely ill with symptoms of sepsis, a diffuse infection likely due to the pressure sores. The nurse practitioner (NP) contacted her HCA to review her acute deterioration in health status and to review the treatment plan, which was consistent with his grandmother's previously made decisions and goals. Her grandson stated he understood his grandmother's wishes and was supportive of the palliative care plan of care. The resident was treated with antibiotics and comfort measures.

However, over the next three days, her oral intake diminished. She ultimately stopped eating and drinking and appeared to be imminently dying. The NP again called the grandson to update him of her continuing decline. He subsequently arrived at the facility and insisted that the resident be transferred to the hospital for acute care, violating his grandmother's known wishes and already executed medical orders. The NP spoke with him to try to help him deal with the reality of the situation. She refused to call 911, because she and all the facility staff knew what the resident wanted and didn't want. However, the grandson called 911. When EMS arrived, the grandson allegedly became quite agitated. He insisted that his grandmother be transported to the hospital. After reviewing the MOLST, the EMS staff called Medical Control for guidance. Because of the grandson's agitation, the resident was transferred to the Emergency Department. She was then admitted to the facility's intensive care unit, where she had a stormy and painful medical course and ultimately died. An analysis of this case revealed the following due to the failure to follow the resident's MOLST orders:

- The resident's legal rights and decisions as evidenced by her MOLST orders were violated. She was transferred against her will and without her consent, and her right to refuse treatment was violated.
- From a medical perspective, the medical staff erroneously failed to follow her documented wishes, in part due to the agitation of the HCA.
- The nursing home staff felt immense moral distress. They felt they had failed their ethical obligations to the resident.
- From a regulatory perspective, there were also violations. CMS Clinical Standards and Quality for Advance Care Planning Survey Deficiency F tag 155 states clearly that the failure to follow MOLST orders by allowing hospitalization results in "Immediate Jeopardy."[16]

Unfortunately, the provisions of the Public Health Law are not always sufficient to ensure that patient rights will be respected.

IV. Why There Are Failures in Following MOLST Orders

- Clinicians, patients, families and medical decision makers are unaware of their moral, ethical and legal obligations to follow MOLST orders and the implications of their failure to follow MOLST orders.
- Unfortunately, advance care planning is not recognized by everyone as a dynamic communication process. Too often, the emphasis is placed on the completion of the forms rather than the communication process. Many clinicians have difficulty with having the discussion and have inadequate training in conflict resolution.
- Sometimes when the attention of the physician is primarily directed on the conversation, appropriate legal documents and/or medical orders may not be completed or may be completed incorrectly.
- One of the most serious problems is that family members tend to avoid having conversations centered on the personal values, beliefs and goals for care. Thus, they do not really understand what matters most to the individual seeking MOLST orders.
- Sometimes the patient has chosen the wrong HCA.
- There is also a lack of understanding by both health care professionals and family of the difference between a traditional advance directive (health care proxy and/or living will) and medical orders (MOLST).

- The assessment of capacity determinations and documentation of capacity as well as the patient's personal values, beliefs and goals for care and the statutory requirements may either be absent or inadequate. Therefore, all of these problems may affect whether a MOLST is or can be honored.
- Unfortunately, the health care system is fragmented. Therefore, key information may not be consistently accessible when there are transitions in patient care. Further, health care professionals are not always able to easily access advance directives and/or MOLST orders in the patient's medical record.

V. Recommendations

A. Clinician Training Should Be Strengthened

In 2014, the Institute of Medicine (IOM) released "Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life," a comprehensive review of end-of-life care in the U.S.[17] The IOM report concluded that the U.S. health care system was poorly designed to meet the needs of patients near the end of life and that major changes to the health care system were needed to meet end-of-life care needs and informed patient preferences in a high-quality, affordable, and sustainable manner. The report proposed a high national priority for a patient-centered, family-oriented approach to care near the end of life.

The Committee recommended the development of quality standards for clinician-patient communication and advance care planning. They also recommended the development of appropriate provider training, certification and licensure to strengthen palliative care knowledge and skills for all clinicians. Because advance care planning and MOLST are key elements of palliative care, they must be integrated into the curricula of all medical, nursing, social work and chaplaincy schools.

B. Public Education and Engagement in Advance Care Planning Should Be Encouraged

"Most people nearing the end of life are not physically, mentally, or cognitively able to make their own decisions about care. The majority of these patients will receive acute hospital care from physicians who do not know them. Therefore, advance care planning is essential to ensure that patients receive care reflecting their values, goals, and preferences."[18]

However, many people do not understand the need for advance care planning, which is the process of planning for future medical care in the event individuals lose the capacity to make their own medical decisions. Lack of capacity can occur suddenly due to unexpected illness or injury, from which an individual may or may not recover. In either case, when an acutely ill person is near death or actively dying, end of life decisions are needed. Advance care planning helps ensure that the patient's treatment preferences are documented, regularly updated, and respected.

Early initiation of advance care planning is relevant at all ages. No age group is immune from acute illness or injury, complex chronic conditions or death. Improving communication and advance care planning is critically important for persons of all ages who are facing the end of life, including adults, adolescents and children. Fact-based public education that encourages advance care planning and shared medical decision-making that is well informed should be made available along the life cycle.

New York State has developed and implemented a community approach to advance care planning with two complementary programs that were highlighted in the IOM Report: The programs were Community Conversations on Compassionate Care (CCCC)[19] and MOLST. Positive outcomes were achieved and lessons were learned from more than a decade's experience.[20]

C. The Use of eMOLST Should Be Expanded

eMOLST[21] is a web-based application that allows eMOLST orders and documentation of the conversation to be accessed from anywhere with Internet access. New York's eMOLST system is accessible to all users at all times at www.NYSeMOLSTregistry.com. eMOLST helps health professionals follow a standard clinical process for the MOLST discussion and guides them through all necessary documentation of the ethical framework and legal requirements. The system includes programming to prevent errors and allows physicians to sign MOLST orders electronically. At the end of the eMOLST process, both a DOH-5003 MOLST form[22] and the appropriate MOLST Chart Documentation Form for Adult Patients[23] or Minor Patients[24] (aligns with NYSDOH Checklists)[25] or the OPWDD MOLST Legal Requirements Checklist for Individuals with Developmental Disabilities[26] are created. eMOLST works for all patients: adults, children and persons with developmental disabilities.

New York's MOLST forms can be completed online in eMOLST and are automatically included in the registry. A copy can be printed for the patient. eMOLST does not require or rely on an EHR system and can be used with paper records. eMOLST is operational statewide and currently operates in all browsers and all devices, including on tablets. eMOLST ensures quality and patient safety, reduces patient harm and helps achieve the triple aim, improving the care experience, health outcome and reducing cost. Use of eMOLST is important, since key policy recommendations in the IOM Report include certain specific relevant actions. These include:

- The encouragement of all states to develop and implement a Physician Orders for Life-Sustaining Treatment (POLST) paradigm program in ac-

cordance with nationally standardized core requirements.

- The requirement to use interoperable electronic health records that incorporate advance care planning to improve the communication of individuals' wishes across time, settings, and providers, documenting (1) the designation of a surrogate/decision maker, (2) patient values and beliefs and goals for care, (3) the presence of an advance directive, and (4) the presence of medical orders for life-sustaining treatment for appropriate populations.

Fortunately, the New York State MOLST is a nationally endorsed POLST Paradigm Program. Further, eMOLST is the only such model in the country and was cited in the IOM Report.[27]

VI. Conclusion

As the populations of both New York State and the United States of America age, the importance of the implementation of advance care planning is significant. Encouraging the completion of advance directives such as the Health Care Proxy, discussions by physicians with patients about their values, wishes and goals and implementing the use of eMOLST to facilitate the completion of MOLST forms is crucial. Finally, end-of-life wishes of patients must be honored by all parties and greater efforts must be made to educate both the general population and all health care professionals.

Endnotes

1. Patient Self-Determination Act of 1990, P. L. 101-508, § 4206 (codified in 42 USC § 1395cc(f)).
2. NY Public Health Law (PHL) § 2994-dd(6); 10 NYCRR § 400.21(b)(6); New York State Department of Health (NYSDOH) Medical Orders for Life-Sustaining Treatment (MOLST). https://www.health.ny.gov/professionals/patients/patient_rights/molst/.
3. PHL § 2982(2). Under PHL Article 29-C, the term "health care proxy" refers to the document; the term "health care agent" refers to the person appointed. PHL § 2980(5), § 2980(8).
4. PHL Article 29-CC.
5. SCPA 1750-b(4).
6. PHL §§ 2981(4); 2982(1); 2989(2); 2994-d(3)(a)(ii).
7. PHL §§ 2982(2); 2994-d(4).
8. PHL §§ 2964(2)(c); 2994-f; 2994-ee.
9. NYSDOH MOLST Checklist 2 – adult with health care proxy any setting (5/1/13), available at https://www.health.ny.gov/professionals/patients/patient_rights/molst/docs/checklist_2.pdf.
10. Burke, K., Herb, A. and Swidler, R. *Three Stubborn Misconceptions About the Authority of Health Care Agents*, NYSBA Health Law J., 10(3):63-70 (Summer/Fall 2005).
11. Choose a Spokesperson (Choose the Right Health Care Agent), http://www.compassionandsupport.org/index.php/for_patients_families/advance_care_planning/choose_a_spokesperson.
12. *Deciding About Health Care: A Guide for Patients and Families*, http://www.health.ny.gov/publications/1503.pdf. NYSDOH MOLST Checklist 3 – adult with FHCDA surrogate (3/2012), available at https://www.health.ny.gov/professionals/patients/patient_rights/molst/docs/checklist_3.pdf.
13. PHL § 2994-d(4)(a).
14. SCPA 1750-b(2).
15. Indeed, a health care provider need not seek the consent of a surrogate under FHCDA when the patient has already made a decision about the proposed health care. PHL § 2994-d(3)(a)(ii).
16. Center for Clinical Standards and Quality/Survey & Certification Group F tag 155, http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-16.pdf. Hospital patients and nursing home residents have a right to refuse medical treatment. 10 NYCRR §§ 405.7(b)(10); 415.3(e)(1)(ii).
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A Quarter-Century Since *Baby M*: Why New York Should Reconsider Its Surrogacy Law

By Shawna Benston

I. Introduction

Alex Kuczynski feared she'd never see her and her husband's faces reflected in their child's. Indeed, "[a]fter a total of 11 failed I.V.F. cycles and four failed pregnancies, stretched out over five years, actual hope becomes a mawkish pretense."[1] She had long desired to be a mother, and, viewing this role as "the natural outgrowth of a loving relationship" since marrying her husband, 39-year-old Alex remained determined and was rewarded when gestational surrogacy "found its way into [her] brain" after yet another miscarriage.[2] As she would learn—and share with her *New York Times Magazine* audience in November 2008—gestational surrogacy offered the Kuczynskis the chance to welcome a biological child into their lives. Embarking on her search for the ideal surrogate, Alex acquired a rather extensive knowledge base about what surrogacy entails, who offer themselves as potential surrogates, and what it means for the role of carrier to be shifted from the biological mother to a paid third party.

Surrogacy is generally unnerving: "like abortion, [surrogacy] is controversial precisely because it evokes and often contradicts basic concepts about family, motherhood, and gender roles."[3] One author has even asserted that "at the very least, one ought to be especially concerned with any process that disrupts the important bond between mother and child, which derives from both biological and cognitive/psychological aspects of human nature, beginning during gestation and continuing after birth."[4] The act of being a surrogate and the decision to lend one's body and time to aid the intended parents are even more difficult to comprehend than the more general notion of surrogacy: "While it is easy to understand the unhappiness and despair that motivate an infertile, childless couple, who desire children, to enter into a surrogacy arrangement, the motives of women who choose to be surrogate mothers, despite general public disapproval of third party assisted reproduction, are more puzzling and more suspect."[5]

This article strives to humanize and expand on the notions of surrogacy, the surrogate herself, and the intended parents: what is each party's reason(s) for entering into such a delicate and important relationship in order to produce a baby, and why does each party need legal protection not yet provided in New York? Finally, what considerations must the New York legislature include in its potential restructuring of the New York surrogacy law?

II. Surrogacy-Related Terms

There are two types of surrogacy: traditional and gestational. Traditional surrogacy finds the surrogate serving as both carrier and genetic mother of the baby after having undergone artificial insemination, which can be done with or without fertility drugs to boost the surrogate's egg production.[6] Since the advent and proliferation of physicians able to perform in vitro fertilization (IVF), "surrogacy agencies report that the numbers have shifted markedly away from traditional surrogacies toward gestational surrogacies."[7] As Alex vividly demonstrates, the desire for motherhood is not necessarily unconditional—indeed, Alex herself rather matter-of-factly states that "[i]f [she had] never met the man, [she] would [have] skip[ped] the baby"[8]: the latter would serve as a symbolic outgrowth of Alex and her husband's preexisting relationship. Therefore, gestational surrogacy, which would offer the chance of the couple's genetic intertwining and fused resemblance, was Alex's clear last resort.

Gestational surrogacy entails the use of IVF, an invasive and intensive process. First, hormonal treatment is administered to the surrogate to suppress her natural monthly cycle and stimulate development of a receptive uterine lining. Then, laboratory-fertilized embryos (created from the genetic mother's eggs and the genetic father's sperm) are implanted into the surrogate's uterus.[9] IVF, while continuously honed by scientists, has proved to be "a procedure with few guarantees"[10] because "one in three embryos resulting from IVF have chromosomal abnormalities that prevent the development into a full-term pregnancy."[11] (Recently, a promising, and even relatively affordable,[12] new test to determine successful embryos was introduced. While this new test is beyond the purview of this article, it is worth mentioning simply for the recognition that assisted reproductive technology is continually refined and expanded.) Furthermore, because a woman, such as Alex, could have a healthy[13] uterus and have miscarried a fetus that had "no sign of genetic defect,"[14] making her an ostensibly promising IVF candidate, she might still have an unexplained reason for her infertility[15] that renders the retrieval portion of IVF applicable to her, and the implantation portion applicable to a surrogate. Thus, gestational surrogacy allows the intended parent to be the biological parent, while the surrogate has no genetic link to the baby.

This article explores the relationship between surrogate and intended parents, informed consent, surrogates' altruism narrative, and the debated right to procreate.

Intended parents are the parents for whom the surrogate is carrying the baby. Such parents might be homosexual or heterosexual, married or unmarried, a couple or an individual, and either the biological or adoptive parents of the baby.[16] Alex was the heterosexual, married, biological intended parent of the baby her surrogate carried for her. Informed consent, defined by the American Medical Association as "a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention,"[17] requires full disclosure by the physician about risks and benefits of, and alternatives to, the proposed treatment in order to protect "[the] patient's right to self-determination, bodily integrity, and…his or her voluntariness in the health care decisionmaking process."[18] Finally, the surrogate's altruism narrative is a rather complex mode of discussion in which the surrogate emphasizes her desire to help others rather than benefit monetarily from the service. Due to a long history of aversion to baby-selling,[19] our cultural rhetoric surrounding surrogacy is couched in philanthropic diction, with references to finances conspicuously absent. However, as Alex's story starkly demonstrates, finances—and, specifically, financial disparities—continue to fuel surrogacy arrangements between intended parents and previously unknown surrogates.

III. Current Perspectives on Surrogacy

A. American Culture's Reception and Interpretation of Surrogacy since *Baby M*

The landmark *Baby M* case centered on a traditional-surrogacy contract that Mrs. Whitehead, the carrier—and biological mother—wanted to violate by maintaining custody of the baby.[20] The contract provided that Mrs. Whitehead would surrender her parental rights upon the baby's birth and that the Sterns, the intended parents, would become the baby's legal parents,[21] with Mrs. Stern adopting the baby.[22] Mrs. Whitehead's biological connection to the baby was the dominant impetus in her quest to keep the baby: "She talked about how the baby looked like her other daughter, and made it clear that she was experiencing great difficulty with the decision."[23]

The trial court, using a "best interests of the child" standard, concluded that custody with the Sterns was preferable to custody with the Whiteheads and upheld the terms of the contract.[24] However, the Supreme Court of New Jersey invalidated the contract, basing its reasoning on the contract's divergence from both state statutes and public policies.[25] The court found the use of money for the purpose of adoption "illegal and perhaps criminal" and the biological mother's pre-birth and pre-conception contractual commitment to surrender the baby coercive.[26] Equally objectionable, the court found, was the biological mother's agreement not to contest proceedings to terminate her parental rights.[27]

Baby M reignited debate concerning procreative liberties within the penumbra[28] of privacy rights derived from the Due Process Clause of the Fourteenth Amendment.[29] While "[s]urrogacy proponents argue that contractual agreements that enable couples to procreate should be a constitutionally protected liberty under the [F]ourteenth [A]mendment,"[30] the Supreme Court has "never recognized a right to procreate via contract."[31] Thus, debate since *Baby M* has found proponents of surrogacy contracts asserting their "logical extension of procreative liberty" deserving protection under the *Griswold-Roe* rationale,[32] and opponents emphasizing such contracts' "inherent enforceability difficulties because of public policy considerations."[33]

Indeed, the New York legislature did address this debate, after the New York State Task Force on Life and the Law, in direct response to *Baby M*, recommended that all surrogacy contracts, including gestational surrogacy contracts, be void and unenforceable.[34] The conclusion was that "the practice could not be distinguished from the sale of children and placed children at significant risk of harm."[35] The resulting law in New York, NY Domestic Relations Law Article 8, "declare[d] all surrogate parenting contracts 'contrary to the public policy of this state'…[and] prohibit[ed] the payment of fees other than reasonable medical expenses incurred because of pregnancy and childbirth and fees to individuals who 'act as brokers for the arrangements.'"[36] The law provided that enforcement would range from civil penalties for first-time violations by the surrogate carrier, her spouse, and/or the genetic parent(s), to conviction of a felony for repeat violation (e.g., for paying a prohibited fee more than once). Implications of this law are New York's flat prohibition of both genetic and gestational surrogacy, and its classification of repeat offenders as felons (after having imposed substantial civil penalties).[37]

During and immediately after *Baby M*, concern[38] about litigation between surrogates and intended parents flared. For example, scholarly commentary on the case prior to the New Jersey Supreme Court's ruling included the assertion that "surrogacy should be permitted to infertile couples *only* if conducted for altruistic purposes."[39] This concern has declined: "[T]he politics and social meaning of surrogacy have slowly changed, and the alarm and hostility have diminished substantially," allowing for "[a]n alternative framework…in which altruistic surrogates (contractually bound and compensated nonetheless) provide the 'gift of life' to deserving couples."[40] As will be discussed below, this narrative of altruism is itself a double-edged sword; but for now, we can recognize a swift cultural shift away from fear of legislation against surrogacy agreements and toward a more open-ended discussion that—although in need of legislative change to reflect society's new perspective—allows for a more nuanced understanding of the relationships among surrogates, intended parents, and the babies born via surrogacy.

The reframing of surrogacy expanded concerns from solely coercion of the surrogate and corruption and degradation of procreation to women's autonomy (with respect to both surrogates and intended mothers) and services protected by contract. Thus, the current surrogacy debate centers primarily on the balancing of women's autonomy against their need for protection from abuse. However, both of these analytic strains concern women's protection—the former from paternalistic and overcompensating protection,[41] and the latter from the very real threat of coercion.

Another related strain of the surrogacy discussion centers on the right to contract—itself an outgrowth of individual autonomy. While scholarly commentators have explored whether to evaluate surrogacy within the family law or contract law context, they nearly universally determine that the latter is preferable.[42] Because "[j]udicial resolution pursuant to family law standards seeks to safeguard the fetus by settling disputes in accordance with the best interest of the child,"[43] presumptions made under such standards "come at the expense of women's autonomy and freedom to contract."[44] One recommendation is that New York "amend its Domestic Relations Law and combine aspects of other states' laws to allow for, and enforce, gestational surrogacy contracts."[45] While this particular recommendation aims to protect intended parents, those looking to protect surrogates include the same goal of contract enforcement: "Acknowledging the legal validity of contracts that are consistent with the surrogate's interests advances the notion that women are competent to act as rational agents with regard to their reproductive capacities."[46]

Beyond the recognition of a general right to contract, women in particular are seen now, as opposed to during *Baby M*, as empowered by contract, a choice emblematic of individual autonomy and self-determination. Just as "[f]eminist advancements allowed women to pursue opportunities which caused them to postpone childbearing and suffer age-related declines in fertility," so, too, have they "provide[d] the basis for the argument that women must be empowered to retain control over their own bodies."[47] The frequently unaligned trajectories of biology and career demand a greater acceptance of women's need to approach procreation more creatively.[48] In turn, the suggestion is that women who are able to carry a child for those who cannot should be permitted to do so as an exercise of autonomy.

Perhaps paradoxically, the proliferation of literature concerning potential and actual problems suffered by surrogates indicates a wider acceptance of the practice. Such literature essentially acknowledges that surrogate agreements will be made and alerts us to potential dangers that must be systematically eradicated. Somewhat analogous to other medical and scientific advancements, as "technology has made [surrogacies] safer and more likely to succeed,"[49] our country has witnessed an increase in the number of surrogacies and in society's implicit acceptance of the practice. Indeed, once the practice was more culturally accepted, explorations of surrogates' actual experiences have been made possible in an effort to reveal and diminish their psychological, physical, and interpersonal problems associated with surrogacy. Furthermore, "[a]lthough regulatory legislation arguably legitimizes the practice of surrogacy, it is necessary to protect more fully the interests of the parties and to inject greater predictability into the process."[50] Therefore, a wider cultural acceptance—even that which is revealed incongruously through criticism—of surrogacy, along with some states' updated regulatory legislation, demands further scrutiny of the many facets of the surrogates' experience so as to render the process healthier and more uniformly understood. However, many concerns linger and even fester in American society.

B. The New Normal: Societal Reflections on Procreation

While society is generally more accepting of surrogacy (see *supra*, "American Culture's Reception and Interpretation of Surrogacy since *Baby M*"), many remain uneasy with it. Indeed, the Comments and subsequent Letters section relating to Alex Kuczynski's article reveal mixed feelings inspired in Alex's readers. One commenter jumps to Alex's defense, wondering whether the comments would be as "scathing" had "the author been, say, a woman who had survived cancer yet left infertile due to chemotherapy"; furthermore, this commenter suggests that "the greatest 'failure' of the article (or the blindness caused by the assumptions, biases, and stereotypes of the readers) was not conveying the emotional turmoil of infertility."[51] However, Alex's story elicited far more outrage than support. Many readers found abhorrent Alex's unfiltered honesty concerning her and her husband's seemingly bottomless wealth, which allowed the couple the freedom to try IVF eleven times. Then, of course, the couple's surrogacy—a process that included hiring a lawyer, retrieving and fertilizing Alex's eggs, transferring the embryo into the surrogate, and a $25,000 fee to the surrogate—proved costlier than most individuals or couples could afford.[52] However, what readers reacted to most viscerally was Alex's rather brazen depiction of her "exploit[ing] [her] last few months of nonmotherhood by white-water rafting down Level 10 rapids on the Colorado River, racing down a mountain at 60 miles per hour at ski-racing camp, drinking bourbon and going to the Super Bowl."[53] While it might appear to some readers that these actions, and Alex's deliberate commitment of them to paper, represent her overcompensation for feelings of inadequacy and deprivation due to her inability to carry a baby to term, other readers deplored Alex's starkly unmaternal—perhaps even unwomanly, as will be discussed—approach to the time of her baby's gestation. For example, one reader sent a letter that expressed her "revulsion" aroused by Alex's story and specifically at her having paid another woman to have her baby when there are "so

many children who cannot find homes"; this reader even asserted that the baby is the surrogate's, not Alex's.[54]

Some readers' wariness and disapproval of Alex's pursuance of surrogacy even led them to view Alex as a masculine onlooker to a real woman's pregnancy. Stirred by the article's very title and by Alex's stark assertion that her surrogate was "[s]trictly speaking…a vessel, the carrier, the biological baby sitter, for [her] baby," one reader finds "the author as the stand-in life-force impregnator, situated outside the nine-month process of creating a child but claiming responsibility for and complete ownership of the result."[55] This comment invites discussion beyond the confines of this article concerning gender identity, especially in light of the same reader's allusion to "Aristotle's view that a woman is a receptacle for the life force implanted by a man through intercourse."[56]

Within the purview of this article, Alex's readers embody this cultural struggle to comprehend, accept, and adapt to a woman's role within what might be termed the "new normal": family structures that veer away from the traditional one containing two married heterosexual parents and 2.5 children[57] welcomed into the family by more varied means. We must recall that Alex was 39 years old when she first thought of gestational surrogacy and lunged toward it. She thus found herself in a dual crossroads: One was personal, as she struggled against her own biology to reconcile booming professional success with elusive fertility. The other crossroads was cultural, as she, perhaps inadvertently, found herself epitomizing a conundrum arguably born of feminism: the pressure on women to "lean in"—to take the greatest advantage of career-building years before fulfilling the goal of womanhood itself, baby-making—simultaneously encourages professional achievement and neglects to adequately advise women on how best to incorporate motherhood.

The "lean in" jargon, coined by Sheryl Sandberg in her 2013 book, *Lean In: Women, Work, and the Will to Lead*,[58] is offered to young female professionals to encourage them to achieve the greatest possible professional success—to "aspire to leadership"[59]—before engaging in maternal duties. This jargon attempts to respond to the inadvertent pressure, derived from feminism's call for workforce equality, on women to "have it all" by raising a family while climbing the corporate ladder. While strong encouragement of women's efforts to rise to the top of the workforce is welcome—especially in a country in which women make 77 cents for every dollar a man makes[60]—Sandberg's advice is "at best half a loaf."[61] With the "maternal wall"[62] rearing itself in the middle of a typical professional's career trajectory, and with slow progress at workplaces to accommodate motherhood, most women are still faced with a difficult choice—made consciously or unwittingly, the latter due to natural career development inertia—between young motherhood and solid professional success. Many choose the latter and find themselves, like Alex, struggling to have children in their mid- to late-thirties when their chances of becoming pregnant have declined significantly.[63]

So, is surrogacy becoming a "new normal"?[64] Certainly parenthood—and, particularly, motherhood—remains front-and-center in our society's ongoing conversation about and struggle with achieving normalcy. In addition to the television show "The New Normal," seemingly countless shows and movies center on the familial structure and parental problems in particular.[65] With respect specifically to mothers, a new genre is emerging: the "momance."[66] While "[t]he decision to have—or not have—children has been a perennial obsession that blooms in a thousand blog posts and talk show debates every time science pushes a new boundary or The New England Journal of Medicine prompts a new scare,"[67] the modern "24-hour tabloid culture,"[68] including exposure to celebrity older mothers and gay adoptions, is "in vogue and in the news."[69] Indeed, "[t]he topic doesn't grow old, mothers do."[70] The topic of fertility, or lack thereof, has become culturally normalized—perhaps because of medicine's expansion to include viable solutions to infertility, at least for those who can afford them. Societal interest in—even fascination with—so-called alternative family structures has resulted in a natural progression toward greater acceptance of difference and the needs for reproductive assistance that accompany it.

Even the traditional family structure is frequently redefined. While women continue to be bombarded by images touting the joys of motherhood, they struggle to determine whether and how best to approach this phase in their lives. This often-wrenching dichotomy of societal opinions and pressures and personal decision-making is embodied by the physical juxtaposition of a Johnson & Johnson advertisement with the online iteration of a *New York Times Magazine* article[71] penned by the author of the book *Perfect Madness: Motherhood in the Age of Anxiety*.[72] The ad asserted, "Love is the Most Powerful Thing on the Planet: Enjoy and Share Caring Stories Now," depicting simply an adult hand holding a baby's hand. The article, meanwhile, explored the difficulties mothers experience trying to reinsert themselves into the workforce after having voluntarily removed themselves a decade prior to serve as stay-at-home moms. While money was at issue for some women, especially due to the recession, which occurred after their decisions to "opt out" of the workforce, the more pervasive problem was one of self-identity: "what haunted many of them, as they reckoned with the past 10 years of their lives, was a more unquantifiable sense of personal change."[73]

While none of the women interviewed for the *New York Times Magazine* article voiced regrets about having had children when they did, most encountered extreme difficulty reclaiming their intellectual selves after having devoted a decade to children-oriented obligations. These women embody a post-recession recognition that things just don't always go as planned—career, family, or the

combination thereof—and there needs to be a softer place for them to fall should they need help. Young women today find themselves surrounded by "lean in" advice and admonitions of women who opted out. But in our choose-your-own-adventure, American-dream cocktail, how are they to know and pursue the best route to personal and professional success? Is Alex Kuczynski, who chose never to abandon her successful career but wait to have her baby, a more accurate depiction of a woman "having it all," and, if so, why doesn't the New York legislature support such a vision of success?

IV. The Surrogate's Experience

A. The Altruism Narrative of Surrogates

"It is an act of love, but also a financial transaction, that brings people together like this."[74] Surrogacy necessarily involves selflessness and a sacrificial inclination on the part of the surrogate, but must also confront the issue of monetary compensation. Indeed, compensation is crucial for surrogates' sense of fairness and ability to contribute financially to their own families. While many, if not all, surrogates do cite the desire to help others as a driving force to act as surrogate, our cultural narrative of pure altruism has become "one of the most effective blocks to women's self-awareness and demand for self-determination"[75] by silencing surrogates' other, equally valid concerns. One danger of continuing to view surrogacy through the lens of altruism is surrogacy agencies' "exploit[ing] this perception in their online material by reassuring prospective parents of the surrogates' willingness to participate ('You will soon have that beautiful bundle of joy safe and sound at home!') as well as making reference to surrogates' feelings of altruism."[76] Tangentially, a persistent "social devaluation" of childless women—especially those who are childless by choice—renders such agencies' offer of hope coercive.[77] A delicate balance in the regulation of payment must respond to concerns about commodification of "individual characteristics such as weight, race, health, and diet"[78] and about the commercialization of the process, and also to the potential for the surrogate's exploitation.

This is not to say that altruism does not play a fundamental role in the surrogacy process. One surrogate stated that "[b]eing a surrogate is like giving an organ transplant to someone…only before you die, and you actually get to see their joy."[79] Surrogates can feel that the "sense of empowerment and self-worth is one of the greatest rewards surrogate mothers experience."[80] They might enjoy the actual experience of pregnancy—"the natural high that comes from 'all those rushing hormones'"[81]—while being free from the commitment to another person upon his or her birth. The knowledge that one is "doing something good for somebody else"[82] might be a driving force. Military wives, a demographic in which many surrogates can be found, might be so influenced by their spouses' particular risks as to take their own; as one such wife stated, "I think that being married to someone in the military embeds those values [going to extremes, fighting for your country, risking your life] in you. I feel I'm taking a risk now, in less of a way than he is, but still a risk with my life and body to help someone."[83]

What is difficult to read between these lines of benevolence is many surrogates' coercion into proclaiming such altruistic sentiments at their own expense. Indeed, "surrogates often express their motivations in what Ragone refers to as a 'scripted' manner to reflect culturally accepted ideals of motherhood, female reproduction, and family."[84] A general cultural, and specifically feminist, concern that women not be commodified or babies sold has resulted in surrogates' insistence, often to their own autonomy's detriment, that they have little to no monetary interest when agreeing to serve as surrogates. They thereby lose the ability to contract honestly and fairly.

With the understanding that the adoption of an altruistic model of motivation necessarily weakens and even threatens surrogates, one must determine how best to broach regulation of payment. While it might seem obvious that "[to deny women payment for their labor] is an unfair denial of the valuable service that a surrogate provides as well as the risks she faced when she bears a child,"[85] the issue of regulation is not so clear-cut:

> On the one hand, not to regulate compensation is inappropriate because it will likely lead to increased commercialization of the process. But, to allow unlimited compensation would make surrogacy even more inaccessible to the non-wealthy than it already is and exacerbate concerns about surrogacy's exploitative potential.[86]

Furthermore, assigning a monetary value to one's "willingness to engage in procedures such as prenatal testing, termination, multifetal pregnancy reduction (MFPR) or selective reduction"[87] arouses ethical concern. Therefore, policy changes must reflect the need for surrogate payment and protection from exploitation. It has been argued that such policy should err on the side of payment: "[e]ven if the surrogate is vulnerable to some exploitation, respect for her autonomy means not wholly removing paid surrogacy as one of her options."[88] Indeed, one recommendation is that while New York should follow Washington State's lead in implementing provisions that "defin[e] compensation as any payment of money 'except payment of expenses incurred as a result of the pregnancy,'" there are "some circumstances [in which] fees in addition to medical expenses are appropriate."[89] A more nuanced approach to codifying compensation for surrogacy would greatly enhance the process for everyone involved.

B. Informed Consent

If, as has been recommended,[90] surrogacy contracts are to be considered permissible and enforceable, such policy must consider how best to ensure surrogates' informed consent. The issue of informed consent pervades literature on surrogacy; some obvious issues in this arena should be addressed if new policy is to be successful and enduring.

One specific example of surrogates' inadequate comprehension of the surrogacy process can be found within the military wives demographic. One surrogate interviewed in an article for *The Daily Beast* reported her devastation upon giving up a baby, saying "she thinks things would have been different had she been counseled more by the agency on attachment issues."[91] Because the operation was "small and less than professional (and there are plenty of those in the unregulated world of surrogacy agencies),"[92] this surrogate suffered psychological repercussions that could have been avoided. Military wives are, one might argue, particularly baited by fertility agencies that "may offer a potential surrogate with [Tricare health insurance, which has some of the most comprehensive coverage for surrogates in the industry] an extra $5,000."[93] Such agencies' aggressive, cash-laden approach to attractive surrogate candidates understandably piques such candidates' interest: the husbands earn very little,[94] and the wives want to contribute to the family funds, too. As mentioned above (see *supra*, "The Altruism Narrative of Surrogates"), such payment helps surrogates contribute financially to their own families; indeed, because surrogates are universally required to have had a baby prior to engaging in surrogacy, they inextricably have at least one other person for whom to provide. This need, coupled with surrogates' natural desire to share the provider role with their husbands, renders military wives especially vulnerable to the arguably predatory approach of surrogacy agencies.

The combination of coercion and lack of adequate information prior to consent indicates the need for regulation of surrogacy agreements: these agreements, if adopted, should cap the amount of non-medical compensation to avoid coercion. Furthermore, they should indicate procedures prior to agreement so that potential surrogates can fully understand the transaction and emotions that accompany it. If surrogacy agreements remain unregulated in New York, they will clearly continue to be made—as Alex's story demonstrates—but will lack the protections for both the intended parents and the surrogates: the intended parents won't have legal recourse if the surrogate tries to keep the baby (a rare but real possibility),[95] and the surrogate won't be protected against repercussions from a lack of informed consent or the equally rare, yet possible, rejection of the child by the intended parents. Finally, and most importantly, the children born from surrogacy won't be protected should any conflict arise between the surrogate and the intended parents.

Some suggestions have been made as to how best to regulate surrogacy contracts. One involves a "soft law" approach that would require potential surrogates to participate in a "short class on contract pregnancy."[96] Analogous to getting a driver's license prior to driving or a medical license prior to practicing, taking such a class would be a prerequisite for serving as a contract surrogate. This soft law approach to paid surrogacy "can address the vulnerability arguments…while guarding a woman's reproductive freedom."[97] An assertion concerning the regulation of the contract itself is that "[a] surrogate-focused contract model would shift the balance of power during negotiations and preclude the appearance of involuntary servitude."[98] Indeed, the same article states that "[in] the absence of legislation delineating the rights and obligations of the contracting parties, the foremost consideration should be protection of the party most vulnerable to exploitation—the surrogate."[99] With respect to New York specifically, it has been suggested that New York courts should monitor surrogacy contracts to "ensure the parties understand what they are agreeing to,"[100] and that the legislature should include a provision "requiring the surrogacy contract to specify child custody in the event of a 'change of circumstances' and to state the responsibilities of the parties to the contract."[101]

Indeed, most literature post-*Baby M* seems to have shifted the focus from the rare possibility of surrogate misbehavior (e.g., trying to keep the baby) and toward surrogates' general vulnerability; such literature emphasizes the need to consider the surrogates' position first so that they don't become ensnared in a potentially damaging or exploitative contract with the intended parents.

C. Surrogates' Psychological and Physical Experience

A better understanding of what surrogates endure can reveal the need for more protective legislative provisions for surrogacy contracts. Perhaps due, at least in part, to the aforementioned altruism narrative of surrogates, "[v]ery little is understood about the world of the surrogate."[102]

i. Surrogates' Relationship with Intended Parents

The relationship between surrogates and intended parents is necessarily a delicate one, but one that can be mutually rewarding. Indeed, one study examining this relationship ten years after the baby's birth revealed that although frequency of contact decreased over time, the majority of intended parents who did remain in contact with their surrogates "reported…harmonious relationship[s] with [them]."[103]

Such a positive report notwithstanding, better and more in-depth preparation for the relationship with the

intended parents would likely render the surrogate's experience more emotionally manageable. Indeed, "pre- and post-birth experiences, relationship with the contracting couple, and whether expectations about surrogacy are met are important influences on the surrogate mothers' level of satisfaction."[104] As confirmed by several studies, "the surrogate mother generally forms a relationship with the couple rather than the child,"[105] and so it is the sudden deprivation of that relationship—and generally not the baby itself—that can cause a sort of postpartum depression in the surrogate. Ultimately, "it is the quality of the relationship with the couple that largely determines the surrogate mother's satisfaction with her experience"[106] and that informs a surrogate's decision whether to act as a surrogate again.[107]

Notably, "as contact with the couple begins to taper off, [some surrogates] become increasingly dissatisfied with the surrogacy arrangement"[108]; it appears that while intended parents might view the arrangement as the time period between the agreement is made and the baby is given to them, at least some surrogates have expectations of a longer friendship that lasts significantly beyond the birth. Because some couples will choose not to extend their relationship with their surrogate beyond the baby's birth, and because "[c]ouple interaction with the surrogate immediately post birth appears important,"[109] both the intended parents and the surrogate should be counseled in how best to approach their relationship—or lack thereof—following the birth.

ii. Surrogates' Physical Experience

Surrogates risk not only complications associated with all pregnancies, but also unique dangers that emerge within the surrogacy process. The risks are not identical for all surrogates, since such risks vary depending on "the health and age of the woman serving as a surrogate, the type of surrogacy (gestational or traditional), what hormones or drugs the surrogate is instructed to take, how many IVF or AI cycles a surrogate undergoes before reaching a successful pregnancy, the number of embryos implanted, the age of the woman providing her eggs, whether the eggs and/or embryos are frozen or fresh, whether the individuals providing gamete material have any infectious diseases."[110] Furthermore, because "the medical risk begins before the intended parents have even agreed to hire the surrogate,"[111] a surrogate might easily receive no compensation for at least some physical and emotional discomfort or even anguish.

This pre-agreement risk-taking involves agencies' invasive screening process comprised of both physical tests and the provision of a "highly personal"[112] medical and sexual history. This screening process risks violating surrogates' right to privacy and confidentiality by requesting "the names of several references with whom the surrogate's intention [is] discussed."[113] Potential gestational surrogates endure even more than do traditional surrogates, often being required to undergo a hysterosonogram or hysterosalpinogram, or both, which investigate uterine health prior to embryo implantation.[114] Risks associated with these tests—beyond pain and discomfort, which can include cramping, bleeding, dizziness, nausea, or vomiting—include bacterial infections, bleeding, cervical and other trauma, allergic reactions, fainting, and radiation exposure.[115] Even the mildest potential side effects, such as fainting, infection, and allergic reaction can, in rare circumstances, lead to major surgery and tissue loss.[116]

Intended parents' potential desire to cut costs might motivate them to choose "low-quality medical facilities, where the risks are greater."[117] Furthermore, multiple pregnancies common to surrogacy augment the risk associated with any pregnancy.[118] Finally, contractual provisions mandating surrogates' strict adherence to "certain risky medical protocols that enhance the probability of a birth, such as fertility treatment and multiple embryo transfer," as well as the "unfavorable allocation of financial burden in the event of a medical emergency during pregnancy," render surrogate pregnancy radically more hazardous than typical pregnancy.[119]

iii. Surrogates' Psychological Experience

Perhaps the most complex element of the surrogacy experience is the psychological one: how well are potential surrogates prepared to engage in surrogacy, and how do they feel after giving the baby to the intended parents? We see the altruism narrative emerge as a socially accepted explanation for the surrogate's sacrifice[120]—but as we have seen above, adhering to this narrative prevents us from fully understanding who the surrogate is and what she endures. Furthermore, "[s]mall, non-representative samples; lack of control groups; and ambiguous or flawed comparisons with test norms make it difficult to reach any conclusions about the personal traits of women who become surrogate mothers."[121]

What has been uncovered is that "the majority of surrogates felt well informed about the practical and medical aspects of surrogacy, but knowledge of the legal, psychological and social aspects was not good."[122] Furthermore, so-called traditional surrogates' grasp of their own perception of genetic importance is not universally strong. For example, while one surrogate in a study expressed her "emotional discomfort with the…'child which is half mine walking around somewhere,'"[123] generally "the surrogate de-emphasizes her biogenetic tie to the child."[124] Again, this is emblematic of inadequate informed-consent efforts and follow-up care after the birth within the intangible realm of emotional and psychological response to the surrogacy process.[125] While this particular issue—traditional surrogates' inconsistent perceptions of biological importance—is essentially moot due to the modern penchant for gestational surrogacy, it serves as a not-too-

distant reminder that, generally, surrogates remain at a distinct informational disadvantage when compared to intended parents, who educate themselves thoroughly during the often drawn-out period of their infertility discovery.

Indeed, research has indicated that, in addition to a positive relationship with the intended parents, as discussed above, "[surrogates'] satisfaction was increased due to access to competent professionals who helped guide them through the process and deal with emotional issues and any problems that arose."[126] Moreover, because of intended parents' noted "awkwardness of maintaining contact with the surrogate"[127] after the birth, surrogates' need for continued professional therapy seems especially crucial. Even though this need for continued therapeutic help is not universal among surrogates,[128] it seems that the safer approach is to provide it to all surrogates and allow them to decide whether to avail themselves of it.

V. The Intended Parents' Experience

A. The Debated Right to Procreate

Was Alex Kuczynski exercising an intuitive or even a constitutional right to procreate when she enlisted the help of—and contracted with—her surrogate? Regardless of the answer to this question—if such an answer can ever be conclusively arrived at—another, arguably more important, question arises: once someone procreates, what duties do parents, and even society, owe to the offspring?

The debate surrounding the right to procreate, and its converse right *not* to procreate, has been a perpetually divisive one in the United States. The line of Supreme Court cases starting with *Roe v. Wade* embodied a relatively recent history of abortion legislation (prior to 1821, English common law controlled the realm of abortion[129]). The Court's focus on the Fourteenth Amendment's right to privacy would sharpen in subsequent cases involving abortion and contraception, such as *Eisenstadt v. Baird* and *Planned Parenthood v. Casey*, in which liberty was also cited as encompassing "the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life."[130] Indeed, it is these dual concerns about privacy and liberty, and their inextricable link to individuals' notions of selfhood and meaningfulness, that drive the parallel debates surrounding abortion and the right to procreate.

Many of the comments to Alex's *New York Times* article questioned her dedication to biological procreation, suffering eleven rounds of IVF and, finally, surrogacy instead of adopting one of many children in need. Carson Strong, author of *Ethics in Reproductive and Perinatal Medicine: A New Framework*,[131] offers many compelling reasons for biological reproduction that shed light on the desperation many people (both men and women) can feel in the search for self-realization. The perhaps unwitting desire to create an entity with a self-consciousness of its own motivates some to engage in procreation.[132] A more commonly recognized motivation for biological procreation is the strengthening of a partner relationship by means of the partners' genetic fusion.[133] Still another force fueling the urge to reproduce is the desire for a genetic link to the future, which in turn could secure one's legacy.[134] Finally, the experiences of pregnancy, childbirth, and/or child rearing impel many to attempt biological reproduction.[135]

Alex made clear her desire to manifest her marital love in the form of a biological baby. Indeed, she focused on "motherhood as the natural outgrowth of a loving relationship,"[136] asserting that she had never thought of "raising a child as a goal in itself."[137] Still, because Alex did not carry her baby in pregnancy or give birth to him, she was haunted by the questions, "Would I really be his mother? Was the key to motherhood carrying the baby?"[138] She "worried that [she] was missing out on some great and essential preparation,"[139] wondering what it meant to not have this experience and whether "a genetic connection [was] enough[.]"[140] Was Alex's thinking in accordance with Kantian ethics, which would admonish against treating a baby, or even the idea of a future biological child, as anything but an end in itself? Arguably, not. However, it seems nearly impossible to choose surrogacy and comply with Kantian ethics, especially in a country in which far too many children live precariously in foster care.[141] With respect to children engendered by means of surrogacy, the risk threatens their landing in the foster-care system in states that are silent on the issue of surrogacy, and of their suffering "in limbo"[142] perhaps even until they reach the age of 18.

However, since surrogacy will inevitably continue—as Alex demonstrates in her contracting with a Pennsylvania-based surrogate despite New York's lack of surrogacy recognition[143]—especially as medical science improves, states' active recognition of surrogacy agreements can be enormously beneficial to the children. Indeed, while perhaps people lack a fundamental *right* to reproduce by means of surrogacy (discussed below), "other important concepts in moral discourse, including harms, benefits, responsibilities, virtues, and features of human relationships such as caring and fidelity"[144] should guide us in determining how best to protect the most innocent parties to surrogacy: the children.

Fundamentally, the question remains: regardless of the foster care situation, or any other concerns surrounding the decision to procreate, did Alex have the *right* to procreate? The notion of a right to procreate is intrinsically problematic: if we do, in fact, have such a right, where lies the corresponding duty to help us achieve procreation? Or, is this a negative right—i.e., one that demands simply a lack of interference, rather than active help, as with a positive right?[145] It seems most likely that

a right to procreate, if one exists, is a negative one, requiring no direct, positive help from others but, instead, non-interference. Indeed, if we return to the parallel abortion-rights debate, the argument presented in the *Roe v. Wade* line of cases is not that any given individual has a duty to provide an abortion to a woman seeking one, but that the decision to have an abortion should be legal and made by the woman and an individual who is willing to provide the abortion. Thus, it can be argued that individuals have the right to *try* to procreate biologically, but that they do not have the right to actually successfully reproduce. This is what was reflected in *Skinner v. Oklahoma* (see *supra*, note 48), which essentially concludes that one's physical potential for procreation cannot be taken away against one's will. Thus, *Skinner* asserts the negative right to be allowed to attempt procreation, but not the positive right to become a biological parent.

Of importance is what constitutes a negative right. If one applies a Kantian framework, one recognizes a negative right as one that, when violated by interference, affects an individual's treatment as an end in herself.[146] As discussed above and further by Strong, the quest for self-realization and self-identity can be manifested in biological procreation. It follows that interference with biological procreation can rupture individuals' sense of self and amount to disrespect for a person as an end in herself.[147] Indeed, psychological reactions to infertility can be enormously burdensome: "It is typical for infertile couples to experience a grief response involving one or more features, including shock, denial, anger, guilt, and depression."[148] Furthermore, couples might retreat from normal social interaction in order to avoid others' probing questions about their inability to conceive, and to avoid glimpses at others' growing families. Alex harbored an acute self-awareness of this "self-enforced secrecy of the infertile,"[149] consciously rejecting this approach in a perhaps unusual über-public account of her own battle with infertility. Individuals might fear resentment and even abandonment by their partners, and sink into a depression laced with feelings of inferiority.[150]

Ultimately, it appears clear that while one lacks an absolute right to reproduce, one maintains the right of noninterference with one's attempts at procreation. If sexual intercourse fails to result in a viable pregnancy, or if a couple is homosexual and simply cannot reproduce without medical intervention of some sort, or if an individual wants to become a single parent, the couple or individual must be allowed to seek medical intervention if it is desired. While Alex might have been shunned by many readers due to her ostentatious account of her seemingly endless financial capacity for multiple rounds of IVF followed by surrogacy, she nevertheless was merely exercising the right to use her money in this way. She broke no laws—choosing to contract out of state in order to skirt New York's lack of recognition and enforcement of surrogacy—and was working to fulfill a more complete sense of self by means of biological procreation.

B. Full Faith and Credit

It bears repeating that Alex acted within the law with her surrogacy arrangement: although a New York resident, she was able to find a suitable surrogate in Pennsylvania, where the baby was ultimately born. Alex was then able to bring the baby home to New York, where her and her husband's legal parentage would remain recognized, despite the baby's Pennsylvania birth. This recognition is legally codified in the U.S. Code in Title 28, Part V, Chapter 115, Section 1738A, which explains how full faith and credit is given to child custody determinations. There is comity for custody determinations (with limited modification exceptions),[151] which means that when an individual is found to be the legal parent of a baby in one state, all of the other states must recognize that legal parentage.

While this might seem rather obvious to a casually interested citizen, this comity provision has wide-ranging implications in the rare event that a surrogate brings a custody suit against the intended parents. The crucial definition in this statute is that of "home State," which "means the State in which, immediately preceding the time involved, the child lived with his parents, a parent, or a person acting as parent, for at least six consecutive months, and in the case of a child less than six months old, the State in which the child lived from birth with any of such persons."[152] In states that recognize surrogacy contracts, when questions of parentage arise, the court will likely look at the parties' intentions as indicated in the contract; the likely result, therefore, will be to enforce the contract and maintain the intended parents' legal parentage and custody.

This is precisely what happened in *In re Doe*,[153] which involved the determination of whether certain individuals engendered by gestational surrogacy could be beneficiaries of a trust established by a family member who specified that no adopted children could do so.[154] After finding that the settlor did not intend to exclude children born to a surrogate,[155] the New York Surrogate's Court explored the issue of parentage, ultimately giving full faith and credit to California's judgment that the intended parents were, in fact, the children's parents. The Court stated:

> It is clear that in California the twins were not adopted, and recognizing this result in New York is appropriate.… [I]n gestational surrogacies, as here where the birth mother is implanted with a fertilized ovum genetically unrelated to her the basic question of who should be considered the natural mother must be answered in light of the advanced technologies that permit such a procedure. In *Johnson*, California developed an analysis that has become known as the intent test: those who intended to be parents, absent other compelling circumstances, should

> be considered the parents. Applying that test, the *Johnson* court declared the genetic mother, who intended from the beginning to be the mother, instead of the gestational surrogate mother, to be the natural mother.… New York also has a separate article, article 8 (§§ 120-124) of the Domestic Relations Law, dealing with surrogate parenting. Unlike California, it forbids recognition of surrogate parenting contracts, and considers them void and unenforceable. Nonetheless, New York courts entertain petitions for declarations of maternity, and do not require parents to go through an adoption proceeding in cases of in vitro fertilization and gestational surrogacy agreements.… Finally, no reasoning justifies a denial of full faith and credit to the California judgment. Where a judgment of a sister state is issued with jurisdiction of all parties, New York must afford it full faith and credit.… Although New York forbids enforcement of surrogacy contracts, the enforcement of the contract is not at issue here. More importantly, the legislature did not punish or prejudice the rights of children born from such arrangements. Instead, the statutory scheme explicitly contemplates full and fair proceedings to determine 'parental rights, status and obligations' (Domestic Relations Law § 124).[156]

Therefore, when another state has engaged in an intention-based analysis of parentage and has issued a judgment thereon, New York will recognize and honor that judgment, giving it full faith and credit. The implications of this comity and granting of full faith and credit are substantial: intended parents like Alex and her husband can legally contract out of state with a surrogate (who then gives birth to the baby out of state), and thereby acquire legal parentage in states that recognize surrogacy agreements; then such intended parents—and newly legal parents—can return with the baby to New York and be recognized legally as the baby's parents. Ultimately, this means that New York's prior decision not to recognize or enforce surrogacy contracts has little to no effect on those New York residents who have the resources for and dedication to gestational surrogacy.

Further underscoring New York-resident genetic parents' ability to cement their legal parentage is the decision in the recent case *T.V. (Anonymous), et al. v. New York State Department of Health*.[157] This case recognized the right of a genetic mother using a gestational surrogate to have her name on the baby's birth certificate. This decision cited *Stanley v. Illinois*, in which it was stated that "[t]he rights to conceive and to raise one's children have been deemed essential, basic civil rights of man, and rights far more precious…than property rights."[158] It appears that this decision exemplifies the New York courts' likely support for, or at least inclination toward, legalizing commercial surrogacy agreements.

C. Implications of Current New York Law on Parties to New York-Based Surrogacy Agreements

Now that we can recognize New Yorkers' continuing ability to engage in surrogacy contracts without fear of losing their legally granted parental rights and custody, we should ask: what price do they pay for doing so? And what about those who still choose to engage in surrogacy agreements within the bounds of New York? We must turn our attention to the implications of New York's current lack of recognition and enforcement of surrogacy contracts for New York-resident surrogates and intended parents.

As discussed above (*supra* "Informed Consent"), surrogates are more likely to be uninformed about and financially unequipped for legal representation. Even if they can afford legal representation, New York-based surrogates are especially vulnerable to potential coercion and exploitation due to their inability to record their own intentions in a legally recognizable agreement. Ultimately, crude as the semantics are, surrogacy has a marketplace,[159] and the weakest surrogates are those who remain at a legal disadvantage without the protection of a valid contract.

A New York case that arose not long after *Baby M* found the traditional surrogate petitioning the Family Court for consent to the adoption of her baby by the intended parent.[160] These parties had written a 49-page "Surrogate Parenting Agreement" that provided that the surrogate would surrender custody of the baby in exchange for $10,000.[161] This $10,000 was in addition to pregnancy-related expenses, and the agreement specifically indicated that this fee "is in no way to be construed as a fee for termination of parental rights by [the surrogate] or a payment or exchange for a consent to surrender the child for adoption or to assist in the adoption of the child or as payment of any expenses for living or maternity care between the birth of the child and the adoption of the child by [the intended parent]."[162] The court found payments pursuant to a surrogacy contract in violation of New York law, without a constitutional protection that would override the state law;[163] ultimately, the surrogate had to swear under oath that she had not requested, accepted, or received, and would not request, accept, or receive the $10,000 in order for the court to terminate her parental rights.[164] Thus, the surrogate did not receive her promised consideration for her promise to surrender the baby to the intended parent.

This case is rather confusing: both the surrogate and the intended parent wanted the same thing—namely, for the baby to be surrendered by the former and adopted by

the latter. However, the surrogate paid a hefty price—the forced abandonment of a promised $10,000—while the intended parent, through no fault of his own, came out ahead. Indeed, this case serves as precedent for potential ill-intentioned intended parents to similarly bait and switch their New York-resident surrogates; regardless of whether any such scenario has occurred, the current New York law leaves surrogates vulnerable to agreements conducted in bad faith by intended parents.

Furthermore, although this case occurred in 1990, before gestational surrogacy became the preferred method of surrogacy, the law has not been adapted to account for scientific and societal development. As two relatively recent articles published in The Huffington Post rather passionately assert, New York has failed, thus far, to carve out a consistent, clear, legal path for gestational surrogacy.[165,166] Although New York has legalized gay marriage, gay couples (as well as single individuals and infertile heterosexual couples) must find a surrogate in a '"friendly' state"[167] and engage in the quest for biological parenthood rendered costlier than ever due to "the need to travel across state lines for medical procedures and legal representation."[168] A journalist assigned to cover the *Baby M* case asserts that "[i]t is far past time for states to pass laws that create a clear cut, irrevocable path for participants in surrogate arrangements to follow. Failure to do that is an open invitation to more and very painful legal battles. It can also create lifelong scars for the child everyone professes to love."[169]

Encouraging anything akin to baby selling would be both illegal and immoral. Equally immoral, however, is entrapment—whether inadvertent or deliberate—of an uninformed surrogate in New York through a potentially bad-faith offer of monetary compensation. Rather than flatly refuse to recognize or enforce surrogacy contracts, therefore, New York should consider a more tempered approach.

Whether such a tempered approach means requiring a judge to approve a surrogacy contract before the actual surrogacy is executed or providing a ceiling for extra-pregnancy-related monetary gifts from intended parents to surrogates, New York would be wise to protect potential surrogates by not turning a blind eye to what they reasonably believed would be their benefits. Some other states offer examples of different policies that seem to work well and that New York might emulate. For example, many states allow for a pre-birth order of parentage,[170] which helps all parties avoid post-birth custody controversy. New Hampshire serves as a pertinent example of how to fuse a liberal provision with court supervision: under this state's surrogacy statute, a court must issue such a pre-birth order "before the procedure to impregnate the surrogate."[171] However, where New Hampshire takes a problematic turn is in allowing the gestational surrogate to maintain the right to take up to 72 hours after the baby's birth to change her mind and keep the baby. New York would do well to adopt the pre-birth-order provision but not the 72-hour change-of-heart one. A small handful of states' liberal policies concerning who can procure a pre-birth order would also serve as a positive influence.[172] In those states, there are no restrictions as to who can get such an order: married couples using their own egg and sperm, married couples using a donor, unmarried couples, single parents, and same-sex couples all can procure pre-birth orders.[173]

The more open and accepting the state policy, the more protective of all parties to a surrogacy arrangement and the resulting baby. New York would do well to consider the above-mentioned policy provisions if it reevaluates its surrogacy law.

VI. Conclusion

We can see that New York should recognize and enforce surrogacy contracts to protect all parties involved. In not doing so thus far, New York—perhaps inadvertently—allows for a greater "potential for exploitation and coercion of parties to surrogate arrangements"[174] by denying parties standing to bring a contract claim. More specifically, recognition and enforcement of surrogacy contracts would help empower the weaker parties—the surrogates—who are at a distinct disadvantage: "a surrogate generally occupies an inferior bargaining position in surrogacy arrangements."[175] This is due to surrogates' relative lack of comprehension of what surrogacy entails (since intended parents have likely become well-versed in assisted reproduction technology, while the surrogates have not), and likely financial and educational inability to hire legal representation.[176] Regulation of surrogacy contracts should consider "economic compensation, access to medical treatment, psychological support, and informed consent."[177] Surrogates' access to independent counsel has been cited as crucial due to potential conflicts of interest, surrogates' relatively weak position, and the "intensely emotional nature of the process."[178]

New York's refusal to recognize or enforce surrogacy contracts is outdated: it does not align with other policy decisions adopted by New York—for example, the legalization of gay marriage—or with more universal lifestyle changes chosen by American women. New York's stance on surrogacy—a tremendous sacrifice that apparently should go uncompensated—hurts both intended parents and surrogates. Intended parents, whether infertile, single, or homosexual, suffer from being unable to exercise their right to contract with willing potential surrogates and know that the resultant contract is legally viable. Such prospective parents are also denied a protected right to procreate—specifically, the right to attempt biological procreation—by being left with essentially no legal recourse should a surrogate breach agreement terms. Surrogates, meanwhile, are left vulnerable to potentially unreliable intended parents. In New York, there is no clear legal recourse, for anyone involved, in the (rare) event

that the agreement is not abided by one party or another; all parties involved are at a stark disadvantage compared to those residing in states that do recognize and enforce surrogacy contracts. The recognition and enforcement of surrogacy contracts would allow all parties to have a clear direction for how to approach such contracts, which would, ideally, provide guidance as to monetary compensation caps, what to do in case of a medical emergency that endangers the surrogate's life, and whom to entrust care of the baby in the event of the intended parents' deaths. Most important, the children born from surrogacy would not be left at the mercy of legally questionable custody arrangements or at risk of falling between the cracks into the foster care system.

Furthermore, the legislature should consider the modern penchant for gestational, rather than traditional, surrogacy. While not its foremost goal, one result of gestational surrogacy is surrogates' more successful avoidance of a strong emotional attachment to the baby, an attachment normally fueled during pregnancy by an acute awareness of a biological connection. Therefore, any remaining fears of the *Baby M* situation, itself extremely rare and feared only during and immediately after this case, should be quelled by the knowledge that gestational surrogacy is the surrogacy mode of choice, with surrogates generally feeling that the babies are "not [theirs] to give."[179]

Beyond the legal difficulties posed by New York's current stance on surrogacy contracts, varied new—or, at least, newly accepted—lifestyle choices and biological needs run perpendicular to the solitary vision of the surrogacy-engendered family imagined by the legislature, namely, a heterosexual couple hiring a surrogate, who threatens—and perhaps wins—a fight for the baby after its birth. Today is a time of slow-forming yet true acceptance—of gay marriage and rights, of single parenthood, of parenthood begun after the typical fertile years, and of women working to achieve professional success prior to motherhood. The law should reflect and support such acceptance, but the New York surrogacy law does neither.

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46. London, *supra* note 41, at 410.

47. *Id*. at 402–403.

48. Recall that the right to procreation is constitutionally protected as seen in Skinner v. Oklahoma Ex. Rel. Williamson, 316 U.S. 535, 536 (1942) ("Oklahoma deprives certain individuals of a right which is basic to the perpetuation of a race—the right to have offspring.").

49. Lorraine Ali, *The Curious Lives of Surrogates*, The Daily Beast (in Newsweek Magazine), *available at* http://www.thedailybeast.com/newsweek/2008/03/29/the-curious-lives-of-surrogates.html, Mar. 29, 2008.

50. Brandel, *supra* note 38, at 515.

51. "AML," in Kuczynski, *supra* note 1, at Readers' Comments, #404.

52. Kuczynski, *supra* note 1.

53. *Id*.

54. Shira Saperstein, *Letters: Her Body, My Baby*, The New York Times Magazine, Letters (Dec. 14, 2008), *available at* http://www.nytimes.com/2008/12/14/magazine/14letters-t-HERBODYMYBAB_LETTERS.html?pagewanted=all.

55. Janet Benton, *Letters: Her Body, My Baby*, The New York Times Magazine, Letters (Dec. 14, 2008), *available at* http://www.nytimes.com/2008/12/14/magazine/14letters-t-HERBODYMYBAB_LETTERS.html?pagewanted=all.

56. *Id*.

57. *See, e.g.*, Misty Harris, *'Domestic Dream' of 2.5 Children Per Woman Long Gone as Fertility Rate Declines for Third Year in Row*, National Post, *available at* http://news.nationalpost.com/2013/07/09/domestic-dream-of-2-5-children-per-woman-long-gone-as-fertility-rate-declines-for-third-year-in-row/ (last visited Aug. 8, 2013) (commenting on the declining fertility rate in Canadian women).

58. Sheryl Sandberg, Lean In: Women, Work, and the Will to Lead (2013).

59. Anne-Marie Slaughter, *Yes, You Can: Sheryl Sandberg's 'Lean In*,' The New York Times (Mar. 7. 2013), *available at* http://www.nytimes.com/2013/03/10/books/review/sheryl-sandbergs-lean-in.html?pagewanted=all.

60. National Committee on Equal Pay, http://www.pay-equity.org/.

61. Slaughter, *supra* note 59.

62. *Id.*, quoting law professor Joan Williams.

63. *See, e.g.*, *How Age Affects Fertility*, FertilityFactor.com ("Statistically speaking, the changes of pregnancy for women over 30 start to decline by about 3.5% per year."), http://www.fertilityfactor.com/age_and_fertility.html.

64. *See, e.g.*, Fred Silberberg, *Is Surrogacy on Its Way to Becoming 'The New Normal'?* The Huffington Post (June 20, 2012), *available at* http://www.huffingtonpost.com/fred-silberberg/surrogacy_b_1610804.html (last visited Aug. 2, 2013).

65. Just a couple examples of television shows, in addition to "The New Normal" (NBC, 2012-2013), are "Parenthood" (NBC, 2010-2015), which follows a family's various parent-child relationships across generations and includes issues of foster care, adoption, infertility, and single-parenthood; and "Modern Family" (ABC, 2009-present), which involves different familial structures, including so-called traditional (heterosexual parents with three children) and untraditional (homosexual parents adopting a foreign baby; older man marrying a younger woman who is the mother of a young son). A small sample of relevant movies includes "The Family Stone" (2005), which involves various familial and romantic relationships, including a homosexual and interracial couple who adopt a baby; "Baby Mama" (2008), a comedy about surrogacy; and "The Back-Up Plan" (2010), which involves artificial insemination.

66. Alessandra Stanley, *Tina Fey's 'Admission' and Other Comedies Eye Maternity*, The New York Times (Mar. 15, 2013), *available at* http://www.nytimes.com/2013/03/17/movies/tina-feys-admission-and-other-comedies-eye-maternity.html?pagewanted=all&_r=1& (last visited Aug. 3, 2013).

67. *Id.*

68. *Id.*

69. *Id.*

70. *Id.*

71. Judith Warner, *The Opt-Out Generation Wants Back In*, The New York Times Magazine (Aug. 7, 2013), *available at* http://www.nytimes.com/2013/08/11/magazine/the-opt-out-generation-wants-back-in.html?pagewanted=4&_r=1&hp (last visited Aug. 8, 2013).

72. Judith Warner, Perfect Madness: Motherhood in the Age of Anxiety, Riverhead Books: New York (2005).

73. Warner, *supra* note 71, at p. 4 (online iteration).

74. Ali, *supra* note 49.

75. Brandel, *supra* note 38, at 521.

76. Katherine Drabiak et al., *Ethics, Law, and Commercial Surrogacy: A Call for Uniformity*, 35 J. L. Med & Ethics 300, 305 (2007).

77. Brandel, *supra* note 38, at 496.

78. Ethics Committee of the American Society for Reproductive Medicine, *Consideration of the Gestational Carrier: A Committee Opinion*, Fertility and Sterility (2013), at 1839.

79. Ali, *supra* note 49.

80. *Id.*

81. *Id.*

82. *Id.*

83. *Id.*

84. Drabiak, *supra* note 76, at 305.

85. Brandel, *supra* note 38, at 521.

86. *Id*. at 522.

87. Ethics Committee of the American Society for Reproductive Medicine, *supra* note 78, at 1839.

88. Jennifer Damelio and Kelly Sorensen, *Enhancing Autonomy in Paid Surrogacy*, Bioethics, Vol. 22, No. 5 (2008), at 274.

89. McMahon, *supra* note 34, at 377.

90. *See, e.g.,* McMahon, *supra* note 34, at 360.

91. Ali, *supra* note 49.

92. *Id*.

93. *Id*.

94. *See* Ali, *supra* note 49 ("Military wives who do decide to become surrogates can earn more with one pregnancy than their husbands' annual base pay (which ranges for new enlistees from $16,080 to $28,900)").

95. Ethics Committee of the American Society for Reproductive Medicine, *supra* note 78, at 1840.

96. Damelio & Sorensen, *supra* note 88, at 269.

97. *Id*. at 275.

98. London, *supra* note 41, at 414.

99. *Id*. at 410.

100. McMahon, *supra* note 34, at 374.

101. *Id*. at 375.

102. Ali, *supra* note 49.

103. V. Jadva et al., *Surrogacy families 10 years on: relationship with the surrogate, decisions over disclosure and children's understanding of their surrogacy origins*, Hum. Reprod., Vol. 27, Issue 10 (2012), at 3011.

104. Ciccarelli and Beckman, *supra* note 5, at 32.

105. *Id*.

106. *Id*.

107. Olga Van Den Akker. *Genetic and Gestational Surrogate Mothers' Experience of Surrogacy*. Journal of Reproductive and Infant Psychology. Vol. 21, No. 2 (May 2003), at 154 ("The main reason for wishing to be a surrogate again was the importance they attached to the intended mother's friendship….The most positive feelings about the surrogacy were the deep and meaningful friendships they felt they had developed with the intended couples and the hope they can give people with no other options.").

108. Ciccarelli & Beckman, *supra* note 5, at 32.

109. *Id.*

110. Magdalina Gugucheva, *Surrogacy in America*. Council for Responsible Genetics (2010), at 17.

111. *Id*. at 19.

112. *Id*.

113. *Id*.

114. *Id*. at 19–20.

115. *Id*. at 20.

116. Gugucheva, *supra* note 110, at 20.

117. *Id*.

118. *Id*. at 23.

119. *Id*. at 24.

120. *Id*. at 30 ("Contrary to popular beliefs about money as a prime motive, surrogate mothers overwhelmingly report that they choose to bear children for others primarily out of altruistic concerns.…Rather, the women have empathy for childless couples and want to help others experience the great joy of parenthood.").

121. *Id*. at 31.

122. Akker, *supra* note 107, at 152.

123. *Id*. at 147.

124. *Id*. at 156.

125. *Id*. at 159.

126. Ciccarelli & Beckman, *supra* note 5, at 34.

127. *Id*. at 35.

128. *Id*. at 34.

129. George Cole & Stanislaw Frankowski, Abortion and Protection of the Human Fetus: Legal problems in a Cross-Cultural Perspective 20 (1987).

130. Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833, 851 (1992).

131. Carson Strong, Ethics in Reproductive and Perinatal Medicine: A New Framework, 18–22 (1997).

132. *Id.* at 18.

133. *Id*. at 18–19.

134. *Id.* at 20.

135. *Id.* at 20–22.

136. Kuczynski, *supra* note 1.

137. *Id.*

138. *Id.*

139. *Id.*

140. *Id.*

141. U.S. Department of Health and Human Services; Administration for Children and Families; Administration on Children, Youth and Families; Children's Bureau, *Child Welfare Outcomes 2007-2010: Report to Congress*, *available at* http://archive.acf.hhs.gov/programs/cb/pubs/cwo07-10/cwo07-10.pdf: Despite a 22-percent decrease in the number of children in foster care between 2002 and 2010, "[n]ationally, there were approximately 415,000 children in foster care on the last day of FY 2010. During that year, an estimated 250,000 children entered foster care, and 248,000 children exited foster care," for a net increase of children in foster care of approximately 2,000. Furthermore, cause of the decrease between 2002 and 2010 "currently [is] not possible to determine" (i). Moreover, of the 213,000 children who exited foster care in 2010, 52,000 were discharged to adoption, while 7,000 left for reasons other than permanent homes or emancipation, "such as transfer to another agency or to another State" (ii).

142. Stephanie Saul, *Building a Baby, With Few Ground Rules*, The New York Times (Dec. 12, 2009), *available at* http://www.nytimes.com/2009/12/13/us/13surrogacy.html?pagewanted=1&_r=1&fta=y, at 2.

143. Kuczynski, *supra* note 1.

144. Strong, *supra* note 131, at 23–24.

145. *See, e.g.,* Strong, *supra* note 131, at 23.

146. Strong, *supra* note 131, at 24.

147. *Id.*

148. *Id.* at 15.

149. Kuczynski, *supra* note 1.

150. Strong, *supra* note 131, at 15.

151. 28 U.S.C. 1738A(f) and (h).

152. *Id.* at (b)(4).

153. In re Doe, 793 N.Y.S.2d. 878 (2005).

154. *Id.* at 879.

155. *Id.* at 880–81.

156. *Id.* at 880–81.

157. T.V. (Anonymous), et al. v. New York State Department of Health, 88 A.D.3d 290 (2011).

158. Stanley v. Illinois, 405 U.S. 645, 651 (1972).

159. *See*, *e.g.*, Diane Dimond, *Surrogacy on Upswing: Laws Still in Infancy*, The Huffington Post (June 19, 2013), *available at* http://www.huffingtonpost.com/diane-dimond/surrogacy-on-upswing_b_3465120.html (last visited Jul. 31, 2013).

160. Matter of Adoption of Paul, 550 N.Y.S.2d 815 (1990).

161. *Id.* at 815.

162. *Id.* at 816.

163. *Id.* at 818.

164. *Id.* at 818–19.

165. Dimond, *supra* note 159.

166. Lila Sutphen, *Surrogacy Soapbox*, The Huffington Post (June 19, 2013), *available at* http://www.huffingtonpost.com/lilah-sutphen/surrogacy-soapbox_b_3467493.html (last visited Jul. 31, 2013).

167. *Id.*

168. *Id.*

169. Dimond, *supra* note 159.

170. Diane S. Hinson, *State-by-State Surrogacy Law: Actual Practices*, Family Advocate (Fall 2011). States that clearly allow for both surrogacy contracts (by statute, lack of prohibitory law, or case law) and pre-birth orders of parentage include Arkansas, California, Colorado, Connecticut, Georgia, Illinois (which actually has an easier process that skips the court process), Kansas, Kentucky, Maine, Maryland, Massachusetts, Montana, New Hampshire, North Dakota, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, and West Virginia.

171. *Id.* at 6.

172. *Id.* (California, Connecticut, Maine, Maryland, Rhode Island, and South Dakota).

173. *Id.* at 2.

174. Drabiak, *supra* note 76, at 302.

175. London, *supra* note 41, at 414.

176. Gugucheva, *supra* note 110, at 23.

177. Ethics Committee of the American Society for Reproductive Medicine, *supra* note 78, at 1839.

178. *Id.*

179. Kerri MacDonald, *Letting Go of a Baby, but Not the Emotions*, The New York Times (May 10, 2013), *available at* http://lens.blogs.nytimes.com/2013/05/10/letting-go-of-a-baby-but-not-the-emotions/ (last visited Aug. 5, 2013).

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Mitochondrial Replacement: Changing the Family Structure

By Caitlin Davie

The family dynamic has evolved over the last several decades. In vitro fertilization (IVF) techniques, surrogacy and other scientific advances have played a significant role in that changing dynamic. But scientific advancements and surrogacy do more than just change the family structure, they also create unique ethical and legal consequences. The legal and ethical consequences of some IVF treatments and surrogacy arrangements are well known and have played out on the pages of newspapers and magazines. But the ethical and legal implications of some scientific advances, such as the one discussed in this article, have not yet been addressed by the courts and legislatures.

Most parents select IVF procedures because their health issues prevent the natural conception and birth of a child. One particular subset of diseases that has driven the creation of an entirely new type of IVF treatment is mitochondrial diseases.

Mitochondria are present in all cells and reside in the fluid around the nucleus.[1] Mitochondria have DNA, which is referred to as mitochondrial DNA or mtDNA.[2] Mitochondrial DNA is necessary to carry out mitochondrial functions such as converting food energy into a form that becomes the cell's main source of energy.[3] A mitochondrial disease or disorder results from a defect in the mitochondrial DNA.

The DNA contained in the nucleus is nuclear DNA.[4] Mitochondrial DNA is separate from the DNA contained in the nucleus.[5] Mitochondrial DNA contains 37 genes that carry the instructions for the creation of enzymes and molecules that are necessary for healthy mitochondrial function.[6] Genes that make up the nuclear DNA give each person his or her unique features.[7] An individual receives two copies of most genes, one from each parent. [8] Most DNA is contained in the nucleus; the DNA found in the mitochondria is only a "small fraction of the total DNA in cells."[9]

Mitochondrial diseases occur when there is a change in the mitochondrial DNA caused by mutation, deletion, or rearrangement of the segments of mitochondrial DNA.[10] Because only the egg cells supply mitochondria to the embryo, the biological mother passes on mitochondrial diseases.[11] Although only females can pass mitochondrial diseases to their children, these diseases affect both males and females.[12]

Mitochondrial diseases can have devastating effects on those who are afflicted. For example, a mutation in mitochondrial DNA is responsible for Leigh syndrome, which affects mainly infants and causes patches to form on the brain that in turn cause loss of mental function and movement abnormalities.[13] Leigh syndrome is deadly; those afflicted often die within a few years, typically due to respiratory failure.[14] Defects in the mitochondrial DNA have also been linked to deafness, diabetes, and some cancers.[15]

Mothers who are carriers of mitochondrial diseases have various options to avoid passing the disease on to their children. These options include adoption, in vitro fertilization (IVF) with donor eggs, pre-implantation genetic diagnosis (PGD), and prenatal diagnosis (PND). [16] Adoption and IVF with donor eggs may not be a desirable option for mothers who prefer to have a genetic connection to their children.[17] These options are also very expensive. PGD allows women to increase their chances of having a healthy child by first creating an embryo, through the use of IVF, and then testing the embryos for the presence of mitochondrial diseases.[18] Not all mitochondria will necessarily be affected, so those embryos with the least amount of unhealthy mitochondria will be implanted.[19] PGD reduces, but does not eliminate, the chance the child will develop the disorder.[20] PGD may also create ethical issues for some parents regarding what to do with the embryos that were not chosen. PND is performed by testing a fetus that has been conceived naturally to determine whether or not the fetus has the disease.[21] If the fetus tests positive for a mitochondrial disease, parents are left with the difficult decision of whether or not to abort the fetus.[22]

Researchers at Newcastle University in the United Kingdom have developed two innovative techniques that could help prospective parents avoid mitochondrial disorders while remaining the biological parents of their children. Both innovative techniques are called mitochondrial replacement. Simply put, these processes allow scientists to replace the unhealthy mitochondria with healthy mitochondria.

There are two ways that this can be accomplished.[23] One is the Maternal Spindle Transfer (MST).[24] MST requires an egg from the intended mother and a donated egg from another woman.[25] The maternal spindle, which houses the egg's nuclear DNA, is removed from the donor egg and is replaced with the intended mother's maternal spindle.[26] This procedure creates an egg that has the intended mother's nuclear DNA and the donor mother's mitochondrial DNA.[27] Following the procedure, the egg can be fertilized by the intended father.[28]

The second procedure is called Pro-Nuclear Transfer (PNT).[29] This procedure requires an embryo from the intended parents and a donated embryo.[30] Each embryo contains one pronucleus from the sperm and one pronucleus from the egg, and each pronucleus contains the nuclear DNA of the respective parent.[31] The procedure involves the removal of the pronuclei, the pronucleus from the egg and the pronucleus from the sperm, from the donor embryo and replacing it with the pronuclei of the intended parents.[32] The nuclear material that was removed from the donor embryo will be destroyed.[33] This procedure creates an embryo that has the intended parents nuclear DNA and the donor mother's mitochondrial DNA.[34]

The most important difference between these two procedures is that MST requires the destruction of an egg,[35] whereas PNT requires the destruction of an embryo.[36] Both of these procedures produce a child that has the nuclear DNA of the intended parents and the mitochondrial DNA of the donor mother. Thus, the child will have three biological parents.

Ethical Considerations

While these procedures will provide families with new and potentially life-changing options, they are not without ethical concerns. The destruction of an egg in the MST procedure and the destruction of an embryo in the PNT procedure are of particular ethical concern to families with certain religious beliefs and to certain religious organizations. For some religions, eggs and embryos have aspects of personhood.[37] For example, Catholics are opposed to the destruction of embryos because in Catholicism life begins at conception, which is the fertilization of the egg.[38] Some in the Buddhist and Hindu religions also oppose the destruction of embryos.[39] However, many people of the Jewish faith, as well as other religious groups, do not believe embryonic life is sacred.[40] Similarly in the Islamic religion, there generally is no opposition to the destruction of an embryo.[41]

There are other concerns worth noting. The effects of mitochondrial replacement on future generations are largely unknown and there is evidence that the procedure itself is not without risks.[42] For example there are risks to the donor.[43] The egg donor risks psychological and physical injuries such as injury to organs, decreased fertility or infertility, ovarian, breast and colon cancer, as well as hemorrhage and thromboembolism from the donation process itself.[44] However, women undergo these risks everyday when they donate their eggs in standard egg donation cases.[45] It should also be noted that these risks are relatively low. So while these risks should not be ignored or taken lightly, they should not prevent the donation of mitochondrial DNA.

Additional concerns exist regarding the potential adverse effects on health.[46] "[E]nergy production critically hinges on extensive cross-talk between genes dispersed across the nucleus and the mitochondria. Because phenotypes with less-than-ideal cross-talk are disfavored by natural selection, coordinated mitochondrial-nuclear interactions become highly specific over evolutionary time. If [mitochondrial replacement] disrupts such specific, highly coordinated mito-nuclear allelic interactions, adverse health outcomes might occur."[47] Indeed, in studies involving male mice and mitochondrial replacement, the mice had reduced learning, performance and exploratory capacity.[48] The study of mitochondrial replacement in humans is limited and the serious consequences in mice highlight the potential adverse consequences in humans.[49]

There is also a more philosophical concern regarding a possible change in the personality of the child who undergoes this procedure. A child who grows up with a mitochondrial disease will have very different life experiences than a child who grows up healthy.[50] While genetics plays an important role in forming an individual's personality, life experiences are also significant.[51] Thus mitochondrial replacement may not only affect the child's disease state, but also other aspects of the child's personality.[52]

Mitochondrial replacement also has the unique risk that it will negatively impact researchers' abilities to study demographic and migration patterns, and ancestral lines using mitochondrial DNA.[53] Mitochondrial DNA is often used to determine a person's direct female ancestral line.[54] And because mitochondrial DNA is only passed to offspring through the mother, this type of mapping allows researchers to find female ancestors who might not have been found because of changes in surnames.[55] The procedure could also confuse the genealogical links between individuals, making it more difficult for future generations to accurately trace their ancestry and find important information related to their background and familial history.[56]

The gravity of these risks leads to the argument that prospective parents should just adopt. However, that is simply not the reality of the society we live in. Adoption can be expensive, time consuming and unsuccessful for any number of reasons. Even if adoption was a viable option for every family, genetics is often important to parents. A genetic connection is what drives some people to seek alternatives that would allow for at least a partial genetic link between the parents and the child. This is often done through the use of a surrogate. Surrogacy is hardly a simple or easy solution. Surrogacy agreements are fraught with legal complications and are expensive. Surrogates can cost anywhere between $30,000-35,000 plus medical and legal costs and many people require private financing to undergo surrogacy.[57] For some, the costs reach six digits and costs also increase with complex pregnancies.[58] Despite these shortcomings, the number of gestational surrogacy[59] arrangements has been increasing.[60] People's

willingness to undertake such potentially heartbreaking and bank-breaking risks just so that they can have a child that is genetically related to them clearly shows the value society puts on genetics in parental relationships.

Legal Considerations

Beyond these important ethical considerations are the legal ramifications associated with mitochondrial replacement. The children born using this procedure will have three biological parents. If the child has three biological parents, theoretically all of these parents should have rights to visitation and custody, and a corresponding obligation to provide child support. However, the law generally recognizes only two parents for each child. Stepparents only assume parental rights and obligations when they replace one of the parents.

Genetic Donors

Historically, the law has presumed that a child can only have two legal parents.[61] Traditionally, genetic ties or legal adoption have determined the parents of a child. Technological advances have confused these traditional assumptions. For example, egg donation and surrogacy[62] have forced the legal system to consider whether the genetic or gestational mother should have legal rights and responsibilities to the resulting child. Courts have looked to the intent of the parties to determine whether the gestational or genetic mother should be regarded as the legal mother. In the particular situation of mitochondrial replacement, genetics cannot be used as determinative because all three parities are genetically related to the child.

In *Johnson v. Calvert*, a couple entered into a surrogacy agreement in which the surrogate would be implanted with an embryo that was created from the egg of the wife and the sperm of the father.[63] After the relationship between the couple and the surrogate deteriorated, the surrogate claimed that she was the legal parent of the child.[64] The Supreme Court of California held that while gestation and genetic ties could both establish maternity, in cases where the genetic and gestational mother are not the same person then "she who intended to procreate the child—that is, she who intended to bring about the birth of a child that she intended to raise as her own—is the natural mother."[65] By contrast, "in a true 'egg donation' situation, where a woman gestates and gives birth to a child formed from the genetic material of another woman with the intent to raise the child as her own, the birth mother is the natural mother."[66]

In *McDonald v. McDonald*, the New York State Appellate Division, Second Department followed the ruling in *Johnson* and also adopted the intent test.[67] In *McDonald*, a couple filed for divorce and the father sought custody of their children.[68] He claimed that he was the "only genetic and natural parent available" because the couple used an egg donor when conceiving their children and, although the wife carried the pregnancy and was the gestational mother, she did not have genetic ties to their children.[69] The Court held that this was a "true egg donation" situation as envisioned by the California Supreme Court and because the gestational mother intended to the raise the children as her own she was the natural mother.[70]

These cases are instructive in determining a child's legal parents in cases involving mitochondrial replacement.[71] The intent test can be used if the woman who donates the mitochondrial DNA agrees to forgo any parental rights. The couple that initiated the mitochondrial replacement would be the natural parents, not the donor, because they intended to raise the child as their own.[72] Without the intended parents decision to have the child, this child would not have been born, so the intended parents are the ones who should have parental rights.[73]

Issues involving the donor mother's decision to assert parental rights can be avoided with mitochondrial DNA by using anonymous donations. If donors are aware from the outset that they are making anonymous donations and that once they have donated their DNA they no longer have parental rights, controversies over parental rights should be avoided. Issues concerning parenthood should also be less of an issue with mitochondrial replacement than with donor eggs because donors of mitochondrial DNA will not have the same physical traits as the child. The nuclear DNA, which the child will receive from the intended parents, almost exclusively determines physical characteristics.[74] The donor's limited genetic connection to the child, paired with the fact that the donor mother does not carry the child, also makes it unlikely that the donor mother would later attempt to assert parental rights.

Anonymous donation also helps protect donors from parents who might later attempt to collect child support from donors. However, donors would likely be protected from claims for child support anyway because the donor did not intend to raise the child as her own and therefore, under the intent test, would not be liable for the child's support.

Where the courts have been unable to rely on the intent of the parties—for example, where there has been a mistake by a fertility clinic—the courts have relied on genetic relationships rather than gestation to determine the child's legal parents. For example, in *Perry-Rogers v. Fasano*, a mix-up at an IVF clinic resulted in Mrs. Fasano being implanted with embryos that were formed using her eggs and her husband's sperm and embryos that were formed using another couple's eggs and sperm.[75] Mrs. Fasano had two children, one that was genetically hers and one that was genetically the Perry-Rogers'.[76]

The appellate court treated the case as analogous to a surrogacy situation. However, Ms. Fasano did not consent to carry a child for another person, but rather used the IVF clinic so that she could have children of her own.

Therefore, this case is as similar to an egg donation case as it is to a surrogacy situation. The court also attempted to apply the intent test noting that the Perry-Rogerses intended to have and raise their own genetic child.[77] However, this case cannot be solved so easily. While it is true that the Perry-Rogerses wanted a child and they were using an IVF clinic to accomplish this purpose, Mrs. Fasano also intended to have a child and certainly never agreed to be a surrogate. Mrs. Perry-Rogers did not consent to donate her egg and Mrs. Fasano did not consent to be a surrogate. The court wrote that it wasn't relying solely on genetics in finding in favor of the Perry-Rogerses[78] but neither the intent test nor the surrogacy analogy completely explains the decision.

Three Intended Parents

Mitochondrial replacement creates the possibility of three genetic parents and also the potential for three intended parents. Why shouldn't the legal system accommodate three parents? Society already recognizes parental arrangements that involve stepparents, but generally stepparents do not have the legal rights of a parent.[79]

A New Trend

Courts and legislatures are beginning to recognize that limiting parental rights to two-parent families is not always best for the children. Sometimes there are others who should have rights to visitation, custody, and decision-making on the child's behalf. Judge Kaye, in her dissenting opinion in *Allison D.*, calls attention to the importance of recognizing unique family structures. She emphasizes that a child's welfare, happiness, and best interests should be most important in determining who a child's parents are.[80] Judge Kaye argues that by limiting children's familial choices, we are "limiting their opportunity to maintain bonds that may be crucial to their development."[81]

Legislatures have recognized the importance of allowing persons other than parents to have visitation rights by enacting grandparent and sibling visitation laws. In *Troxel*, the Supreme Court examined the constitutionality of a Washington State law that permitted any person to petition for visitation.[82] The Court found the statute unconstitutional because it was too sweeping and did not give enough deference to the parents' decision.[83] The court stated that "there is a presumption that fit parents act in the best interests of their children"; thus if the parents deny visitation, there is a presumption that the decision was in the best interest of the child and generally the state should not intervene.[84] As a result of the ruling in *Troxel*, visitation laws must be limited and give deference to the parents' decision that visitation is not in the best interest of the child.[85]

Several states have legislation granting grandparents standing to petition for visitation with their grandchildren.[86] For example, in Arkansas a grandparent can rebut the presumption that a parent's choice to deny visitation is in the child's best interest by proving that "(A) [the grandparent] has established a significant and viable relationship with the child…and (B) [v]isitation with the [grandparent] is in the best interest of the child."[87] Many states have similar visitation laws for siblings. For example, in Maryland, if siblings are separated in foster care or by adoptive placements, they have standing to petition for visitation. [88]

Some jurisdictions such as the District of Columbia and Delaware, have explicitly recognized multiple parents even if there are more than two by allowing "de facto parents." In the District of Columbia a de facto parent is

> an individual (A) Who: (i) Lived with the child in the same household at the time of the child's birth or adoption by the child's parent; (ii) Has taken on full and permanent responsibilities as the child's parent; and (iii) Has held himself or herself out as the child's parent with the agreement of the child's parent or, if there are 2 parents, both parents; or (B) Who: (i) Has lived with the child in the same household for at least 10 of the 12 months immediately preceding the filing of the complaint or motion for custody; (ii) Has formed a strong emotional bond with the child with the encouragement and intent of the child's parent that a parent-child relationship form between the child and the third party; (iii) Has taken on full and permanent responsibilities as the child's parent; and (iv) Has held himself or herself out as the child's parent with the agreement of the child's parent, or if there are 2 parents, both parents.[89]

In D.C., a person who has established that he or she is a de facto parent will be considered a parent when determining custody and child support.[90]

Delaware has a similar statute that allows for de facto parents. In Delaware a de facto parent

> is established if the Family Court determines [that the individual]: (1) Has had the support and consent of the child's parent or parents who fostered the formation and establishment of a parent-like relationship between the child and the de facto parent; (2) Has exercised parental responsibility for the child…and (3) Has acted in a parental role for a length of time sufficient to have established a bonded and dependent relationship with the child that is parental in nature.[91]

Once it has been established that a person is a de facto parent, that person has the same rights and responsibilities as the child's other established parents.[92]

Some courts have been unwilling to hold that there are more than two parents without an express directive from the legislature. In *In re M.C.*, M.C. was raised by her biological mother, Melissa, and her mother's domestic partner, Irene.[93] After the relationship ended, Melissa conspired with her then-boyfriend to murder Irene, but they were unsuccessful.[94] With Melissa in jail, the future of M.C. was left to the courts.[95] The possible parents were Melissa, Irene, or M.C.'s biological father.[96] The California court ultimately determined that all three were presumptive parents, but rejected the lower court's decision that all three could be the child's parents.[97] The court made it clear in its decision that it would not use this case as an opportunity to recognize "novel parenting relationships," but the court did invite the legislature to do so.[98]

The California Legislature acted on the court's suggestion. On October 3, 2013, Governor Jerry Brown signed legislation allowing a child to have three or more legal parents.[99] The legislation allows a court to find that a child has more than two legal parents when limiting a child to two parents would be detrimental to the child.[100] The Legislature found that "[s]eparating a child from a parent has a devastating psychological and emotional impact on the child" and the explicit purpose of the law was to abrogate the holding in *In re M.C.*.[101]

Unlike the California Court in *In re M.C.*, the Superior Court of Pennsylvania held in *Jacob v. Shultz-Jacob* that there could be three legal parents, even though the legislature had not expressly recognized such arrangements.[102] In *Jacob*, a dispute arose as to who should have custody and responsibility for child support for two children, Co.J. and Ca.J., who were raised by a lesbian couple since birth.[103] The non-biological mother was arguing for sole custody of the children but the trial court ruled that all parties—the sperm donor father, the non-biological mother and the biological mother—should have shared custody.[104] The non-biological mother was required to pay child support, while the sperm donor was not.[105] The trial court found that the law did not allow three parents to be responsible for child support.[106] The sperm donor, despite his designation as such in the case, was in fact active throughout the children's lives, providing financial support as well as suggesting that they call him "Papa."[107] The Superior Court affirmed the custody decision, but determined that all three parents should be responsible for child support.[108]

Conclusion

Mitochondrial replacement creates a child that has the DNA of three different people. Whether three-parent families should be allowed comes down to the intent of the parties because "recognizing the intending parents as the child's legal, natural parents should best promote certainty and stability for the child."[109] The courts and legislatures should work together to allow the families themselves to decide how many parents their particular family will have.

Where three parents have decided to have a child using mitochondrial replacement and raise the child together, then all three parents should be able to assert their parental rights. If any of these three people were unable to be legally considered a parent to that child, it would significantly affect that person's ability to adequately care for the child. The excluded parent may be left out of daily decisions for the child that can only be made by a parent, such as health care decisions. More important, if one or more of the three parents decide that they no longer want to continue with this arrangement, the parent that was excluded from having parental rights could be denied visitation and custody rights to their own child. Three-parent families can provide significant benefits to a child when all three adults are able to provide emotional and financial support. Additionally, having three parents might ensure that a child is provided with a well-rounded upbringing. Disagreements caused by souring relationships or significant disagreements over the child's well-being can be resolved in the same manner as when a child's two parents disagree. The foregoing reasons underscore the importance of allowing of three parent families in the case of mitochondrial replacement.

In cases where there are only two people who intend to raise the child, the two-parent paradigm should be followed. Those who intended to raise the child as their own should be the parents. Giving a third party donor parental rights in this situation could be potentially damaging to the child. Unsuspecting families may not have vetted the donor prior to the procedure for attributes that would make the donor an adequate parent and the family unit may be dysfunctional. Unless the parties have agreed prior to the procedure that all three would be the legal parents, then only the intended parents should have parental rights.

Thus, the intent of the parties should be the ultimate determinative factor when deciding who the legal parents are. These considerations are unique to mitochondrial replacement because prior to this medical advancement, genetics could always be used as a determinative factor when intent was unclear. Mitochondrial replacement changes this equation because now all three parents are genetically related and all three should have the opportunity to parent if that arrangement works best for the family. Advancements in medical technology that further the societal goal of having healthier children will continue, and the law must be able to adapt to these changes to ensure that these children will be well cared for and have a stable family life.

Endnotes

1. *Cells and DNA*, National Library of Medicine, (Feb. 10, 2014), http://ghr.nlm.nih.gov/handbook/basics?show=all.
2. *Id.*
3. *Id.*
4. *Id*.
5. *Id.*
6. *Id*.
7. *Id*.
8. *Id*.
9. *Mitochondrial DNA*, National Library of Medicine (Feb. 10, 2014), http://ghr.nlm.nih.gov/mitochondrial-dna.
10. *Id.*
11. *Inheriting Genetic Conditions*, National Library of Medicine, (Feb. 10, 2014), http://ghr.nlm.nih.gov/handbook/inheritance?show=all.
12. *Id.*
13. *Leigh syndrome,* National Library of Medicine (February 10, 2014), http://ghr.nlm.nih.gov/condition/leigh-syndrome.
14. *Id*.
15. *Mitochondrial DNA*, *supra* note 9.
16. *Current treatment options*, Human Fertilisation Embryology Authority, http://mitochondria.hfea.gov.uk/mitochondria/what-is-mitochondrial-disease/current-treatment-options/ (Last visited Feb. 16, 2014).
17. *Id.*
18. *Id.*
19. *Id.*
20. *Id.*
21. *Id.*
22. *Id.*
23. *Maternal Spindle Transfer (MST)*, Human Fertilisation Embryology Authority, http://mitochondria.hfea.gov.uk/mitochondria/what-is-mitochondrial-disease/new-techniques-to-prevent-mitochondrial-disease/maternal-spindle-transfer/ (last visited February 6, 2014); *Pro-nuclear transfer (PNT)*, Human Fertilisation Embryology Authority, http://mitochondria.hfea.gov.uk/mitochondria/what-is-mitochondrial-disease/new-techniques-to-prevent-mitochondrial-disease/pro-nuclear-transfer/ (last visited February 6, 2014).
24. *Maternal Spindle Transfer, supra* note 23.
25. *Id.*
26. *Id*.
27. *Id.*
28. *Id*.
29. *Pro-nuclear transfer, supra* note 23.
30. *Id*.
31. *Id*.
32. *Id*.
33. *Id*.
34. *Id.*
35. *Maternal Spindle Transfer, supra* note 23.
36. *Pro-nuclear transfer, supra* note 23.
37. Giovanni Frazzetto, *Embryos, Cells and God,* 5 European Molecular Biology Organization 553 (2004).
38. *Id.* at 553.
39. Andrew Dutney, *Religion, Infertility and Assisted Reproductive Technology,* 21 Best Practice & Research Clinical Obstetrics and Gynaecology 169, 175-176 (2007).
40. John H. Evans, Kathy Hudson, *Religion and Reproductive Genetics: Beyond Views of Embryonic Life?* Vol. 46, Journal for the Scientific Study of Religion, at 567 (2007).
41. *See Frazzetto, supra* note 37, at 554; *see also* Dutney, *supra* note 39, at 176.
42. Françoise Baylis, *The ethics of creating children with three genetic parents*, 26 Reproductive BioMedicine Online, 531, 532-34 (2013).
43. *Id*. at 532-33.
44. *Id.*
45. *Id*.
46. Klaus Reinhardt et al., *Mitochondrial Replacement, Evolution, and the Clinic*, 341 Science 1345, 1345-46 (2013).
47. *Id*. at 1346.
48. *Id.*
49. *See id.*
50. Baylis, *supra* note 42, at 532.
51. *Id.*
52. *Id.*
53. *Id*. at 533.
54. *What is genetic ancestry testing?* National Library of Medicine, (Feb. 10, 2013), http://ghr.nlm.nih.gov/handbook/testing/ancestrytesting.
55. *Id.*
56. Baylis, *supra* note 42, at 533.
57. Deborah L Cohen, Surrogate pregnancies on rise despite cost hurdles, Reuters: US Edition, (March 18, 2013), http://www.reuters.com/article/2013/03/18/us-parent-surrogate-idUSBRE92H11Q20130318.
58. *Id.*
59. *See infra* note 62 (definition of gestational surrogacy).
60. *Id.*
61. Megan S. Calvo, *NOTE: UNIFORM PARENTAGE ACT —Say Goodbye to Donna Reed: Recognizing Stepmothers' Rights*, 30 W. New Eng. L. Rev. 773, 785 (2008).
62. Traditional surrogacy involves a surrogate who has been artificially inseminated with the sperm of the intended father with an agreement that the surrogate will give up the child and rights to it (Anthony Miller, *ARTICLE: Baseline, Bright-line, Best Interests: A Pragmatic Approach for California to Provide Certainty in Determining Parentage*, 34 McGeorge L. Rev. 637, 671 (2003)). Traditional surrogacy carries a larger risk of having the surrogate mother claim parental rights because the surrogate has genetic ties to the child (*see* Abigail Lauren Perdue, *ARTICLE: For Love or Money: An Analysis of the Contractual Regulation of Reproductive Surrogacy*, 27 J. Contemp. Health L. & Pol'y 279, 284-85 (2011)).

    Gestational surrogacy involves a donated egg that is fertilized and the resulting an embryo is placed in the woman who will be carrying the child but who will not be the mother (34 McGeorge L. Rev. at 671-72). Gestational surrogacy is medically and legally complicated (*id.*). Its legal complexity stems from the fact that there can be as many as five potential parents: two intended but unrelated parents, the egg donor, the gestational carrier, and the sperm donor (*id.*). However, gestational surrogacy allows one or both intended parents to be genetically related to their child when normal conception and/or gestation is not an option (*see id.*).

In the context of this article, surrogacy refers to gestational surrogacy unless stated otherwise because the goal of the intended parents considering mitochondrial replacement is to maintain a genetic connection with their child.

63. *Johnson v. Calvert*, 5 Cal 4th 84, 87 (1993).
64. *Id*. at 87-88.
65. *Id*. at 93.
66. *Id*. at note 10.
67. *McDonald v. McDonald,* 196 A.D.2d 7, 12 (2d Dep't 1994).
68. *Id*. at 9.
69. *Id*.
70. *Id*. at 12.
71. *See also In re Marriage of Buzzanca*, 61 Cal. App. 4th 1410 (1998). (In *Buzzanca* the couple used a surrogate, egg donor, and sperm donor (*id.* at 1412). After the couple divorced the intended father attempted to disclaim any parental rights or responsibilities to the child (*id*.). The court cited *Johnson* and held that the intended father was in fact the father of the child because this child would not have been born without his intention to be a father (*id.* at 1412-13).
72. *See Johnson,* 5 Cal 4th at 93.
73. *See id.* at 93-94.
74. *Supra* note 1.
75. *Perry-Rogers v. Fasano*, 276 A.D.2d 67, 69 (1st Dep't 2000).
76. *Id.* (Initially, the Perry-Rogerses and the Fasanos agreed that the Perry-Rogeres' genetic child was legally theirs and the Perry-Rogerses agreed to visitation by the Fasanos (*id.* at 70). The lower court granted the Perry-Rogerses sole and exclusive custody but gave visitation to the Fasanos (*id.* at 71). However, the Perry-Rogeres later objected to the visitation order (*id*.). The Appellate Court held that because the Perry-Rogerses are the legal and genetic parents to the child, this particular situation is akin to giving the wrong child to the wrong mother at the hospital (*id.* at 74). This was based on the fact that the implantation was a mistake and Fasanos were aware soon after the implantation that the "nominal parenthood over Akeil [the Perry-Rogeres' child] should have been treated as a mistake to be corrected at soon as possible*, before the development of a parental relationship*"(*id*.)).
77. *Id.*
78. *Id*. at 73.
79. Bryce Levine, *Note: Divorce and the Modern Family: Providing in Loco Parentis Stepparent Standing to Sue for Custody of their Children in a Dissolution Proceeding*, 25 Hofstra L. Rev. 315, 323 (1996) (The author argues in favor of providing stepparents with parental rights after the marriage between a stepparent and parent dissolves when it is in the best interest of the child (*id.* at 340-41.)); Ruth Padawer, *Who Knew I Was Not the Father?*, New York Times (Nov. 17, 2009), http://www.nytimes.com/2009/11/22/magazine/22Paternity-t.html?pagewanted=all&_r=0.html (The article explores how different fathers handle issues of custody and child support after finding out the children they have been raising as their own biological children are not genetically related to them. Several of the men chose to continue paying child support and fought to remain in their children's lives. One of the men Tanner Pruitt, was awarded full custody of his daughter even though he was not genetically related to her).
80. *Alison D. v. Virginia M.*, 77 N.Y.2d 651, 659 (1991).
81. *Id*. at 658.
82. 530 U.S. 57, 60 (2000).
83. *Id.* at 67.
84. *Id.* at 68-69.
85. *See id.*
86. *See* Ala. Code § 30-3-4.1(d) ("the court shall determine if visitation by the grandparent is in the best interests of the child. Visitation shall not be granted if the visitation would endanger the physical health of the child or impair the emotional development of the child. If the child is living with one or both biological or adoptive parents, there shall be a rebuttable presumption for purposes of this section that the parent or parents with whom the child is living know what is in the best interests of the child."); *see* N.J. Stat. § 9:2-7.1(a) ("A grandparent or any sibling of a child residing in this State may make application before the Superior Court, in accordance with the Rules of Court, for an order for visitation. It shall be the burden of the applicant to prove by a preponderance of the evidence that the granting of visitation is in the best interests of the child.").
87. Ark. Code § 9-13-103(c).
88. Md. Family Law Code Ann. § 5-525.2(b); *see also* R.I. Gen. Laws § 15-5-24.4 ("(a) The family court, upon miscellaneous petition of a brother, sister, half-brother or half-sister, stepbrother, stepsister, or on behalf of any of those persons by his or her legal guardian, for visitation rights for the petitioner's sibling, half-sibling or stepsibling …may grant reasonable rights of visitation of the sibling to the petitioner. The court, in order to grant reasonable rights of visitation, must find and set forth in writing the following findings of fact: (1) That it is in the best interests of the child that the petitioner [petitioning sibling] is granted visitation rights with the child; (2) That the petitioner is a fit and proper person to have visitation rights with the child; (3) That the petitioner has repeatedly attempted to visit his or her sibling, half-sibling or stepsibling during the thirty (30) days immediately preceding the date the petition was filed and was not allowed to visit the child during the thirty (30) day period as a direct result of the actions of either, or both, parents of the child; (4) There is no other way that the petitioner is able to visit his or her sibling, half-sibling or stepsibling without court intervention; and (5) That the petitioner, by clear and convincing evidence, has successfully rebutted the presumption that the parent's decision to refuse the petitioner's visitation with the child was reasonable."); *see also* NY Dom Rel § 71 ("…a brother or sister or, if he or she be a minor, a proper person on his or her behalf of a child, whether by half or whole blood, may apply to the supreme court by commencing a special proceeding or for a writ of habeas corpus to have such child brought before such court, or may apply to the family court pursuant to subdivision (b) of section six hundred fifty-one of the family court act; and on the return thereof, the court, by order, after due notice to the parent or any other person or party having the care, custody, and control of such child, to be given in such manner as the court shall prescribe, may make such directions as the best interest of the child may require, for visitation rights for such brother or sister in respect to such child.").
89. D.C. Code § 16-831.01.
90. D.C. Code § 16-831.03.
91. Del. Code tit. 13, § 8-201(c).
92. Del. Code tit. 13 § 8-203.
93. *In re M.C.,* 195 Cal. App. 4th 197, 204 (2011).
94. *Id.*
95. *Id*. at 204-206.
96. *Id.* at 216-17.
97. *Id.* at 223 (The court ultimately remanded the case to the juvenile court to first determine which of the two out of the three would be M.C.'s parents and then determine who should receive custody (*id.* at 224)).
98. *Id.* at 214.

99. The amended version of Cal Fam Code § 7601, which defines a "natural parent" and a "parent and child relationship," also states in subsection (c) that "[t]his part does not preclude a finding that a child has a parent and child relationship with more than two parents" and in subsection (d) that "[f]or purposes of state law, administrative regulations, court rules, government policies, common law, and any other provision or source of law governing the rights, protections, benefits, responsibilities, obligations, and duties of parents, any reference to two parents shall be interpreted to apply to every parent of a child where that child has been found to have more than two parents under this part."
100. The amended Cal Fam Code § 7612(c) states that "[i]n an appropriate action, a court may find that more than two persons with a claim to parentage under this division are parents if the court finds that recognizing only two parents would be detrimental to the child. In determining detriment to the child, the court shall consider all relevant factors, including, but not limited to, the harm of removing the child from a stable placement with a parent who has fulfilled the child's physical needs and the child's psychological needs for care and affection, and who has assumed that role for a substantial period of time. A finding of detriment to the child does not require a finding of unfitness of any of the parents or persons with a claim to parentage." The act became effective on Jan 1, 2014 (2013 Cal AB 1403).
101. 2013 Legis. Bill Hist. CA S.B. 274.
102. *Jacob v. Shultz-Jacob*, 923 A.2d 473, 482 (2007).
103. *Id.* at 476. (The court also ruled on the custody of two other children in the family (*id*.). The other two children, A.J. and L.J., were adopted by Appellee who was the biological mother of Co.J. and Ca.J (*id*.). A.J. and L.J. had no relationship with the sperm donor and he was not granted custody or required to make child support payments (*id*.). Their custody dispute is not discussed further because the dispute was only between the non-biological mother and the biological mother, and not all three parents.).
104. *Id.*
105. *Id*. (The trial court ruled that the non-biological mother and sperm donor should have partial custody of the children, while the biological mother should have primary physical custody (*id.* at 476)).
106. *Id.* at 482.
107. *Id*. at 476, 481.
108. *Id*.
109. *Johnson*, 5 Cal. 4th at 95.

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Franken-Food or Scare Tactics? The Science, Law and Policy of Genetically Modified Foods

Excerpts from an Expert Panel Discussion

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Introduction

On September 10, 2013, the NYSBA Health Law Section's Committee on Medical Research and Biotechnology[1] held a public symposium to explore the scientific, legal and public health issues involved with genetically modified organisms (GMOs). The goal of the symposium was to start a public dialogue in light of the significant legislative activity and proposals surrounding GMOs particularly in the states of California and New York.

Genetically modified foods have been marketed and consumed for many years in the United States. Farmers have been selecting for particular strains of plants or animals for thousands of years through selective breeding, a technique that crosses plants and animals from related species. Another method of producing crops with useful traits is genetic engineering, the product of which we call GMOs. These are plants or animals that have deoxyribonucleic acid (DNA) from other organisms (such as bacteria or viruses) intentionally introduced into that crop or animal using recombinant DNA laboratory techniques. The combining of genes from those different species doesn't usually occur in nature or through traditional breeding methods. In the United States, crops that have been engineered includes soybeans, cotton, canola, corn, sugar beets, Hawaiian papaya, alfalfa, and squash (zucchini and yellow). Food manufacturers estimate that over 70% of the food products consumed in the U.S. today contain at least one ingredient made from a GMO crop. In addition, GMOs (e.g., bacteria, fungi) are widely used by food manufacturers as processing agents to produce specific ingredients. Common ingredients derived from GMOs include corn oil, soybean oil, cottonseed oil, high-fructose corn syrup, table sugar, and soy lecithin. With the increased prevalence of genetically modified (GM) ingredients in food, there is much debate regarding the safety of those ingredients on human health and the impact of GM crops on the environment. For consumers, it can be difficult to determine which ingredients are made from engineered crops as new GMO crops may be entering the market soon (such as engineered apples and potatoes). There have been recent calls to strengthen legislation and regulations regarding GMOs from measures to ban the growing of GM crops to require mandatory labeling of foods using ingredients made from GMOs.

The symposium addressed the following topics:

- GMO safety, environmental impact, and impact on food production;
- Perspectives on the benefits and risks of GMOs;
- The current state and federal regulatory frameworks regarding labeling and other legal issues that apply to GMOs;
- The European Union's approach to GMOs.

The program panelists and moderator for the evening included:

- **David O. Carpenter, M.D.**, (Panelist) Director, Institute for Health and the Environment, University at Albany School of Public Health. Previously, he was the Director of the Wadsworth Laboratories for the New York State Department of Health. Dr. Carpenter has an active research program focusing on the study of human diseases in relation to exposure to environmental contaminants.
- **Dr. Cathleen Enright, Ph.D.**, (Panelist) Executive Vice President of the Food and Agriculture Section in The Biotechnology Industry Organization (BIO), a 1,100+ member organization in the United States and abroad.
- **Mr. Gregory Jaffe, J.D.**, (Panelist) Biotechnology Project Director at the Center for Science in the Public Interest (CSPI), a nonprofit consumer organization located in Washington, D.C. working on food and nutrition issues. He was previously at

the Department of Justice and EPA as an environmental civil litigator. CSPI originally petitioned the FDA in 1995 to mandate the labeling of trans-fat, which is now in place.

- **Ms. Patty Lovera**, (Panelist) Assistant Director of Food & Water Watch, a consumer advocacy organization focusing on food policies ranging from the Farm Bill to food labeling and safety standards as well as water issues.
- **Ms. Beth Roxland, J.D.**, M. Bioethics, (Moderator) Adjunct Professor, New York University School of Law and Associate of the Division of Medical Ethics, New York University Medical School, who provided an overview of the legal issues. She was previously Executive Director of the New York State Task Force on Life and the Law and Special Advisor to the Commissioner on Stem Cell Research Ethics.

Following is an edited transcript from the meeting.

Ms. Roxland: With all the concerns surrounding GMOs, how are they currently regulated in this country?

Mr. Jaffe: The federal regulation of these crops is a little convoluted. Depending on the crop and the trait, it can fall under the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and/or the U.S. Department of Agriculture (USDA).

Ms. Lovera: While the federal government has oversight over what is or is not included in an ingredient list, there has been tremendous lobbying activity in the area of GMOs. So, it has been the FDA's policy for over 15 years not to include GMO in those labels. Today, there is an increasing groundswell of public interest for lots of reasons which build on the predecessor controversy surrounding the use of recombinant bovine growth hormone (rBGH), an artificial growth hormone given to dairy cows to promote more milk production. In both instances, these products are controversial in terms of health questions, generating much conversation about safety and whether they should be approved. Like GMOs, rBGH usage was approved with no mandatory labeling and no disclosure that it was used on the cows. So while we would prefer that the federal government list genetically engineered (GE) ingredients on a product label, we don't think that the feds will lead on this right now. As a result, we're talking to state legislatures. But the question is where will this information be placed if not on the label?

Dr. Carpenter: A bigger issue, in my judgment, that is the government (federal or state) doesn't regulate a lot of things that are very much more dangerous than GMOs, in particular the presence of known carcinogens in our food supply. Certain foods may contain high doses of chlorinated pesticides like DDT, or dioxins or PCBs. The FDA standards for allowing these foods to be sold are very, very loose and nobody is informing the consumer about that when they buy fish from the Great Lakes, for example. One can talk about the plasticizers in all of our plastic products that are endocrine disrupters that feminize little boys and increase the risk of breast cancer. This may be a debate, makes great press, but it's not really regulated. So, I think one has to put the GMOs in the context of other things that our government does not regulate.

Ms. Roxland: Who else in the federal government is looking at this?

Mr. Jaffe: The USDA, under the Plant Protection Act (PPA), regulates any crop that could be a plant pest.[2] If a developer or a researcher wants to do a field trial of GMO crops, they will need a permit from USDA. At the end of their field trials, the developer must prove to the USDA's satisfaction that there are no plant pest characteristics with that crop so it can obtain "nonregulated" status and be freely planted by farmers. The EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act. If the engineered crop produces a biological pesticide (such as a gene from Bacillus Thuringiensis (Bt) that produces a biological toxin) the engineered crop needs to be registered under FIFRA, which requires both the performance of an environmental risk assessment and the setting of a food safety tolerance for any potential pesticide residues.

Dr. Enright: Interestingly, none of the products of the other breeding technologies (i.e., selective breeding, hybridization, mutagenesis, somaclonal variation) goes before the FDA because genetic engineering was considered an extension of traditional breeding. Because of a concern about public acceptance, companies voluntarily submit safety information to the FDA for review.

Ms. Roxland: Is it correct that the FDA requires a voluntary submission on the part of the developer when reviewing the food safety of a GE plant or crop entering our food supply? If so, how is it different from what is going on in other countries?

Mr. Jaffe: Generally the burden of proof as to whether a product, a drug or pesticide, for example, is safe, is on the developer of that product. Once the developer overcomes that burden, the product is approved. Though the FDA oversees the safety of our food supply, including the safety of foods produced from plants, there's no formal approval process for GMOs. Under the Food, Drug and Cosmetic Act, only food additives require mandatory premarket approval from FDA. The FDA made a scientific and factual determination in 1992 that introducing new DNA and proteins generally does not make an existing crop a food additive. It is instead generally recognized as safe (GRAS). Under these circumstances, companies developing GMO crops can self-affirm GRAS. GMO developers can voluntarily provide the FDA with safety data through a voluntary consultation process. The FDA

reviews that data package to make sure that the developer hasn't missed anything, and asks questions as they see fit. Ultimately, the responsibility for safety rests on the developer. So far, this voluntary process has been followed for all commercialized GMO crops. The European Union, on the other hand, has developed a more rigorous mandatory regulatory process. So, if we want to sell corn and soybeans to Europe or Japan, we must satisfy their regulatory requirements.

Dr. Enright: Even though the system at the FDA is voluntary, the companies don't pick and choose what data is required for submission. As a result, there is a mandatory system similar to our voluntary system. One of the questions I am asked is: "Well, what if there's data that's not favorable to the product?" The information that our companies provide to USDA, EPA and FDA is largely the same information that they've presented to the European scientific body, the European Food Safety Association (EPSA).

Mr. Jaffe: In the case of GMOs, the international standards are set forth by the Codex Alimentarius, and the required data submission in Canada, Europe and Japan mirror the data that's generally submitted by the companies to FDA here in the U.S. The difference is that FDA does not tell the American public its opinion on the safety of the GMO crop. My criticism with this system is there needs to be a change in the burden of proof. Under the current system, the law allows the FDA to go after companies that market "adulterated" food. It's the FDA's burden to show that it's adulterated, as opposed to the developer showing it's safe before it enters the food supply. In other countries, before it even gets on the market, they have to get approval from the regulatory body. To me, that's a difference in burden of proof even if the data that's submitted or the actual safety is not any different.

Ms. Lovera: The European Union looks at this as a novel food technology. Our regulatory system is not equipped to deal with what is a new technology. We have a patchwork that doesn't really step up and give the public an independent objective look at it. This comes up not just for transgenic animals or other biotech but also in many food technologies. Accountability is currently an issue as well related to who is supplying this data, whether anyone else is able to look at it, can it be replicated and whether there is any non-industry funded work. This is not the FDA's job under the existing regulatory scheme. Our government does not provide grants to study the hazards of GMOs so we are dependent on industry-funded reports. That's not to say it's all wrong, but there should be a counterbalance of independent investigation. We think that it's time to have that conversation about an adequate way to regulate this. The Pew Charitable Trust is doing a big project about how [the current system is] really not adequate to protect the public health on anything you're adding to food, let alone something that we think brings in lots new issues like genetic engineering. The last thing that I'll say is we haven't yet talked about genetically engineered animals. There has been one in the pipeline: genetically engineered salmon. These animals are being regulated as a veterinary drug, which is incredibly not a transparent process for the public. What we have now, after three years of very public debate on this, is our summary charts and that which the FDA made public. We don't have access to the data though. Much like a drug approval, that information will not be public until it has been approved.

Ms. Roxland: The FDA issued guidelines on labeling in 1992 and later in 2001 issued for notice and comment a draft set of guidelines on voluntary labeling of GMO products.[3] To date, the FDA never finalized the guidance and there are now calls to finalize that guidance.

Mr. Jaffe: FDA has draft guidance on labeling of foods made from GMO crops. FDA said that because there is no difference between the safety of a genetically modified crop and a non-genetically modified crop, there is no mandatory requirement to label GMOs. The guidance states GMO ingredients need to be labeled if there is a nutritional change or different functional characteristics for the ingredient produced by the GMO (e.g., high oleic soybean oil instead of soybean oil). I think that one of the biggest reasons behind the whole labeling debate is that many members of the public are not convinced that GMOs are safe. In my opinion, the most important public policy to address that concern would be to have a mandatory FDA premarket approval for GMOs prior to allowing them to enter our food supply. Ensuring safety before marketing the crop is much better than putting GMOs out there, identifying them with a label, and letting the public choose based on whatever they may or may not know about those foods. We'd make our regulatory system similar to Canada's, Japan's and other countries around the world where our consumers would hear from FDA about whether the GMO is safe, see the relevant data in a transparent process with public participation, and understand FDA's analysis and reasoning behind their determination of safety. This should be the number one legislative priority. Labeling should not be a surrogate for safety. The other point I'd like to make concerning labeling is this. There are over 65 countries that have mandatory labeling regulations but those national requirements are not uniform. For example, China exempts soybean oil totally from GMO labeling while Japan requires a GMO label only if one of the first three ingredients came from a GMO crop. So, any labeling should be based on science and facts and must be both accurate and not misleading.

Ms. Roxland: Based on our discussion, it seems that the federal government won't mandate labeling based on a "right to know" premise, but only perhaps if there are safety concerns or nutrients or allergens. What can citizens focus on if they want their state to pass a labeling law?

Ms. Lovera: This issue continues to evolve. We have changed the laws on labeling because debate leads to that change. Why? Because what consumers need to know to make an informed decision about what they are buying is evolving. We didn't always get ingredient labels or nutrition facts. We have country of origin labeling on foods because the public said that they wanted it. There are a lot of conversations about whose job it is to fix this. We think the federal government has failed on this. People have been beating their heads against the wall at the FDA for a long time trying to get them to listen to what most people want to know. This year, there were bills introduced in approximately 26 states. In the public health arena we're missing an opportunity to see what happens to people who eat GMOs and trace it back by not affirmatively including GMOs in labels. We know where GMOs are not found because certain food certifications, such as "certified organic" and other third party certifications, don't allow it.

Ms. Roxland: New York State actually has proposed a bill which is similar to the California initiative. Under the proposed bill, a GMO product would be misbranded/mislabeled if it did not carry a "genetically engineered" or "genetically modified" label on the front of the package or above/below the ingredients. This GE label would not be specific to the actual ingredients that were modified. The GE label would not be specific to the actual ingredients that were modified, such that a consumer would not necessarily know which component of their package was genetically engineered. There are also multiple exemptions listed in the bills. The issue here is whether or not these terms are sufficiently educational. Would it be more helpful to provide GE information elsewhere (such as on a website)? Do these terms belong on a label to begin with?

Ms. Lovera: With some slight variations, all these bills talk about labels that say either "Contains genetically engineered ingredients," or "Made with genetic engineering." They aren't warnings. They're statements of fact. Yet, despite their outward statements of support, there has been active opposition from trade associations like BIO and biotech companies in every state capital trying to stop these bills which would require these types of food labels. As an example, Pennsylvania's Department of Agriculture had proposed a rule making it illegal for dairy producers to state they were not using GE. A few months later, it popped up in another state and then by January 2013, it popped up in state legislatures all over the place. Suddenly we were in ten states trying to maintain the right for dairy producers to say that they weren't using this technology with the asterisks. That's already been established by the FDA that people were going to put that caveat on there, so it's a little hard for us to reconcile that with statements about how interested this industry is in having us know when they're actively fighting what we think are common sense disclosures that people have been consistently demanding based on polling over the years. This seems very basic to people that they should get to know what we think is a basic difference. It's not just over health concerns. We haven't really talked about the rest of the real social and economic impacts of this technology. Consumers are waking up to this. They want to vote on this but they need information to do that.

Dr. Enright: The biotech industry supports a consumer's right to know. We're very proud of the products we make. We have full confidence in their safety. The foods grown from those crops grown from our seeds are the most tested agricultural product in the history of food manufacturing and agriculture. We understand that calls for legislation around this topic won't be going away. But we also understand that it's not necessarily just based on a right to know but also a desire to move away from biotechnology, our technology and our seeds. Because we believe in the technology, we believe in the seeds and stand by the safety of the food made from it. As such, we cannot support efforts to try to, in some way, use a label to convey to consumers that this food is less good, less nutritious, less safe, or has a health concern associated with it. The science doesn't support it.

Mr. Jaffe: One of the principles that FDA ensures for all labeling is that it must be "accurate and not misleading." For labeling required by a state or the federal government, I think that's a really good principle. I think you have to look at the details of each state GMO labeling bill and figure out whether or not the information the consumer is going to get from these labels is accurate and not misleading. For example, do you need to use words such as "derived from genetically engineered corn" instead of "made with genetically modified organisms" to make the label accurate? Is labeling appropriate if there is no physical—or biological—difference between the GMO ingredients and its non-GMO equivalent, such as with high fructose corn syrup? The same could be said for sugar made from GMO sugar beets, which doesn't contain any DNA or protein. While those highly processed ingredients might require a label under a state labeling law, it would be misleading because the products are identical. On the other hand, requiring a label on the engineered sweet corn you are consuming would at least be factually accurate because each corn kernel has both the introduced new DNA and the protein made from that DNA. So one of the things to think about in all these labeling debates is not just whether it's mandatory or voluntary, but what will be labeled. Is that going to be accurate or misleading to the consumer, and what useful information will the consumer receive? The New York law prohibits actually putting which ingredient is genetically engineered in the ingredient list, which in my opinion might be a more factually accurate way to label. If you have a salad dressing and it has a little soybean oil in it, it would be more accurate to write in the ingredient list "genetic engineered

soybean oil" than to say on the front of the package that the salad dressing is "genetically engineered" (assuming of course that oil with no DNA or protein is required to be labeled at all). That soybean oil might be ingredient number 20 in terms of its percentage in the salad dressing. The N.Y. bill would require "genetically modified" somewhere on the package but that could be misleading because the engineered ingredients are a really small component of that food. I think one needs to think about these things.

Afternote: Where Does that Leave the NY Consumer?

Proposed 2015 Bills: S485-2015 and A617-2015

Democratic Assemblywoman Linda Rosenthal of Manhattan, and her co-sponsor, Republican Sen. Ken LaValle of Suffolk, drafted a bill in 2013 (re-introduced in 2014 and 2015) providing for the labeling of seeds, food or food products that contain a genetically engineered material or that are produced with a genetically engineered material.

The labeling requirement can be met in a variety of ways. While the manufacturer must label the food, in a clear and conspicuous manner on the package of such food, it can choose to use the words "produced with genetic engineering" or any other derivative of those words, or the initials "ge," "gm," "gmo," or derivative of those phrases.

The bill also anticipates some of the most difficult questions about labeling. For example, for livestock, it exempts:

> Food consisting entirely of, or derived entirely from, an animal that has not itself been produced by genetic engineering, regardless of whether the animal has been fed with any food produced with genetic engineering or treated with any drug or vaccine that has been produced with genetic engineering.[4]

And for processed foods, it exempts from labeling products that include genetically engineered materials as long as the genetically engineered materials do not account for more than 9/10ths of 1% of the total weight of the processed food.

The bill does not require restaurants or other food retailers to label their menu items, nor does it require individual ingredients to be labeled as GM on a product label.

Current status

The bill was, in a surprising development, voted down in the Consumer Protection Committee at the very end of the 2013 session, resulting in allegations that lobbyists for Monsanto and other manufacturers had succeeded in shifting members' votes.

Reintroduced for the 2015 session, the NY GMO Labeling bill (A.617) was successfully voted out of the Assembly Consumer Affairs and Protection Committee on March 3, 2015 in a 9 to 6 vote. As of this writing, it is under review by the Assembly Codes Committee.[5]

Passage of a labeling law in Vermont

Notably, Vermont passed a labeling law, effective July 1, 2016. It is the first state to do so. It is currently being sued by the industry, which seeks to have the law invalidated.

Endnotes

1. The NYSBA Health Law Section, Committee on Public Health, Health Law Committee of the New York City Bar Association, and the NYSBA Food, Drug and Cosmetic Law Section also participated in sponsoring this symposium.
2. "Pursuant to that grant of authority [the PPA], the Animal and Plant Health Inspection Service (APHIS) promulgated regulations that presume genetically engineered plants to be "plant pests"—and thus "regulated articles" under the PPA—until APHIS determines otherwise. However, any person may petition APHIS for a determination that a regulated article does not present a plant pest risk and therefore should not be subject to the applicable regulations. APHIS may grant such a petition in whole or in part." Monsanto Co. v. Geertson Seed Farms, 570 F.3d 1130 (2010).
3. Food Drug Administration (2001) DRAFT Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering. (FDA Maryland). Last accessed Feb. 2, 2015 at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm.
4. S485-2015 and A617-2015 §15(D)(I). Last accessed Feb. 4, 2015 at open.nysenate.gov/legislation/bill/A617-2015.
5. For up to date status of the bill, see: http://assembly.state.ny.us/leg/?default_fld=&bn=A00617&term=&Summary=Y&Actions=Y.

The Tension Between the Affordable Care Act and EMTALA and Its Potential Legal Implications

By Daniel Shapiro

I. Introduction

Even with the Supreme Court's rejection of the latest constitutional challenge to the Patient Protection Affordable Care Act (ACA), it remains apparent that there are still several politically influential groups that oppose a law that seeks to create universal access to health care for all citizens.[1] However, long before this country began debating the constitutionality of the ACA and its "individual mandate"—which requires individuals to acquire health insurance or else face federal tax penalties—emergency departments across the nation have been grappling with their own mandate.[2]

The Emergency Mandate Treatment and Active Labor Act (EMTALA) was enacted by Congress in 1986.[3] Commonly referred to as the "anti-patient dumping law," EMTALA is designed to prevent hospitals from discriminating against uninsured or Medicaid patients by transferring them to public hospitals before providing minimal treatment and necessary screening to ensure that they are stable for transfer.[4] Specifically, the law requires hospitals to: (1) screen any individual who comes to an emergency room and; (2) treat that patient until his or her medical condition is resolved or until the patient is stabilized.[5] If the facility is not capable of treating the condition, it must transfer the patient to another hospital that has the capacity to treat the patient.[6] Under EMTALA, the qualified receiving hospital is obligated to accept the transfer. Thus, at its core, EMTALA guarantees all individuals access to a certain level of emergency care whether or not they are insured or can otherwise afford the cost of treatment.[7]

II. Hospital and Physician Liability Under EMTALA

An unintended yet foreseeable consequence of EMTALA's passage was that indigent or uninsured patients began flocking to local emergency rooms to seek treatment for unmet health needs, including those that did not call for emergency treatment.[8] Over time, emergency rooms (especially those serving densely populated urban areas) were forced to adapt by perfecting their triage procedures as waiting rooms overflowed with patients who presented with both emergent and non-emergent medical conditions.

Since EMTALA expressly dictates that "[a] participating hospital may not delay provision of an appropriate medical screening examination…in order to inquire about [an] individual's method of payment or insurance status," emergency room overcrowding has made hospitals far more vulnerable to EMTALA-based lawsuits and federal penalties.[9] Hence, while EMTALA literally opened the doors of the emergency room to any individual who required emergency treatment, regardless of his or her financial status, national origin, insurance status and race, it exposed hospitals to new forms of liability outside the realm of the standard malpractice and negligence claims they were accustomed to defending.

Under EMTALA, hospitals and both treating and on-call physicians face federal fines of up to $50,000 per violation.[10] The law also provides patients with a private right of action against the hospital (but not physicians) for injuries they sustain as a result of EMTALA non-compliance.[11] In this regard, EMTALA plaintiffs may "obtain those damages available for personal injury under the law of the state in which the hospital is located, and such equitable relief as is appropriate."[12]

While EMTALA does not serve as a replacement for a plaintiff's state law malpractice claim, it does serve as vehicle to have the claims heard in federal court and adjudicated before a federal jury. This is significant because some federal courts have held that EMTALA preempts procedural and substantive limitations imposed by state law, sending the message that plaintiffs may be better served by pursuing EMTALA-based claims in federal court (where the court may retain supplemental jurisdiction over their state law-based malpractice claim) rather than proceeding with their cases in state court. For example, courts have refused to apply state notice statutes and malpractice damage caps to EMTALA-based claims.[13] Further, plaintiffs are in a far better position to leverage a fruitful settlement with hospital defendants that may be forced to not only reimburse the complainants for their personal injuries, but also may be subject to onerous fines imposed by the federal government when the facts of their EMTALA-based noncompliance are fleshed out at trial.[14]

As a result of an influx of EMTALA-based cases, federal courts have sought to narrowly restrict the types of claims that truly fall within the law's purview. The Circuit Courts of Appeal routinely dismiss lawsuits on jurisdictional grounds where plaintiffs have disguised medical malpractice claims as EMTALA claims in an attempt to obtain EMTALA-based relief.[15] Courts have repeatedly cautioned: "EMTALA is not a federal medical malpractice statute."[16] Nevertheless, where the plaintiff's claims are actually grounded on the emergency department's failure to adequately screen and stabilize the patient, the claims will withstand Federal Rule 12(b)(6) and Rule 56 motions.

The success of an EMTALA-based claim generally hinges on whether a plaintiff is able to prove that he or she was not screened and/or stabilized in a manner commensurate with his or her medical condition and that the hospital's failures resulted in further quantifiable harm.[17] Naturally, defenses based on emergency room overcrowding, lack of resources, limited staffing or poor funding are not valid affirmative defenses even though such impediments are often the cause of the hospital's EMTALA violation.

III. Early Interaction Between EMTALA and the ACA

Before the ACA was enacted in 2010, its proponents, including President Barack Obama, argued that with more people insured, fewer would turn to the emergency room for treatment as their first line of defense.[18] The idea was that patients would schedule appointments with their newly assigned primary care physicians or with in-network specialists who would provide necessary treatment and preventative care, which would also serve to minimize the likelihood that those patients would require emergency care later. Such a conclusion seemed logical. However, early studies reveal that the intended results have yet to materialize. In fact, the current numbers contradict the theories espoused by the ACA proponents who saw the law as a panacea to emergency room overcrowding.

An April 2014 survey conducted by the American College of Emergency Physicians (ACEP) found that 46% of emergency physicians had experienced a rise in patients presenting to the emergency room since the enactment of the ACA, while 23% reported a decrease and 27% reported no change.[19] Additionally, 45% of emergency physicians expect a "slight" influx in emergency room patients over time, while 41% expect that they will face a far greater increase in the next three years.[20] Strikingly, 77% of the physicians polled think that their facilities are not sufficiently prepared to handle the influx they anticipate.[21] Although the figures cited in ACEP's survey are by no means conclusive—as they are entirely based upon the voluntary online submissions of emergency medicine physicians—the American Hospital Association (a national non-profit organization that represents nearly 5,000 hospitals, health care systems and network providers) has defended the survey's findings.[22]

The problem of emergency room overcrowding is also compounded by the fact that the nation's population continues to grow at an increasing rate. With the demand for physicians on the rise and the projections revealing that we will face a shortage of primary care physicians in the future, demand for non-emergency based care is expected to exceed supply by 2025.[23] The impact that this shortage will have on emergency rooms is potentially devastating.

In New York, the consequences are particularly dire. According to ACEP, New York State has the highest hospital occupancy rate in the nation, and the fourth fewest emergency departments per capita.[24] New York also suffers from the fourth longest average time that patients spend in the ER (366 minutes) before being transferred to their hospital bed or discharged.[25] The national average is 272 minutes.[26] Given these figures, it is not surprising that patients have died while awaiting treatment in ER waiting rooms in New York.[27] However, it does bear noting that the state remains focused on addressing these issues and has implemented a Delivery System Reform Incentive Payment (DSRIP) program as a preemptive measure. Through this program, the state has allocated eight billion dollars for distribution to Medicaid providers over the next five years, with the funds being tied to projects and reforms focused on reducing avoidable hospital use.[28] The state's expressed goal is ambitious. It intends to achieve a 25% reduction over this period.

Regarding the question of whether more patients who were not previously insured will be more likely to seek treatment in the emergency room given the ACA's mandate, a 2013 landmark study performed by the Oregon Health Insurance Experiment proves illustrative.[29] In short, the study concluded that the expansion of Medicaid to low-income individuals increased both their visits to primary care centers and to emergency rooms. The study reviewed records from 25,000 low income patients, some with Medicaid access and some without, and determined that those with insurance ended up in the emergency room with a 40% greater frequency while many of the conditions that brought them there were deemed non-emergent.[30] Also, in February 2015, the *American Journal of Emergency Medicine* published a related study based on research performed by the Wayne State University School of Medicine in Detroit, Michigan. This study found that Americans who receive public insurance under the ACA use the emergency department more frequently than before they were insured.[31] Although there are many groups in the medical community that do not subscribe to the theory that emergency room overcrowding is tied to hospitals still having to provide non-urgent care to Medicaid and other low income patients in the emergency room, it is difficult to deny that there exists a relationship between the two.[32]

IV. Public Policy vs. Strict Interpretation of EMTALA's Provisions

The implications of these reports, (as they relate to hospital overcrowding and EMTALA liability), are clear. On the legal front, hospitals have a multitude of reasons to be concerned as their exposure to liability will surely be impacted if these trends hold. And based on a recent newsworthy case in which a court denied whistleblower protections to a physician who complained that his hospital was not properly screening patients in its overcrowded

emergency room, it appears the judiciary is doing little to help calm the storm that looms overhead.

In the Tenth Circuit case titled *Genova v. Banner Health, et al.*, a doctor plaintiff whose staff privileges at the private hospital where he worked had been terminated, alleged that he had been retaliated against for reporting that the hospital was "hoarding" emergency room patients for financial reasons rather than transferring them to another facility where they could be treated more expeditiously.[33] EMTALA contains a whistleblower provision which provides that:

> A participating hospital may not penalize or take adverse action [1] against a qualified medical person…or a physician because the person or physician refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized or [2] against any hospital employee because the employee reports a violation of a requirement of this section.[34]

Even though EMTALA bars hospitals from disciplining physicians who refuse to transfer unstabilized patients suffering from emergency medical conditions, the Court determined that the doctor's actions did not qualify for whistleblower status.[35] The Court strictly interpreted the language of the statute and held that because the doctor neither claimed that he had been harmed as a result of an EMTALA violation nor had he been discharged for reporting a EMTALA violation arising out of the hospital's failure to screen or stabilize a patient or based on its transfer of an unstable patient, his claims failed as a matter of law.[36] Notwithstanding, the Court did note that patient "hoarding" could ultimately lead to the type of patient dumping that EMTALA was enacted to prevent.[37] But it also reasoned that the law permits a suit only where a plaintiff was harmed "by or reported an *existing* EMTALA violation, not an *impending* one."[38] Parenthetically, the American Academy of Emergency Medicine filed an *amicus* brief with the Tenth Circuit on behalf of the plaintiff urging it to protect physicians who voice concerns related to EMTALA violations, whether they presently exist, are imminent or appear foreseeable.[39] Evidently, the Court did not adopt this public policy argument.

As our country enters into a new health care age, the problems that we will assuredly face will run the gamut. One thing that is clear is that emergency rooms will be forced to navigate new roadblocks as the mandates set out in EMTALA and the ACA appear to be headed for a collision course. Absent adequate government funding, universal emergency department guidelines and a greater supply of quality physicians, Congress may be forced to take on the health care debate down the road, yet again. Unfortunately, taking up the debate is far simpler than enacting effective legislation.

Endnotes

1. The Supreme Court granted *cert* in the case titled *King v. Burwell*, 759 F.3d 358 (4th Cir. 2014), *cert. granted*, No. 14-114, 2014 U.S. LEXIS 7428, at *1 (U.S. Nov. 7, 2014) to resolve the issue of whether the IRS may extend tax subsidies to states that had not set up their own health care exchanges under the ACA. The case raised constitutional issues related to state sovereignty and state's rights. A decision was issued on June 25, 2015 upholding the ACA.
2. The ACA generally requires people living in the United States to obtain health insurance or pay a tax penalty called a "shared responsibility payment." 26 U.S.C. § 5000A and 26 C.F.R. § 1.5000A-1.
3. 42 U.S.C. § 1395dd.
4. Office of the Inspector Gen., Dep't. of Health & Human Servs., The Emergency Medical Treatment and Labor Act: Patient Dumping Archive, *available at* https://oig.hhs.gov/fraud/enforcement/cmp/patient_dumping.asp.
5. 42 U.S.C. § 1395dd(a) requires hospital emergency department to provide for an "appropriate medical screening examination" to determine whether an "emergency" medical condition exists. 42 U.S.C. § 1395dd(e)(3)(A) defines "stabilize" as "provid[ing] such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility, or, with respect to an emergency medical condition described in paragraph (1)(B), to deliver (including the placenta)."
6. 42 U.S.C. § 1395dd(b)(1)(B).
7. Because EMTALA applies to all Medicare-participating hospitals with emergency departments and because hospitals are dependent on Medicare reimbursement payments and subsidies as an income source, the law's mandate has a global application.
8. Although commentators continue to debate whether this surge in ED usage is primarily attributable to EMTALA or is multifactorial—attributable to hospital closures, increased population, hospital implementation of cost cutting measures, etc.—since the law's enactment, emergency department use has surged from 85 million visits per year to almost 140 million visits per year. *See* Laura D. Hermer, *The Scapegoat: EMTALA and Emergency Department Overcrowding*, 14 J.L. & Poly 695 (2006); *see also* Centers for Disease Control, Dep't of Health & Human Servs., Emergency Dep't. Visits Archive, *available at* http://www.cdc.gov/nchs/fastats/emergency-department.htm; Cindy Mann, Centers For Medicare and Medicaid Services, Informational Bulletin: Reducing Nonurgent Use of Emergency Departments and Improving Appropriate Care in Appropriate Settings, *available at* http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/CIB-01-16-14.pdf; Lynne D. Richardson, et al., *Emergency Department Crowding as a Health Policy Issue: Past Development, Future Directions*, 40 Ann. Emergency Med. 388, 388-93 (2002).
9. 42 U.S.C. § 1395dd(b)(1)(B).
10. 42 U.S.C. § 1395dd(d).
11. It is generally settled that plaintiffs may prosecute EMTALA claims against the hospital for damages they sustained, but several courts have held that EMTALA does not create a private cause of action against individual physicians. *See e.g. Eberhardt v. Los Angeles*, 62 F.3d 1253, 1256 (9th Cir. 1995), *King v. Ahrens*, 16 F.3d 265, 271 (8th Cir. 1994); *Delaney v. Cade*, 986 F.2d 387, 393-94 (10th Cir. 1993); *Baber v. Hospital Corporation of America*, 977 F.2d 872, 876-878 (4th Cir. 1992); *Gatewood v. Washington Healthcare Corp.*, 933 F.2d 1037, 1040 n.1 (D.C. Cir. 1991); *Fisher by Fisher v. New York Health & Hosps. Corp.*, 989 F. Supp. 444 (E.D.N.Y. 1998).
12. 42 U.S.C. § 1395dd(d)(2)(A).
13. *See e.g. Cox v. Cabell Huntington Hosp., Inc.*, 2012 WL 685870, No. 3:110843 (S.D. W.V. Mar. 2, 2012) (plaintiff permitted to file an EMTALA claim despite failing to provide the state law required

notice of claim to health care providers and/or a verification of merit to the court as required under state law); *Godwin v. Memorial Medical Center*, 25 P.3d 273, 281-282 (N.M. App. 2001) (Court held that New Mexico's 90-day notice-of-claim requirement for tort claims was preempted by EMTALA's two-year statute of limitations with respect to EMTALA causes of action); *Jackson v. East Bay Hospital*, 980 F. Supp. 1341, 1348-1350 (N.D. Cal. 1997) (state's damage cap for malpractice claim did not apply to EMTALA claim); *Cooper v. Gulf Breeze Hospital, Inc.*, 839 F. Supp. 1538, 1541-1543 (N.D. Fla. 1993) (same); *Bird v. Pioneers Hosp.*, 121 F.Supp.2d 1321 (D.C. Colo. 2000) (Colorado's notice statute does not apply to EMTALA claims).

14. Both the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General (OIG) have administrative enforcement powers with regard to EMTALA violations. There is a 2-year statute of limitations for civil enforcement of any violation. *See* American College of Emergency Physicians, News Media, EMTALA, *available at* http://www.acep.org/News-Media-top-banner/EMTALA/.

15. *See e.g. Eberhardt v. City of Los Angeles*, 62 F.3d 1253 (9th Cir. 1995); *Repp v. Anadarko Municipal Hosp.*, 43 F.3d 519 (10th Cir. 1994); *Holcomb v. Monahan*, 30 F.3d 116 (11th Cir. 1994).

16. *Repp v. Anadarko Municipal Hospital*, 43 F.3d 519, 522 (10th Cir. 1994); *Power v. Arlington Hospital Ass'n*, 42 F.3d 851, 856 (4th Cir. 1994); *Gatewood v. Washington Healthcare Corp.*, 933 F.2d 1037, 1039 (D.C. Cir. 1991); *Cleland v. Bronson Health Care Group, Inc.*, 917 F.2d 266, 271-72 (6th Cir. 1990); *Brenord v. Catholic Med. Ctr. of Brooklyn & Queens, Inc.*, 133 F. Supp. 2d 179, 185 (E.D.N.Y. 2001).

17. *See e.g. Brooks v. Maryland Gen. Hosp.*, 996 F.2d 708 (4th Cir. 1993) (patient complaining of acute weakness and a sudden inability to walk who presented to the emergency room and experienced excessive delays in treatment and evaluation, could assert a screening claim under EMTALA); *Scruggs v. Danville Regional Medical Center of Virginia, LLC*, No. 08-00005, 2008 U.S. Dist. LEXIS 68630, *10-12 (W.D. Va. Sept. 5, 2008) (denying motion to dismiss plaintiff's EMTALA screening claim, where plaintiff asserted that over 11½ hours had elapsed between the time he presented himself to the emergency room and the time that he was examined by a doctor); *Byrne v. Cleveland Clinic*, 684 F. Supp. 2d 641 (E.D. Pa. 2010) (dismissal of plaintiff's EMTALA claim that it took two hours after his arrival for an ED physician to attend to his condition denied).

18. Brandy Zadrozny, *Obamacare Has a New Problem: It Won't Fix Emergency Rooms*, The Daily Beast, Jan. 2, 2014, *available at* http://www.thedailybeast.com/articles/2014/01/02/obamacare-has-a-new-problem-it-won-t-fix-emergency-rooms.html.

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25. *Id*.

26. *Id*.

27. In June 2008 a woman died on the floor of the psychiatric emergency room at Kings County Hospital Center after waiting for more than 24 hours for treatment. *See* Sewell Chan, *City to Pay $2 Million in Death After Hospital Wait*, The New York Times, *at* http://www.nytimes.com/2009/05/28/nyregion/28settle.html (May 27, 2009). In January 2014, a 30 year old man was found dead in the waiting room of Saint Barnabas Hospital in the Bronx eight hours after he arrived to the ER complaining of a rash. *See* Rich Schapiro, *Man, 30, found dead after 8-hour wait in Bronx Emergency Room For Rash*, New York Daily News, *at* http://www.nydailynews.com/new-york/bronx/man-30-dies-8-hour-wait-bronx-emergency-room-article-1.1591629 (Jan. 26, 2014).

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34. 42 U.S.C. § 1395dd(i).

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36. *Id*. at 1098–1101.

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39. Brief of *Amicus Curiae* American Academy of Emergency Medicine in Support of Appellant, *Genova v. Banner Health*, 734 F.3d 1095 (10th Cir. 2013) (NO. 12-1314), *available at* http://www.aaem.org/UserFiles/Genovaamicuscuriaefiling.pdf.

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OMIG Reminds Providers That Compliance Officer Must Be an Employee of the Provider

By Philip Rosenberg, Laurie T. Cohen and Brooke A. Lane

New York State law requires certain Medicaid providers, including hospitals, home care agencies, mental health clinics, Article 16 clinics and other providers that derive a substantial portion of their business from the Medicaid program, to operate and maintain an effective compliance program. Pursuant to that law, one of the essential components of an effective compliance program is to vest an employee of the provider with the responsibility of overseeing the day-to-day operations of the compliance program.

The New York State Office of the Medicaid Inspector General ("OMIG") has released guidance reminding those Medicaid providers of their obligation to employ such a person. To be considered an employee, an individual must qualify as an employee for state or federal tax purposes. Independent contractors, consultants and volunteers are not considered employees.

The compliance guidance also addresses the situation where multiple corporate entities are controlled by a parent holding company. In that situation, the holding company may operate or coordinate a compliance program throughout the enterprise. The guidance explains that, even though the parent holding company may not actually be participating in the Medicaid program, it may employ a compliance officer on behalf of wholly owned subsidiaries that are participating in the Medicaid program because there is a unity ownership and control.

Similarly, the compliance guidance states that a wholly owned subsidiary may employ the compliance officer on behalf of the parent holding company if the employee of the subsidiary:

a. is vested by the parent company with responsibility for the day-to-day operation of the parent company's compliance program;

b. satisfactorily carries out all of the compliance responsibilities;

c. reports directly to the parent company's chief executive officer or other senior administrator; and

d. periodically reports directly to the parent company's governing body on the activities of the parent company's compliance program.

If the subsidiary is not wholly owned by the parent company, however, the OMIG will not consider a parent company to have "unity of ownership and control" over the subsidiary. That means that an employee who is the compliance officer of a subsidiary will not be deemed to be an employee of the parent holding company. The same individual, however, may serve as the compliance officer for the parent company and individual subsidiaries if the individual has separate employment relationships with each entity.

The compliance guidance applies the same rule to joint ventures that are participating in the Medicaid program. Because a joint venture does not involve unity of ownership and control between the joint venture and its owners, a compliance officer employed by either owner will not be considered to be an employee of the joint venture itself. A joint venture required to have a compliance program will thus have to separately employ an employee who is vested with the day-to-day operation of the compliance program. But, again, that individual may enter into separate employment arrangements with the joint venture and one or more owners.

Similarly, providers that choose to delegate responsibility for carrying out compliance activities to a management company will have to ensure that a provider employee is the compliance officer vested with the responsibility for the compliance program.

Providers should examine their compliance program and ensure that the designated compliance officer's employment status complies with the regulatory requirements.

Philip Rosenberg and Laurie T. Cohen are partners in Nixon Peabody LLP and practice health law from the firm's Albany office. Brooke A. Lane is an associate at Nixon Peabody LLP and practices health law in the firm's Long Island office.**This article originally appeared in the firm's publication *Health Law Alert*, and is reprinted with permission**

Out-of-Network Law Frequently Asked Questions

Healthcare Association of New York State (HANYS)

On March 31, New York's out-of-network (OON) law went into effect. The law is the result of negotiations between the Department of Financial Services (DFS), Department of Health (DOH), the legislature, hospitals, physicians, and health plans. It follows years of debate over the adequacy of out-of-network reimbursement and the outcry over surprise balance bills sent to consumers.

The law intends to hold patients harmless for emergency services and surprise bills; creates new disclosure requirements for hospitals, physicians and health plans; creates an independent dispute resolution (IDR) process for patients, plans, and physicians who disagree about out-of-network reimbursement for emergency and surprise bills; and bolsters network adequacy requirements and the state's authority to enforce such standards.

This following Frequently Asked Questions (FAQ) represent HANYS' initial analysis of the law to date based on statutory language, regulations, and guidance issued by the Department of Health (DOH) and Department of Financial Services (DFS). The answers provided may change over time as the law takes effect and state agencies issue updated guidance.

General Questions

1. What health plans are subject to the Out-of-Network (OON) Law?

The law applies to all state-regulated insurance products, including health maintenance organizations (HMOs), preferred provider organizations (PPOs), exclusive provider organizations (EPOs), municipal health benefit plans, student health plans, and Medicaid managed care plans.

Medicaid fee-for-service, Employee Retirement Income Security Act (ERISA)-preempted, Medicare Advantage, Medicare fee-for-service, and self-insured health plans are not required to comply with state law. However, there are other rules and requirements regarding out-of-network services that apply for Medicare and Medicaid patients.

2. When does the out-of-network law take effect?

The law is effective for dates of service on and after March 31, 2015. Specific effective dates for all components of the law are listed below:

Provision	Effective Date
Health Plan Disclosure Requirements	Effective for insurance policies and contracts on issuance or renewal on and after March 31, 2015.
Provider Disclosure Requirements	Effective for healthcare services provided on and after March 31, 2015.
Right to OON if No In-Network Provider	Currently effective for HMOs. Effective for insurance policies and contracts on issuance or renewal on and after March 31, 2015.
External Appeal Rights for OON Service Denials for Insurance Coverage	Currently effective for HMOs. Effective for insurance policies and contracts on issuance or renewal on and after March 31, 2015.
New External Appeal Rights for OON Referral Denials	Effective for HMO and managed care insurance product denials on and after March 31, 2015. For all other insurance policies and contracts, effective on issuance or renewal on and after March 31, 2015.
Independent Dispute Resolution Process for Surprise Bills and Emergency Services	Effective for healthcare services provided on and after March 31, 2015.
Hold Harmless for Emergency Services	For emergency services billed under Current Procedural Terminology (CPT) codes 99281 through 99285, 99288, 99291 through 99292, 99217 through 99220, 99224 through 99226, and 99234 through 99236, effective for healthcare services provided on and after March 31, 2015. For all other emergency services, effective for insurance policies and contracts on issuance or renewal on and after March 31, 2015.

Provision	Effective Date
Utilization Review Notification Requirements	Effective for healthcare services provided on and after March 31, 2015.
Network Adequacy Requirements	Effective for insurance policies and contracts on issuance or renewal on and after March 31, 2015.
OON Make Available Benefit	Effective for insurance policies and contracts on issuance or renewal on and after March 31, 2015.
Claim Forms	For non-participating physicians, the requirement to send a claim form with a bill for OON services is effective for healthcare services provided on and after March 31, 2015. For health plans, requirements regarding claim submissions are effective for insurance policies and contracts on issuance or renewal on and after March 31, 2015.

Disclosure Requirements

3. What does the law specifically state regarding hospital disclosure requirements for charges?

A hospital must post on its website, to the extent required by federal guidelines, a list of the hospital's standard charges for items and services provided by the hospital, including for Diagnosis Related Groups (DRGs).

In the federal fiscal year (FFY) 2015 Inpatient Prospective Payment System final rule, the Centers for Medicare and Medicaid Services (CMS) reminds hospitals of their obligation to comply with this provision and is providing flexibility as to how hospitals should make their charges public. CMS states that hospitals should either make public a list of their standard charges (whether that be the charge-master or in another form of their choice), or their policies for allowing the public to view a list of those charges in response to an inquiry.

4. What other information must a hospital post on its website?

The hospital must post the following information on its website:

- a list of the health plans in which the hospital participates;
- the name, mailing address, and telephone number of the physician groups that the hospital has contracted with to provide services, including anesthesiology, pathology or radiology; and instructions on how to contact these groups to determine the health plan participation of the physicians in these groups; and
- the name, mailing address, and telephone number of physicians employed by the hospital and whose services may be provided at the hospital, and the health plans in which they participate.

5. What information must the hospital provide to its patients in registration/admission materials?

In addition to the website disclosure requirements, hospitals must provide written information to patients in advance of non-emergency hospital services, in registration or admission materials.

Hospitals must provide a statement advising the patient to check with the physician arranging the hospital services to determine the name, practice name, mailing address, and telephone number of any other physician whose services will be arranged by the physician; and whether it is anticipated that physicians who are employed or contracted by the hospital will provide services to the patient (including anesthesiology, pathology, and/or radiology). Hospitals must also provide the patient with information on how to timely determine the health plans with which the other physicians participate.

6. Is there a template that hospitals can use to fulfill its disclosure requirements?

Yes, HANYS and Greater New York Hospital Association (GNYHA) created a Hospital Disclosure Template to help members comply with the new hospital disclosure requirements. Both DOH and the Department of Financial Services (DFS) have stated that they will accept the template disclosure form from hospitals that use it to satisfy both the website and registration material requirements, which take effect March 31, 2015.

7. What information must a physician disclose to patients?

Physician disclosure requirements come in two parts:

- For referrals and coordination of services: The physician must provide the patient with the name, practice name, mailing address, and telephone number for any health care provider scheduled to perform those services specifically referenced in the law (anesthesiology, laboratory, pathology, radiology, or assistant surgeon services) in connection with care provided in the physician's office; as coordinated by the physician; or as referred by the physician.
- For scheduled hospital admissions or outpatient hospital services: The physician must provide the

patient and the hospital with the name, practice name, mailing address, and telephone number of any other physician whose services will be arranged by the physician and are scheduled at the time of pre-admission testing, registration or admission, and information how to determine in which health plans the physician participates.

8. How does the law define physician and provider?

A provider is defined as an appropriately licensed, registered or certified health care professional pursuant to Education Law Title 8, or comparably licensed, registered or certified by another state, or a facility licensed or certified pursuant to Public Health Law Articles 5, 28, 36, 44 or 47, or Mental Hygiene Law Articles 19, 31 or 32, or comparably licensed by another state.

A physician is defined as an individual licensed to practice medicine pursuant to Education Law Article 131 or as provided under the law of the state where the individual practices medicine.

Emergency Bills

9. Are OON emergency bills for hospital charges subject to the independent dispute resolution process?

No, the independent dispute resolution process for emergency services applies only to physician services in a hospital. Emergency bills for hospital charges are not eligible for independent dispute resolution.

10. If an OON emergency bill for hospital charges is not eligible for the independent dispute resolution process, how do those charges get paid?

Beginning on March 31, 2015, Insurance Law 3241(c) requires insurers to hold insureds harmless for charges in excess of the in-network deductible, copayments or coinsurance for OON emergency services. This hold-harmless requirement for OON emergency services applies both to physician services in a hospital and hospital charges. For disputes involving OON emergency hospital services that are not eligible for the independent dispute resolution process, health plans may need to pay more than the reimbursement required under the Affordable Care Act to ensure that an insured is held harmless.

11. If an emergency room physician requests that a specialist provide a patient in the emergency room a consultation and the specialist does not participate with the patient's health plan, would this be considered part of the emergency service?

Yes, according to guidance issued by the Department of Financial Services (DFS), in this scenario a bill from a specialist would be considered a bill for emergency services and could be subject to the independent dispute resolution process because it flows directly from the emergency service.

Surprise Bills

12. What is a surprise bill?

Financial Services Law 603(h) defines a surprise bill as a bill for health care services, other than emergency services, received by:

- an insured for services rendered by a non-participating physician at a participating hospital or ambulatory surgical center, where a participating physician is unavailable, or a non-participating physician renders services without the insured's knowledge, or unforeseen medical services arise at the time the health care services are rendered; provided, however, that a surprise bill shall not mean a bill received for health care services when a participating physician is available and the insured has elected to obtain services from a non-participating physician; or
- an insured for services rendered by a non-participating provider where the services were referred by a participating physician to a non-participating provider without the explicit written consent of the insured acknowledging that the participating physician is referring the insured to a non-participating provider and that the referral may result in costs not covered by the health plan.

13. When does a referral to a non-participating provider occur?

A referral to a non-participating provider occurs when:

- the health care services are performed by a non-participating health care provider in the participating physician's office or practice during the course of the same visit;
- the participating physician sends a specimen taken from the patient in the physician's office to a non-participating laboratory or pathologist; or
- for any other health care services when referrals are required under the insured's contract (i.e., gatekeeper).

14. How does the state define an "available" provider?

For the participating physician to be considered "available," the insured should have a meaningful opportunity to choose an in-network physician in advance of the services.

15. Does the hold-harmless provision apply to surprise bills?

Financial Services Law 606 requires providers to hold insured patients that have completed an assignment of benefits form harmless for a surprise bill. HMOs and gatekeeper EPOs are also required to hold insureds harmless for a surprise bill pursuant to hold-harmless requirements imposed under the Public Health Law and regulations. The provider shall not bill or seek payment from the insured ex-

cept for any applicable copayment, coinsurance, or deductible that would be owed if the insured utilized a provider in-network.

16. An insured is admitted to a participating hospital following emergency services and during that hospital stay a non-participating specialist provides consultation services. Would this qualify as a surprise bill?

This would qualify as a surprise bill if:

- a participating physician is unavailable;
- a non-participating physician renders services without the insured's knowledge; or
- unforeseen services arise at the time other services are rendered.

17. If an insured is admitted to a non-participating hospital and during that stay consultation services are provided by a non-participating specialist, would this qualify as a surprise bill?

No, this would not be considered a surprise bill because the patient is already OON and cannot reasonably expect that physicians at an OON hospital are in-network.

Independent Dispute Resolution (IDR) Process

18. How do you submit a dispute for review by an independent dispute resolution entity (IDRE)?

Emergency bills: A health care plan, a non-participating physician, or a patient who is not an insured or self-insured may submit a dispute regarding emergency services to the Superintendent of DFS for review by an IDRE.

Surprise bills: A health care plan, a non-participating physician, a non-participating referred provider, an insured who does not assign benefits, or a patient who is not an insured or self-insured may submit a dispute regarding a surprise bill to the Superintendent for review by an IDRE.

19. How do the OON law and the IDR process apply to the uninsured and patients who are insured under ERISA or self-funded plans?

Employee Retirement Income Security Act (ERISA) and self-funded plans are not state-regulated; therefore state laws do not extend to these plans. Patients insured under ERISA or self-funded plans will be treated as uninsured for the purposes of emergency and surprise bills. The patient may submit his or her remaining portion of the bill, if not the entire bill, to DFS for independent dispute resolution and the dispute resolution process will involve the patient and the physician.

20. Are any physician bills for emergency services or surprise bills exempt from the IDR process?

Yes, when physician fees are subject to schedules or other monetary limitations under any other law, including Workers Compensation, no-fault, managed long-term care, Medicare, and Medicaid fee-for-service. Additionally, Medicaid managed care is exempt from IDR if the bill is for emergency services, and is not exempt from IDR if the bill is a surprise bill.

21. Once an application for review is submitted, does the dispute automatically qualify for an IDRE?

No. Once an application for dispute is submitted, the IDRE has three business days to screen the application for eligibility (assuming no conflicts of interest exist). The IDRE is responsible for determining if the dispute qualifies as an emergency or surprise bill.

22. What factors does the IDRE take into consideration when reviewing disputes?

The IDRE shall have the dispute reviewed by a neutral and impartial reviewer with training and experience in health care billing, reimbursement, and usual and customary charges. All determinations shall be made in consultation with a neutral and impartial licensed reviewing physician in active practice in the same or similar specialty as the physician providing the service that is subject to the dispute. To the extent practicable, the reviewing physician shall be licensed in the state of New York.

23. How long does the IDRE have to make a final determination?

The IDRE shall make a determination within 30 days of receiving the request for dispute resolution.

24. Who is responsible for paying the fee for the dispute resolution process?

If the IDRE determines that the health plan's payment is reasonable, payment for the dispute resolution process shall be the responsibility of the provider or physician.

If the IDRE determines that the provider or physician's fee is reasonable, the health plan shall be responsible for the fee of the dispute resolution process.

If good faith negotiations directed by the IDRE result in a settlement between the health plan and provider or physician, the prorated fee for the dispute resolution process shall be split evenly between the two parties.

For disputes that are rejected as ineligible or due to the requesting provider, physician, or health plan's failure to submit information, an IDRE may charge an application processing fee, which shall be the responsibility of the requesting provider, physician, or health plan.

For disputes involving an uninsured patient, if the IDRE determines that the physician's fee is reasonable, the patient will be responsible for the fee for the dispute resolution process. However, if the Superintendent determines that that payment would pose a hardship to the patient, the IDRE shall waive payment.

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NEWS flash

What's Happening in the Section

Kenneth R. Larywon

Kenneth R. Larywon took office as Chair of the Health Law Section on June 1, 2015. He is a senior partner and trial attorney with Martin, Clearwater & Bell, and practices out of the firm's New York City office. He focuses his practice on the defense of professional liability cases and health care law matters. For over 30 years, Mr. Larywon has defended physicians and hospitals in claims arising out of the delivery of medical care. He has also represented health care professionals in disciplinary proceedings before the Office of Professional Medical Conduct and the Department of Education.

Mr. Larywon has extensive experience in counseling and defending hospitals, and in physician and nursing staff credentialing matters. On over 100 occasions, Mr. Larywon has lectured on risk management issues to physicians, nurses, and other health care professionals at many hospitals in the metropolitan area. Mr. Larywon co-authored a series of articles about managed care issues for the *New York Law Journal.*

Previously, Mr. Larywon was Chair of the Professional Discipline Committee of the Health Law Section. That Committee addresses issues related to agencies such as OPMC and OPD. He has also served as the Secretary and Vice-Chair of the Section.

Mr. Larywon earned his law degree in 1978 from Notre Dame Law School.

Officers

The other section officers who took office on June 1 are:

Chair-Elect:	**Raul A. Tabora, Jr.**, Bond Schoeneck & King, PLLC (Albany)
Vice-Chair:	**Lawrence Faulkner**, ARC of Westchester (Hawthorne)
Secretary:	**Robert A. Hussar**, Manatt, Phelps & Phillips (Albany)
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